APPLICATION FOR A PART B ENVIRONMENTAL PERMIT FOR A COATING ACTIVITY

REDACTED VERSION

UK BATTERY INDUSTRIALISATION CENTRE

This Part B environmental permit application is structured as follows:

Section 1 contains the completed application form.

Section 2 includes two drawings showing the external layout of the site and the locations of the atmospheric emissions points. These are the drawings referred to in item B3 of the application form.

Section 3 contains the environmental permit Supporting Document which presents the technical information required under item C of the application form. The Supporting Document includes seven appendices:

- **Appendix 3.1** is the non-technical summary of an Environmental Statement prepared for the Whitley South Technology Campus, the development within which the UKBIC plant is located. This is the summary referred to in item C4(d) of the application form.
- **Appendix 3.2** is a technical note prepared to assess data necessary to inform UKBIC's Site Condition Report (SCR). The ground investigation technical note is not required for a Part B Application and has thus been removed from the redacted copy.
- **Appendix 3.3** contains process flow diagrams which supplement the description of the electrode manufacture process given in Section 5 of the Supporting Document.
- **Appendix 3.4** is a technical note on N-Methylpyrrolidone (NMP), the solvent used in the manufacture of the battery's cathode electrode. Emissions of the solvent vapour are minimised by means of a condenser and activated carbon bed. However, small residual amounts of the vapour are ultimately discharged to atmosphere via an exhaust stack. The technical note, which is the document referred to in item D of the application form, presents an assessment of the environmental impact of the discharge.
- **Appendix 3.5** provides an overview of the Megtec/Durr solvent recovery system for the cathode manufacturing process.
- **Appendix 3.6** contains four further documents which provide background information on NMP and its use:
  - A position paper on the usage of NMP prepared by EUROBAT, the Association of European Automotive and Industrial Battery Manufactures.
  - A report "Proposal for identification of a substance as a category 1A or 1B CMR, vPvB or a substance of an equivalent level of concern – 1-Methyl-2-pyrrolidone as SVHC" prepared by the European Chemical Agency.
  - A "Report on the state of art for N-Methyl-2-pyrrolodone in the production of lithium-ion battery cells" prepared by RWTH Aachen University.
  - A Concise International Chemical Assessment of NMP prepared by the World Health Organisation.

  These documents are referred to on Section 4.2 of the Supporting Document.
- **Appendix 3.7** contains the site drainage drawing referred to in Section 9.5 of the Supporting Document.

Section 4 addresses additional information requirements requested by Warwick District Council in its 'Notice for Information', dated 27th November 2019.

SECTION 1

COMPLETED APPLICATION FORM

Application for a Part B permit

Environmental Permitting (England and Wales) Regulations 2010

Introduction

When to use this form
If you are sending an application to a Local Authority under the Environmental Permitting (England and Wales) Regulations 2010 and the installation requires an air pollution control permit (known as "Part B" installations).

Before you fill in this form
Do please read relevant parts of the Defra general guidance manual. Chapter 4 is about making an application, Chapter 7 is about how permits are decided, and Chapter 12 gives the meaning of Best Available Techniques (BAT). Other chapters introduce the Regulations and give information about various issues.

You also need to read the relevant process guidance note to see what standards and requirements are likely to be expected of your installation.

Pre-application discussions
It is usually sensible to talk to one of our pollution control officers before you complete and submit the application. Contact [ ]

Which parts of the form to fill in
Please fill in as much of it as possible and enclose the appropriate fee. Then send it to:

Warwick District Council, Riverside House, Milverton Hill, Leamington Spa, CV32 5HZ

Other documents you may need to submit
You will need to send us various other documents. The application form tells you which ones. It will be simplest for all concerned if you give a reference number for each document and record it on both this form and on the document itself. Please use any existing documents where you can and they are suitable.

Using continuation sheets
Feel free to use a continuation sheet, but you need to clearly identify where you have done so.

Copies - *not relevant for e-applications*
If you are submitting a paper application, please send the original and [ ] copies of the form and all other supporting material, for consultation purposes.

LAPPC application form: to be completed by the operator		
For Local Authority use		
Application reference	**Officer reference**	**Date received**

A The basics

A1 Name and address of the installation

U.K. Battery Industrailisation Centre
Rowley Road
Coventry
CV8 3AL

A2 Details of any existing environmental permit or consent *(for waste operations, please include planning permission for the site, including established use certificates, a certificate of lawful existing use, or why the General Permitted Development Order)*

Reference no.	Issuing regulator	Type of permit

A3 Operator details (*The 'operator' = the person who it is proposed will have control over the installation in accordance with the permit (if granted).)*

Name Mr. Jeff Pratt [Managing Director] UKBIC

Trading name, if different

Registered office address
Council House
Earl Street
Coventry CV1 5RR

Principal office address, if different
I.D.L. Building
University of Warwick
Coventry CV4 7AL

Company registration number

A4 Any holding company?

Is the operator a subsidiary of a holding company within the meaning of section 1159 of the Companies Act 2006? If "yes" please fill in details of the ultimate holding company.

No ☑ Yes ☐

Name

Trading name, if different

Registered office address

Principal office address, if different

Company registration number

A5 Who can we contact about your application?

B The installation

What activities are or will be carried on at the installation? Please include "directly associated activities" – this term is explained in Annex III in Part B of the general guidance manual

Main activities	Section in Schedule 1 to the EP Regulations
Coating activity	Sect: 6.4 Part B (a)(iv)

Directly-associated activities (including waste operations)	Schedule 1 references (if any)

B2 Why is the application being made?

☑ new installation

☐ change to existing installation means it now needs a permit

B3 Site maps

Please provide:-

- A location map showing with a red line round the boundary of the installation

  Doc reference ____________________

- A site plan or plans showing where all the relevant activities are on site, including storage areas, emission/discharge points, and any directly associated waste operations

  Doc reference ① CPW: External site layout.
  ② CPW: Emissions

C The details

C1 How will the installation operate?

Doc reference: Supporting Document: Section 4.

C2 Emissions, techniques and monitoring?

What pollutants (including odour) and how much are expected to be emitted into the atmosphere? Please say which stage of the process each emission will come from and also whether from a particular chimney, vent or other source (fugitive). Please include emissions during starting and shutting down the plant, and from possible breakdowns or accidents identified by a risk assessment. *(Using process flow diagrams may help to simplify this.)*

What techniques will be used to minimise each emission in line with BAT? What monitoring has been undertaken (give results) and what monitoring is proposed?

Doc Reference: Supporting Document: Section 5.4

C3 Environmental management?

What environmental management procedures and policy will you deploy?

Doc Reference: Supporting Document: Section 4.2

C4 Impact on the environment?

a) what are the potential significant local environmental effects (including nuisance) of the foreseeable emissions?

b) are there any sites of special scientific interest (SSSIs) or European protected sites nearer than any of the following distances to the proposed installation:

- 2km - where the installation includes Part B combustion, incineration (not cremation), iron and steel, or non-ferrous metal activities
- 1km - where the installation involves mineral or cement and lime activities
- ½ km - in all other cases?

No ☐ Yes ☑

c) if "yes", is the installation likely to have a significant effect on these sites and, if so, what are the implications for the purposes of the Conservation (Natural Habitats etc) Regulations 1994 (see appendix 2 of Annex XVII of the general guidance manual)

d) has an environmental impact assessment been carried out for the installation under planning legislation or for any other purpose. If so, please provide a copy

Doc Reference: ① Non-technical summary: Whitly South technology Capus
② Atkins technical Note: Ground investigation technical Note.

D Anything else?

Please tell us anything else you would like us to take account of.

Doc Reference Atkins: NMP Emissions Assessment Report.

E Application fee

You must enclose the relevant fee with your application. If your application is successful you will also have to pay an annual subsistence charge, so please say who you want invoices to be sent to.

MR. R. Lowe - Financial Director / Company Secretary.
C/o UKBIC 1 DL Building, University of Warwick
Coventry CV4 7AL

F Protection of information

G1 Any confidential or national security info in your application?

If there is any information in your application you think should be kept off the public register for confidentiality or national security reasons, please say what and why. General guidance manual chapter 8 advises on what may be excluded. *(Don't include any national security information in your application. Send it, plus the omitted information, to the Secretary of State or Welsh Ministers who will decide what, if anything, can be made public.)*

Doc Reference _______________________

G2 Please note: data protection

The information you give will be used by the Council to process your application. It will be placed on the relevant public register and used to monitor compliance with the permit conditions. We may also use and or disclose any of the information you give us in order to:

- consult with the public, public bodies and other organisations,
- carry out statistical analysis, research and development on environmental issues,
- provide public register information to enquirers,
- make sure you keep to the conditions of your permit and deal with any matters relating to your permit
- investigate possible breaches of environmental law and take any resulting action,
- prevent breaches of environmental law,
- offer you documents or services relating to environmental matters,
- respond to requests for information under the Freedom of Information Act 2000 and the Environmental Information Regulations 2004 (if the Data Protection Act allows)
- assess customer service satisfaction and improve our service.

We may pass on the information to agents/representatives who we ask to do any of these things on our behalf.

G3 Please note: it is an offence to provide false etc information

It is an offence under regulation 38 of the EP Regulations, for the purpose of obtaining a permit (for yourself or anyone else), to:

- make a false statement which you know to be false or misleading in a material particular,
- recklessly make a statement which is false or misleading in a material particular
- intentionally to make a false entry in any record required to be kept under any environmental permit condition
- with intent to deceive, to forge or use a document issued or required for any purpose under any environmental permit condition.

If you make a false statement

- we may prosecute you, and

- if you are convicted, you are liable to a fine or imprisonment (or both).

H Declarations A and B for signing, please

These declarations should be signed by the person listed in answer to question A3. Where more than one person is identified as the operator, all should sign. Where a company or other body corporate is the operator, an authorised person should sign and provide evidence of authority from the board.

Declaration A: I/~~We~~ certify

EITHER- No offences have been committed in the previous five years which are relevant to my/our competence to operate this installation in accordance with the EP Regulations.

OR- The following offences have been committed in the previous five years which may be relevant to my/our competence to operating this installation in accordance with the regulations:

No offences have been committed in previous five years

Signature J Pratt Name Mr Jeff Pratt

Position Managing Director Date 20th January 2020

Declaration B: I/~~We~~ certify that the information in this application is correct. I/We apply for a permit in respect of the particulars described in this application (including the listed supporting documentation) I/we have supplied. *(Please note that each individual operator must sign the declaration themselves, even if an agent is acting on their behalf.)*

Signature J Pratt Name Jeff Pratt

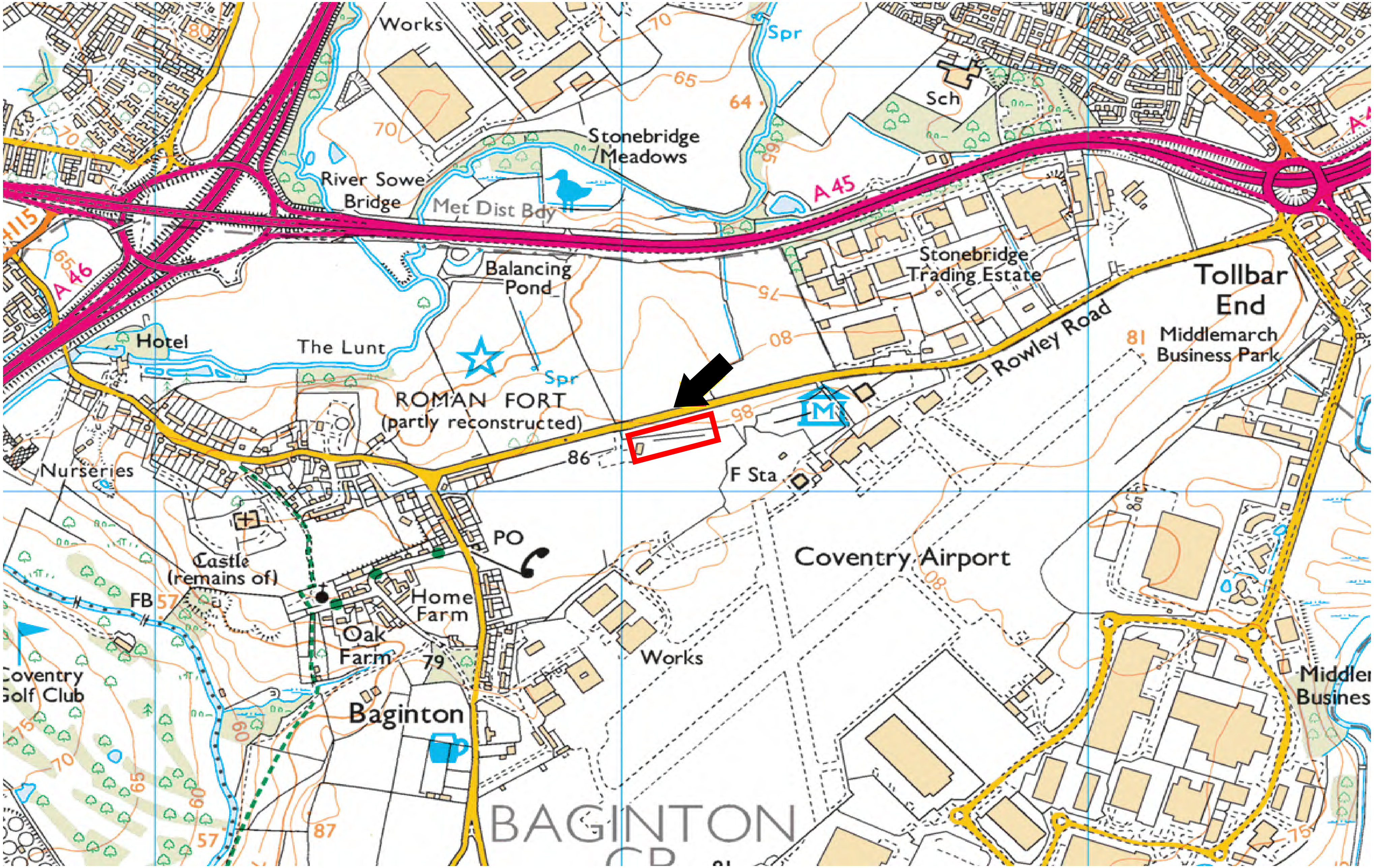
Position Managing Director Date 20th January 2020

Signature__________ Name__________

Position__________ Date__________

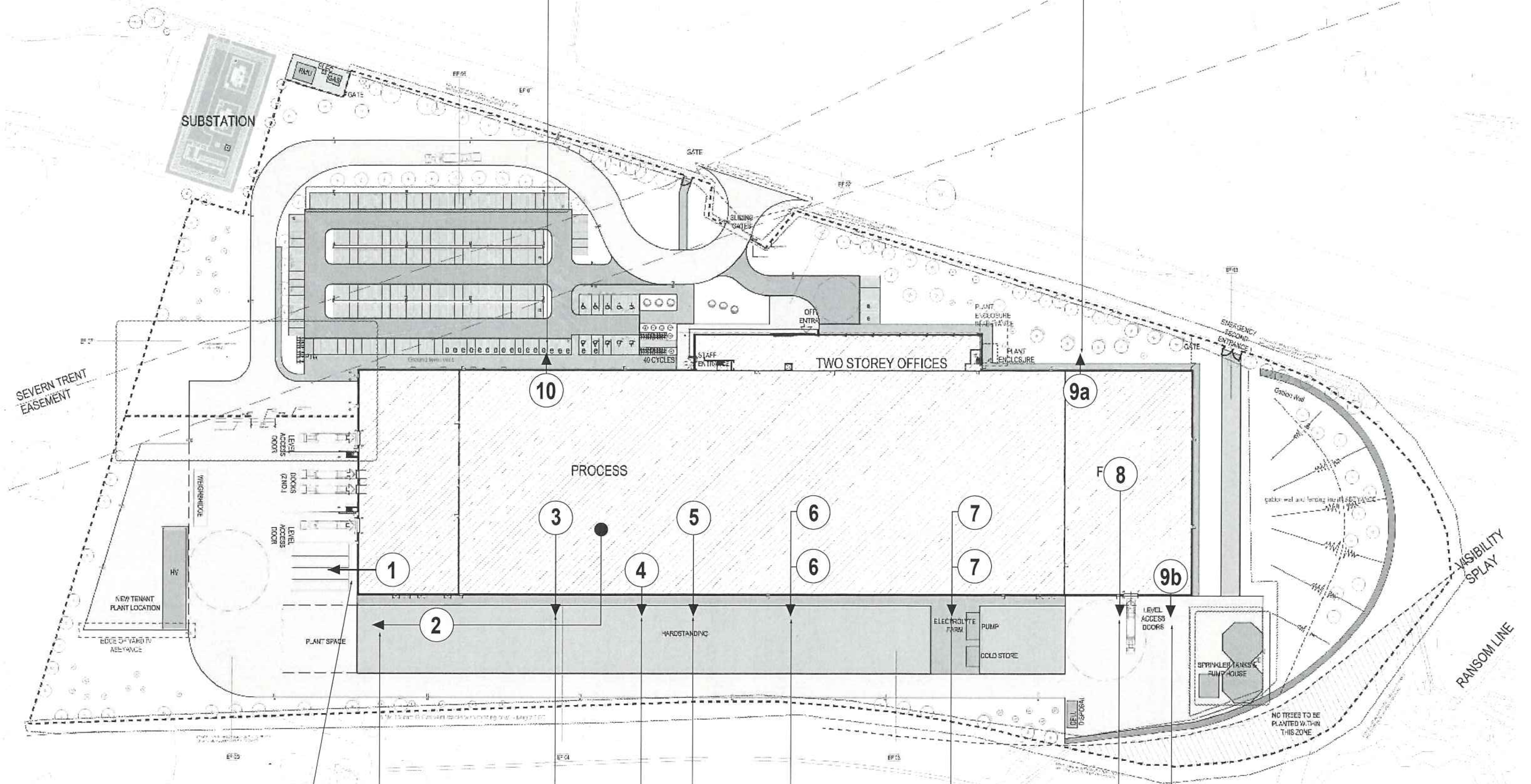
SECTION 2

SITE MAPS


Works
Spr
70
65
64
Sch
80
70
Stonebridge Meadows
River Sowe Bridge
A 45
Met Dist Bdy
A4115
A 46
65
Balancing Pond
Stonebridge Trading Estate
75
Tollbar End
Hotel
The Lunt
80
Rowley Road
81
Middlemarch Business Park
Spr
ROMAN FORT (partly reconstructed)
85
86
F Sta
Nurseries
PO
Castle (remains of)
Coventry Airport
80
FB
57
Home Farm
Oak Farm
79
Works
Coventry Golf Club
Baginton
75
70
65
60
60
57
87
BAGINTON
Middlemarch Business

EMISSION POINT 10
LABORATORY
ANALYSIS
GASEOUS
TRACE: ELECTROLYTE / NMP
ACTIVATES ON BURST
TO ATMOSPHERE VIA

EMISSION POINT 9a
FA & T
SPACE HEATING
GASEOUS
CO, CO2
-
TO ATMOSPHERE



EMISSION POINT 1
PLANT EQUIPMENT
GAS BOILER FOR PLANT HEATING
GASEOUS
CO, C02
216 m³/hr
TO ATMOSPHERE

EMISSION POINT 2
ELECTRODE
CATHODE DRYER
GASEOUS
SOLVENT VAPOUR
14,000 m³/hr
CONDENSER CARBON BED

EMISSION POINT 3
ELECTRODE
ANODE DRYER
GASEOUS
WARM AIR
54,000 m³/hr
TO ATMOSPHERE

EMISSION POINT 4
ELECTRODE
CATHODE EMERGENCY PURGE
GASEOUS
SOLVENT VAPOUR
-
EMERGENCY ACTUATION ONLY

EMISSION POINT 5
PLANT EQUIPMENT
CLEAN & DRY DEHUMIDIFICATION
GASEOUS
CO, C02
-
TO ATMOSPHERE

EMISSION POINT 7
CELL ASSEMBLY
ELECTROLYTE FILLING
GASEOUS
TRACE: ELECTROLYTE VAPOUR
37 m³/min
TO ATMOSPHERE

EMISSION POINT 6
CELL ASSEMBLY
VACUUM DRYER
GASEOUS
TRACE: SOLVENT VAPOUR
4 m³/min
TO ATMOSPHERE

EMISSION POINT 9b
FA & T
SPACE HEATING
GASEOUS
CO, CO2
-
TO ATMOSPHERE

EMISSION POINT 8
FORMATION
DE-GASSING CELL
GASEOUS
TRACE: ELECTROLYTE VAPOUR
90 m³/hr
TO ATMOSPHERE

REV	DATE	DESCRIPTION	BY	YE

couchperrywilkes®
engineering change

Birmingham	+44(0) 121 709 6600	☒
Nottingham	+44(0) 115 924 3348	☐
Huntingdon	+44(0) 148 045 7488	☐
Leeds	+44(0) 113 247 0709	☐
Bristol	+44(0) 117 315 5201	☐
Leicester	+44(0) 116 255 7397	☐
London	+44(0) 203 870 4780	☐
Manchester	+44(0) 161 074 7536	☐

RIBA STAGE 2☐ RIBA STAGE 3☐ RIBA STAGE 4☐

STATUS
WORK IN PROGRESS

CLIENT
UK BATTERY INDUSTRIALISATION CENTRE

PROJECT
UK BIC

DRAWING TITLE
EMISSIONS FACILITY PLAN

Scale (A1)	DATE	BY	YE
1:500	AUG 19	TR	

DRAWING NUMBER
-
REV
WIP
CPW Project No.-

SECTION 3

SUPPORTING DOCUMENT FOR EPR PART B PERMIT APPLICATION

UK BATTERY
INDUSTRIALISATION
CENTRE

Environmental Permit

Supporting document for EPR Part B Permit application (Redacted Copy)

Author – Tony Richardson

List of Tables

1 ABBREVIATIONS

UKBIC	United Kingdom Battery Industrialisation Centre
WMG	Warwick Manufacturing Group
APC	Advanced Propulsion Centre
WDC	Warwick District Council
FA&T	Formation, Aging and Testing
NMP	Cathode solvent – 1-Methyl-2-Pyrrolidinone
LiPF^6	Electrolyte solution – Lithium Hexafluorophosphate
GHS	Global Harmonisation System
SVHC	Substance of Very High Concern
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
M&P	Module and Pack
SoC	(Battery) State of Charge
SoH	(Battery) State of Health
Electrode	Anode and Cathode coated onto a metallic sheet
Cell	Electrochemical Battery Component
SEI	Solid Electrolyte Interface
EH&S	Environmental, Health and Safety
ISO 14001	Environmental Management System
PPE	Personal Protective Equipment
OEM	Original Equipment Manufacturer
ES	Environmental Statement
SCR	Site Condition Report
BMS	Battery Management System
ASRS	Automated Storage Retrieval System

2 INTRODUCTION

The UK Battery Industrialisation Centre (UKBIC) is a contributory governmental project to deliver the UK's Industrial Strategy's. It will fill a strategic gap in the UK – facilitating scale up to high volume processes for battery materials, cells, modules and packs, developing the processes to transition the UK to become a world leader in design, development and manufacture of batteries for vehicle electrification

The UKBIC will be a key precursor to full scale, high volume battery manufacturing and high-volume electric vehicle production. This vision, from the UK Automotive Council and developed with the automotive industry, recognises the importance of, and value that will be derived from, advances in manufacturing technology and process expertise in the delivery of the next generation of battery systems across electrode, cell, module and pack levels.

The Centre addresses the joined-up electrification agenda, developed by the UK Automotive Council and the Advanced Propulsion Centre, and is a key element in leveraging the opportunities in electrification potentially worth £5-£50bn per year and driving significant jobs growth across the UK. Being centrally located in the heart of the UK, in the Coventry and Warwickshire area, it will provide excellent transport links and is near an established automotive supply chain. The location allows future expansion to include suppliers and other business opportunities.

This open access facility will enable industry users (from materials suppliers to vehicle OEMs) to achieve an internationally competitive position in scaling up and commercialising advanced technologies central to the design, development and manufacture of batteries, Initial focus is driven by the automotive sector, but with wider application to trial and develop high volume battery manufacturing processes, demonstrating 'run-at-rate' with flexibility to material, cell and module format; enabling development of manufacturing KPIs and plant 'blueprints' for its industrial users. It will be a critical link in the development chain, to enable the most promising early and mid-stage research and development activities, to feed through into prototyping and commercial exploitation. UKBIC will act as a focal point for UK industrial collaboration and skills development and will provide a learning environment for UK technology to reach the market at ground-breaking levels of performance and quality.

The flexible production research facility will enable the production of new manufacturing processes as well as the use of new materials, new cell formats, new module structures and new packaging structures.

The research and testing of new lithium-Ion anode and cathode products and materials will be carried out in collaboration with the scientific support of the University of Warwick, Warwick Manufacturing Group (WMG) where only proven technology will be introduced to the UKBIC facility.

The facility will also provide a training environment whereby clients can learn the technical aspects associated with the chemistry, manufacturing techniques and safety matters.

The independent, open access facilities within UKBIC will be used by:

- Material suppliers
- Component suppliers
- Equipment suppliers
- Cell manufacturers
- Module / pack manufacturers
- OEMs Education and Skills development organisations

The facility will operate during normal working hours on a single shift, typical working hours will be 8am – 5pm. The exception to this is for the FA&T process that will be manned 24 hours a day, 7 days a week.

The UKBIC facility is part of the greater Whitley South Technology Campus, a development partnership between Jaguar Land Rover and Coventry City Council. The development extends to the land area to the north and south of the A45 between the Festival and Tollbar Island junctions of the A45 and A46; to the north of Coventry Airport.

An environmental statement was produced by Oxalis Planning for the developer (RSK) to identify likely environmental effects on the proposed development area.

The facility is located outside of the Air Quality Management zone.

3 THE INSTALLATION

3.1 PROCESS OVERVIEW

The process will consist of four main manufacturing areas;

Electrode Manufacture

The electrode manufacture is the initial stage of the battery process; the raw materials consisting of powders and aqueous materials are brought together within an automated closed system to generate an electrode slurry. The electrode slurry will be in the form of semi-aqueous Anode and Cathode material. This is precision coated onto a metallic sheet, dried and compressed (Calendering) to increase the energy density. The finished electrode, in a continuous sheet, is rolled onto a coil, vacuum sealed and either stored or forwarded into the cell assembly.

Cell Assembly

The electrode material in the form of a rolled 'mother roll' is passed through a slitting process; the purpose of which is to cut the coated sheet into the precise width as required for a cylindrical or pouch (future) cell type. The cell then passes through an automated assembly process whereby the respective cell is constructed including the electrolyte filling process. The individual cells are automatically presented into pallets in preparation for transferring into the Formation, Aging and Testing process. All of which is carried out within a Clean & Dry room environment.

Formation, Aging and Testing (FA&T)

Formation - Follows the cell assembly process and typically takes several days for the electro-chemical process to complete. A system of gradually charging & discharging the cells to generate the SEI (Solid Electrolyte Interface) on the Anode surface and activate the electrode materials, transforming the cell into a useable battery form. This process is carried out in a self-contained conditioning unit. It is this formation process whereby any manufacturing imperfections of the cell are realised. The process of Formation is rigidly monitored where deviation from set parameters of Voltage, Temperature and Amperage, the cell is rejected. The whole operation of cell / pallet movement is managed by means of an automated loading/unloading crane.

Aging - The cells are stored within the FA&T area in a palletise form at a nominal state of charge where the cell chemistry is aged. This process consists of a High temperature and Normal temperature zones where the cells are held within the area for an extended period of time.

Note: The purpose of the high temperature zone is to accelerate the curing process time.

Testing - The testing requirements are yet to be defined but will consist of performance related electrical testing of the Module and Pack prior to storage or shipping.

Note: The Formation and Aging areas are serviced by means of a (ASRS) crane where cell pallets are loaded / unloaded automatically within the respective area.

It is worthy of note that it is recognised the higher risk of battery cell failure is within the Formation and Aging area therefore significant levels of protection are employed to prevent aberrant thermal events and detection / suppression to address and mitigate any resultant fire.

Module and Pack Assembly

The Module and Pack assembly process has not yet to be defined for the facility. The intention of the business is for the process to be procured and installed Q3 2020.

It is anticipated that the Module and Pack process will have limited environmental impact.

The principles of the process include the following:

The finished cells are received from the FA&T in the singular cell form, and semi-manually assembled into Modules. The cells will be assembled together within a housing or Module, the cells are directly connected by means of internal busbars. Several Modules are assembled together within a larger housing and connected by means of further busbars to create the battery Pack.

The Module and Pack processes incorporates an end of line testing function at the end of the assembly process whereby

3.2 MANAGEMENT SYSTEMS

UK Battery Industrialisation Centre is a newly formed business and as such the respective management systems are presently in development stage.

As the facility and associated equipment are installed, all processes, procedures and risk assessments will be developed and in place prior to operation.

The senior management team are committed to achieving ISO status for Health, Safety, Environment, Quality and Security.

The aim for 2020/21 is to be certified to ISO 14001, ISO 45001, ISO 9001 and ISO 27001 within an integrated management system that will provide the business with a high level of qualification as a facility that adheres to the best practices and processes and that safety and security of the environment are key indicators of the business model.

4 ELECTRODE MANUFACTURE

4.1 PROCESS DESCRIPTION:

The battery cell raw materials are brought together by means of two separate process manufacturing lines to form Cathode and Anode electrode slurry. The separation of such materials is for the purpose of eliminating cross-contamination concerns with the electrode materials.

The slurry material will be in a semi-fluid state of viscosity that is evenly spread across a copper (anode) or aluminium (cathode) sheet. The material is then presented through a warm air drier where the moisture content is reduced to an almost absolute dry state. The coated material is then passed through a Calendering process (The Calendering is a precision compression / rolling process whereby the material is reduced to a thickness of ~150 µm, increasing the electro-chemical energy density). The finished material is thereby rolled into a 'Mother Roll', vacuum sealed and stored or taken forward into the cell assembly manufacturing process.

The dry materials will be brought together via a closed, gravity feed powder/material handling system and fed directly into the mixing vessels.

The Cathode slurry liquid composition is entirely made up of the solvent NMP (1-Methyl-2 pyrrolidinone).

Note: This specific material is used as the main liquid component within the Cathode Battery Cell Manufacturing Industry with no substitute currently available.

The Anode slurry liquid composition is de-ionised water and the future plan will be for the water to be generated to the appropriate grade by means of an on-site reverse osmosis plant.

The slurry coating activity is precision application process onto the raw copper (Anode) and aluminium (Cathode) sheets similar to that of a printing process. The coated metallic sheets are dried by means of an electrically powered indirect heated air stream. The purpose of which is to remove the moisture content to as close to zero moisture percent as possible.

Solvent recovery – The drying activity for the Cathode process incorporates a solvent recovery system in the form of a condensation solvent recovery treatment process and a secondary abatement process of activated carbon adsorption unit to end of pipe. The abatement process description in detailed within section 4.3 Abatement methodologies for NMP

Note: Moisture within any electrode material is detrimental to the performance of the material and can create failure within the cell structure.

The following process step is Calendering – A process by which the dried coated anode and cathode sheet are compressed between two precision heated rollers applying force to the coated sheet to further reduce the porosity and increase the energy density.

The dried, coated respective anode and cathode sheets will then be wound onto a roll and vacuum enclosed to ensure exposure to contamination and humidity are eliminated.

Note - The anode and cathode materials will require complete segregation to prevent cross contamination due to the nature of the electro-chemistry associated with the technology.

The mixing, coating and Anode Calendering activities will be carried out in a Clean environment. The Cathode Calendering and cell assembly activities will be carried out in a Clean and Dry room environment; a technical requirement for the battery material quality – moisture sensitivity.

Slitting – The activity of Slitting is the precision process to cut the respective anode and cathode sheet to their required width – suitable for the specific cell assembly.

4.2 CATHODE MATERIAL: N-METHYL-PRROLIDONE (NMP)

NMP is the liquid material utilised within the manufacture of the Cathode electrode. The purpose of NMP is to dissolve the PVdF (Polyvinylidene difluoride) and act as the binding agent of the active materials to the metallic foil.

NMP *CAS NO (872-50-4)* is listed within REACH and was placed on the candidate list as a SVHC. GHS records the material with a Hazard Phrase of H360D (May cause damage to the unborn child) therefore significant Health, Safety and Environmental restrictions have been placed on suppliers and downstream users.

Article 5 of the Solvents Emissions Directive identifies substances with the Hazard Phrase of H360D (formally R61) with a mass flow of greater or equal to 10g/h, an emission limit value of 2mg/Nm^3 is to be complied with. Based on the calculations provided by the abatement supplier, the mass flow for the UKBIC chosen abatement system will be 2.8g/h.

There are currently no alternatives or substitutes that are commercially available. The report associated with the supporting document; 'Report on the state of art for N-Methyl-2-pyrrolidone in the production of Lithium-ion battery cells', addresses the elimination & substitution options by academic research and has been commissioned by UKBIC to Aachen University, Germany. A leading research university establishment on Lithium-ion batteries and their main competencies are in the manufacturing production environment. Aachen university are involved in the Giga-factory technical development within Europe. Aachen specifically are the lead institute for the German battery facility equivalent to that of UKBIC.

The report summary concludes that elimination or substitution of the substance NMP currently is not technically feasible. This is in essence due to a) the solvent alternative(s) are not commercially viable and only being utilised at research levels and b) any change from known technologies require compliance with strict certification and approval routes.

Note - See attached documents

- ***EUROBAT- Association of European Automotive and Industrial Battery Manufactures – Position paper May 2017 Recommendation about n-methyl-pyrrolidone (NMP) proposal for inclusion in Annex XIV for authorisation.***
- ***ANNEX XV – Proposal for identification of a substance as a category 1A or 1B CMR, vPvB or a substance of an equivalent level of concern - 1-Methyl-2-pyrrolidone as SVHC – European Chemical Agency***
- ***Aachen report – Report on the state of the art for N-Methyl-2-pyrrolidone in the production of lithium-ion battery cells.***

In relation to the environmental impact *1-Methyl-2-pyrrolidone* has on the environment, NMP is expected to be readily decomposed by bacteria or other living organisms and therefore is not expected to accumulate in the environment.

Note – See attachment

- *World Health Organisation – Concise International Chemical Assessment Document 35*

4.3 ABATEMENT METHODOLOGIES FOR NMP

4.3.1 Abatement Selection for BAT

UKBIC has considered the following techniques / technologies for the purpose of minimisation emissions of solvent from the battery manufacturing Electrode process:

- Condensing System
- Carbon Bed;
- RTO: Regenerative Thermal Oxidiser;
- Concentrator

A brief description of each technique is provided below and the relative merits / disadvantages for each technique are compared in the Table 1.

Condensing System:

The condensing system consists of a three-stage air \ water heat exchange condensing system attributed to a warm air dryer.

- Stage 1 – Cooling air is chilled by means of a chilled water supply;
- Stage 2 – Solvent is condensed and drained out of the system; and
- Stage 3 – The heated air re-circulates into the dryer reducing energy consumption.

The warm air is electrically heated, re-circulated and exhausted via a condenser

Carbon Adsorption

In the case of the UKBIC process the Carbon Bed is to be utilised in conjunction with a Condenser. The exhaust stream is directed from the Condenser into an externally located activated carbon bed via ductwork. The carbon bed consists of two separate units operating in parallel and each containing 2500kg of activated carbon with an operability of switching between the two units when necessary i.e. saturation.

Regenerative Thermal Oxidation (RTO):

A thermal process to decompose VOC's (Volatile Organic Compound), a recognised method for the abatement treatment of high concentrations of organic substances.

By means of a super-heated gaseous stream normally natural gas, in excess of 1300^{O}F (700^{O}c) whereby the hydrocarbon (VOC) is converted to carbon dioxide and water.

Concentrator:

A large rotor concentrator system utilises a hydrophobic zeolite media wheel to adsorb VOCs from a process exhaust stream.

Solvent laden exhaust `air is drawn through the HoneyCombe rotor where VOCs are removed from the airstream by adsorption onto the hydrophobic zeolite. After passing through the rotor, the cleaned air is discharged into the atmosphere.

The Solvent media wheel passes through a heating process to destroy the adsorbed VOC.

Table 1 - Comparison of the various abatement options considered:

	Condensing System	Carbon Bed Adsorption	Regenerative Thermal Oxidation (RTO)	Concentrator
Main Pros/Cons	Recognised Best available Technique for the reduction of VOC emissions. NMP easy to condense out of exhaust stream. Condensed solvent can be recovered and re-used.	Commonly utilised as a 'Polishing' process following a Condensing abatement system.	Commonly used method for the abatement of VOCs in high concentrations. NMP in an RTO generates NOx and therefore may require an additional SCR system to abate the NOx.	Exceeds the adsorption capability of Activated Carbon Efficiency effected by environmental humidity Utilised generally for large processes. Incorporates a Thermal Oxidiser to remove and destroy the solvent from the media wheel.
% Solvent removal / efficiency	99.73%@ Maximum solvent throughput.	99% can be achieved for low levels of VOC concentrations	99% oxidation can be achieved	Typical efficiencies of 96% can be achieved.
Operational flexibility	Used in conjunction with a chilled water supply, the Condenser abatement is an appropriate method to meet the operational requirements of the UKBIC process: Intermittent and not continuous	Used in conjunction with a Condenser system, the activated carbon polishes the low levels of VOC emissions from the Condenser to reduce the emission to <2mg/m3 at end of pipe.	Thermal process is required to be at optimum temperature for the oxidation efficiency to be realised.	A combination of adsorption and thermal oxidation
Operational 'capacity' issues	The scope of the UKBIC Condenser system has been sufficiently sized to manage the VOC volume expected for the Electrode process. Efficiency is reliant on the appropriate supply of chilled water (5^{0}C)	Activated carbon relies on the adsorption of VOC onto the carbon. Saturation of the carbon reduced the efficiency.	Generally utilised in the abatement of large volumes of VOC laden gaseous exhaust streams. Can be designed to accommodate specific exhaust volumes.	Generally utilised for larger installations

	Condensing System	Carbon Bed Adsorption	Regenerative Thermal Oxidation (RTO)	Concentrator
	and product residence time in dryer.			
Reliability	Reliant on the correct chilled water temperature for maximum efficiency	Maintenance of the activated carbon before saturation levels ensures high efficiency rates	Reliant on an efficient heat source i.e. natural gas burners to be operating effectively otherwise can generate other pollutants namely CO (and associated health effects)	High reliability due to the limited parts.
Physical/size constraints	Condenser is of significant size within the facility	Externally located, the CB is significant in size and requires maintenance for the replenishment of the carbon – within 15m of hard standing for goods vehicle	RTO is of a significant size installed externally to the process. Result in long ducts of significant size.	Concentrator is similar to that of an RTO in size and associated constraints. Installed externally to the process. Result in long ducts of significant size.
Readily available / reliable technology	Readily available technique	Readily available technique	Readily available technique	Not listed BAT but utilised globally
Opportunity for solvent recovery / re-use	High opportunity for Solvent recovery	No opportunity for Solvent recovery	No opportunity for recovery, Solvent destroyed by oxidation	No opportunity for recovery, Solvent destroyed by oxidation
Use of raw materials (in the abatement technique)	None	Activated carbon replenishment when saturated	Natural gas (or similar)	Natural gas (or similar)
Use of raw hazardous substances (in the abatement technique)	None	None	Natural gas	Natural gas
Availability / cost of raw materials	N/A	Readily available Carbon replacement ~£1500	Dependant on usage and effectiveness of any heat recovery – Generally high on-costs of raw materials	Dependant on usage and effectiveness of any heat recovery – Generally high on-costs of raw materials
Energy use / efficiency	Utilising facility chilled water supply Heat recovery from return gas flue	No impact – Gas flow adsorption	Significant energy consumer but can be improved by heat recovery	High energy consumption
Energy / heat recovery	N/A	N/A	Heat recovery designed into the system.	Design to incorporate heat/energy recovery
Fuel use	N/A	N/A	Natural gas (or similar)	Electrical + Natural gas (or similar)
Water use	Recirculatory chilled water supply	N/A	N/A	N/A
Water re-use / recycling	N/A	N/A	N/A	N/A
Emissions to air (other than solvent)	Emissions directed via Carbon Bed	End of Pipe emissions to meet regulatory ELV	RTO end of pipe emissions to meet regulatory ELV. Potential for the generation of oxides of Nitrogen which may require further abatement	RTO end of pipe emissions to meet regulatory ELV. Potential for the generation of oxides of Nitrogen which may require further abatement
Emissions to water	N/A	N/A	N/A	N/A
Emissions to land	N/A	N/A	N/A	N/A

	Condensing System	Carbon Bed Adsorption	Regenerative Thermal Oxidation (RTO)	Concentrator
Waste generation	None	Regenerated carbon	Capture of water from oxidation	Capture of water from oxidation
Waste recycling opportunities	N/A	Regenerated activated Carbon is placed back onto the market as raw material	N/A	N/A
Noise	Internal noise levels below CoN@W regs No External noise impact	Low levels of noise impact	Medium noise impact: may need attenuation	Medium noise impact: may need attenuation
Odour	None	Low levels of emissions insignificant to create an odour impact	Generally, no odour impact Potential for Urea odour from SCR	Generally, no odour impact Potential for Urea odour from SCR
CAPEX	Initial installation cost = Medium	Initial installation cost = Medium	Initial installation cost = Very High	Initial installation cost = Very High
OPEX	Operational costs = Low	Operational costs = Low	Operational costs = High	Operational costs = High
Materials handling issues	Recovered solvent collected by automated system to chemical storage area	Mechanical method to remove / replenish activated carbon	None	None
Materials storage issues	Recovered solvent stored in suitable receptacle and located in bunded chemical storage area	None	None	None
Potential for accidents	Highly unlikely for aberrant conditions.	Highly unlikely for aberrant condition.	Highly unlikely for gaseous release. Generation of CO/NOx has potential health effects.	Highly unlikely for gaseous release. Generation of CO/NOx has potential health effects.
Emergency requirements / controls (e.g. in case of loss of power, etc)	Equipment emergency shutdown in the event of solvent release. Plant emergency procedure in the event of aberrant release of solvent	No power supply for carbon bed. Directly associated with emissions from Condenser	Emergency shutdown procedure	Emergency shutdown procedure
Safety issues	Maintenance of recovered solvent outlet to receptacle	Working at height for maintenance / Monitoring	Working at height for maintenance / Monitoring Generation of CO/NOx has potential health effects.	Working at height for maintenance / Monitoring Generation of CO/NOx has potential health effects.
Monitoring	In-process control monitors the solvent concentration for explosivity.	TBC – Third party VOC monitoring	TBC – Third party VOC monitoring	TBC – Third party VOC monitoring
Stack requirements	None	Stack monitoring points and platforms provided	Stack monitoring points and platforms provided	Stack monitoring points and platforms provided

4.3.2 Conclusion

Based on the above it is considered that a combination of Condensing and Adsorption on Activated Carbon represents BAT for the purposes of minimising emissions of solvent from the battery manufacturing electrode process.

- Condensing extends to the collection of condensed solvent with the opportunity for re-use.
- There is no fuel utilised in the operability of either the condenser and the carbon bed and for the reason of energy consumption are regarded as most preferred option(s).
- The RTO and Concentrator destroy the solvent eliminating the option for re-use.
- The RTO and Concentrator have the additional impact of generating Oxides of Nitrogen which may require further abatement and monitoring dependant on the levels of NOx emitted.
- The RTO and Concentrator initial capital expenditure is significantly higher than that of the Condenser and Carbon Bed.
- The RTO incorporates efficient heat recovery however utilises significant energy to operate.
- External noise levels would be minimal with the Carbon Bed as opposed to the RTO and Concentrator.

4.4 SOLVENT ABATEMENT

The solvent recovery system for the Cathode process is to be provided by Megtec/Durr and consists of a three-stage air water heat exchange condensing system attributed to a warm air dryer. The warm air is electrically heated, re-circulated and exhausted via a condenser and then directed into an activated carbon bed.

- Stage 1 – Cooling air is chilled by means of a chilled water supply
- Stage 2 – Solvent is condensed and drained out of the system
- Stage 3 – The heated air re-circulates into the dryer reducing energy consumption

The dryer will be formed of 8 heating zones interconnected; each zone will be controlled by means of organic detection sensors monitoring the levels of organic vapour within the specific zones. The purpose of which is to ensure the level of organic vapour does not exceed the lower explosive limit (LEL). The controlling system will have two action levels to prevent an explosive atmosphere from existing.

1. The high-level action point is actuated when 35% of the LEL is detected
2. The high-high-level action point is actuated when 50% of the LEL is detected as an additional safe-guarding control measure.

The action point(s) triggers a controlled process stop however the abatement process continues ensuring the evolving vapours are reduced to below the respective LEL levels. The action points are indicated on the equipment HMI to inform the technician is aware of the situation. Only when the organic levels reduce to normal operational levels can the equipment be re-instated.

In the event of a site power failure, the emergency purge actuates expelling the vapour contents of the dryer externally without passing through the abatement system.

The condenser is to be mounted/installed directly above the dryer, the carbon bed is located externally and connected via ductwork.

The carbon bed consists of two separate units operating in parallel each containing 2500kg of activated carbon and an operability of switching between the two units when necessary. The lifetime of each units has been calculated as 650 operational hours.

The abatement efficiencies reported by the equipment supplier (Megtec) are as follows:

Table 2 - Abatement efficiencies

Exhaust out of the condenser (to carbon filter)	1400 Nm^3/h
Concentration out of the condenser (to carbon filter)	661 mg/Nm^3
NMP flow out of condenser to carbon bed	925.4 g/h
Amount of carbon needed to adsorb 1 kg of NMP	4 kg/kg
Amount of carbon needed per hour	3,7016kg/h
Carbon Filter Size	2500kg (*2)
Time to saturate 1 carbon filter	675.4 hours
NMP output from carbon filter	**2 mg/Nm^3**
NMP output from carbon filter	**2.8 g/h**
@coating speed of 32m/min	
Condenser efficiency (%)	99.73%
Total System efficiency (%)	**99.9992%**

With reference to the BAT guidance document reference '*Surface treatment using Organic Solvents'*; the preference of a combination of chilled water (5°C) Condensation and Carbon Adsorption achieve the anticipated abatement emission limits (ELV) and incorporates the recovery of the solvent for re-use. Re-use can consist of using the condensed solvent as a process cleaning substance where the level of solvent does not meet the quality standard equivalent to 'fresh' solvent and/or can be sold as a raw material for use in other industrial processes.

An alternative abatement method of Thermal Oxidation is highly energy intensive and does not incorporate heat or solvent recovery.

The Carbon Bed has the effect of polishing the remaining ~2% of the exhaust stream from the condenser. Both proven and effective abatement technologies.

UKBIC have taken into consideration and estimated the worst-case situation whereby due to short periods of abnormal process operating conditions could result in emission levels to a value of 4mg/m^3 at the carbon bed stack. Due to the in-process controls, the potential for this very low and may be realised during a whole facility power failure. In the event of such power failure, the solvent abatement system automatically actuates an emergency purge. The purpose of which is for that of safety and prevention of a hazardous flammable atmosphere within the dryer. The emergency purge outlet is separate from the Carbon Bed stack and is released through the nearest external wall of the facility, at a high level and will consist of warm extract with solvent vapour and for a short period of time. The manufacturers have given instruction that this purge will be for a period of two minutes whereby the residue of solvent vapour will have sufficiently evolved within the dryer and prevented the potentially flammable atmosphere.

In normal operation and where the activated carbon is allowed to surpass the point of adsorbent saturation, there is potential for higher levels of emissions to be released. The manufacture has provided UKBIC with conservative calculations relating to the residence time of organic vapour has on the carbon prior to saturation. The UKBIC design have two carbon beds so where saturation of the activated carbon is close, the duty bed can be swapped to the stand-by bed and replenishment arranged.

Condensate recovered from the Solvent abatement process will be returned to the external chemical area and stored within a dedicated IBC. Due to the moisture sensitive nature of NMP, the cleaning process cannot introduce water into any part of the equipment including that of the associated pipework, the only suitable material for cleaning is that of NMP. UKBIC are investigating whether the solvent condensate material can be used as the primary washing / flushing material for the process equipment. The waste washing from the cleaning process will be returned to a further waste IBC and this material will be sent for specialised treatment by an appropriate waste management company.

4.5 MONITORING STRATEGY

The monitoring strategy proposed for the Cathode abatement: The end of pipe for the cathode extraction will be at the Carbon Bed. The height of the efflux is being designed to be three meters above the haunch of the building (9m) and a total height of 12m.

Considering the only recognised method for continuous monitoring of organic substances is that of FID (Flame Ionisation detection) if required is technical and potentially out of the ability of the current UKBIC staff, expensive and results of which are required to be analysed by a third party.

The proposal of UKBIC is to maintain quarterly monitoring by an external third-party consultant for a period of two years where the results are shared directly with the District Council. Where results are found to be compliant and the management of the process and associated abatement system meet the required standard of the enforcement body, the external monitoring will revert to annual monitoring.

This will be supported by on-site monitoring by the UKBIC EH&S team as part of their occupational health monitoring programme. A handheld instantaneous PID (Photoionisation detection) where readings are recorded and available for audit purposes.

5 CELL ASSEMBLY

5.1 PROCESS DESCRIPTION:

The Battery Cell assembly process includes the assembly of two cell types; a cylindrical and pouch cell: a cylindrical cell is a metallic cylinder with the anode and cathode electrodes rolled within (Jelly Roll).

The pouch cell type consists of a flexible laminated Aluminium (Polyethylene terephthalate or Polypropylene) Film pouch of varying dimensions, where electrodes are assembled in layers within a flat design.

The cylindrical cell assembly process incorporates an automated process where the rolled coils follow the process steps as detailed in figure 1. The pouch cells are stacked together; anode, cathode and separator and then contained within the laminated pouch.

Both types contain the electrolyte solution to enable the positive ions transportation during discharge and the ions reverse during the charging process.

Vacuum drying – an independent heating process for the rolled coils to be further dried to remove any residue moisture prior to passing into the assembly process. The vacuum dryers for the cathode incorporate an extract of heated air with the potential of trace amounts of NMP vapour. The fate of this extracted air is planned to be directed to atmosphere.

5.1.1 Cylindrical cell assembly

- Welding of Tabs – the bottom tab is welding into the metallic cell. The welding process is laser type and the resultant fumes will be locally extracted, filtered and re-circulated into the facility;

- Cutting and Winding – The respective anode and cathode electrodes along with a polypropylene separator between each cell are rolled together; Known as the 'Jelly Roll'.
- Insertion into the can – The rolled cells are then inserted into the can;
- Bottom Tab Welding – Welding Tool inserted into the centre of the Roll to Weld the tab to the bottom of the Can;
- Centre Pin Insertion – The centre pin is then inserted into the centre of the Jelly Roll;
- Top Insulator and Grooving – Top Insulator is inserted into the cell after die punching, Top of Can is then grooved to a predetermined shape
- Electrolyte Filling – The cell is then filled with an electrolyte solution
- Welding (Tab) to lid – Weld the Cathode Tab with the Top Cap
- Cell Sealing – Seal the Cell by Crimping the Can and the Top Cap
- Cleaning – Cell is cleaned with Deionized water to remove any excess Electrolyte

5.1.2 Pouch cell assembly

- The respective electrodes and separator are pressed /cut to the required pouch size;
- The individual anode and cathode electrodes are stacked; anode, separator, cathode, separator, anode etc
- The contact tabs are welded onto the electrodes and the stack is then inserted within the pouch
- The pouch is partially sealed by means of a heat treatment press
- The electrolyte solution is then injected into the cell followed by a period of soaking
- The pouch is sealed and then inserted into a loading pallet in preparation of being processed within the FA&T.

The assembly process activity will be carried out in a Clean and Dry room environment as is required for the battery material quality due to the moisture sensitivity of the electrolyte solution.

The electrolyte solution delivery system:

The electrolyte delivery system will be a stand-alone structure located external to the building immediately adjacent to the cell assembly process area. The delivery system incorporates a purpose-built housing, environmentally controlled and fully bunded. Design of the supply system is still in progress and to be agreed however it has taken into consideration the requirements to;

Protect the operatives from exposure to the harmful effects of NMP and

Assessed appropriately in accordance with DSEAR for Fire & Explosion risk and

Reduce the opportunity for fugitive emissions

The delivery system will be an automated process where the only human interface required is to replace the respective empty tote (container) with a full one. This will be carried out within the constraints of an operational procedure by fully trained staff.

Note: Electrolyte solution is the recognised substance; Lithium salt solution used in the battery cell manufacture. The electrolyte solution serves as the catalyst to make a battery cell conductive by promoting the movement of ions from the cathode to the anode on charge and in reverse on discharge. The electrolyte solution is a generic term for the solution typically containing Lithium Hexafluorophosphate, Ethylene Carbonate and Diethyl Carbonate as base materials with additional substances dependant on customer requirements. These materials are typically confidentially sensitive due to the nature of the battery industry.

6 FORMATION, AGING AND TESTING

6.1 PROCESS DESCRIPTION

Formation

Follows the cell assembly process and typically takes several days for the electro-chemical process of gradually charging & discharging the cell to activate the materials, transforming the cell into a useable battery form. The formation process consists of a number of 'Formation Pods' where pallets of individual cells are loaded onto pallets. The automated ASRS crane loads the pallets into the respective formation pod.

Note: the formation pods control the electrical charge/discharge process and have integral detection for deviation from set parameters of voltage, resistance, temperature. There is also detection in the event of a fire. The formation pod is recognised as the 'Fire Box'.

The principle of the 'Formation Pod' is to complete the electrical process but has the additional functionality of containing any thermal event should one occur. The formation process is where the cell is activated into an energy component however should there be any underlying faults, it is this process where faults are realised. A fault will result in a short circuit of the cell where the two electrodes come together potentially creating an exothermic reaction and resultant fire. The Formation Pod is designed to contain and withstand any such thermal event preventing any spread of fire to adjacent cells.

It is then transferred via the ASRS crane into the Aging area.

Aging

The pallet of active cells from the formation area are loaded into a racked area. There are two areas within the aging area; the normal temperature and the high temperature areas. The cells are held in these areas for a period where they are 'Aged'. The high temperature has the effect of accelerating the aging process.

The aging process allows for the electro-chemistry to create a Solid Electrolyte Interface (SEI) layer on the Anode. This layer protects the active materials on the Anode from the Electrolyte.

Testing

An Open Circuit Voltage (OCV) test is completed after the aging to determine whether the cell has short circuits or has been damaged during the final sealing process. The OCV also measures the resistance and final mechanical dimensions.

Note – The FA&T area will be manned 24 hours a day, 7 days a week.

7 MODULE AND PACK ASSEMBLY

The Module and Pack process equipment has yet to be finalised through procurement therefore the ultimate equipment detail is unknown.

The principles of the Module and Pack process incorporates the assembly of finished singular cell form and combined with identical cells will be assembled into Modules (several single cells joined together within a housing or Module), directly connection by means of busbars. The completed modules are assembled together within a larger housing and connected by means of further busbars creating the battery Pack.

The process culminates with an End of Line test; a performance related test to confirm operation of the equipment where faults / performance issues are identified. The functional test incorporates charging / discharging / performance against test profiles (SoC & SoH)

The battery pack also incorporates an integral BMS and cooling system, the purpose of which monitors the pack whilst in-vehicle to manage aberrant conditions where high parameters of temperature, voltage or short-circuit are identified.

The singular cells can be received from the FA&T process or where an independent campaign utilises the Module and Pack process only, the cells can be sourced from a 3rd party supplier by the campaign company.

8 STORAGE OF RAW MATERIALS

8.1 STORAGE

The materials to be utilised within the facility will be based on the requirements of the specific campaign/projects running at any point in time. There will be no planned long-term storage of chemical materials within the facility. The materials will be scoped and ordered as part of the project planning exercise prior to any production commencement.

The Logistics area will be the receipt and holding location for all materials and the management of such will be controlled by a UKBIC Logistics Goods-In operative. All materials held and stored on site are to be managed by means of the site warehouse management system – namely; Manufacturing Execution System (MES) and/or Enterprise Resource Planning (ERP) system. This area of the business is in development.

Materials will be delivered by goods vehicles from suppliers to the secure access area to the West of the facility. The secure area controls vehicular movement into and out of the logistics area. Control of the vehicular access point is by means remote electrically operated gate operated from the Goods-in office. The Goods-in technician will have visibility and facility to speak to the respective driver and operate the barrier.

Vehicles will only be accepted during normal working hours, outside of these the main access gate will be closed.

In relation to the storage of the bulk liquid materials; NMP (N-Methyl-2-pyrrolidinone) & Electrolyte solution (Lithium hexafluorophosphate). Both materials will be stored externally on a dedicated platform, suitably bunded and (ground) protected location.

The NMP material will be supplied in various sized containers and utilised within the plant adjacent to the Electrode manufacturing plant equipment.

The Electrolyte will be delivered directly to the cell assembly plant equipment from an externally located distribution system. (See section 8.2 – Electrolyte delivery and storage area)

Liquid material storage will comply with the 'The Control of Pollution (Oil Storage) (England) Regulations' 2001.

There will be a number of minor liquid additions within the process of which are low volume and storage appropriate in line with their specific chemical nature.

In relation to the storage and handling of Powder materials

The two main bulk dry powder materials to be utilised on site will be;

- Graphite (for the Anode electrode)
- Li-NMC (Lithium Nickel Manganese Cobalt Oxide) for the Cathode electrode

These materials and other smaller volumes of dry powder materials will be stored internally within the Logistics hall; in suitable containers and locations taking into consideration the separation and compatibility measures.

8.2 ELECTROLYTE AND NMP DELIVERY & STORAGE AREA

The section indicated on the site drawing as Chemical area is a dedicated Chemical receipt area where the electrolyte and NMP delivery system, liquid chemical waste & storage is to be located. This is situated to the rear of and south side of the facility. The area consists of a hard standing suitable for the use by heavy goods vehicles and Forklift trucks. The area is sufficiently sized to accommodate a goods vehicle and be loaded/unloaded and remain within the perimeter drainage scheme. The drainage is an ACO type floor drainage system and incorporates a Penstock valve and in-line oil interceptor prior to release into the surface water drainage system. Procedurally, the loading and unloading activity will involve the closing of the Penstock.

The principle for the protection in the event any spillages in the electrolyte delivery area is to provide a dedicated loading/unloading area for vehicular deliveries.

The foreseeable risk is one of 'spillages' from one container during an unloading activity. The loading and unloading activity will be proceduralised within the business management system. Only UKBIC trained, assessed and audited operatives will be authorised to carry out the loading/unloading process.

The external 'Chemical Area' will consist of;

- Electrolyte delivery system: - a purpose-built housing for the electrolyte system internally bunded;
- Recovered NMP solvent IBCs: - bunded and high-level indication fed back to the process equipment;
- Waste electrolyte material IBCs: - bunded and high-level indication fed back to process equipment;
- NMP & Electrolyte storage facility: - bunded storage unit.

The chemical area will consist of a hard standing suitable for goods vehicles and boundary drainage. This specific drain leads to a foul water drain with in-line Penstock and associated shut-off valve and interceptor prior to being released into the Foul water stream. See Site Drainage section (9.5)

Safety Data Chemical information

No environmental hazards identified – Substance or mixtures contain no components considered to be either persistent, bioaccumulative and toxic or very persistent and very bioaccumulative (at levels >0,1%)

There are no environmental specific 'H' hazard phrases listed within the respective SDSs from the above substances.

The respective 'P' phrases listed in the SDSs for the above relate to the appropriate storage and ventilation methods that will be adopted by UKBIC.

Table 3 – Chemical inventory

Name of substance	Synonyms	Process Area	Form	Material type	Environmental Hazards Risk Phrases (H 400+)	Usage (Kgs/Year)	Fate
Lithium nickel manganese Cobalt Oxide	Li-NMC	Electrode - Mixing	Solid - Powder	Cathode	None identified	6900	In product
Lithium Nickel Cobalt Aluminium	LI-NCA	Electrode - Mixing	Solid - Powder	Cathode	None identified	* Unknown	In product
Lithium Nickel Manganese Nickel Oxide	Li-NMO	Electrode - Mixing	Solid - Powder	Cathode	None identified	* Unknown	In product
Lithium Cobalt Oxide	Li-CO	Electrode - Mixing	Solid - Powder	Cathode	None identified	* Unknown	In product
Carbon	C	Electrode - Mixing	Solid - Powder	Cathode	None identified	1440	In product
Poly(vinylidene fluoride)	PVdF	Electrode - Mixing	Solid - Powder	Cathode	None identified	1440	In product
N-methyl-2-pyrrolidinone	NMP	Electrode - Mixing	Liquid	Cathode	None identified	30000	Evaporated and recovered
Graphite	C	Electrode - Mixing	Solid Powder	Anode	None identified	4600	In product
Styrene-butadiene Copolymer	SBR	Electrode - Mixing	Liquid	Anode	None identified	960	In product
Sodium Carboxymethylcellulose	CMC	Electrode - Mixing	Solid – powder	Anode	None identified	960	In product
Lithium Titanate	LTO	Electrode - Mixing	Solid – powder	Anode	None identified	* Unknown	In product
Silicon Monoxide	SiO	Electrode - Mixing	Solid – powder	Anode	None identified	* Unknown	In product
Silicon	Si	Electrode - Mixing	Solid – powder	Anode	None identified	* Unknown	In product
Electrolyte Solution: Lithium Hexafluorophosphate solution. Comprising of lithium salt dissolved in organic carbonates. Ethylene Carbonate [EC] Propylene Carbonate [PC] Di-Ethyl Carbonate [DEC] DiMethoxyethane [DME]	LiPF6	Cell Assembly	Liquid	Electrolyte	None identified	3600	In product
• Materials are future potential materials with an unknown annual usage at this time.							

9 EMISSIONS

9.1 EMISSIONS TO AIR

9.1.1 Facility

Facility heating will consist of three gas fired boilers – located to the south west corner of the building and will provide hot water and heating for welfare purposes. Extractions for the gas boilers will be aggregated into one common flue and will be vented via the external wall to atmosphere.

Additionally, there will be two gas fired boilers within the FA&T area for the purpose of space heating. Extractions will be separate and vent directly to atmosphere.

See 9.6 Emissions table - table 3 (Point 1 & 9)

The battery manufacturing process incorporates Dry rooms. These rooms will have significantly reduced humidity to facilitate a moisture free environment. To achieve the levels of humidity required, the air handling equipment (de-humidifiers) will consist of 8 gas fired adsorbent wheel de-humidifiers. The emissions from these has yet to be defined but will exhaust externally.

See Emissions table 9.6 (Point 5)

9.1.2 Electrode Manufacturing

There will be three emission points from the electrode manufacturing area.

1. Anode extraction directly from the dryer to atmosphere;

   The Anode extraction will consist of warm moist air and will be directed to atmosphere at height without treatment. See Emissions table 3 (Point 2)

2. Cathode extraction via the abatement system and vented to atmosphere at the carbon bed;

   The Cathode dryer extraction will pass through the condensation unit where the solvent will be recovered and then pass through the activated carbon and then released to atmosphere. See Emissions table 3 (Point 3)

3. Cathode emergency purge directly from the dryer to atmosphere:

   The condenser incorporates an evacuation purge process and the principle is for this purge to actuate where the facility experiences a power outage: the dryer would be purged with factory air directly to atmosphere allowing for an immediate discharge of potentially flammable vapour from the cathode dryer. See Emissions table (Point 4)

9.1.3 Cell Assembly

There will be two extraction points from the cell Assembly area;

1. Vacuum dryer(s) (Pouch (future) and Cylindrical)
   The dried electrode reels are further dried to remove any residue moisture; it is anticipated the moisture content at this stage will be less than 0.001% weight and the moisture will be contained within the integral cold trap. Both extract streams will be captured in one common flue and vented externally. It is anticipated that the cathode may have negligible volumes of NMP and the anode trace volume of water. See Emissions table (Point 6)
2. Electrolyte filling zone (pouch (future) and Cylindrical)

The local exhaust from the electrolyte filling and tab welding area for the Pouch and Cylindrical processes will be captured in one common flue and vented externally. It is anticipated that the electrolyte concentrate will be at trace levels. See Emissions table (Point 7)

9.1.4 Formation, Aging & Testing

There will be two emission points from the FA&T area;

1. *De-gassing & Formation Pod
   The degassing process is related to the future pouch cell whereby during the formation process, the cell generates a small volume of carbon dioxide and electrolyte gas. This gas is released and vented directly to atmosphere. (see note below)
   Associated with this extraction will be the Formation Pod exhaust. This exhaust is for the exhaust of the products of combustion in the event of an over-heating or fire event. See emissions table 3 (point 8)
2. The FA&T area will also house two gas fired space heating boilers. The two units will be located within the FA&T area at height at diagonally opposed corners. The extracts will be vented via the external wall to atmosphere. See Emissions table 3 (Point 9)

*During the formation process, the pouch cell (future) generates carbon dioxide gas and trace LiPF6 (Electrolyte gas) within the Laminated Aluminium (Polyethylene terephthalate or Polypropylene) Film pouch. This gas will be released from the pouch at the de-gassing station still within the formation area, and the pouch re-sealed. The respective gas is captured locally, combined with the extract from the formation pods and vented externally to atmosphere. The fugitive gaseous emission contained within the pouch is deemed insignificant and is to be released direct to atmosphere.

Note: The Nissan battery plant in Sunderland initially installed an RTO (regenerative thermal oxidiser) to abate the respective exhaust air from their Formation area. It was established by Sunderland District Council and the Environment Agency that the RTO was not appropriate for the treatment of the exhaust gas. The levels monitored by the facility for the EA were deemed insignificant and the consumption of natural gas during the operation had a significant negative impact that outweighed the benefit.

9.1.5 Module and Pack assembly

The Module and Pack assembly process has not yet to be defined for the facility. The intention of the business is for the process to be procured and installed Q3 2020.

It is anticipated the environmental impact for the module and Pack will be insignificant. There will be two defined process areas; Module assembly and Pack assembly. It is anticipated at this time that both areas will incorporate a laser welding process. Any such fumes from the respective processes will be extracted, filtered and re-circulated accordingly.

When the process equipment has been procured, the application will be updated.

9.1.6 Fugitive Emissions

Fugitive emissions from the processes will be kept to a minimum and where there is potential release to exist, measures will be taken to suppress.

Internal fugitive emissions will be kept to final cleaning activities with Local Exhaust Ventilation, where personnel will wear respiratory protective equipment as an additional control measure.

The external chemical area will house several IBCs containing condensate NMP, waste NMP and waste electrolyte, each with associated vents. These vents will have an activated carbon filter installed to capture the fugitive emissions.

9.2 EMISSIONS TO THE WATER COURSE

- De-ionised water effluent
- Cell assembly rinse washing effluent

Initial discussions with the local water undertaker (Severn Trent), a discharge licence will be required for the authorisation of the effluent. The discharge licence will be applied for once the water supply and respective meter has been fitted and commissioned. Any discharge licence required will be in place prior to any operation. In the case of the licence not being in place, any waste effluent will be captured, stored on site and removed by a licence waste contractor.

There will be the provision for both emissions, sampling points located in an obvious and safe location.

9.3 EMISSIONS TO LAND

There are no intentional emissions to land anticipated.

9.4 ENVIRONMENTAL NOISE EMISSIONS

The operation of the facility will be a single shift with typical working hours of 8am - 5pm. The exception to this would be a 24-hour staff attendance for the monitoring of the Formation process. This process requires continuous monitoring and human interface 24 hours a day 7 days a week. It is anticipated that the on-duty staffing will be restricted to a minimum of two persons.

Outside of these hours there will be no deliveries.

The closest receptor (residential) would be that of the village of Baggington.

The external logistics area is located to the West of the site, some 500m to Baggington.

UKBIC will comply with boundary noise requirements as detailed within the WDC Outline Planning Permission – application reference: W/16/0239. There are no high noise sources planned for the external areas of the site therefore it is anticipated noise pollution will not be a concern.

It is anticipated that UKBIC will obtain a third-party environmental noise survey prior to operation. This will be supported by routine in-house noise monitoring.

9.5 SITE DRAINAGE

There are no drainage points planned within the main body of the facility, all drains are located at the extremities of the building.

Overview of the site drainage layout plan – appendices Drawing No. 4008/51 -Buckingham Group Contracting dated Feb 19

The drain layout drawing identifies the respective foul and surface water drains and associated connections to the local authority main drainage.

The area of note is that of the planned 'Chemical Area'; this specific area will be dedicated for the chemical delivery system and storage of the liquid chemicals utilised within the facility. The area has associated sub-surface drains connected to the surface water system. Integral to this drain is a Penstock and interceptor at the South West of the facility. The Penstock will serve the purpose of preventing any spillages from the Chemical area entering the surface water drain. Any inadvertent spillage will be contained at the DSW CP 15 whereby giving the ability for UKBIC to pump out the catch pit.

The Penstock will be managed procedurally whereby during any loading or unloading of hazardous materials in this area, the Penstock will be closed.

9.6 EMISSIONS TABLE

Table 3 – Emissions table

	Equipment	Source Location	Description	Type	Abatement	Contaminant	Volume	Emission point	Fate
1	Gas boilers x3	Plant heating - South west corner at first floor mezzanine level	3off - Building heating/hot water	Gaseous	None	CO, CO2	125m^3/hr	South west corner @ building grid A1 - Mezzanine level	Directed to atmosphere
2	Electrode Dryer	Electrode Manufacture Cathode drying	Warm air solvent condenser. Activated Carbon filter prior to end of pipe	Gaseous	1.Solvent condenser. 2.Activated Carbon filter	Solvent - (NMP) N-Methyl-2-pyrrolidinone	1400m^3/hr	South wall @ building grid A4	To atmosphere
3	Electrode Dryer	Electrode Manufacture Anode drying	Warm air exhaust	Gaseous	None	None	1400m^3/hr	South wall @ building grid A22	To atmosphere
4	Electrode Dryer	Electrode Manufacture Cathode drying Emergency purge	Emergency purge for the solvent condenser	Gaseous	None	Solvent (NMP)	30000 m^3/hr Upon emergency actuation for short periods	South west corner @ building grid A10 Electrode Manufacture Emergency purge	To atmosphere via 1.5m Diameter duct (**Emergency release**)
5	De-Humidification Wheel	Process hall mezzanine	De-humidification of Dry room air	Gaseous	None	CO, CO2	*2250 m^3/hr	South wall	To atmosphere
6	Cell assembly	Cell assembly – Cylindrical & Pouch from within the Clean & Dry room(s)	Vacuum dryer exhaust	Gaseous	None	Trace: NMP vapour	7500 m^3/hr	South wall - common extract for Cylindrical and Pouch	To atmosphere
7	Cell Assembly	Cell assembly – Cylindrical & Pouch from within the Clean & Dry room(s)	Automated cylindrical cell assembly line - Electrolyte dispensing	Gaseous	None	Trace LiPF6 vapour	2300 m^3/hr	South wall - Common extract for Cylindrical and Pouch	To atmosphere
8	Formation process	FA&T Area	Gassing Off of pouch cells * Smoke extraction in the event of thermal event	Gaseous	None	Trace: CO2, H, LiPF6	1600 m^3/hr	South wall	To atmosphere
9	Gas boilers x 2	FA&T Area	Space heating	Gaseous	None	CO, CO2	125 m^3/hr	1 x North wall 1 x South wall	To atmosphere
10	Quality Laboratory	Process Hall	Environmental cabinet	Gaseous	None	Trace: Electrolyte & NMP vapour	Upon emergency actuation for short periods	To atmosphere	Emergency release upon actuation of bursting disc

10 EMERGENCY RESPONSE

Emergency response procedure – There will be a site-wide emergency response procedure to cater for the identified abnormal events that are foreseeable.

Procedures will include:

- Emergency action in the event of a Fire event
- Emergency action to be taken in the event of a personal accident
- Emergency action to be taken in the event of a Chemical Spill
- Action for vehicle fuel spillage
- Escalation process in the event of an emergency situation

In the event of a Fire, the fire water run-off will be captured to a degree, within the facility. There are no internal drains at ground level planned within the process and logistics area. The logistic vehicular area to the west of the facility can be utilised to contain in the region of 230m^3 fire water run-off.

There are two access points for the Emergency services: The primary entrance will be gained from the main site entrance; a secondary entrance is via the North perimeter fence-line and allows emergency access only to the rear of the facility

10.1 SPRINKLER PROTECTION

Facility sprinkler – based on FM Global specifications and approved by the UKBIC insurer.

Fire sprinkler tank supply – There are two water tanks planned for the facility with a total capacity of 596 m^3. The water supply is served by two diesel automatic sprinkler pumps: one pump will be duty with the other stand-by. Both of which capable of 100% of the system duty required.

Fire pumps – The Fire water supply for the site sprinklers are to be supplied from two tanks. The provisional capacity and sprinkler design have been carried out in conjunction with the business insurers, specialist contractors and the UKBIC design team and conforms with the Global FM standard.

Fire hydrant(s) – The UKBIC site will be served by two fire hydrants.

1. Within the main entrance of the facility and will supply the mains potable water.
2. A second supply is to be provided to feed the two, fire water main sprinkler tanks. A hydrant is to be provided from this supply and will be located to the east, rear of the facility. This provides the fire service with two local authority-maintained hydrants at strategic positions of the site in the event of a fire.

11 UNINTENTIONAL RELEASES

It is the intention of UKBIC to ensure suitable measures are employed to prevent any release or escape of any pollutant that may or will cause harm to the environment.

The developing management system will incorporate necessary Policies and Procedures to ensure personnel practices are carried out in a safe and effective manner. Typically, in the area of emergency response, (See section 10 Emergency Response) any foreseeable detrimental event will be proceduralised and trained out to ensure competency for all authorised staff.

In the event of a significant release of liquid chemicals from the chemical area, the primary, secondary and tertiary protective measures have been designed and planned to ensure no pollutant will enter any water course. (See section 9.5 Site Drainage & section 8.2 Electrolyte and NMP delivery and Storage system)

In the event of a thermal event, it is anticipated that any fire water run-off from the building sprinklers will be captured within the building additionally the goods in delivery area can hold a significant volume of water with drain covers applied.

In the event of a major power failure, the solvent abatement system will, for the purposes of safety, purge the cathode dryer. The purge will be a short release of warm extract from the dryer directly to atmosphere. Any such release would be for the purpose of preventing a hazardous flammable atmosphere build up within the dryer and would be reported to WDC as required with any permit condition.

APPENDIX 3.1

WHITLEY SOUTH TECHNOLOGY CAMPUS – ENVIRONMENTAL STATEMENT NON-TECHNICAL SUMMARY

NON-TECHNICAL SUMMARY

WHITLEY SOUTH - TECHNOLOGY CAMPUS

An application for development on behalf of
Jaguar Land Rover and Coventry City Council

WHITLEY SOUTH

www.whitleysouth.co.uk

Jaguar Land Rover Coventry City Council

WHITLEY SOUTH

CONTENTS

Coventry City Council

WHITLEY SOUTH

1. INTRODUCTION

This Environmental Statement (ES) has been prepared by a specialist consultancy team on behalf of Jaguar Land Rover and Coventry City Council in support of an outline application for the development of a strategic employment site together with strategic highway improvements and structural landscape works on land to the north and south of the A45 between the Festival and Tollbar Island junctions of the A45 and A46; to the north of Coventry Airport.

Works are also proposed to land at junctions on the surrounding highway network, namely the junctions of the A45 and A46 at Festival and Tollbar Islands, the junction of the A444 (Stivichall & Cheylesmore By-Pass) with the A4114 (London Road) and the junction of the A46 with Stoneleigh Road.

The application covers part of the site proposed to be allocated for development in the emerging Warwick Local Plan, and part of the former Coventry and Warwickshire Gateway (CWG) application which was resolved to be approved by Warwick District Council and Coventry City Council but which was refused by the Secretary of State in February, 2015 following the Calling-In of the application for determination. The scheme fully accords with the emerging Local Plan.

The application is supported by a full Environmental Assessment. It includes appropriate mitigation measures to ensure that the environmental effects of the scheme are not unacceptable. In this regard reference to the CWG scheme is relevant because the Secretary of State found that application acceptable in design and environmental terms.

The aim of the proposal is to support the continued growth and expansion of Jaguar Land Rover who have, over the last 3 years, created 12,000 manufacturing and technology jobs in the UK which is a significant step to helping the Government achieve its aim of rebalancing the UK economy. Jaguar Land Rover have also invested £3.5 billion in product creation and capacity expansion in the UK in the year to the end of March 2015.

With this level of rapid growth comes a requirement for more and better accommodation, the need to continually streamline the business and improve efficiency. The Jaguar Land Rover World Headquarters site at Whitley has grown significantly resulting in pressures on space and a need for expansion.

Development of the Whitley South site would form a vital part of Jaguar Land Rover's expansion plans at its Whitley site, with extensive wider benefits to the local, regional and national economy.

Environmental Impact Assessment Process

The ES is submitted in support of the application and should be read together with other material submitted with the application. Likely significant environmental effects have been examined as part of the Environmental Impact Assessment (EIA) of the proposed development. Effective mitigation measures have, where appropriate, been identified and assessed.

Coventry City and Warwick District Council’s are the local planning authorities for the application site.

The EIA process undertaken and outlined in the ES and in the summary below, involved the following steps:

- Identifying features of the existing environment likely to be affected;
- Undertaking a consultation process;
- Identifying and incorporating design, mitigation and enhancement measures as an integral part of the scheme; and
- Assessing and determining the likely significant environmental effects of the development.

2. DEVELOPMENT PROPOSALS

The Application is described as:

Outline application for the comprehensive development of land to the north and south of the A45 between the Festival and Tollbar Island junctions of the A45 and A46 comprising demolition of existing structures and the erection of new buildings to accommodate offices, research & development facilities and light industrial uses (Use Class B1), hotel accommodation (Use Class C1), car showroom accommodation, small scale retail and catering establishments (Use Classes A1, A3, A4 and/or A5), new countryside park, ground modelling work including the construction of landscaped bunds, construction of new roads/footpaths/cycle routes, remodelling of junctions on the existing highway network, associated parking, servicing and landscaping.

A detailed description of the development for the purposes of the Environmental Assessment is out below. This should be read in conjunction with the Parameters Plan and the detailed highway drawings.

Technology Campus (development and landscape area):

- Demolition of existing structures (see existing land use plan);
- The remediation of the site together with ground modelling including the creation of development plateaux and landscape bunds;
- The development of up to 70,683 sq m of mixed B1 buildings intended primarily for Automotive Technologies together with Hotel(s) (Use Class C1); Retail unit(s) (Use Class A1, A3, A4 and A5); and car showroom(s), comprising:

o Up to 56,766 sq m of B1 (primarily B1b/B1c space) and car showrooms (of which a maximum of 4,645 sq m will be used for car showrooms)
o Up to 2,300 sq m of ancillary A1, A3, A4, A5 floorspace
o Up to 11,617 sq m of C1 floorspace.

- Associated access, parking, servicing, infrastructure and landscaping;
- Strategic landscaping including the creation of publicly accessible open space in a Countryside Park.

Highway Works

- New highway works comprising:

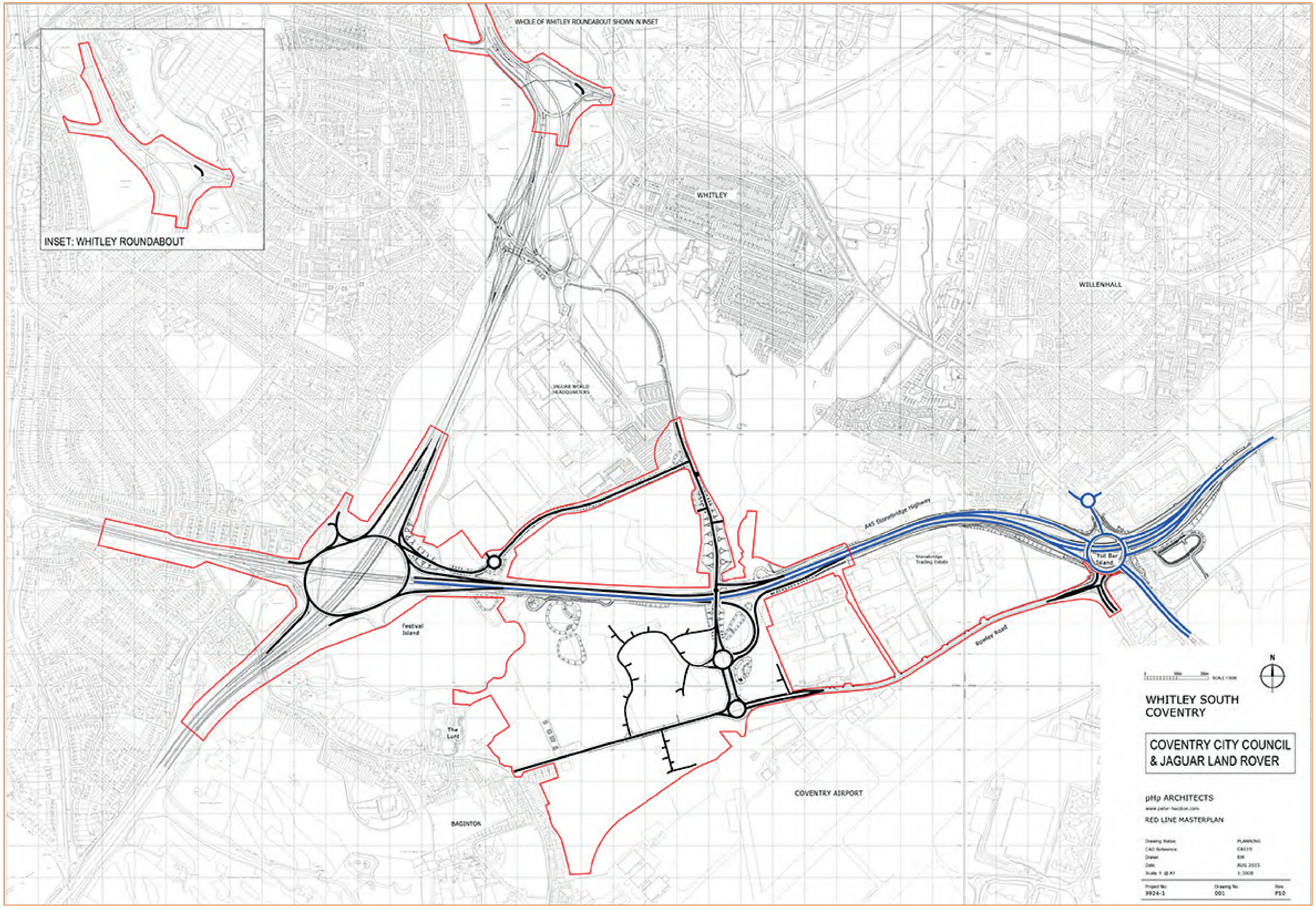
I. Works to the A45 including a new slip road for access to the site and a new bridge over the A45;
II. Works north of A45 which includes alterations to the two link roads which would connect the site and existing Jaguar Land Rover Headquarters to the A444 and Festival Island;
III. Works to access the development south of the A45 off Rowley Road and from Toll Bar Island;
IV. Works to Festival Island;
V. Works to Whitley Roundabout;
VI. Works to Stoneleigh Interchange off the A46.

It is also important to note the scheme is interrelated with JLR's expansion plans for the Whitley Business Park site which they have recently acquired. The scheme includes infrastructure on and around the Whitley Business Park site, and these works will help to facilitate the development of that site.

The application site totals approximately 105 ha. This can be broken down having regard to the Parameters Plan, as follows:

Technology Campus development plot	- 28.17 ha
Technology Campus landscaped area	- 21.53 ha
Highways works	- 55 ha

Copies of the application site plan, parameters plan and illustrative masterplan are copied here for ease of reference.


WHOLE OF WHITLEY ROUNDABOUT SHOWN IN INSET
INSET: WHITLEY ROUNDABOUT
WHITLEY
WILLENHALL
JAGUAR WORLD HEADQUARTERS
A45 Stonebridge Highway
Stonebridge Trading Estate
Toll Bar Island
Festival Island
Rowley Road
The Lunt
BAGINTON
COVENTRY AIRPORT
N
SCALE 1:5000
WHITLEY SOUTH
COVENTRY
COVENTRY CITY COUNCIL
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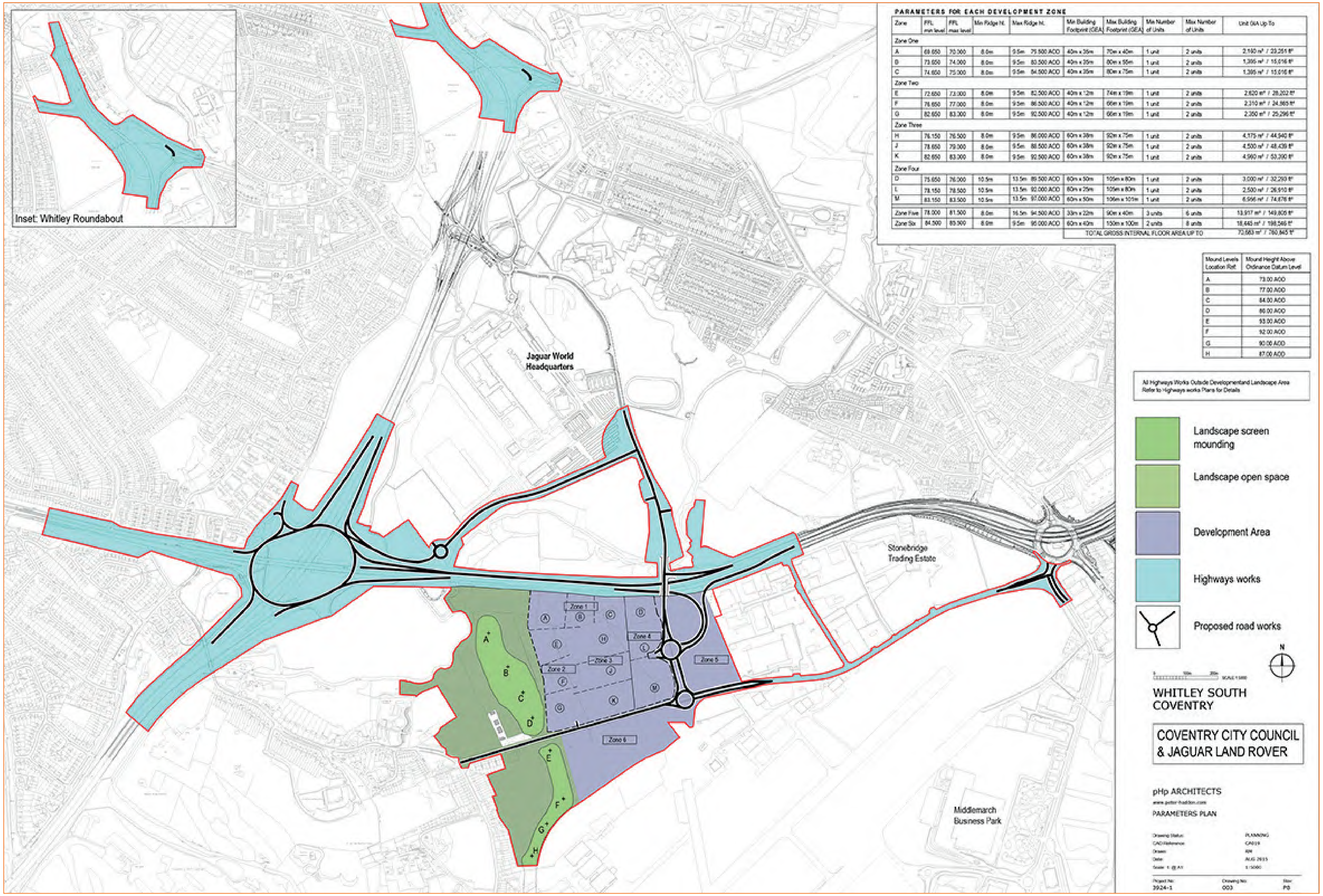
RED LINE MASTERPLAN
Drawing Status
PLANNING
CAD Reference
CA019
Drawn
Date
AUG 2015
Scale 1 @ A1
1:5000
Project No
3924-1
Drawing No
001
Rev
P10



PARAMETERS FOR EACH DEVELOPMENT ZONE

Zone	FFL min level	FFL max level	Min Ridge ht.	Max Ridge ht.	Min Building Footprint (GEA)	Max Building Footprint (GEA)	Min Number of Units	Max Number of Units	Unit GIA Up To
Zone One									
A	69.650	70.300	8.0m	9.5m 79.500 AOD	40m x 35m	70m x 40m	1 unit	2 units	2,160 m² / 23,251 ft²
B	73.650	74.300	8.0m	9.5m 83.500 AOD	40m x 35m	80m x 56m	1 unit	2 units	1,395 m² / 15,016 ft²
C	74.650	75.300	8.0m	9.5m 84.500 AOD	40m x 35m	80m x 75m	1 unit	2 units	1,395 m² / 15,016 ft²
Zone Two									
E	72.650	73.300	8.0m	9.5m 82.500 AOD	40m x 12m	74m x 19m	1 unit	2 units	2,620 m² / 28,202 ft²
F	76.650	77.300	8.0m	9.5m 86.500 AOD	40m x 12m	66m x 19m	1 unit	2 units	2,310 m² / 24,865 ft²
G	82.650	83.300	8.0m	9.5m 92.500 AOD	40m x 12m	66m x 19m	1 unit	2 units	2,350 m² / 25,296 ft²
Zone Three									
H	76.150	76.500	8.0m	9.5m 86.000 AOD	60m x 38m	92m x 75m	1 unit	2 units	4,175 m² / 44,940 ft²
J	78.650	79.300	8.0m	9.5m 88.500 AOD	60m x 38m	92m x 75m	1 unit	2 units	4,500 m² / 48,439 ft²
K	82.650	83.300	8.0m	9.5m 92.500 AOD	60m x 38m	92m x 75m	1 unit	2 units	4,950 m² / 53,280 ft²
Zone Four									
D	75.650	76.300	10.5m	13.5m 89.500 AOD	60m x 50m	105m x 80m	1 unit	2 units	3,000 m² / 32,293 ft²
L	78.150	78.500	10.5m	13.5m 92.000 AOD	60m x 25m	105m x 80m	1 unit	2 units	2,500 m² / 26,910 ft²
M	83.150	83.500	10.5m	13.5m 97.000 AOD	60m x 50m	106m x 101m	1 unit	2 units	6,956 m² / 74,876 ft²
Zone Five	78.000	81.500	8.0m	16.5m 94.500 AOD	33m x 22m	90m x 40m	3 units	6 units	13,917 m² / 149,805 ft²
Zone Six	84.500	85.300	8.0m	9.5m 95.000 AOD	60m x 40m	150m x 100m	2 units	8 units	18,443 m² / 198,546 ft²
					TOTAL GROSS INTERNAL FLOOR AREA UP TO				72,683 m² / 780,845 ft²

Mound Levels Location Ref	Mound Height Above Ordinance Datum Level
A	73.00 AOD
B	77.00 AOD
C	84.00 AOD
D	86.00 AOD
E	93.00 AOD
F	92.00 AOD
G	90.00 AOD
H	87.00 AOD

All Highways Works Outside Developmentand Landscape Area Refer to Highways works Plans for Details

WHITLEY SOUTH
COVENTRY

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& JAGUAR LAND ROVER

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PARAMETERS PLAN

Drawing Status: PLANNING
CAD Reference: CA019
Drawn: RW
Date: AUG 2015
Scale: 1 @ A1 1:5000

Project No: 3924-1
Drawing No: 003
Rev: P0

C1 HOTEL (5 floors)		
R	5	11,617 m² 125,048 ft²

A1/A3/A5 RETAIL		
S	1	1,603 m²
T	1	697 m²
TOTAL		2,300 m² 24,757 ft²

CAR SHOWROOMS		
B	1	1,395 m²
C	1	1,395 m²
TOTAL		2,790 m² 30,032 ft²

B1b/ B1c	Unit storeys	Unit GIA
A	2	2,160 m²
D	3	3,000 m²
E	2	2,620 m²
F	2	2,310 m²
G	2	2,350 m²
H	2	4,175 m²
J	2	4,500 m²
K	2	4,960 m²
L	3	2,500 m²
M	3	6,956 m²
N	2	3,920 m²
O	2	3,300 m²
P	2	4,750 m²
Q	2	6,475 m²
TOTAL		53,976 m² 581,008 ft²

N

SCALE 1:2500

WHITLEY SOUTH
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ILLUSTRATIVE DEVELOPMENT PLAN

Drawing Status: PLANNING
CAD Reference: CA019
Drawn: BM
Date: AUG2015
Scale 1 @ A1: 1:2500

Project No	Drawing No	Rev
3924-1	002	P10

3. PLANNING POLICY

Relevant planning policies are identified in Section 3 of the Environmental Statement. A detailed appraisal of the application having regard to relevant planning policies is contained the Planning Statement.

The Planning Statement undertakes an assessment of development control issues, and concludes that the application proposal has been well planned and subject to considerable scrutiny both through this application preparation process but also the application process for the Coventry and Warwickshire Gateway application which culminated in an Inspector's and Secretary of State's judgement on these matters. It is concluded that there are no development control reasons why the application should not proceed.

The application is for B1 space, predominantly for research and development and light industry. JLR would be the anchor, taking the majority of space, with the opportunity for core other businesses including JLR suppliers to co-locate improving efficiency for JLR and their suppliers. Other uses would complement these main uses, with a hotel, retail uses to meet the needs of employees, and the potential for showroom space for JLR to 'show' their vehicles. The scheme would directly support the creation of 3-4,000 jobs. The scheme would also directly help to secure jobs and investment at JLR's existing Whitley site.

The location of the application site in the Green Belt means that very special circumstances must exist for the proposals to outweigh the harm to the Green Belt and any other harm, and for the application to be approved. The Secretary of State concluded that such circumstances did not exist when he considered the Coventry and Warwickshire Gateway application a year or so ago. However this application differs from the CWG scheme presented previously because of the specific and special circumstances of the applicant. Other changes have also occurred which are material and which directly address the concerns of the Secretary of State and the Inquiry Inspector, and demonstrably alter the planning balance in favour of granting consent.

This includes the significant delay to the Warwick Local Plan which was not envisaged at the time of the Secretary of State's decision. The Inspector expected an examination in 2014 and the balance of his judgement was clearly informed by the speed at which he expected a Local Plan to be in place. Progress on the Local Plan has been significantly slower than anticipated with at least a two year delay. The need for positive decisions to be made on land in the Green Belt increases as time passes and has increased since the SoS's decision. This weighs in favour of the proposals.

It is also relevant to note that the Coventry and Warwickshire local authorities have agreed to undertake a sub-regional Green Belt Review as part of their Local Plan processes to identify land to accommodate their very significant housing and other land use requirements. As part of this there is agreement that Coventry City cannot accommodate its housing or employment needs, and neighbouring authorities have agreed that they will need to identify land to accommodate this unmet need. These needs will be met close to Coventry in order to meet needs close to where they arise and to meet sustainable development objectives.

Notwithstanding the continued, and extended delay to the Local Plan process, Warwick District Council have submitted their Local Plan for examination and the Submission Draft Plan now specifically allocates the Whitley South site for development and proposes to remove the land from the Green Belt. This can be given some weight in the determination of the application and is a positive change since the Gateway decision which further shifts the Green Belt balance in favour of the application.

A material change in circumstances also includes publication of the comprehensive Employment Land Study undertaken by CBRE on behalf of the LEP and work undertaken by G L Hearn to inform the preparation of the Coventry Local Plan. The CBRE Study addresses deficiencies in evidence highlighted by the Inspector and Secretary of State; it identifies serious shortages in land supply, extremely strong demand and the need for the identification of significant land, in addition to the Coventry and Warwickshire Gateway site, for employment requirements over the next 15 years. It concludes that the growth in the area will be constrained unless land is brought forward quickly to meet demands.

The Draft Coventry City Local Plan, having regard to the work undertaken by CBRE and G L Hearn concludes that the City will not be able to meet all of its employment land requirements and that there will be a shortfall of 241 ha of land which will need to be identified in Warwickshire, but adjacent to the City boundary. The Draft Plan specifically supports the allocation of the application site.

In combination these factors, together with those identified as major beneficial components previously by the Secretary of State, amount to very special circumstances which outweigh the harm to the Green Belt and a compelling case for permission to be granted without delay.

4. SOCIO-ECONOMIC CONSIDERATIONS

It is considered that with additional enhancement measures the proposed development would support construction industry employment within the Study Area over an estimated 5-year period. Any individuals that develop skills over this period will be in a better position to continue in employment after the construction of this scheme concludes, which is to their advantage and also of potential benefit to the general economy in the future.

The proposed scheme could directly support between 3,000 to 4,000 jobs as a result of JLR's planned expansion. Taking into account the potential effects of displacement and leakage in the labour market, the net additional direct employment within Warwick and Coventry is estimated to be some 2,300 to 3,067 jobs. In the overall Study Area the net additional employment is estimated to be between 3,344 and 4,458 positions.

Skills and qualifications amongst the workforce would be improved through continued in-house and external training provision, facilitated by Jaguar Land Rover over the long-term. This is regarded as a major impact at the Warwick and Coventry LPA area level, which is considered to be a moderate/major beneficial, an effect which is assessed as significant.

In terms of input to the Warwick and Coventry LPA area economy, after deducting leakage and displacement and then adding the potential additional spend on services and supplies, the net effect is projected to be an additional £92 million to £123 million GVA each year. This is considered to be a major beneficial impact at the LPA area level, and therefore a moderate/major effect, which is significant.

When estimating the effects across the wider Study Area, the net change is projected to be an overall increase of £134 to £179 million into the economy of Warwick, Coventry, Rugby, and Nuneaton and Bedworth (this includes the £92 million to £123 million above).

The proposed development will yield significant employment opportunities, providing a high-quality research and development/industrial facility in a strategic location identified in the emerging Warwick District new local plan. In summary, the employment and economic impact is considered to represent a moderate/major beneficial effect that is assessed as significant.

In respect of cumulative effects, a broad estimate of the employment that could be accommodated in the units that are as yet to be occupied within these schemes indicates that an additional 7,650 jobs could be brought forward as these are developed over the coming years. Using the same assumptions for 'additionality' as in the assessment of Whitley South above, in terms of the input to the Warwick and Coventry LPA area economy, the net effect is projected to be an additional £236 million GVA each year.

5. LANDSCAPE & VISUAL EFFECTS

The proposed site occupies an urban and urban fringe landscape defined and contained by a variety of uses and elements, including Coventry Airport and existing surrounding employment uses, the A45 road corridor and other connecting major roads and junctions, areas of housing and settlement, farmland and a variety of landscape and open space areas. The character of the site's immediate context is influenced by the existing edge of Coventry, the airport and Middlemarch Business Park.

Published landscape character assessments and relevant landscape studies covering the site and its broader context also characterise the landscape as including a rolling landform, with plateau fringes more enclosed, primarily agricultural land cover away from the urban edges and middle distance views enclosed by woodland and woodland edges. The assessments also recognise that there is rarely screening planting and other treatment of an appropriate scale to some new developments.

At a local scale, the landscape character of the site and its immediate context is largely shaped by the combination of existing urban fringe uses and features. The local landscape assessment undertaken identifies the site as including areas of Low/ Medium landscape condition. It also indicates that the site does have the landscape capacity to accommodate significant change, in the form of new built development and landscape enhancement measures.

The existing landscape comprises a mix of developed or previously disturbed areas, farmland and the settlement of Baginton, with the A45 beyond. The remaining parts of the site largely comprise stretches of existing or new highway corridors and these areas are dominated by the existing roads and associated infrastructure.

In landscape and visual terms and notwithstanding the condition and sensitivity of much of the site landscape, there are a number of important local issues and considerations that are particularly relevant to the proposed development and its resultant effects and to the landscape strategy proposals to be devised as part of the overall scheme. These can be summarised as follows:

- Potential effects upon the landscape characteristics and "openness" of the Green Belt;
- Potential effects upon views from Baginton (including the Lunt Fort) and other surrounding settlement and properties;
- Opportunities to create a connected and robust network of public open space and green infrastructure surrounding the site – with greater public access and localised improvements for nearby and surrounding residents;
- Opportunities to deliver significant landscape enhancement and improvements and to maximise these in the short and longer terms.

The proposed development and accompanying landscape strategy have been carefully considered and assessed in the context of the published and more detailed local landscape assessments. The proposals will include the creation of a significant landscape framework comprising the conservation of the vast majority of existing woodland, trees and hedgerow planting surrounding the site, new woodland and other planting and habitats throughout the site. These proposals will assist in mitigating many of the adverse landscape and visual effects of the built development and offer many valuable longer term landscape and green infrastructure benefits.

The approach reflects the broad principles detailed in both the Warwick and Coventry Green Infrastructure studies. Conserved trees, hedgerows and other habitats will be strengthened with new planting and all will be comprehensively managed in the long term. The proposals will be appropriate in landscape character terms and will utilise native tree and shrub species indigenous to the local area. New Sustainable Drainage (SuDs) features will be designed to contribute positively to the landscape and new routes for pedestrians and cyclists will be integrated into the landscape proposals, providing public access where none exists at present.

New “off road” footpaths and cycleways will be accompanied by high quality country park style furniture, signage and maps, interpretation and gateways. Other footpaths and cycleways will also be created as part of the built development and highway proposals and all will link together and greatly improve public access throughout the local area.

The landscape measures will include the creation and establishment of approximately 21 hectares to include new native woodland and tree planting, new native hedgerows, together with other significant habitat creation measures broadly to the east of Baginton. These will connect to and complement the existing conserved habitat and planting within the site.

The open landscape setting and the pasture fields nearest to Baginton and along its eastern edge will be conserved, with sympathetic new planting and landscape management works undertaken to maintain an area of separation between the proposed built development and Baginton. This is particularly important in the context of the Green Belt and the Lunt Fort.

The resultant landscape character effects arising from the proposed development will vary between negligible (for the effects upon the very broad landscape character areas) to minor/ moderate adverse (for the initial effects upon part of a local landscape character area). The specific effects of the proposed development upon landscape features within the site will vary between negligible and moderate adverse during construction and between minor adverse and moderate beneficial upon completion of the proposals. The local beneficial effects upon the landscape character and features will increase over time with the maturing and management of the conserved and new landscape strategy proposals.

In visual terms, the effects of the proposed development will vary depending on the nature and extent of the existing view towards the site and on the particular phase of the development. In general terms the greatest visual effects will arise during the construction process, with the subsequent effects lessened through the formation of the perimeter earthworks and landscape strategy proposals. During construction, the most notable visual effects will arise for those properties with the clearest views on the eastern edge of Baginton, for the Lunt Fort viewpoint positions and from the nearest public rights of way to the south of the site. The majority of the effects upon these locations will be moderate adverse during construction. From most of the other locations where views are possible towards the construction activity, the resultant visual effects will vary between negligible and minor/ moderate adverse, depending on the nature and extent of the available view.

It is however, important to note that these stated significance of effects are for a short period of time during the construction process when the works will be most visible from the identified viewpoint location. Notably, upon completion and during the operation of the proposed development, the visual effects will be reduced and significantly so in some cases as the new landscape and planting proposals establish and mature. Upon completion and during the operation of the proposals, the visual effects will generally vary between negligible and minor/ moderate adverse and in the longer term these effects will be lessened further with the maturing of the planting and landscape proposals.

In visual terms, the proposed landscape strategy will have a valuable benefit in screening and filtering views towards the proposed built development areas and components. The conserved and new landscape proposals along the eastern side of Baginton will substantially screen views, including those existing towards the airport, leading to a localised beneficial visual effect for some properties close to this part of the site.

North of Rowley Road, careful attention has been paid to the potential visual effects upon the Lunt Fort and properties with views towards this part of the site. The landscape strategy for this area will ensure that the existing relatively open views from the Fort towards the east are maintained and that the built development is seen in the middle distance filtered by intervening woodland copses and tree planting.

Overall, the landscape and visual effects are considered to be predominantly localised and contained. The most notable landscape effects arise from changes to the landscape character of part of the site and for the visual effects upon some edge of settlement and scattered properties and from a small number of other locations. The proposed development is not considered to give rise to any effects that should preclude it on landscape and visual grounds. Subsequent care and attention to the detailed design, implementation and subsequent management of the landscape strategy will however be important to ensure that the effects are minimised and the identified opportunities for enhancement are maximised.

The scheme includes an extensive and robust landscape strategy that has been carefully devised to provide a suitable green structure to the site and to conserve and extend existing features and habitats of value. Notably, it will also open up to public access a retained and enhanced landscape area adjacent to the existing urban edge and offers the opportunity to extend the proposed network of footways, cycleways and bridleways in the future.

NOTES

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KEY:

① New Sustainable Drainage (SuD's) features designed and managed for multi-functional environmental benefits - to include open water and marshy habitats

② Pedestrian access between the proposed development and Public Open Space (POS)

③ New access track and footway route between Rowley road and the SuD's features

④ Access and views to the new ponds to include seating and interpretation

⑤ Conserved mature trees and planting to the banks of the River Sowe. Opportunities for sympathetic habitat management

⑥ New heritage viewing platform (incorporating interpretation and seating) offering views back towards the Lunt Fort. To form part of the circular walk from the Fort car park

⑦ Scattered copses and individual native trees

⑧ Improvements to existing hedgerows, including infill planting and hedgerow trees and management works

⑨ Footway connection to Rowley Rd

⑩ Conserved pasture fields, hedgerows and trees

⑪ Circular "heritage" walk, with connection to/from the existing Fort car park. To include new signage and interpretation. Walk to be constructed as a country park type compacted gravel surface. New and infill hedgerow planting to the Rowley Rd boundary with some hedgerow tree planting

⑫ Potential new car park

⑬ Conserved existing habitats, including trees, scrub and grassland. To include implementation of an appropriate long term management regime to improve wildlife interest. Additional native "thorny" planting to be established to the rear of properties where deemed appropriate

⑭ Mounding and native tree and shrub planting towards the built development. To integrate with the existing conserved habitats (see 14) and to include grassland on the lower slopes. Shallower slopes of 1:4 - 1:7 facing towards Baginton; relatively steeper slopes of 1;3 - 1:4 facing towards the development and airport

rev	date	description	dm	chkd
J	16.12.2015	Amended Site Boundary & Proposals	CMW	TRJ
K	-	-	-	-
L	22.01.2016	Amended Rendering and Scale	CMW	TRJ

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arboriculture

FPCR Environment and Design Ltd
Lockington Hall
Lockington
Derby DE74 2RH

t 01509 672772
f 01509 674565
e mail@fpcr.co.uk
w www.fpcr.co.uk

client
Coventry City Council & Jaguar Land Rover

project
Whitley South,
Coventry

drawing title
LANDSCAPE FRAMEWORK
(Detailed Area: North East Baginton)

scale
1:2000 @ A1

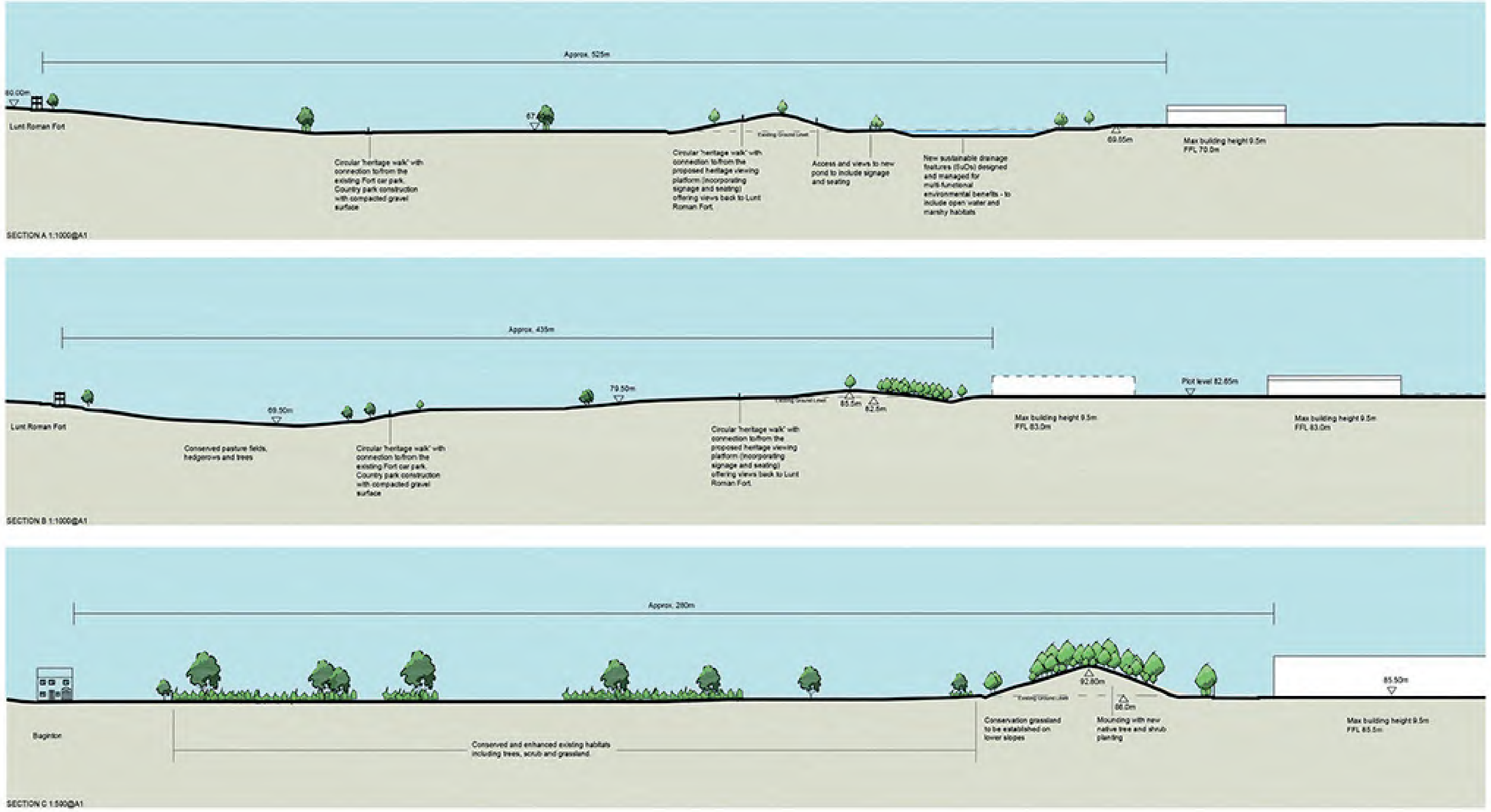
drawn / checked
CMW / KMS

revision date
22 January 2016

drawing number
FIGURE 5.12

rev
L

CAD file: J:\4700\4772\CAD\LANDSCAPE FRAMEWORK Rev L.dwg



NOTE: ALL LEVELS SHOWN ARE APPROXIMATE AND INDICATIVE AT THIS STAGE AND SUBJECT TO CONFIRMATION

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rev	date	description	drn	chkd
E	22.01.2016	ISSUE	KMS	
D	16.12.2015	Added key and ground hatching and distances checked	CMW	TRJ
C	17.12.2015	Amended site sections to fit new building proposals	CMW	TRJ
B	17.12.2015	Removed extended site proposals	CMW	TRJ

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landscape design ▪
urban design ▪
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architecture ▪
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FPCR Environment and Design Ltd
Lockington Hall
Lockington
Derby DE74 2RH

t 01509 672772
f 01509 674565
e mail@fpcr.co.uk
w www.fpcr.co.uk

client
Coventry City Council & Jaguar Land Rover

project
Whitley South,
Coventry

drawing title
CROSS SECTIONS A, B and C

scale	drawn / checked	revision date
1:5000 @ A1	CMW / TRJ	January 2016

drawing number
FIGURE 5.13 rev **E**

CAD file [illegible]

6. ECOLOGY & NATURE CONSERVATION

The Biodiversity Records Centre, Local Badger Recorder and the MAGIC website were consulted to obtain existing information regarding the site and surrounding area and responses collated and fully considered to identify potential receptors and environmental effects within and surrounding the site.

The following ecological surveys were completed by experienced personnel, with the appropriate licences as required in 2012 and updated where necessary in 2015:

- Extended Phase 1 habitat survey
- Hedgerow survey
- Great crested newt survey
- Breeding bird survey
- Winter bird survey
- Reptile survey
- Otter survey
- Water vole survey
- Bat survey of trees and buildings
- Bat activity surveys
- Badger survey including bait marking where required
- Invertebrate survey of areas identified as having good potential for invertebrates
- Phase 2 habitat survey where necessary

All methodologies followed published guidelines as accepted by statutory and non-statutory agencies including Natural England.

The Lower Sowe & Sherbourne Valleys Local Wildlife Site (LWS), Lower Sowe & Sherbourne Valleys Extension potential Local Wildlife Site (pLWS), Leaf Lane LWS, River Sowe LWS, The Lunt pLWS, Bagington Flood Meadows pLWS, Howes Lane Ecosite, A45 / A46 Roundabout Ecosite, Stonebridge Highway St Martin’s Lane A46 Ecosite and Rowley Road Ecosite occur within the development area. Development proposals involve works directly adjacent to the Stonebridge Meadows Local Nature Reserve (LNR) Lower Stoke Railway & London Road Allotments LWS, Fenside Avenue Ecosite, River Sherbourne A46 Embankment Ecosite and River Sherbourne Abbey Road Woodland Ecosite.

The site includes a variety of land uses and habitat types. The majority of the habitats recorded including ponds, improved grassland, semi-improved grassland, tall ruderal vegetation, amenity grassland, built environments, scrub and a small number of hedgerows (Natural Environment and Rural Communities Act 2006 (NERC 2006) and LBAP habitat), were valued as being of negligible, site or local level nature conservation value, however semi-natural woodland (NERC 2006 and LBAP habitat), and veteran trees (LBAP habitat), of District value were also present.

Fauna recorded within the site comprised, a small grass snake population (NERC 2006 and LBAP priority species and protected from killing and injury under Wildlife & Countryside Act 1981 (as amended) and breeding and wintering bird assemblages including several NERC 2006, Schedule 1 and Red List species.

Avoidance of impacts on fauna will be achieved wherever feasible through undertaking vegetation clearance works at appropriate times of the year and creation of new habitats. The design of the scheme incorporates an area of approximately 105ha of created and retained habitats, stretching around the western side of the proposed built development area, which will comprise grassland, woodland and wetland habitats created and managed for the benefit of nature conservation.

In order to ensure that the scheme can provide biodiversity enhancements the scheme has entered into the Biodiversity Offsetting Pilot, whereby biodiversity benefits for biodiversity losses, are calculated in a measurable way. The outcome of this was that the delivery of onsite habitat retention and creation efforts provided mitigation for all effects, with an overall increase in Biodiversity units. As a result, offsite mitigation is not required.

Following mitigation and compensation minor residual effects that will remain include impacts on non-statutory designated sites within the site boundary which would result in small areas of habitat loss. Replication of these habitats is not feasible within the Green Infrastructure of the scheme. There are likely to be minor adverse effects on foraging and commuting bats due to an increase in lighting around the development and associated roads.

There will also be minor positive residual effects within parts of the site, for example where diversification of habitats is proposed through creation of new hedgerows and wetland features. This would potentially benefit fauna including reptiles. The production of a Biodiversity Management Plan will ensure that the habitats retained and created will provide maximum biodiversity benefits in the long-term ensuring their contribution towards strong linking corridor habitats within the context of the wider Green Infrastructure.

7. GEOLOGY, SOIL & GROUNDWATER

The current conditions at the site have been established by means of undertaking detailed desk based Geo-environmental and Geotechnical Risk Assessment Report, supplemented by available historic ground investigation data and assessments provided by various parties and in the public domain from past applications.

The PSSR reports included a site walkover survey and gathering and assessment of available data sources from;

- Environmental data bases
- Local Authority
- British Geological Survey

In addition geological and historical mapping and topographical survey data (where available) has also been reviewed and utilized to assist in the assessments where available.

These assessments have all been undertaken in general accordance with the requirements BS5930 ‘Code of Practice for Ground Investigation’, Environment Agency CLR 11 ‘Model Procedures for the Management of Land Contamination’ (Risk Assessment) Association of Geo-environmental Specialists ‘Guidelines for the Preparation of the Ground Report’ 2003 (Interpretative Report).

This report has enabled the baseline conditions for the site to be established and allowed assessment of potential effects from the development to be established.

The environmental impact of the proposed scheme in relation to Geology, Soils and Groundwater impacts is detailed within Chapter 7 of the Environmental Statement.

No ground conditions have been identified that would prevent the proposed scheme being technically viable using normal civil engineering techniques or which would be considered to present significant detrimental environmental impacts with respect to geology, soils or groundwater and the proposed development.

8. WATER RESOURCES & DRAINAGE

A Flood Risk Assessment has been prepared for the application site and this shows that part of the development falls within Flood Zone 3 and a high flood risk area, in particular the proposed River Sowe Bridge and new slip road crossing of the River Sherbourne. Floodplain compensation works are to be undertaken to account for introducing this structure into the floodplain and prevent an increase in flood risk elsewhere. The remainder of the built development proposals are located in Flood Zone 1 and therefore not at risk of river flooding.

Surface water runoff from the proposed development will be treated by a minimum of two treatment trains, preferably on the surface. The quality of runoff will be improved by the use of sustainable drainage systems (SuDS). Following the implementation of this there shall be no reduction in the quality of runoff as compared to the existing situation. Levels of surface water runoff will be restricted to greenfield discharge rates prior to discharge into the rivers Sowe and Avon to prevent any increase in flood risk elsewhere.

There is a risk to the water environment during the construction stage from, suspended solids, cement, fuel leaks and chemical spillage during the construction works. Construction techniques will be mitigated to ensure water quality is not affected.

After reviewing all of the potential impacts during both the construction and operational phase, once the recommended mitigation is in place all the overall residual impact is likely to be negligible.

9. NOISE & VIBRATION

The noise and vibration chapter of the Environmental Statement contains an assessment of the potential noise and vibration effects of the proposed development. The assessment considers the potential effects resulting from the construction phase and once operational, the associated road traffic noise and other operational noise sources.

At this stage of the scheme, details regarding the construction activities and plant are not available. Therefore it is not possible to accurately predict the effects of the construction phase. Consequently, consideration will be given at the earliest possible stage to the sensitive management of construction works to avoid, as far as is reasonable, adverse effects on the environment.

Prior to the commencement of construction works a Construction Environmental Management Plan (CEMP) will be prepared and agreed with the Local Authority. The CEMP will address how noise and vibration will be mitigated through the use of Best Practicable Means. Some of the construction activities that are likely to create higher noise impacts have been identified and careful consideration will be given to these in the CEMP.

It is likely that piling techniques will be employed for the construction of the new road bridge crossing over the A45 Stonebridge Highway. Significant noise and vibration impacts are not anticipated due to the distance to the nearest sensitive properties. However, vibration should be an important consideration when the piling technique to be adopted is considered.

An assessment of road traffic noise has been considered by comparing a do something scenario against a do minimum scenario for the design year of 2026 for both the daytime and night-time periods. An assessment has been carried out in accordance with the Design Manual for Roads and Bridges (DMRB) Part 7 HD213/11 Noise and Vibration; classification of magnitude of noise impacts in the long term. The road traffic noise effects have been determined for 39 noise sensitive locations in the vicinity of the scheme.

At receiver position T4 Whitely Academy (shown on Appendix 9.3) the traffic noise effect is predicted to be minor adverse. At all other receivers on the surrounding road network during the daytime there are no adverse traffic noise effects. From the assessment of road traffic noise during the night-time period no adverse effects are predicted from road traffic noise.

The assessment has considered whether noise sensitive premises qualify for compensation in accordance with The Noise Insulation Regulations 1975 and ‘The Noise Insulation (Amendment) Regulations’ 1988. The assessment found that no noise sensitive premises qualified.

Operational noise that excludes road traffic has also been considered. The traffic consultants predict that there are no significant numbers or regular pattern of HGVs servicing the commercial development area. Therefore, the operational noise such as the infrequent loading of goods and HGV manoeuvers within the commercial zone is not considered to have any significant impact.

Detailed information regarding mechanical services plant associated with the proposed commercial zone is not currently available. Once the location of the plant has been confirmed and detailed information regarding the plant that is proposed to be installed is available, an assessment will be undertaken to ensure that the noise levels at the nearest noise sensitive receivers are acceptable with respect of the requirements of local authorities.

Mechanical services noise can be easily attenuated through several methods including: selection of quieter plant, silencers/attenuators, appropriate sizing, appropriate location, barriers and enclosures. If the noise levels require attenuation these options can be explored as the mechanical services design progresses. Consequently, it is anticipated that whilst it cannot be calculated at this stage of the scheme, it will be possible to achieve acceptable noise levels at the nearest noise sensitive receivers. It will be possible to determine appropriate target levels at the closest noise sensitive premises based upon the baseline noise levels obtained during the noise survey detailed in the chapter.

The proposed development contains a landscaped open space immediately to the west of the commercial zone that includes earth bunds. Although not essential to comply with current noise standards and guidelines they will be beneficial in reducing noise attributable to the commercial zone and traffic in the general vicinity.

10. AIR QUALITY

This chapter of the Environmental Impact Assessment (EIA) has described and evaluated the air quality impacts of the proposed development in line with current guidance (IAQM & EPUK 2014, 2015) methodologies whilst the operational phase assessment considered the concentrations of key pollutants on site with reference to the UK Air Quality Standards, following modelling using a Defra approved detailed dispersion model (ADMS-Roads).

During construction, and with the adoption of appropriate mitigation measures, dust emissions should not cause any significant off- or on-site effects.

Atmospheric dispersion modelling of traffic data has shown that, during the operational phase, the development is unlikely to expose occupants of any existing dwellings to unacceptable levels of pollution as a result of the development.

Making allowances for the above, the Whitley South development has been determined to be acceptable in terms of its impact on local air quality. With respect to the NPPF and Policy NE5 of the WDC local plan, the development is considered to comply primarily because it is not expected to expose existing receptors with poor air quality.

11. CULTURAL HERITAGE

An assessment of the potential effects of the Proposed Development on cultural heritage resources was undertaken as part of the EIA. This established that no known heritage assets of national importance or of high significance are situated within the Application Site itself. However, a number of such assets are identified within a c.0.5km radius surrounding the Application Site as assessed as the study area. These comprise the scheduled monuments of The Lunt Roman Fort and Baginton Castle; the Conservation Areas of Baginton and London Road, and a single Grade I, and a number of Grade II listed buildings. No direct impacts on any of the designated assets identified above would result from Proposed Development, although its potential to indirectly effect the significance of their associated settings was identified.

A direct effect on potential buried heritage assets recorded within the Application Site is identified. These receptors are considered to be of no more than local to regional importance and the significance of their permanent removal to result in only a Moderate/Minor Adverse effect.

Indirect effects on the significance of the associated settings of a number of built heritage assets and the scheduled monument of The Lunt Roman Fort from Proposed Development are identified arising from visual and noise alterations that would be experienced during construction. However, the impact of effects of Proposed Development on the significance of the settings of these assets is considered low and to be temporary in duration.

A permanent indirect effect on the significance of the setting of the scheduled monument of The Lunt Roman Fort during the operation of the Proposed Development is identified. This effect would result due to the low level of change that would result from Proposed Development on the immediate physical and contextual setting of the monument. In view of the high sensitivity of the monument to changes in its setting, this low level of change is considered to result in a Moderate indirect adverse effect.

The impact of the Proposed Development on buried heritage assets (known and as yet undated) would be suitably offset by the implementation of an appropriate programme of mitigation which would result in an increased knowledge of the archaeological and historic landscape of the area, leading to a Minor Beneficial Residual Effect.

The temporary indirect effects during construction of the Proposed Development on the associated settings of identified built heritage assets would be mitigated by appropriate design and landscaping measures. Early implementation and phasing of the landscaping works within the construction programme would result in reducing the identified effects of construction on these assets to Negligible, with a similar Negligible Residual Effect resulting on the setting of these assets at the operational stage.

Appropriate phasing in the construction programme of proposed landscaping measures within the area of Proposed Development adjacent to the scheduled monument of The Lunt Roman Fort would also serve to reduce further the temporary low level of effect identified on the setting of this asset during construction, although would not remove it entirely. Beyond the design and landscaping measures incorporated within the Proposed Development, no additional mitigation can be identified that could serve to suitably reduce the low level of change that would result on the significance of its associated setting from Proposed Development at its operational stage. However, the Moderate indirect adverse effect identified is considered likely to reduce further once landscaped planting reaches greater maturity and may be further softened through other design considerations such as building orientation, design and materials/finishes, resulting in a more Minor Indirect Adverse Residual Effect. This resultant effect would further be off-set by opportunities that have been taken by Proposed Development to provide enhancements to the public appreciation and experience of the monument within the public open space that is to be created by the landscaping, the result of which in itself would be of Minor benefit to the monuments setting.

Accordingly, it is anticipated that any planning permission granted for development on the site will incorporate a planning condition relating to archaeology and that this condition will incorporate a phased programme of archaeological work, likely comprising areas of controlled excavation (strip, map and record) and archaeological monitoring and recording (watching brief) phased ahead of and during development with reporting as appropriate. The implementation of this programme of investigation would mitigate the adverse effects of the Proposed Development and enable the development to proceed in accordance with development plan policy on archaeology.

12. LIGHTING

The proposed development will be lit after dark to ensure the safety and security of both people and property. This includes roads, car parks, key footpaths/cyclepaths, service yards and loading areas. Lighting will be of the type that only emits light downwards, thus minimising light pollution. Particular care will be taken where new lighting needs to be positioned near the River Sowe and areas frequented by bats, to ensure that wildlife is not affected in any way. Heights will be kept as low as practicable and will almost always be lower than the eaves height of nearby buildings.

All external lighting, whether for construction or operation phase, will comply with the recommended limitations given in the ILP Guidance Notes for an Environmental Zone E1 location. This prevents emission of any upward light and helps to minimise light spill and glare.

It is recommended that planning conditions include a requirement for submission of a fully detailed operation phase Lighting Strategy, giving the design, layout and hours of use of all operation lighting. This lighting will also need to comply with Coventry Airport’s safeguarding requirements. The detailed Lighting Strategy should be based on the principles set out above, which include appropriate embedded mitigation.

In terms of cumulative effects, there are at present many sources of light in the local environment. The major ones are Coventry Airport buildings and car parks, Middlemarch Business Park, Stonebridge Trading Estate and, further away, the city of Coventry. These can be seen in most views, appearing as points of light with localised sky glow above. Given the existing situation, new lighting will make a minor difference for a few viewpoints and a negligible difference for most.

13. TRANSPORTATION

The site is located to the south-east of Coventry and lies to the south of the A45 Stonebridge Highway. For the purposes of assessment, assumptions have been made within the transport part of the submission to cover the application site, based on approximately 4,000 employees by 2026 once fully occupied. It is also assumed that no existing jobs on the Airport or within the Middlemarch Business Park (MBP) will be lost or displaced as a result of the Whitley South development.

In support of the Environmental Statement (ES) for the project, a Transport Submission comprising a total of 17 reports and documents has been prepared. The main Transport Assessment (TA) seeks to address the traffic and transportation aspects of the scheme. The information provided within each of the 17 individual reports is intended to be complimentary and separate documents should therefore be read in conjunction with one another to establish the full transport picture.

The ES Transport Chapter provides only an overview of the findings and reference should be made to the individual reports for further detail. The 17 documents are as follows, with the abbreviated title of each also provided for reference:-

i) Transport Assessment – TA
ii) Accessibility Report (Restricted Accesses) – AR
iii) Travel Plan – TP
iv) Parking Management Strategy – PMS
v) Travel Monitoring Strategy – TMS
vi) Stage 1 Road Safety Audits – RSA’s
vii) Traffic Modelling Report (VISUM Validation) – VISUM (1)
viii) Traffic Modelling Report (VISUM Prediction) – VISUM (2)
ix) Traffic Modelling Report (PARAMICS) – PARAMICS
x) Non-Motorised Users - Context Report - NMU (1)
xi) Non-Motorised Users - Audit Report – NMU (2)
xii) Signage Strategy Signage
xiii) Junction Designs (A1 Plans) Drawings
xiv) Main A45 Bridge Approval in Principle – AiP
xv) Construction Phasing – CP
xvi) Departures Report Departures
xvii) Non-Technical Summary (Transport) – NTS

Development of Whitley South accords with both local and national Planning Policy and further details of this aspect of the scheme are provided in both the TA and ES Transport Chapter. The most important document in this regard is the National Planning Policy Framework (NPPF) which has a presumption in favour of planning being granted for sustainable employment sites. The development has been prepared with this in mind, with provisions included to ensure that the site is accessible from a number of sustainable transport options.

In particular, a new bus route into the City is included as part of the scheme, which will greatly improve accessibility for all non-car users on this side of the City. Overall, measures included in the Travel Plan (when combined with the new bus route) aim to reduce car usage to no greater than 65% of employee commuter travel, against a typical figure of 81% in the surrounding parts of Coventry.

Traffic conditions on all parts of the surrounding local highway network are poor currently. Surveys undertaken in 2012 (prior to Highways England's Toll Bar Island works commencing) within the main area of interest to the TA suggested that at that time, the network operated above capacity during weekday peak periods, with extensive peak hour queuing on the A46 and A45 approaches to Toll Bar Island being commonplace. Whilst the situation is expected to improve locally once the works to Toll Bar are complete, neither the Stivichall Interchange (Festival Island) nor the Whitley Roundabout to the north of Jaguar on the A444 are included in the improvement package. As a result, the significant queuing noted in 2012 at both locations is likely to get worse with time.

Whilst the proposal aim to reduce car usage to 65% is outlined above, the design of the improvements to the highway network has been based on the prevalent 81% figure to ensure sufficient capacity will always be available, this is therefore a robust approach.

Access to the Whitley South site is intended to be from a new grade-separated junction onto the A45. This junction has been designed to accommodate all traffic likely to be generated by the scheme, other committed and planned development and other users up to 2026 (the date by which the development is expected to be fully occupied. The site has a number of other access points however and the management of these is important to ensure that traffic does not cause problems on local roads adjacent to the site. In total, there are four locations where restricted vehicular accesses are proposed and these are discussed in detail within Accessibility Report (AR). These comprise:-

- Along Rowley Road, to the immediate east of Baginton Village;
- Along Rowley Road, between the new site access and Toll Bar Island;
- Leaf Lane, west of the Festival Island at Stivichall;
- Along the A45, where Emergency Accesses are proposed.

In addition, off-site parking, connectivity with existing local facilities provided within Baginton Village and development phasing are also discussed and the proposed arrangements outlined in the AR.

Excluding the restricted accesses outlined above, the base highway package comprises the following:-

i) Construction of a new grade-separated junction onto the A45 Stonebridge Highway to serve the site, including the Jaguar Whitley development to the north;

ii) Construction of new link-roads through the Jaguar Whitley site, to be known as the Jaguar Link Road (JLR) and Jaguar Expansion Road (JER). The JLR route will pass to the east and north of the existing Jaguar industrial facility to connect with the A444, at which point the newly built A444 Whitley Interchange will be modified to provide for bus priority with the help of LTB funding;

iii) Improvement of the A45/A46 Stivichall Interchange (Festival Island) through widening, the introduction of full traffic signal control and rationalisation of the Leaf Lane and north-bound A444 exits, where several options have been included;

iv) Improvement of the A444/A4082 Whitley Roundabout to the north-west of the Jaguar site through better lane segregation, widening and the introduction of full traffic signal control;

v) A Financial Contribution to CCC Highways to allow them to provide commensurate improvements to the A4082 “Asda” Roundabout and the A45/B4113 St. Martin’s Island;

vi) Introduction of traffic signal control at the A46/Stoneleigh Road Junction, including approach widening and removal of the Kenilworth Road Roundabout.

The proposals for the site access have been tailored to fit in with HE’s Toll Bar Island scheme. As a result, substantial alterations to the current improvements are not required to accommodate the new Whitley South A45 junction.

In order to establish the likely impacts of the scheme, other committed developments in the area and the effectiveness of the above combined highway improvements and non-car initiatives, traffic modelling has been undertaken for the combined scheme and this is fully described in the VISUM and PARAMICS reports. In essence, four scenarios have been modelled.

The traffic models were used to provide overall 2026 traffic flow predictions for the various scenarios. Both AM and PM predictions were obtained, covering three hourly periods in both cases (07:00 to 10:00 and 16:00 to 19:00). The resulting impacts on the roads within, entering and leaving, the study area can be then be summarised as follows:-.

i) With the exception of short lengths of the B4113 and B4110, no road entering or leaving the study area would be over capacity in the 2026 Design Year. Overall therefore, no part of the network would operate materially worse with the development in place in 2026 than it would without it.

ii) All roads within the study area were shown to be operating within capacity during both peak hours, in the 2026 without modal split scenario.

iii) All parts of the Site Access Junction would be adequate to serve the development and all associated “committed” developments and allocations in 2026;

iv) Of the 12 off-site Junctions examined, all but the A4082 “Asda” Roundabout, the St. Martin’s and Festival Islands on the A45 and the A45/A429 Kenilworth Road Cross-Roads were shown to have sufficient capacity to allow them to fully function in 2026 with the proposed improvements in place. The former two sites are being dealt with by way of a financial contribution to allow their improvement by CCC Highways, so were not considered further. Impacts at the Kenilworth Road Cross-Roads were deemed to be too small to warrant further improvements, over and above those recently provided by the City Council;

v) All parts of the Festival Island would operate within capacity in 2026 depending on the option chosen for works to Leaf Lane.

Based on the above appraisal and proposed mitigation measure, it is believed that the site can be accessed in an acceptable and sustainable manner, whilst still allowing the existing highway network to function in a safe and efficient way. The effects of Whitley South in traffic impact terms could then be summarised as follows:-

i) As a result of the proposed design measures, the effects of the project on the surrounding local highway network would be not result in any significant adverse effects at any location;

ii) All construction traffic to and from the site would be controlled by routing restrictions in accordance with the AR, which would prevent the use of local roads by such vehicles. As a result, construction traffic would be confined primarily to the A45 and thence the A46 to the north and south, thereby avoiding sensitive areas. No significant adverse effects are therefore expected to occur during construction of Whitley South either, with traffic produced generally being lower than that of the completed scheme;

iii) Material impacts resulting from the scheme would be wholly mitigated up to 2026 by the proposed Highway and Public Transport improvements, which would be funded and implemented as part of the Project. This is true even if any potential new modal split away from private car usage created by Travel Plan is ignored;

iv) Following improvements proposed to the A45 and A46, the Strategic Road Network would continue to operate within capacity to 2026 following development of the site and all associated Draft Local Plan “Committed” schemes. The Project would also provide minor junction improvements at other locations to address any significant adverse effects identified away from the main core routes. As a result, only a small number of roads within the entire model area are projected to be operating over capacity in 2026; those that are would be only marginally so and none are taken over capacity by the combined scheme that would not already be so under the “Do Minimum” scenario. In all such cases, impact is no greater than 5% and in most below 3% under even the Case 2 scenario (mode-split ignored) suggesting that in practise, impacts would be somewhat lower. At these sorts of impact levels drivers would be unlikely to detect any material change in their journey and any residual effects can therefore be regarded as “Negligible” for the purposes of assessment at these few locations.

Notwithstanding the above, as a direct result of the sustainable travel initiatives contained within the Project and the investment in roads contained therein, there will be a net “Major Beneficial” effect on the local road network in and around Coventry overall, once the scheme is completed. This is a benefit of the Project and would relate well to Paragraph 32 of the NPPF; delivering as it would greatly increased modal choice in the area through improved bus services and new pedestrian and cycle routes operating through the site. This will potentially lead to an overall reduction in car traffic to the south of Coventry, to the benefit of all road users.

At Paragraph 32, the NPPF is clear that “Development should only be prevented or refused on transport grounds where the residual cumulative impacts of development are severe”. In this case, the cumulative impacts of the Whitley South scheme, along with all the other schemes in the location likely to come forward over the next 10 years and all strategic traffic growth on the A45 and A46 will be mitigated by the proposals, to the extent that the residual impacts will be significantly beneficial.

14. CUMULATIVE EFFECTS

Cumulative impacts comprise the combined effect of impacts on particular receptors. This can be in the form of impact interactions (e.g. effect from noise and air quality) or the effects of the proposal alongside the effects from other committed development in the area.

A number of development projects in the local area have been identified as projects which could potentially contribute towards a cumulative effect on sensitive receptors. These are:

- The Highways Agency A45 Toll Bar improvements;
- Whitley Business Park scheme (including the Travis Perkins Distribution Facility);
- Ryton site (A45 south of Toll Bar);
- Ansty Business Park (east of the A46);
- Stoneleigh Park;
- Middlemarch Extension.

The ES technical chapters conclude that there will not be any potential significant cumulative effects arising as a result of the Whitley South scheme and the other projects identified. Some minor cumulative effects are predicted in combination with the Highways Agency scheme at Toll Bar and the Whitley Business Park scheme. However these are not considered to be significant over and above the direct assessed impacts from the Whitley South scheme.

Consideration has also been given to the potential cumulative effects of the development of land in the vicinity of Coventry Airport (in addition to the land covered by this application), proposed to be allocated in the submitted Warwick Local Plan. Whilst there is currently no scheme for this land which is in the public domain, consideration has been given to the cumulative effects in terms of the scheme that was previously applied for and refused following a call-in, by the Secretary of State (SoS). That scheme was termed the Coventry and Warwickshire Gateway (CWG). The Environmental Statement that accompanied that application comprehensively assessed cumulative effects, because the application covered both the Whitely South application site and the other land proposed to be allocated in the submitted Warwick Local Plan. A detailed reappraisal of each aspect of cumulative effects has therefore not been undertaken as it is considered that the conclusions of the previous Environmental Statement remain valid and an appropriate basis to consider potential cumulative effects.

The residual environmental effects of the CWG scheme were considered to be acceptable and this position was endorsed by the SoS. Having regard to these conclusions it is considered that subject to the details of any proposals brought forward on the remaining land to be allocated, the cumulative environmental effects are likely to be acceptable and the form of this application will not prevent appropriate development being brought forward on the remaining allocated land. In this regard, this application is acceptable in terms of potential cumulative effects arising from the development of the proposed allocation site.

The cumulative negative effects of the proposal on the environment must be balanced with the identified significant positive benefits of the proposal in terms of the investment and job creation (the socio-economic benefits). These are considered to be significant and potentially wide reaching bringing wider socio-economic benefits to the area.

APPENDIX 3.2

UKBIC BATTERY MANUFACTURING PROJECT – GROUND INVESTIGATION TECHNICAL NOTE

The ground investigation technical note is not required for a Part B Application and has thus been removed from the redacted copy

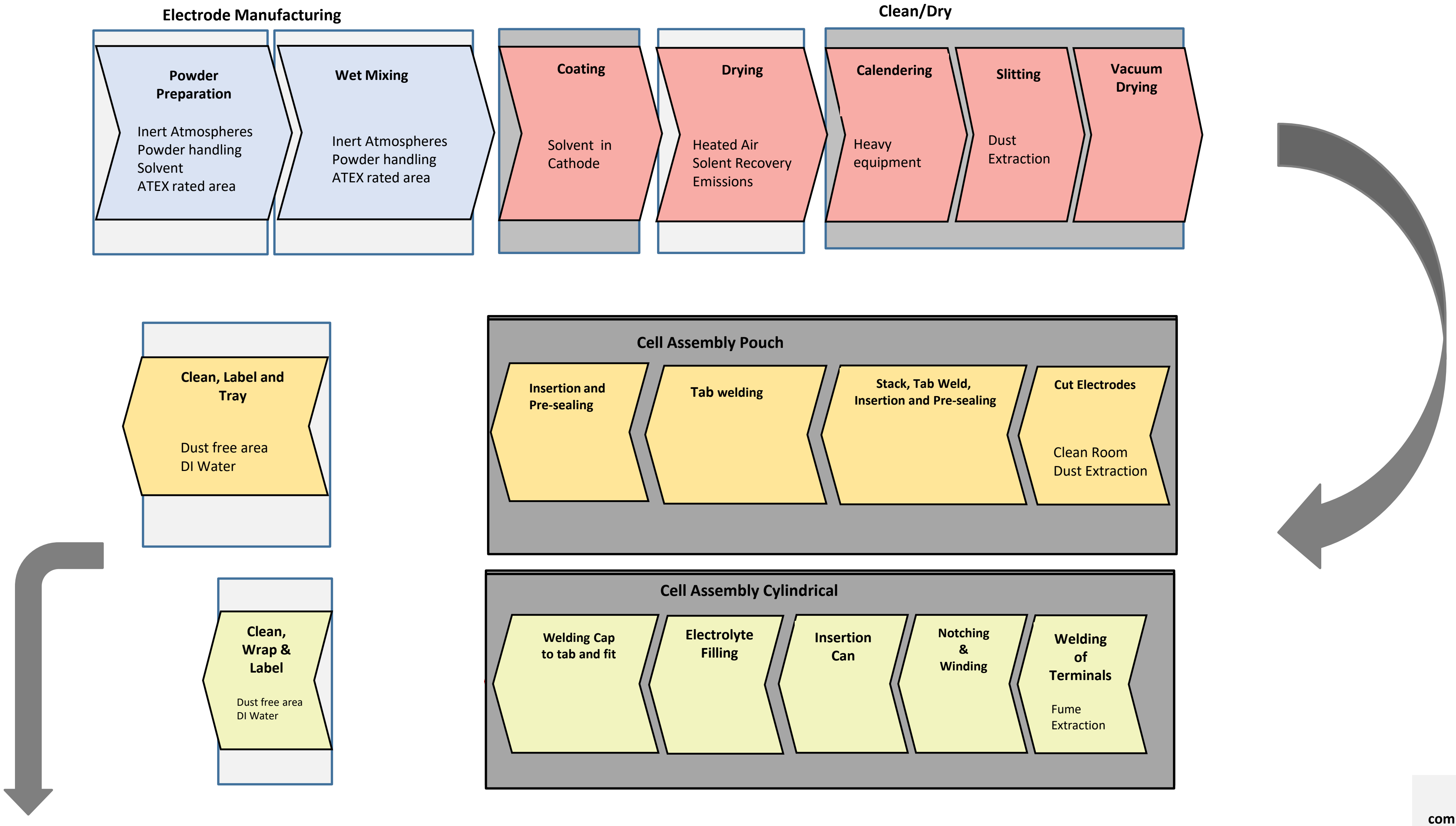
APPENDIX 3.3

PROCESS FLOW DIAGRAMS

Battery Manufacturing Process Steps UKBIC

UK Battery Industrialisation Centre
WMG, University of Warwick

Process Flow



Electrode Manufacturing

Powder Preparation
Inert Atmospheres
Powder handling
Solvent
ATEX rated area

Wet Mixing
Inert Atmospheres
Powder handling
ATEX rated area

Coating
Solvent in Cathode

Drying
Heated Air
Solent Recovery
Emissions

Clean/Dry

Calendering
Heavy equipment

Slitting
Dust Extraction

Vacuum Drying

Cell Assembly Pouch

Cut Electrodes
Clean Room
Dust Extraction

Stack, Tab Weld, Insertion and Pre-sealing

Tab welding

Insertion and Pre-sealing

Clean, Label and Tray
Dust free area
DI Water

Cell Assembly Cylindrical

Welding of Terminals
Fume Extraction

Notching & Winding

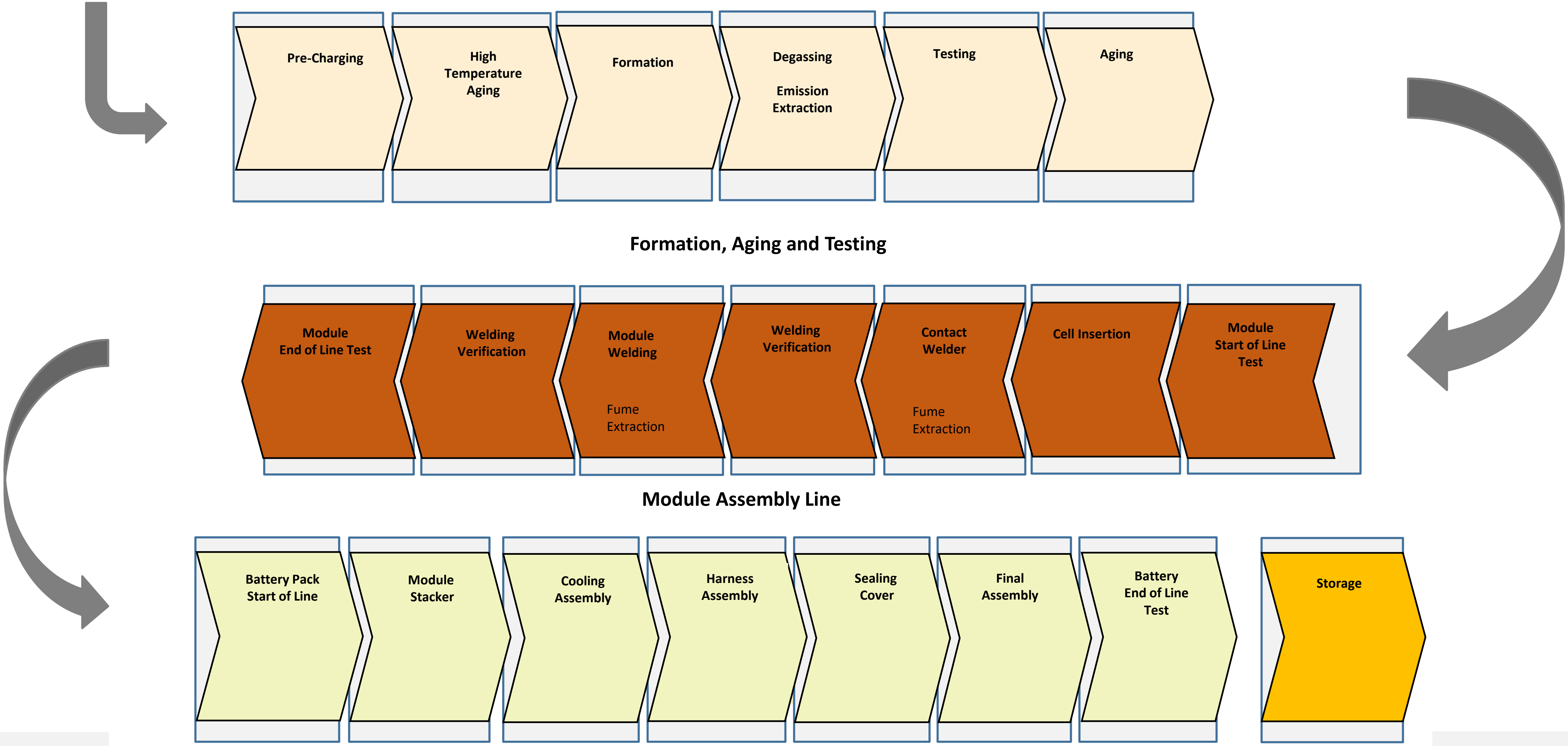
Insertion Can

Electrolyte Filling

Welding Cap to tab and fit

Clean, Wrap & Label
Dust free area
DI Water

Process Flow



Pre-Charging

High Temperature Aging

Formation

Degassing

Emission Extraction

Testing

Aging

Formation, Aging and Testing

Module Start of Line Test

Cell Insertion

Contact Welder

Fume Extraction

Welding Verification

Module Welding

Fume Extraction

Welding Verification

Module End of Line Test

Module Assembly Line

Battery Pack Start of Line

Module Stacker

Cooling Assembly

Harness Assembly

Sealing Cover

Final Assembly

Battery End of Line Test

Storage

Pack Assembly Line

APPENDIX 3.4

NMP EMISSIONS ASSESSMENT TECHNICAL NOTE

Memo

To:	Tony Richardson UKBIC		
From:	John Dickson	Email:	John.dickson@atkinsglobal.com
Date:	17 January 2020	Phone:	
Ref:		cc:	
Subject:	NMP Emissions Assessment		

1. Introduction

UKBIC has engaged Atkins Ltd to provide a technical note on predicted concentrations of N-Methylpyrrolidone (NMP) emitted from the proposed UKBIC battery manufacturing plant, to support UKBIC's Part B Environmental Permit application. This technical note identifies the NMP emission rate, uses the Environment Agency risk assessment method to provide a conservative prediction of maximum ground level concentrations of NMP from the carbon bed emission point, and compares the predicted concentration values against published assessment criteria for the protection of the general public.

2. Assessment Criterion

The European Chemicals Agency (ECHA) Registration, Evaluation, Authorisation & Restriction of Chemicals (REACH) Registration dossier for 1-methyl-2-pyrrolidone (which is the registration entry for NMP) https://echa.europa.eu/registration-dossier/-/registered-dossier/15493/1 identifies "derived no-effect levels" (DNELs). These are concentration levels below which a substance does not adversely affect human health (https://newsletter.echa.europa.eu/home/-/newsletter/entry/4_13_making-use-of-derived-no-effect-levels-generated-under-reach).

The long-term NMP DNEL value for the general population (inhalation route) for developmental/teratogenicity hazard is 3.6 mg/m^3. This is the lowest inhalation NMP DNEL identified in the Reach Dossier for the protection of the general public, and has therefore been selected, in discussion with the Warwick District Council (WDC) Senior EHO, as the appropriate assessment criterion[1].

The REACH dossier (under the entry for NMP DNEL for the general population) further notes:

- No time extrapolation is required for developmental toxicity as increasing exposure duration does not increase the incidence or severity of adverse effects.
- The approach used for DNEL derivation is conservative. No further assessment factors are required.

On this basis, although the averaging period for the long-term DNEL is not specified, it has been assumed to be an annual average value.

3. EA Risk Assessment Screening Tool

The Environment Agency has developed a risk assessment tool that is used when applying for an Environmental permit for industrial activities that the EA regulates (see

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[1] Previous versions of the Environment Agency H1 screening assessment methodology include a method for deriving an Environmental Assessment Level (EAL) from occupational exposure limits. This was mooted as a potential source of assessment criteria for NMP early in discussions with WDC. Given that this is only an appropriate approach where there is no other source of assessment criteria, as the REACH DNEL for the protection of the general public is published, using the H1 route to deriving an assessment criterion from workplace exposure limits is not appropriate.

https://www.gov.uk/guidance/air-emissions-risk-assessment-for-your-environmental-permit). The tool includes an approach to assess air emissions. It is a simple tool, which gives a conservative assessment of whether the emissions can be screened out as being not significant, or identifying whether further assessment (for example by detailed dispersion modelling) is required. The EA website notes that:

> "*The figures the tool gives you are 'worst case' estimates. So the figures you get may be higher than if you calculate PCs* [Process Contributions] *or PECs* [Predicted Environmental Concentrations] *using other methods, for example dispersion modelling software (which analyses how air pollutants disperse in the atmosphere)*.

The assessment can either be carried out using the EA's tool (an access database tool) or by following the steps set out in the website (this is the approach taken for this assessment).

4. Input Values

The UKBIC electrode (cathode) manufacturing process incorporates a coating activity by which a slurry is stuck onto a metallic sheet. The method of adhesion uses a solvent and binder mix which is subsequently dried, driving the solvent off in the form of a vapour.

The solvent used is NMP; the vapour-containing air from the dryers passes through abatement comprising a condenser and activated carbon bed. The treated air is discharged to atmosphere via a stack which is 1.5 m above the highest point of the building (10.5 m building ridge height).

The mass release rate of the NMP in the treated emission in routine operating conditions is 2.8 g/h (this equates to a concentration of 2 mg/m^3). In abnormal/process upset operating conditions emissions may increase for short periods to up to 5.6 g/h (4 mg/m^3), see section 4.4 "Solvent Abatement" of the main application document for details of abnormal/process upset conditions and their expected durations.

5. EA Tool Assessment

The steps in the EA Risk assessment to air are:

To calculate the PC to air, multiply the Dispersion Factor (DF), in micrograms per cubic metre per gram per second, by the release rate (RR), in grams per second.

$$\text{PC (ug/m}^3\text{) = RR (g/s) x DF (}\mu\text{g.s/g.m}^3\text{)}$$

The Dispersion Factor is given in a table in the EA website. It is dependent on the effective stack height of the release. The EA Tool guidance states that the effective height of release should be treated as 0 metres when the emission is released at a point that is less than 3 m above the ground or building on which the stack is located. As the stack is 1.5 m above the highest point of the roof, an effective stack height of 0 m has been used.

The annual average Dispersion Factor for a release with 0 m effective stack height is 148 µg/m^3 per g/s released.

5.1. Routine Operating Conditions

For routine operating conditions the Release Rate is 2.8 g/h or 0.00078 g/s

The long-term PC is therefore

$$\text{PC (}\mu\text{g/m}^3\text{) = 0.00078 g/s x 148 }\mu\text{g.s/g.m}^3$$

Giving a PC of 0.115 µg/m^3 or 0.000115 mg/m^3

5.2. Abnormal Operating Conditions

For abnormal operating conditions the Release Rate is 5.6 g/h or 0.00156 g/s

The long-term PC is therefore

$$\text{PC (}\mu\text{g/m}^3\text{) = 0.00156 g/s x 148 }\mu\text{g.s/g.m}^3$$

Giving a PC of 0.23 µg/m^3 or 0.00023 mg/m^3

6. Results

The PC is the maximum predicted ground level concentration arising from the release that would occur in any direction or distance from the stack; as the EA notes, the assessment methodology is conservative and provides worst case assessments.

6.1. Routine Operating Conditions

The annual average PC of 0.000115 mg/m^3 is four orders of magnitude smaller than the assessment criteria of 3.6 mg/m^3.

6.2. Abnormal Operating Conditions

The annual average PC of 0.00023 mg/m^3 is four orders of magnitude smaller than the assessment criteria of 3.6 mg/m^3.

7. Conclusion

The results of the assessment show that the emission of NMP will be substantially diluted. Using the conservative EA risk assessment approach, the results show that emissions in both routine operation and abnormal operation would result in worst case maximum ground level concentrations of less than a ten-thousandth of the EU-defined derived no-effect concentration.

Following the EA guidance, this would not be regarded as not significant, and no further assessment or modelling would be required.

APPENDIX 3.5

MEGTEC/DURR SOLVENT RECOVERY SYSTEM

7.1.9.4 SOLVENT RECOVERY SYSTEM FOR THE CATHODE LINE

- 3 stage condensing system connected to the dryer consisting of
    - Recirculation fan that replaces the supply fan and the exhaust fan of the dryer
    - Supply air flow will be controlled by dampers instead of frequency drives
    - 3-stage air water heat exchanger
        - Stage 1 is cooling the air coming from the dryer.
          Water source is "cold" coming from Stage 3
        - Stage 2 is cooling the air with chilled water (customer supply).
          Water or NMP is condensing and draining out of the system by gravity.
        - Stage 3 is heating the air going to the dryer.
          Water source is "warm" water coming from Stage 1
    - The unit will be installed on a structure above the dryer
- In case of NMP there is a small flow of about leaving the system.
- This flow goes to a carbon filter where the air is cleaned to a residual of $< 0,5$ g/m^3. The carbon filter contains 2.500 kg of activated carbon and has a lifetime of approximately 650 h.
- Interconnecting ductwork between Dryer, Condenser and Concentrator (installed on platform above the dryer) are included in the price of the solvent recovery option.
- Ductwork to the Carbon Bed (outside building) is not included

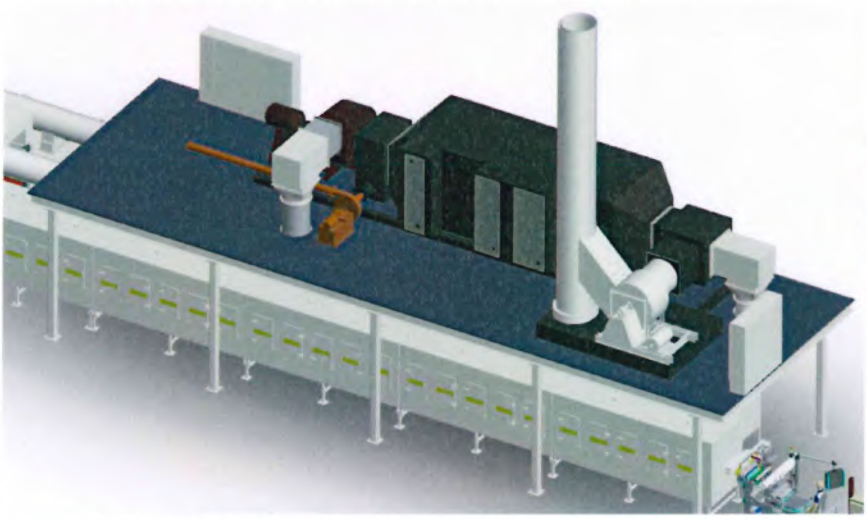


Figure 1: Condenser on Platform above Dryer

Figure 2: Carbon Bed

APPENDIX 3.6

NMP BACKGROUND INFORMATION

EUROBAT Position Paper | May 2017

Recommendation about n-methyl-pyrrolidone (NMP; CAS no. 872-50-4) proposal for inclusion in Annex XIV for authorization.

RECHARGE
The Advanced Rechargeable & Lithium Batteries Association

EUROBAT
ASSOCIATION OF EUROPEAN AUTOMOTIVE
AND INDUSTRIAL BATTERY MANUFACTURERS

Position Paper | May 2017

Recommendation about n-methyl-pyrrolidone (NMP; CAS no. 872-50-4) proposal for inclusion in Annex XIV for authorization.

About the usage of NMP in the lithium-ion battery industry.

Most lithium-ion batteries manufacturing processes are using NMP as a solvent of the electrodes binder , due to stringent solvation and dry atmosphere requirements.

Lithium batteries do not contain NMP. But high performance products are based on the usage of this solvent, totally removed during the manufacturing process.

The NMP used as a solvent is essentially collected after the drying process, reused for cleaning of equipment and finally sent for proper recycling.

The usage of NMP is key for the European battery industry's competitiveness and future development.

The proposal for inclusion in Annex XIV contradicts the opinion given by RAC (Risk Assessment Committee) and SEAC (Socio-Economic Assessment Committee) from ECHA in November 2014 to the EU Commission to opt for restriction for NMP as the best risk management option.

Key recommendations

✓ Do not propose NMP for authorisation

- Usage of NMP for batteries is rather limited in Europe, compared to the rest of the world, as most of the lithium batteries manufacturing is located in Asia.
  This represents less than 4% of the total usage of NMP in EU (as recycling/re-use rates are not published). See data in annex 1.
- **No alternatives are available today for the battery industry use**, as stated in the table C.01 of the background document to RAC/SEAC opinions on NMP (see Annex 3). Indeed, other substances have already been assessed:
  - the usage of NEP as a substitute has not been useful, as it was proven reprotoxic as well (see summary in annex 2).
  - Alternative solvents, including water, have been tested, but are less efficient or still requiring long testing for the manufacturing of high performance batteries.
  - The couple (NMP/PVDF) was replaced successfully by (water/elastomers) for the manufacturing of graphite cathodes for Li-ion batteries, but the physical properties of materials used for the anodes are not compatible with the use of a water based binder: for example, an efficient coating on aluminium collector without corrosion was not achievable.

✓ End the period of regulatory uncertainty by including NMP restriction into Annex XVII.

- The battery as a final product doesn't contain any NMP and it cannot be detected when NMP has been used as a solvent. The NMP hazards are kept under strict controlled industrial use.This was recognized during the RAC /SEAC assessment of NMP in Sept 2014 (see summary annex 3). **The advice given by RAC/SEAC in November 2014 to the EU Commission to opt for restriction for NMP (reduced occupational limit) as the best risk management option, is perfectly suitable for the batteries manufacturing.**
- Investment in Europe for battery manufacturing is uncertain. Many questions are raised about the investment in the EU for battery manufacturing, in particular for electric mobility and energy storage for renewable energy. This uncertainty about the future is even increased when a proposal for authorization is supported. **It is contradictory with the Commission DG GROWTH incentives to develop the batteries manufacturing in Europe as an essential part of the decarbonization program.**

✓ Implement harmonized OHS requirements

- The valid OEL-value for NMP of 40 mg/m^3 as derived by SCOEL is the appropriate protection measure for industrial use. The industry already implemented this limit on a voluntary basis.
- Even if RAC and SCOEL were unable to reach a compromise on a common DNEL for the restriction during the earlier discussions, **there is a need to achieve a harmonized effective new occupational limit for the fair industry competitiveness in Europe**. **Authorization is seen as disproportionate and in contradiction with the restriction, identified as the best RMO for NMP.**

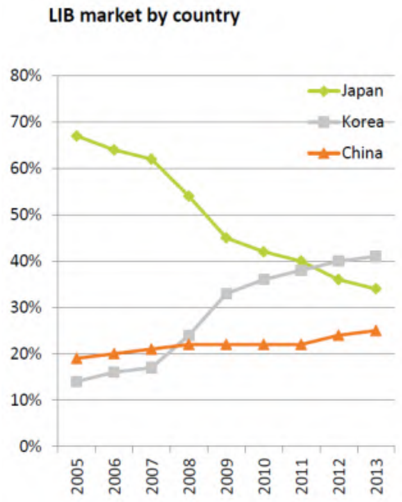
Annex:

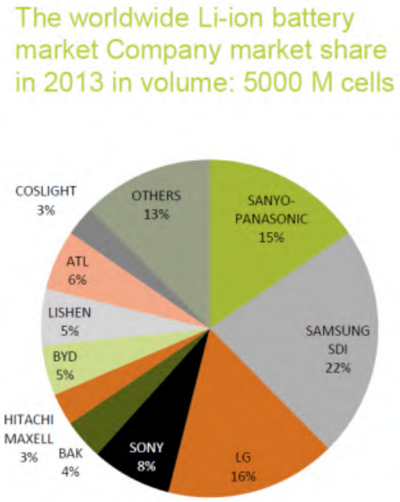
1. Data about the Li batteries manufacturing in EU and the usage of NMP.

- Usage of NMP for batteries is rather limited in Europe, compared to the rest of the world, as most of the lithium batteries manufacturing is located in Asia (data from Avicenne). 2% is manufactured in EU.

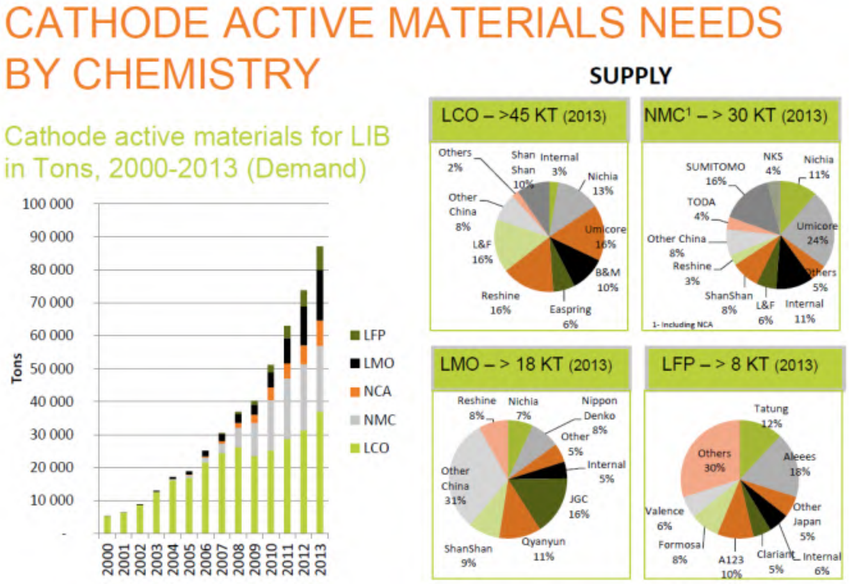
  This quantity represents less than 4% of the total usage of NMP in EU (as recycling/resuse % are not known).

Avicenne 2014





Less than 2% in total Wh of Li-ion batteries are manufactured in EU.



NMP solvent is needed in order to manufacture high performance Li-ion batteries.

The usage of NMP is in the range of 1 g of solvent per Wh of Lihtium-ion battery produced (reference Batteries PEF bill of material – Commission website).

As a result, the NMP usage in EU for the battery application represents less than 4% of the total usage on NMP in EU (in the range of 30 ktons/year).

2. Data about the substitution of NMP as a solvent for Li-ion battery electrodes manufacturing.

- Substitution with water: as previously stated, (NMP/PVDF) was only successfully replaced by (water/elastomers) for the manufacturing of graphite-based negative electrodes coated on copper foil but it was impossible until today to achieve the same substitution for the positive electrodes Several testings are still in progress because replacing NMP by water, in addition to the replacement of an hazardous substance by a non-hazardous one, would represent a significant cost reduction at the level of the cell manufacturing cost.

- Substitution with other organic solvents: no improvement of the toxicity.

Test of NEP as a substitute (a chemical manufacturer mentioned that several companies use NEP instead of NMP).

This practice started when NEP was not classified while NMP was classified as C1b.It was then allowed to transport NEP without hazard label and it was authorized for use in several industries that were banning the use of Carcinogenic substances. From October 22, 2013, NEP has been officially classified as Repr. 1B.

It will most probably be added to the Candidate List and become de facto a potential candidate for Authorization as NMP became.

3. BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON 1-methylpyrrolidin-2-one (NMP) – Several extracts concerning the battery industry -

25 November 2014

"A.1.2 Scope and conditions of restriction(s)

Proposed restriction:

NMP may only be manufactured and used if it can be guaranteed that under normal operating conditions the exposure (as 8-hr TWA (time-weighted average) will remain below 5 mg/m3. Peak exposures (15 min. STEL (short-term exposure limit)) must remain below 10 mg/m3 and must be compensated by lower exposures during the same day in order to remain below the 8-hr TWA value. To give industry sufficient time to adjust their equipment, the restriction entries into force 60 months after inclusion in Annex XVII.

Further NMP may only be manufactured and used if dermal exposure is avoided with protective clothing and gloves, which comply with the requirements of Council Directive 89/686/ECC or other measures.

The exposure level (both inhalation and dermal) must be guaranteed by the use of preventative measures that are applied in the order of the so-called "hierarchy of control", an established concept referred to in the Chemical Agents Directive (Directive 98/24/EC), i.e. substitution, enclosure, increased local exhaust ventilation, increased general ventilation, change in operational conditions and if needed personal protective equipment.

The proposed exposure limits takes into account the use of respiratory and dermal protective equipment, other preventative measures are however preferred (as indicated in the Chemical Agents Directive).

Manufacturers and industrial and professional users of NMP must be able to demonstrate at the request of the local authorities that they comply with the above restrictions. This can be done by maintaining an exposure monitoring program in accordance with the BOHS / NVAA1 Standard or national equivalent."

Usage of NMP in the Battery industries

Information on use of NMP for manufacture of lithium ion batteries was obtained from industry (public consultation Annex SVHC dossier, SVHC-RCOM 10052011) and from the literature. NMP is used both in lithium ion batteries as in other hybrid batteries using nickel, magnesium, or cobalt. In lithium battery production it is applied as a solvent for the binder resins for both the carbon anode and the lithium cobalt oxide cathode, it may be used in gel-polymer lithium ion battery separators/electrolytes, and it may be used in coatings on the outside of the batteries.

In the manufacturing process of the electrode, NMP is used as a solvent for binder resins between a metal foil and an active material for positive/negative electrode agents. From the point of view of proper performance of the electrode, it is essential for a solvent to dissolve PolyVinylidene diFluoride (PVDF) of the binder sufficiently. The solvent with the active material need to be dispersed uniformly on the metal foil with the binder resin. PVDF is often used as a binder to hold the active material particles (e.g. lithium) together and bind them to the cathode. For the anode graphite is mixed with similar binder material. The slurry, made of solvent, binder, active material and additives, needs to disperse the binder uniformly on both sides of the cathode, often made of aluminum foil, and the anode, often made of copper foil. In addition, it is indispensable for the solvent to be vaporized and completely removed from the electrode after coating.

Various electrolytes may be used in lithium batteries. One of the electrolytes that may be applied are polymer gel electrolytes, which are produced by casting solutions of PVDF in acetone, MEK, NMP, or THF into an electrolyte solution (Arora & Zhang, 2004; Yang & Hou, 2012; Michot et al 1999). Arora & Zhang (2004) describe that the originally used supported-liquid membranes made from polypropylene, polysulfone, poly(tetrafluoroethylene), or cellulose acetate, which use relative softer solvents will In contrast, Orendorff (2012) indicate that polyethylene and polypropylene are much more common in commercial non-aqueous lithium ion separators than separators in which PVDF is being used. Also for other hybrid batteries using nickel, magnesium, or cobalt NMP is used in the slurry to bind the active material to the electrodes. A description of the developments in the US battery production is provided by Lowe et al (2010).

The production of lithium and other hybrid batteries needs large amounts of NMP. Because of the high price, NMP is recovered from the exhaust gasses after drying the electrodes and is re-used. Several specialized companies are active in this field.

In addition, NMP is used in this industry for cleaning all apparatus before coating (public consultation 2013/2014).

Substitution of NMP

"As described in part B.2.2, NMP may have various applications in lithium batteries production and is also used for other hybrid batteries using nickel, magnesium, or cobalt. Looking at alternatives for NMP in the battery application, Zackrisson (2010) carried out experiments in which water replaced NMP as a solvent for the PVDF binder of the cathode. As water was used, another binder was applied. The experiments showed that technically it is possible to replace NMP by water, although the commercial application still has to be proved. There are already commercial binders based on styrene butadiene rubber for application as a binder in lithium batteries that do not need NMP (Targray, 2013). There are also several other efforts to replace PVDF by water soluble binders. To conclude, the development on NMP free lithium ion and other hybrid batteries is ongoing, however, at this moment no alternatives have been proven on a commercial scale. Some supporting confidential information has been provided during the public consultation of the Annex XV restriction dossier (public consultation 2013/2014)"

Impacts on the battery sector

"In the battery sector, NMP is used for production of electrodes for lithium batteries. Information from one company suggests that the originally proposed limit of 5 mg/m3 for inhalation is not proportional, as fundamental modifications of dryers are said to be necessary. Costs related to re-engineering of the process

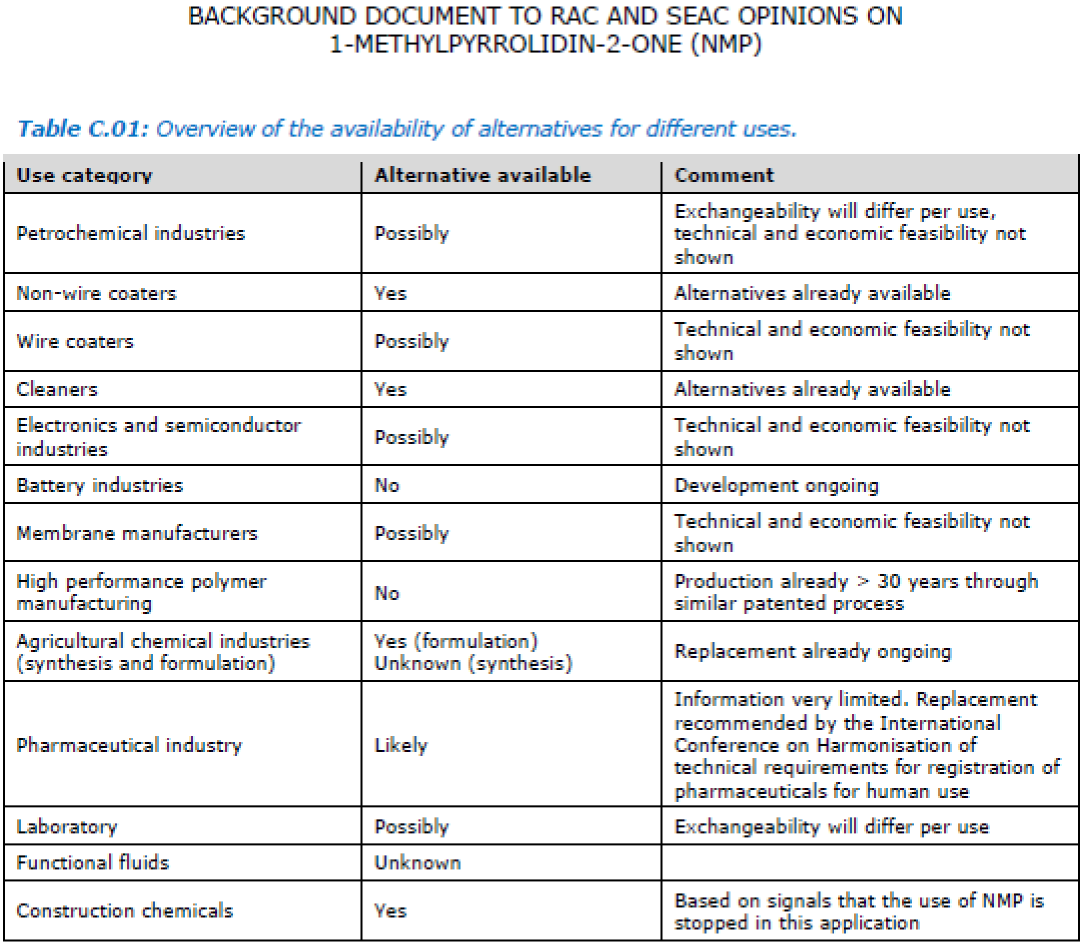
are said to be €1-9 M , and even then the comment (REF PC COM290) indicates that it is uncertain if the desired emission target is achieved. The comment indicated that an inhalation value limit of 20 mg/m^3 with a short term exposure level (STEL) of 40 mg/m^3 could be realized reliably and on a reasonable economic basis. There is no information on the need to modify the machines if the inhalation exposure limit value is established at 10 mg/m^3.

Another comment from this industry suggested that the proposed by the DS limits are already complied with (REF PC COM301).

SEAC therefore concludes that for the battery sector would not be impacted."

"*Turnover and jobs in the battery industries that can be connected to the use of NMP are not known, although signs have been received in the public consultation that these effects will occur for some of the actors in this sector. One actor indicated in the public consultation that besides effects to the sector itself, also supply chain effects might occur, causing additional turnover effects and losses in jobs to down stream users of batteries (e.g. automotive industry)".*

Overview of the availability of alternatives for different uses



BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON
1-METHYLPYRROLIDIN-2-ONE (NMP)

Table C.01: Overview of the availability of alternatives for different uses.

Use category	Alternative available	Comment
Petrochemical industries	Possibly	Exchangeability will differ per use, technical and economic feasibility not shown
Non-wire coaters	Yes	Alternatives already available
Wire coaters	Possibly	Technical and economic feasibility not shown
Cleaners	Yes	Alternatives already available
Electronics and semiconductor industries	Possibly	Technical and economic feasibility not shown
Battery industries	No	Development ongoing
Membrane manufacturers	Possibly	Technical and economic feasibility not shown
High performance polymer manufacturing	No	Production already > 30 years through similar patented process
Agricultural chemical industries (synthesis and formulation)	Yes (formulation) Unknown (synthesis)	Replacement already ongoing
Pharmaceutical industry	Likely	Information very limited. Replacement recommended by the International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use
Laboratory	Possibly	Exchangeability will differ per use
Functional fluids	Unknown	
Construction chemicals	Yes	Based on signals that the use of NMP is stopped in this application

Proposal for Identification of a Substance as a Category 1A or 1B CMR, PBT, vPvB or a Substance of an Equivalent Level of Concern

Annex XV dossier

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CATEGORY 1A OR 1B CMR, PBT, vPvB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance Name(s): 1-methyl-2-pyrrolidone

EC Number: 212-828-1

CAS Number: 872-50-4

Submitted by: European Chemicals Agency at the request of the European Commission

Version: February 2011

PUBLIC VERSION: This report does not include the Confidential Annexes referred to in Parts I and II.

CONTENTS

TABLES and figures

LIST OF ABBREVIATIONS

AISE	International Association for Soaps, Detergents and Maintenance Products
ART	Advanced REACH Tool (for exposure modelling)
BARC	Bottom-side Anti-Reflective Coatings
BMAS	German Federal Ministry of Labor and Social Affairs
BTX	Benzene, Toluene, Xylene
CAS	Chemical Abstracts Service
CEPE	European Council of producers and importers of paints, printing inks and artists’ colours
CICAD	Concise International Chemical Assessment Documents (WHO)
CLH	Harmonised Classification and Labelling
CSR	Chemical Safety Report
DIY	Do It Yourself (home improvement)
DMAC	Dimethylacetamide
DMF	Dimethylformamide
DMSO	Dimethyl sulfoxide
DPM	Dipropylene glycol methyl ether
ECHA	European Chemicals Agency
ECPA	European Crop Protection Association
ERC	Environmental Release Category
ES	Exposure Scenario
ESVOC-CG	European Solvents VOC Co-ordination Group
EU	European Union
GBL	Gamma Butyrolactone
HPV	High Production Volume chemical
IBC	Intermediate Bulk Container
IOELV	EU Indicative OEL values
LEGMC	Latvian Environment, Geology and Meteorology Centre
LEV	Local Exhaust Ventilation
MSCA	Member State Competent Authority
NEP	N-Ethyl Pyrrolidone
NMP	N-Methyl Pyrrolidone
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PGMEA	Propylene Glycol Methyl Ether Acetate
PPE	Personal Protective Equipment
PU	Polyurethane
PU/AC	Polyurethane/polyacrylate
PVC	Polyvinyl chloride

REACH	Registration, Evaluation and Authorisation of Chemicals
RMM	Risk Management Measure
RPE	Respiratory Protective Equipment
SIAR	SIDS Initial Assessment Report (OECD)
SIDS	Screening Information Data Set (OECD)
SPERC	Specific Environmental Release Category
STEL	Short-Term Exposure Limit
TARC	Top-side anti-reflective coatings
TWA	Time Weighted Average
VOC	Volatile Organic Compound

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CATEGORY 1A OR 1B CMR, PBT, VPVB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance Name(s): 1-methyl-2-pyrrolidone

EC Number(s): 212-828-1

CAS number(s): 872-50-4

- The substance is proposed to be identified as substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction category 1 B[1] which corresponds to classifications as toxic for reproduction category 2[2].

Summary of how the substance meets the criteria as category 1B reproductive toxicant.

Pursuant to Regulation (EC) No 1272/2008 as amended and adapted to technical and scientific progress by Regulation (EC) No 790/2009, as of 1 December 2010, N-methyl-2-pyrrolidone is listed as entry 606-021-00-7 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as toxic for reproduction category 1B[1]. Its corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised and classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is toxic for reproduction category 2[2].

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that the substance meets the criteria for classification as toxic for reproduction, in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance? yes

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[1] Classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances.

[2] Classification in accordance with Regulation (EC) No 1272/2008, Annex VI, part 3, Table 3.2 List of harmonised classification and labelling of hazardous substances (from Annex I to Council Directive 67/548/EEC).

PART I
JUSTIFICATION

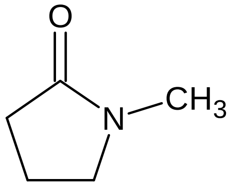
1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	212-828-1
EC name:	1-methyl-2-pyrrolidone
CAS number (in the EC inventory):	872-50-4
CAS number: **Deleted CAS numbers:**	872-50-4 53774-35-9, 57762-46-6, 26138-58-9
CAS name:	2-Pyrrolidinone, 1-methyl-
IUPAC name:	1-Methylpyrrolidin-2-one
Index number in Annex VI of the CLP Regulation	606-021-00-7
Molecular formula:	C_5H_9NO
Molecular weight range:	99 g/mol
Synonyms:	1-Methyl-2-pyrrolidinone 1-Methyl-5-pyrrolidinone 1-Methylazacyclopentan-2-one 1-Methylpyrrolidone AgsolEx 1 M-Pyrol Microposit 2001 N 0131 N-Methyl-α-pyrrolidinone N-Methyl-α-pyrrolidone N-Methyl-γ-butyrolactam N-Methyl-2-ketopyrrolidine N-Methyl-2-pyrrolidinone N-Methyl-2-pyrrolidone N-Methylbutyrolactam N-Methylpyrrolidone NMP NSC 4594 Pharmasolve Pyrol M SL 1332

Structural formula:



1.2 Composition of the substance

Name: 1-methyl-2-pyrrolidone

Description: ---

Degree of purity: ≥80 - ≤100 %

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
1-Methylpyrrolidin-2-one		≥80 - ≤100 %	

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks

Table 4: Additives

Additives	Typical concentration	Concentration range	Remarks
None			

1.3 Physicochemical properties

Table 5: Overview of physicochemical properties[3]

Property	Value	Remarks
Physical state at 20°C and 101.3 kPa	Liquid, colourless with ammonia-like odour	Harreus (2005)
Melting/freezing point	-24.4 °C	Harreus (2005)
Boiling point	204.3 °C at 101.3 kPa	Harreus (2005)
Vapour pressure	0.04 kPa at 25 °C	Lide (1994)
Density	1.028 g/cm^3 at 25 °C	Harreus (2005)
Water solubility	completely miscible with water	Harreus (2005)
Partition coefficient n-octanol/water (log value)	-0.54 at 25 °C	ECHA (2011) Domanska and Lachwa (2002)
Surface tension	52.9 mN/m at 25 °C and 0.1 vol. % 50.1 mN/m at 50 °C and 0.1 vol. % 50.8 mN/m at 25 °C and 1 vol. % 48.0 mN/m at 50 °C and 1 vol. % 48.3 mN/m at 25 °C and 10 vol. % 44.6 mN/m at 50 °C and 10 vol. %	García-Abuín et al. (2008)
pH value	7.7 – 8 Concentration: 10 % aqueous solution	Harreus (2005)
Viscosity	1.796 mPa s at 20 °C	Harreus (2005)
Refractive index	1.469 at 25 °C	Harreus (2005)
Flash point	91 °C (DIN 51758)	Harreus (2005)
Auto-Ignition Temperature	245 °C (DIN 51794)	Harreus (2005)

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[3] *The references of the values reported in Table 5 will be available in the technical dossier. In case references need to be included an additional column could be added manually to Table 5.*

2 HARMONISED CLASSIFICATION AND LABELLING

Pursuant to the first ATP to Regulation (EC) No 1272/2008 (Commission Regulation (EC) No 790/20095) as of 1 December 2010, 1-methyl-2-pyrrolidone is listed with index number 606-021-00-7 in Annex VI, part 3 of Regulation (EC) No 1272/2008 (list of harmonised classification and labelling of hazardous substances) with the following classification:

Table 6: Classification according to part 3 of Annex VI, Table 3.1 ((list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s	Hazard statement code(s)	Suppl. Hazard statement code(s)		
606-021-00-7	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	212-828-1	872-50-4	Repr. 1B Eye Irrit. 2 STOT SE 3 Skin Irrit. 2	H360D*** H319 H335 H315	GHS08 GHS07 Dgr	H360D*** H319 H335 H315		Repr. 1B; H360D: C ≥ 5 % STOT SE 3; H335: C ≥ 10 %	

Repr. 1B, H360D***[4]	May damage fertility or the unborn child.
Eye Irrit. 2 H319	Causes serious eye irritation.
Skin Irrit. 2 H315	Causes skin irritation.
STOT Single Exp. 3 H335	May cause respiratory irritation.

Table 7: Classification according to part 3 of Annex VI, Table 3.2 (list of harmonized classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
606-021-00-7	N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	212-828-1	872-50-4	Repr. Cat. 2; R61 Xi; R36/37/38	T R: 61-36/37/38 S: 53-45	Repr. Cat. 2; R61: C ≥ 5 % Xi; R36/37/38: C ≥ 10 %	

Repr. Cat. 2; R61	May cause harm to the unborn child.
Xi - R36/37/38	irritating to eyes, respiratory system and skin

---

[4] According to Annex VI (Part 1, entry 1.2.3): H360 and H361 indicate a general concern for effects on both fertility and development: 'May damage/Suspected fertility or the unborn child'. According to the criteria, the general hazard statement can be replaced by the hazard statement indicating only the property of concern, where either fertility or developmental effects are proven to be not relevant. In order not to lose information from the harmonised classifications for fertility and developmental effects under Directive 67/548/EEC, the classifications have been translated only for those effects classified under that Directive. These hazards statements are indicated by reference *** in Table 3.1.

3 ENVIRONMENTAL FATE PROPERTIES

Not relevant for the identification of the substance as SVHC in accordance with Article 57c.

4 HUMAN HEALTH HAZARD ASSESSMENT

Not relevant for the identification of the substance as SVHC in accordance with Article 57c.

5 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for the identification of the substance as SVHC in accordance with Article 57c.

6 CONCLUSIONS ON THE SVHC PROPERTIES

6.1 PBT, vPvB assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57c.

6.2 CMR assessment

Pursuant to Regulation (EC) No 1272/2008 as amended and adapted to technical and scientific progress by Regulation (EC) No 790/2009, as of 1 December 2010, N-methyl-2-pyrrolidone is listed as entry 606-021-00-7 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as toxic for reproduction category 1B[1]. Its corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised and classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is toxic for reproduction category 2[2].

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that the substance meets the criteria for classification as toxic for reproduction, in accordance with Article 57 (c) of REACH.

6.3 Substances of equivalent level of concern assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57c.

PART II

The underlying work for development of Part II of this Annex XV report was carried out under contract ECHA/2010/175 SR28 by Entec UK Limited[5], IOM Consulting[6] and BRE[7]

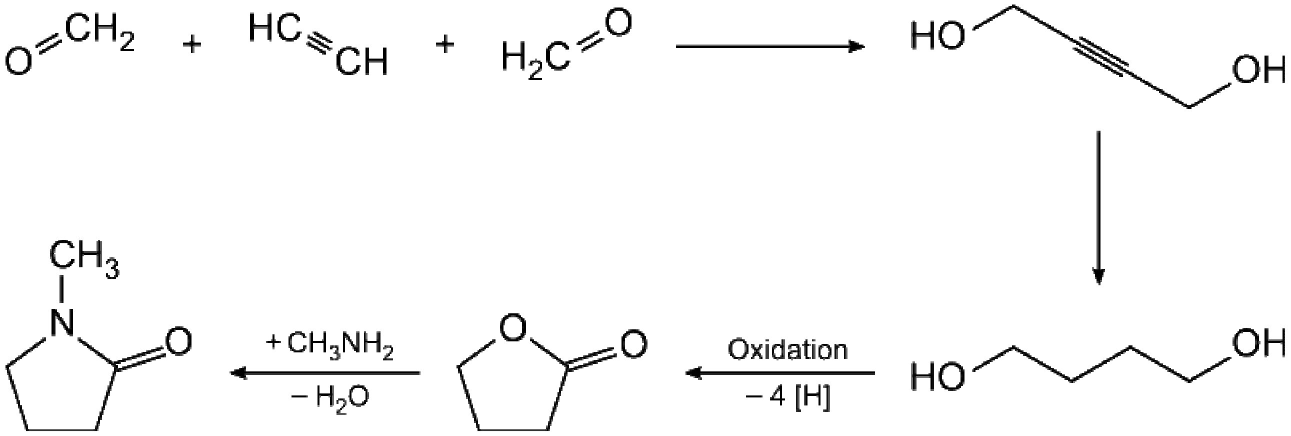
INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

1 MANUFACTURE, IMPORT AND EXPORT

1.1 Synthesis of NMP

According to Wikipedia (2011), the precursor for the synthesis of NMP is γ-Butyrolacton, which is manufactured in a catalytic process from formaldehyde and acetylene (see Figure 1). Adding methylamine, the γ-Butyrolacton is transformed into NMP.

Figure 1: Synthesis of NMP (Wikipedia 2011)



1.2 Manufacturing sites

In data collected for an OECD (2009) SIDS dossier, it was reported that there are three European manufacturing sites of NMP, with a further three in the USA and four in the Asia-Pacific region.

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[5] 17 Angel Gate, City Road, London, EC1V 2SH, United Kingdom

[6] Riccarton, Edinburgh, EH14 4AP, United Kingdom

[7] Bucknalls Lane, Garston, Watford, WD25 9XX, United Kingdom

Information available for the current analysis indicates that the number of manufacturers in Europe is currently understood to be ten or fewer.

Information on known manufacturing companies is included in the confidential annex.

1.3 Manufacture, import, export and use quantities

The European production volume of NMP in 2003 was reported to be 30,000 to 50,000 tonnes, out of a total global production of 100,000 to 150,000 tonnes. European production had reportedly reduced to 20,000 to 30,000 tonnes by 2005 (OECD, 2009).

Information was not received from all manufacturers/importers in terms of completed questionnaires. However, based on the information available in registration dossiers and from consultation:

- The total amount put on to the EU market seems to be between 10,000 tonnes and 50,000 tonnes.
- Of this, the quantity manufactured in the EU is estimated to around 50 %, accounted for by ten or fewer companies.
- The share accounted for by imports is also around 50 %, accounted for by between 10 and 20 companies.

Based on data from questionnaires, it appears that several hundred tonnes of the imports are in the form of mixtures. Further information regarding the NMP content of imported mixtures was not available from the received information. The list of importing companies is included in the confidential annex.

Information available from industry questionnaires indicates exports from the EU in the order of 1,000 to 2,000 tonnes (although it should be noted that this is a limited sample and is not considered to represent the EU as a whole). Furthermore, there are understood to be additional exports in the form of mixtures (e.g. paints).

Based on the information available, it appears that use in the EU could be between 10,000 and 50,000 tonnes per year, taking into account EU manufacture and imports/exports. This figure is deliberately approximate given that confidential information has been used in its derivation and given that the data used to develop the estimate is unlikely to be fully complete. The figure has been used in some of the later analysis, in which it should be recognised that there are inherent uncertainties.

1.4 Trends

Based on data reported in registration dossiers, there does not seem to be a significant trend in imports over the last 3-4 years, with some importers increasing quantities and others decreasing quantities imported. However, the majority importer only provided data for one year (described further in the confidential annex).

It is, however, worth noting that several companies have provided information for this analysis, indicating that they have ceased use of NMP in recent years, particularly due to regulatory concerns following its classification as a reproductive toxicant. Reductions in use are therefore also expected to lead to reductions in manufacture and import of the substance.

Furthermore, a major supplier of the substance expects use to reduce in the coming years and to be more limited to industrial and professional uses, following the classification of NMP as a category 1B reproductive toxicant in 2009.

1.5 Releases from manufacture

1.5.1 Operational conditions of use and existing risk management measures

Based on data provided by industry, the potential for inhalation or dermal exposure to arise in modern chemical plants is generally small. The production of NMP and associated bulk transfers and storage are all contained within closed systems. Bulk loading is undertaken outdoors and under containment. Transfer lines are cleared prior to decoupling. The filling of drums or smaller containers is undertaken at dedicated fill points with extract ventilation. Containment or extract ventilation is in place where sampling is undertaken. Any laboratory analysis of samples from the production process or during subsequent repacking is undertaken within a fume cupboard. Systems are drained down prior to equipment break-in or maintenance. None of the production processes or tasks during subsequent distribution of NMP involves any direct contact with NMP. Gloves are used where incidental dermal exposure is possible and suitable coveralls are used for tasks such as entering drained reaction vessels.

1.5.2 Releases of the substance

Both inhalation and dermal exposures associated with the production and distribution of NMP are predicted to be low. This reflects the high level of containment of modern chemical processes and the use of extract ventilation and gloves for tasks such as sampling or fluid transfer operations where exposure might arise.

Further information is provided in the confidential annex.

2 USES OF THE SUBSTANCE

2.1 Overview of uses

Data for use of NMP products was reported by the OECD (2007) based on data provided by the NMP producers group in 2005. This data is reproduced below.

Table 8: Uses according to NMP Producers reported in OECD (2007) at a global level

Industry	Application	% of total
Coatings	High temperature coating, urethane dispersions, acrylic and styrene latexes	20
Industrial and consumer cleaners	Paint removers, floor strippers, graffiti remover, industrial degreasing, injection head and cast-molding equipment cleaning	20
Agricultural chemicals	Solvent for herbicide, pesticide and fungicide formulations	15
Electronics	Cleaning, de-fluxing, edge bead removal, photoresist stripping	20
Petrochemical processing	Lube oil processing, natural and synthetic gas purification	10
Pharmaceuticals	Solvent	15

Initial information available from one of the major suppliers to the EU market suggests a profile of use that is reasonably similar to this (see the confidential annex).

However, companies representing the majority of supply to the EU market have not been able to provide information on the quantities / proportions in which NMP is used because such information is considered to be confidential.

Therefore, a rough estimate of the quantity used in each application has been derived assuming that total current use of the substance is around 10,000 to 50,000 tonnes and that the split of uses is the same as that at a global level in 2005. The corresponding quantities are therefore as shown in the table below.

Table 9: Approximate split of uses assumed for the analysis

Industry	Application	Use (000t)
Coatings	High temperature coating, urethane dispersions, acrylic and styrene latexes	2,000-10,000
Industrial and consumer cleaners	Paint removers, floor strippers, graffiti remover, industrial degreasing, injection head and cast-molding equipment cleaning	2,000-10,000
Agricultural chemicals	Solvent for herbicide, pesticide and fungicide formulations	1,500-7,500
Electronics	Cleaning, de-fluxing, edge bead removal, photoresist stripping	2,000-10,000
Petrochemical processing	Lube oil processing, natural and synthetic gas purification	1000-5,000
Pharmaceuticals	Solvent	1,500-7,500

The following descriptions of uses have been used for the present analysis:

- Coatings (paints, printing inks);

- Cleaning products (polymer removers, paint strippers/cleaners);
- Agrochemicals;
- Electronic equipment manufacture;
- Petrochemical processing;
- Pharmaceuticals;
- Other uses.

The substance is clearly used in a wide variety of applications and it would be possible to apply various other groupings and categorisations to the uses of the substances. Whilst this is recognised, the above relatively coarse categorisation is used in order to be able to present the information in a manageable format.

2.2 Use #1 – Coatings

2.2.1 Functions of the substance

NMP is used as a solvent in a wide range of different coating products. It is reported (BASF, 2010) to be non-corrosive, of high boiling point with excellent solvent power and chemical resistance. Its effects are favourable for baked coatings that are cured at relatively high temperatures.

NMP is a dipolar aprotic solvent, a class which has specific physicochemical properties that make them miscible both in water and solvents. It appears therefore to be used extensively in waterborne paints (as a co-solvent/coalescing solvent) as well as in solvent-borne coatings and in printing inks.

The ranges of final products to which the coatings are applied appear to be hugely diverse, including for example:

- Decorative and protective waterborne paints;
- Metal coatings;
- Concrete coatings;
- Wood coatings and wood care products;
- Automotive paints;
- Parquet lacquers;
- Artists colours;
- Screen printing inks;
- Inkjet inks (industrial and general public);
- Pen inks;
- Non-stick bakeware/cookware.

Use as a cleaning product is considered separately; although there is some overlap in information provided through consultation (e.g. companies provided information on the use of their products in paints and as thinners/cleaners which are frequently sold to complement use of those paints).

2.2.2 Applications

2.2.2.1 Sectors of use

Based on the information provided for the current analysis, NMP is used in a wide range of different end use sectors, encompassing industrial, professional and consumer uses. Information on the range of different uses is included in the table below. This information may (if appropriate) be consolidated into groups/categories for the purposes of estimating releases/exposure.

Table 10: Information from consultation on uses in coatings

Use	**Quantity**	**Customers**
Examples only used industrially		
Production of enameled wire	715-1,305t	100 % industrial
Wire enameling	100-1,500t	100 % industrial
Coalescing solvent in waterborne paints	c. 500t	100 % industrial
Thinner to aid coating spray application	320t	100 % industrial
Specialist coatings	>200t	100 % industrial
Solvent-based high temperature coatings (solvent and water-based and diluent/cleaner)	140-190t	100 % industrial
Solvent for paint resins	100t	100 % industrial
Manufacturing equipment maintenance	8-25t	
Co-solvent (at c. 5 %) in screen printing inks and thinner	5t	100 % industrial
Automotive waterborne paint	15t	100 % industrial
Coalescing solvent in automotive paints	1.25t	100 % industrial
Additive for coating esp. technical textiles (solvent for thixotropic agent)	1t	100 % industrial
Component in screen inks	0.8t	100 % industrial
Waterborne paint for steel/automotive components	0.3-0.5t	100 % industrial
Wood impregnation product (co-solvent for fungicide)	0.15t	100 % industrial
Use in industrial continuous inkjet mixtures (ink)	<1t	100 % industrial
Metal coating for hot environments (prevent corrosion/chemical attack)		100 % industrial
Examples which also include professional use		
Waterborne paints (automotive and other industrial)	100t per year	100 % industrial / professional
Coatings	0.2t	100 % professional
Printing ink (NMP used at c. 5 % to fuse pigment on PVC film)	0.02-0.2t	100 % professional
Formulation of industrial flooring products	0.001t	100 % professional

Use	**Quantity**	**Customers**
Examples which also include public use		
Waterborne floor finishes	2-4t	95 % professionals, 5 % public
Paint, diluent, remover	2-2.5t	95 % professional, 5 % public
Industrial paints	<2t	95 % professional, 5 % public
Waterborne parquet varnish	1.3t	100 % public
Binder in waterborne PU wood paint	<1t	90 % professional, 10 % public
Binder in waterborne PU topcoat	<1t	70 % professional, 30 % public
Epoxy paints	<1t	90 % professional, 10 % public
Universal pigment preparations	<1t	50 % professional, 50 % public
Artists colours (acrylics)	0.7t	100 % professional/amateur artists
Parquet lacquer	0.53t	30 % professional, 70 % public
Sealer wood varnish	0.04t	7 % industrial, rest professional and public
PC9a: paints for metal, concrete, waterborne wall paints, trimpaints and translucent woodcare paints.	Small amounts	50 % professional painters (trade), 50 % public (retail)
Subtotal (approximate)	**2,220-4,280t**	

A key finding from the information above is that there are several examples where coatings containing NMP are used by the general public. The majority of the REACH registrations for NMP only consider industrial and professional use of coatings. It is understood that the labeling requirements related to classification as a category 1B reproductive toxicant would not apply when the concentration of NMP is below 5 %. Some of the coating products are expected to include NMP at concentrations below 5 % so it is considered feasible that use may continue in those applications.

2.2.2.2 Use in preparations/mixtures

In relation to the use in coatings, NMP is formulated into coating products by coating manufacturers. These mixtures are then used industrially, professionally and by the general public.

It is clear that the concentration of NMP in these products varies significantly. Information from the Latvian Chemicals Database, along with data from companies providing information for this analysis suggests that concentrations of NMP in paints are typically in the range of 1-10 %.

2.2.2.3 Processes involved

The key processes involved include coatings manufacture and coatings application.

A range of information has been provided on the processes involved in coatings manufacture and the range of coating applications by companies involved in the industry.

Coating manufacture will typically involve stages such as bulk transfer of NMP (e.g. from IBCs or drums, though sometimes in closed pipelines); mixing, which may be in open systems; and filling of paint into drums/cans.

Coatings containing NMP have been reported as being applied by the following methods:

- Brushing;
- Rolling;
- Spraying;
- Inkjet printing machines (for e.g. road signs);
- Cleaning of equipment;
- Coil coating;
- Dip coating;
- Industrial roller coating;
- Curtain coating;
- High temperature curing (e.g. up to 425ºC).

In industrial situations, local exhaust ventilation, respiratory protection and protective clothing are reportedly used. In some cases (e.g. industrial inkjet printing) application is typically done in enclosed processes.

2.2.2.4 Use in articles

NMP is not assumed to be present in articles as it is used as a solvent in coatings. The NMP thus evaporates following application.

2.2.3 Quantities involved

Based on the data in Table 10, information provided by organisations that directly responded to the consultation for this analysis represent use of around 2,200 to 4,300 tonnes of NMP per year. However, the total amount may be greater than this. Assuming total EU use of NMP of 10,000 to 50,000 tonnes and a share for use in coatings of 20 % (based on global figures from several years ago in Table 8), the total use in coatings could be up to around 2,000 to 10,000 tonnes. The percentages of use in coatings from other sources (e.g. Member States' registers reported in Annex 3) indicate fairly similar shares of use for coatings.

It can be expected that there will be some move away from NMP in future, particularly given that:

- The registrations for the substance (mostly) do not include use by the general public suggesting that some of these uses may be replaced;

- Several companies providing information for the analysis have indicated that they have replaced NMP in recent years, particularly because of the reclassification as a category 1B reproductive toxicant;

- The trade association CEPE has an exclusion list for chemicals used in printing inks, indicating that substances classified as category 1A or 1B reproductive toxicants (amongst others) are excluded as raw materials for the manufacture of printing inks and related products supplied to printers.

2.2.4 Description of supply chain

The supply chain for coatings is highly complex, with a very large number of companies involved. It has not been possible to estimate the proportion of the total coatings industry that uses NMP but as an indication of the key phases in the supply chains concerned, the table below provides indicative information on possible numbers of companies within key stages. The responses reported by individual consultees are provided for information purposes and conclusions are drawn on the likely possible numbers in total, based on those individual responses (noting that there may well be some overlap if companies in the supply chain purchase different NMP-containing coatings from more than one supplier).

Table 11: Indicative information on potential numbers of companies involved in supply chains for coatings

Supply chain stage	**Number of companies (ranges reported by individual consultees)**	**Possible numbers of companies in total**
Formulation of mixtures used in coatings manufacture	Unknown	
Coatings manufacture	c. 30 companies responded	100-1000
Distributors of coatings	Unknown	
Users of coatings (example groups)		
- Waterborne paints (including e.g. professional/public use)	>>100,000 <10,000 10-100	>100,000 (incl. professionals)
- Wire enamelling	11-100 30-55	100-1000
- Wood coatings	<1000 101-1000	100-1000
- Industrial paint application	20-60 10-40 11-100 3 45-50 <100 48 200-300 >800	>1,000
- Automotive parts	10-100 15-20 10-15	100-1000
- Industrial printers	1 >100 20-30 500	100-1000

The companies involved are understood to be distributed across the EU. No information on geographical concentration in particular Member States is available.

2.3 Use #2 – Cleaning products

2.3.1 Functions of the substance

NMP is a powerful solvent and has a high solvating power for plastics, resins, oil and grease. According to BASF (2010), NMP has been used as an ingredient in paint removers, cleaners and degreasers. It can reportedly be used alone or in blends for removal of oil, carbon deposits and other tarry polymeric residues from metal chambers, pistons and cylinders, as well as for wet cleaning of combustion engines.

2.3.2 Applications

2.3.2.1 Sectors of use

Information on the range of different uses reported by companies that provided input to this analysis is presented in the table below.

Table 12: Information from consultation on uses in cleaning products

Use	**Quantity**	**Customers**
Cleaning solvent	1t	No data
Mixtures for removal of coatings/paint/graffiti by painters or DIY (including use in aerosol cans)	12t (2009) 0t (2010)	30 % industrial, 70 % DIY
Paint remover	27.8t	No data
Cleaning of mixing tanks (dissolving residual coating)	30-50t	100 % industrial
Cleaning agents	1-5t	100 % industrial/professional
Subtotal (approximate)	**60-95t**	

Based on the information on the quantities historically used globally in cleaning products (20 % according to OECD, 2007) and an assumed total use of 10,000 to 50,000 tonnes, the total amount used in cleaning products in the EU could be around 2,000 to 10,000 tonnes, meaning that the volumes reported through companies consulted could be a relatively small share of the total market. However, it appears that use may have decreased in this application in recent years, as described below. Furthermore, other sources of information suggest that the share of the market accounted for by cleaning products could be less than 20 %.

For example, it is understood that NMP use is considered limited for members of AISE (International Association for Soaps, Detergents and Maintenance Products), except possibly for some industrial applications.

Material safety data sheets for the substance indicate use in a range of paint removing products such as:

- Polymer remover containing 30-60 % NMP. This product was primarily used to remove polymer deposits from moulding tools. The company has now replaced NMP in these products due to concerns with the reclassification of the substance.
- Anti-graffiti cleanser containing 5-15 % NMP.
- Stain protecting products containing 1-5 % NMP (used by the general public). Again this product has been reformulated to remove NMP due to labelling concerns.
- Graffiti removing towels containing 10-25 % NMP.

It is of note that several of these products could have been available to the general public and that several of the MSDS only mentioned the classification of NMP as R36/38, not the more recent classification as a reproductive toxicant. Based on the relatively limited information available from consultation, it does appear that the classification has had an effect on the extent to which companies have continued to use NMP in cleaning products, particularly those that may be available to the public.

Additionally, data in Annex 2 from the Norwegian register of products and the Latvian chemicals database also indicate a reduction in the quantities used in cleaning products between 2008 and 2009 (the classification as a category 1B reproductive toxicant was introduced in 2009).

Data from 2003/2004 in the UK indicates that NMP was used on at least four sites as a paint stripper for graffiti removal and seven sites as a solvent in degreasing tanks specifically in the aerospace industry.

NMP is reportedly used as a substitute for methylene chloride in paint strippers (BMAS, 2006).

2.3.2.2 Use in preparations/mixtures

It appears that NMP can be used in a wide range of concentrations in cleaning products. It seems to be frequently mixed with other substances in commercially available products though it is understood that it may also be used neat.

2.3.2.3 Processes involved

It is understood (from submitted registration dossiers) that the cleaning processes that use NMP can be diverse and may include, for example:

- roller application;
- brushing;
- treatment by dipping/pouring;
- spraying;
- wiping.

Application may be automated or by hand.

2.3.2.4 Use in articles

It is assumed that there is no use of NMP in articles related to its use in cleaning products. NMP is a solvent and is expected to evaporate from the products that it is used to clean.

2.3.3 Quantities involved

As indicated above, the quantity used in cleaning products could potentially be around 2,000 - 10,000 t per year. However, the data available suggest that this could be an overestimate, particularly for current levels of use, taking into account changes since the introduction of the category 1B reproductive toxicant classification.

2.3.4 Description of supply chain

It is understood that the supply chain includes the following key types of organisations:

- Companies producing cleaning product mixtures containing NMP (10s);
- Distributors of cleaning products and companies filling dispensing products (e.g. aerosol cans) (10s);
- Companies undertaking industrial application of cleaning products (100s);
- Professionals applying cleaning products (potentially 1,000s);
- Consumers (potentially 100,000s).

There is relatively little information available through consultation with industry on numbers and spatial distribution of actors in the supply chain. The above indications are very broad and based on a limited sample.

2.4 Use #3 - Agrochemicals

2.4.1 Functions of the substance

NMP is reportedly used as a solvent or co-solvent in various agrochemicals. It is used because it is highly polar (BASF, 2010).

2.4.2 Applications

2.4.2.1 Sectors of use

It is understood that NMP is used for the formulation of insecticides, fungicides, herbicides, seed treatment products and bio regulators (BASF, 2010).

No companies have specifically provided information on use in agrochemicals during data collection for this report.

Based on the OECD (2007) SIAR, it is understood that the concentration of NMP in herbicides, fungicides and pesticides is < 7 %.

2.4.2.2 Use in preparations/mixtures

NMP appears to be used in mixtures within agrochemical products. No further information is available.

2.4.2.3 Processes involved

The processes involved are covered in the companies' registration dossiers and include spraying, (trans)-pouring from containers, mixing, equipment clean-downs and disposal.

These have not been investigated in any detail for the purposes of the current assessment.

2.4.2.4 Use in articles

It is assumed that there is no use of NMP in any articles because of the use of the substance in plant protection products. However, this has not been investigated in any detail.

2.4.3 Quantities involved

No comprehensive information is available on quantities of NMP currently used in the EU in agrochemicals. However, based on the global-level percentage split of uses from several years ago (15 %) and the assumed quantity used in the EU (10,000 - 50,000 t), it can be estimated that perhaps 1,500 to 7,500 tonnes of NMP are used in this application each year. Based on the information provided by one major supplier of the substance the total percentage share could be higher than 15 % although it has not been possible to confirm this given the lack of comprehensive data available from industry (see above).

Based on the information in Annex 3, in Sweden, 39 tonnes of NMP were imported in pesticides in 2008 (around 13 % of the total NMP imported in chemical products).

In Norway, 0.41 t of NMP was declared in biocides in 2008 (0.6 % of the total 74 t declared in chemical products). In 2009, the amount was 0.87 t (3.1 % of 28 t). 22.5 t of NMP was declared in plant protection products in 2008 (30 % of the total 74 t) with none declared in 2009.

2.4.4 Description of supply chain

No information is available on the supply chain for this use.

2.5 Use #4 – Electronic equipment manufacture

2.5.1 Functions of the substance

NMP is used as a solvent for the electronics industry and producers of printed circuit boards. Blends of the substance with common solvents are reportedly used for the cleaning and degreasing of single-crystal silicon wafers for integrated circuits (BASF, 2010).

This use is considered separately from the other solvent uses mentioned previously as the conditions of use are considered to be substantially different.

2.5.2 Applications

2.5.2.1 Sectors of use

NMP is reportedly an important solvent for polyimides. The main applications for NMP use are as:

- A photoresist carrier solvent (solvent base for polymer mixtures) used at around 10-100 t per location/company.
- A photoresist stripper (cleaning/stripping to remove resist from wafers and photo masks during semiconductor manufacturing) used at around 10-100 t per location/company.
- In failure analysis (cleaning/stripping) used at < 5 t per location/company.

It is understood that a historical use was as a surface cleaner in clean rooms (tabletop and mat cleaner and electrostatic charge neutralizing agent).

NMP is understood to be used 100 % in industrial applications.

2.5.2.2 Use in preparations/mixtures

The substance is used as a processing aid in pure form or in mixture with other substances (photoresist, BARC and TARC[8]) (ECHA, 2010b).

2.5.2.3 Processes involved

It is understood that the process involves production of semiconductor devices in batch processes in dedicated equipment (litho track tools) in a photolithography process.

Equipment is operated automatically and can be totally or partially enclosed. “Clean room environment” conditions are understood to apply.

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[8] Bottom-side and top-side anti-reflective coatings.

The following main processes are understood to be undertaken:

- loading/unloading of wafers to/from automatic enclosed equipment;
- loading/unloading of wafers into partially enclosed equipment;
- maintenance and cleaning of equipment;
- handling and connection of containers;
- sampling.

In semiconductor process, it is understood that about 90-95 % of the solvent used is collected for offsite incineration, 5-10 % evaporates and <0.5 % is discharged to waste water[9] (ECHA 2010b).

2.5.2.4 Use in articles

It is understood that NMP is not incorporated into the final articles produced.

2.5.3 Quantities involved

Information from ESIA suggests that use in the EU is up to around 270 tonnes per year.

However, it is possible that use in this application could be much higher. For example, at a global level 20 % of NMP use was historically in electronics (OECD, 2007) and, if applied to the 10,000 - 50,000 t potentially used in the EU, the total use in this application might be up to around 2,000 - 10,000 t per year.

No information is currently available on trends in this use. However, whilst not currently using NMP in the EU, one company provided an indication that they expect to start selling NMP-based products for use in manufacture of photovoltaic cells within the near future (potentially several hundred tonnes).

2.5.4 Description of supply chain

Information from ESIA suggests that use of NMP (or mixtures containing NMP) is undertaken in Austria, France, Italy, Ireland, Netherlands, Germany and the UK.

No information is available on the number of companies involved. However, based on the quantities used per company/site, it is assumed that the number of companies is in the order of 10s rather than 100s or 1,000s.

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[9] This is based on semiconductor exposure scenario Substance C, section 9.1 and contributing scenarios at http://guidance.echa.europa.eu/docs/other_docs/es_project_document_v5.pdf

2.6 Use #5 – Petrochemical processing

2.6.1 Functions of the substance

It is understood that NMP is used in the large-scale recovery of hydrocarbons by extractive distillation. Hydrocarbons are highly soluble in NMP and differences in volatility are sometimes considerably increased in the presence of NMP (BASF, 2010).

NMP is used particularly because, unlike other commercial solvents and extraction media, its use does not lead to the formation of azeotropes[10] and because NMP has high resistance to heat and chemicals.

Relatively little information has been made available on this use. It is also considered to be a relatively lower priority for investigation because use takes place in industrial facilities rather than by professionals or consumers.

2.6.2 Applications

2.6.2.1 Sectors of use

The main sectors of use in relation to this application are in:

- manufacture of bulk, large scale chemicals (including petroleum products) (SU8);
- manufacture of fine chemicals (SU9).

It is understood that this use relates entirely to use of the substance at industrial sites.

2.6.2.2 Use in preparations/mixtures

It is understood that NMP may be used in mixtures in this application, although no detailed information is available.

2.6.2.3 Processes involved

It is understood that the processes involved will include recycling/recovery, material transfers, storage, maintenance, loading, sampling and associated laboratory activities.

2.6.2.4 Use in articles

No information is available to suggest that NMP is present in articles related to its use in petrochemical processing.

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[10] Which would reduce/remove the potential for distillation of hydrocarbon components.

2.6.3 Quantities involved

Based on data from OECD (2007), historical use in this application was estimated as 10 % of global use. If the same is true for current use in the EU, the total use in this application could be around 1,000 -5,000 t/y. Based on information provided by one major supplier of the substance, this estimate seems to be broadly accurate.

There is no information thus far to indicate whether use in this application is expected to change substantially in the future. However, in the absence of other drivers, it is assumed that the use would remain relatively stable because this is an industrial use which is less likely to be affected by the labelling of NMP as a reproductive toxin.

2.6.4 Description of supply chain

The supply chain is understood to include chemical manufacturers. It is understood that manufacturers of NMP may also use the substance themselves in petrochemical processing.

2.7 Use #6 - Pharmaceuticals

2.7.1 Functions of the substance

According to the OECD (2009) SIDS dossier, NMP is used as a penetration enhancer for a more rapid transfer of substances through the skin. Use as a solvent and extraction medium is reported by industry (Taminco, 2010).

There is limited information that suggests NMP could be used as a solvent during the preparation of pharmaceuticals as well as being present in some pharmaceutical products (Jouyban et al, 2010). These authors state that NMP is one of the main pharmaceutical co-solvents and that it is an important solvent used in the extraction, purification and crystallisation of drugs. It is not known whether NMP is used in this way within the EU.

2.7.2 Applications

2.7.2.1 Sectors of use

The relevant sectors are presumably pharmaceutical manufacturers, distributors, retailers and the general public. However, no specific information was available on this use.

2.7.2.2 Use in preparations/mixtures

The use as a penetration-enhancer and solvent (where present in the final product) is presumed to include use in mixtures.

No detailed information has been made available on use in pharmaceuticals during data collection for this report.

2.7.2.3 Processes involved

No information was available on the processes involved.

2.7.2.4 Use in articles

In theory, there could be some articles in which NMP may be present through its use in pharmaceuticals (e.g. for delivery of the pharmaceuticals). However, no specific information is available on this.

2.7.3 Quantities involved

No comprehensive information is available on quantities of NMP currently used in the EU in pharmaceuticals. However, based on the global-level percentage split of uses from several years ago (15 %) and the assumed quantity used in the EU (10,000 -50,000 t/y), it can be estimated that perhaps 1,500 to 7,500 tonnes of NMP are used in this application each year. Based on the information provided by one major supplier of the substance the total percentage share could be lower than 15 % although it has not been possible to confirm this given the lack of data available.

2.7.4 Description of supply chain

No information is available on the supply chain for this use.

2.8 Other uses

2.8.1 Functional fluids

Based on information from the registration dossiers, industrial and professional use of NMP takes place as a functional fluid, for example in cable oils, transfer oils, coolants, insulators, refrigerants, hydraulic fluids in industrial equipment including maintenance and related material transfers.

No specific information on this use has been received from industry through consultation and the quantities used in this application are unknown. .

2.8.2 Use in laboratories

The registration dossiers for the substance include its use in laboratories. This use has not been investigated further and no specific information has been received from industry on this use.

It is noted that use in scientific research and development is exempt from authorisation according to Article 56(3) of the REACH Regulation.

3 RELEASES FROM USES

3.1 Introduction

This section includes information on releases from uses, including occupational, consumer and environmental releases and exposure. These three routes are considered in turn.

Obviously a significant level of effort has already been made by industry in estimating releases within the chemical safety assessments submitted as part of registration dossiers for the substance. It was not considered feasible or desirable to try to reproduce the work undertaken by industry in their CSAs within the scope of the current project. Taking this into account, the following approach was adopted for undertaking the estimates of releases from exposure:

- A review of information from the registration dossiers.
- Review of additional information beyond the information submitted by the registrants, including:
    - information from consultees other than registrants provided in questionnaire responses and other submitted information (which covered some uses other than those in the registration dossiers such as use of NMP-containing coatings by the general public);
    - information from consultees regarding process descriptions and the application of risk management measures for the purpose of cross-checking the assumptions used in the CSRs and making alternative assessments if necessary.
- In summary, this involved a review of the information in the CSRs against the information provided through consultation and reported in the literature to cross-check and identify any additional exposures and/or discrepancies rather than a full assessment of releases such as would be undertaken for a risk assessment.

3.2 Information sources used in the estimation of releases from uses

The estimates of releases from uses will take into account the following sources of information that have been identified:

- Questionnaire responses. Manufacturers and users of the substance have provided a wide range of estimates of exposure to the substance and also on risk management measures and process descriptions. These are not reproduced in the report thus far but can be provided to ECHA if desired.
- These include estimates of releases from uses in the following categories, as reported in the registration dossiers:
    - *Manufacture of NMP*
    - *Distribution of NMP*
    - *Formulation and (re)packing of substances and mixtures*
    - *Use of NMP in coatings (industrial and professional)*

  - *Use of NMP in cleaning agents (industrial and professional)*
  - *Use of NMP in functional fluids (industrial and professional)*
  - *Use of NMP in laboratories (industrial)*
  - *Use of NMP in agrochemicals (professional)*
  - *Use of NMP in road and construction applications (professional)*
  - *One CSR also covers use in inks by consumers.*

- The 2001 CICAD includes some information on historical use in Section 6.
- Data provided by the Austrian MSCA on exposure, including measurements from the Austrian Central Labour Inspection on the control of OELs, which have not been exceeded and also measurements during a VOC inspection study in 2007 for paints by the Austrian Environment Agency.
- Information from the Netherlands MSCA, based on a review of relevant literature.
- Other references from the open literature.

3.3 Existing legislative requirements

Under Directive 2009/161/EU[11], an occupational exposure limit was introduced for NMP. This includes an 8h-TWA limit of 40 mg/m^3 and a 15 minute STEL of 80 mg/m^3 (with uptake via the skin noted as being possibly significant).

NMP was classified as toxic for reproduction category 1B in 2009. Under point 30 of Annex XVII of the REACH Regulation, such substances cannot be used in substances and preparations placed on the market for sale to the general public in concentration equal to or greater than the relevant concentrations specified in Annex I to Directive 67/548/EEC or Directive 1999/45/EC. The substance and mixtures must also be marked as ‘restricted to professional users’.

The introduction of the OEL and the classification of NMP as toxic for reproduction category 1B at the start of 2009 are expected to have had an effect on reducing exposure compared to historical levels.

3.4 Occupational releases and exposure

3.4.1 Introductory note

The EU Indicative OEL values (IOELVs) for NMP are 10 ppm (40 mgm^{-3}) as an 8 hour average and 20 ppm (80 mgm^{-3}) as a 15 minute average (Commission Directive 2009/161/EU).

In the following text, exposures are ranked according to the following scheme in relation to the EU OEL of 10 ppm (8h TWA) which gives an intake over a typical 8 hour shift of about 100 mg (=3.43

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[11] Directive 2009/161/EU of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC.

mg/kg/day) based on an assumed inhalation volume of 10 m^3 over a typical 8 hour shift (see the table below).

Table 13: Ranking of inhalation and dermal exposures relative to the OEL

Ranking	**Inhalation concentration ppm**	**Dermal exposure mg/kg/day**
Very high	>10	>3.5
High	7-10	2.5-3.5
Moderate	3-7	1-2.5
Low	1-3	0.3-1
Very low	<1	<0.3

3.4.2 Coatings

3.4.2.1 Operational conditions of use and existing risk management measures

NMP is used in a very wide range of different types of coatings (paints, inks, adhesives etc) applied by a variety of different methods. Coatings may be formulated or applied at ambient or elevated temperatures. NMP is used in coatings because it is relatively volatile and can be used as a carrier that subsequently evaporates. This gives rise to the potential for exposure to NMP in air. In addition, some applications involve manual operations with a high potential for direct contact with NMP to occur (e.g. as drips and splashes). Exposure may arise during the:

- Formulation of coatings;
- Industrial use of NMP in coatings;
- Professional use of NMP in coatings; and
- Use of NMP in construction and roads.

Given the diversity of coating applications that employ NMP it is likely that current standards of industrial hygiene are variable, particularly in smaller businesses. In the guidance on safe use provided in the registration dossier, a range of RMMs is specified to minimise operator exposure. It is anticipated that a relatively high level of exposure control may be achieved in some industrial applications where it is possible to establish permanent engineering controls such as dedicated booths and local exhaust ventilation. It may be more difficult to control exposure for some professional users such as painters and in parts of the construction industry where it is not possible to provide forced ventilation and where it may be necessary to work in relatively confined spaces. Compliance with recommended RMMs such as the use of RPE may be poorer where people are working alone or in small numbers with little or no supervision as may occur during the professional use of products containing NMP.

Formulation and (re)packing of coatings containing NMP

The formulation and packing of coatings (preparations/mixtures) containing NMP includes a wide range of processes undertaken on a variety of scales. Tasks include liquid transfer operations – to and from bulk storage/IBCs/drums/smaller containers, mixing in batch or continuous operations, sampling and analysis, storage and cleaning and maintenance operations. Processes may be performed at temperatures close to ambient or much higher.

The current deployment of RMMs is unknown but it is anticipated that relatively high levels of containment would be in place and extract ventilation employed in many workplaces and that laboratory work would typically be undertaken in a fume cupboard. There should be no requirement for direct dermal contact with fluids containing NMP, fluid transfer operations should be enclosed and extract ventilation in place where there is the potential for NMP to be released. Information from a small number of companies involved in the formulation of different types of coating product including paints and parquet lacquer indicates that the RMMs outlined in the guidance on safe use are in place. For example, liquids are piped between drums and tanks, and LEV and/or general room ventilation is employed. One company indicated that pumps are used for loading of fluids, dissolvers are used for mixing, LEV and RPE are employed and protective clothing is used.

Industrial use of NMP in coatings

The industrial application of coatings containing NMP includes a wide range of processes undertaken on a variety of scales. Tasks include liquid transfer operations – to and from bulk storage/IBCs/drums/smaller containers, mixing in batch or continuous operations, preparation for application, application by spraying, brushing, roller, directly by hand (finger paint), dipping/immersion, film formation or within a fluidised bed system, sampling and analysis, storage and cleaning and maintenance operations. Processes may be performed at temperatures close to ambient or much higher.

The current deployment of RMMs is unknown but it is anticipated that extract ventilation would be employed in many workplace at the locations where coating is undertaken, processes such as spraying would be typically undertaken within a dedicated booth and that laboratory work would typically be undertaken in a fume cupboard. Good general ventilation is a minimum requirement for the use of coatings containing NMP where operations are performed indoors. Protective clothing, gloves and RPE are employed in some workplaces. Other RMMs include limits on the NMP content of coatings and on the time spent on specific tasks such as manual application and avoidance of handling of wet pieces.

Use of NMP in coatings (professional use)

The professional application of coatings containing NMP includes tasks such as liquid transfer operations – to and from IBCs/drums/smaller containers, mixing in containers and preparation prior to application, application by spraying, brushing, roller, directly by hand (finger paint), dipping/immersion and pouring, sampling and analysis, storage and cleaning and maintenance operations. Coatings may be applied at temperatures close to ambient or at much higher temperatures.

Typically the professional use of coatings such as paints will occur at a variety of locations such that total containment and/or dedicated extract ventilation would be extremely difficult to achieve. The quantities of NMP used are likely to be smaller than in many industrial environments. The current deployment of RMMs is unknown but it is anticipated that standards of ventilation are likely to be variable. Similarly compliance with recommended PPE – coveralls, gloves and respirators – is likely to be variable, with potentially low levels of compliance where work is undertaken by individuals or small numbers of workers working in isolation with limited supervision. Ideally coatings should be applied outside or, if applied indoors, a good standard of general ventilation is should be used. In the absence of extract ventilation, it would be desirable to use a respirator (Type A filter or better) while working with coatings containing NMP. Gloves should be used to limit dermal exposure. For tasks such as spraying, dipping, immersion or pouring and hand application of coatings where extensive dermal and inhalation exposure are possible, it is desirable to limit the NMP content of coatings and the length of time dedicated to these tasks on an individual shift.

Use of NMP in coatings in road and construction applications

NMP is used in surface coatings and binders in road and construction activities including paving, manual mastic and in the application of roofing and water-proofing membranes. Tasks are performed outside and include drum/batch transfers, rolling, brushing, machine application of bitumen cutbacks, machine application by spraying/fogging, dipping, pouring and equipment cleaning. RPE (Type A filter or better) is recommended where transfers are carried out at temperatures ≥20°C above ambient temperatures, rolling, brushing and for machine application by spraying/fogging. Other measures that can reduce exposures include the use of long handled tools, automation of the application of bitumen cutbacks and operator training to stay upwind/keep distance from source. In addition, the time spent on individual tasks such as spraying that may give rise to elevated exposures should be limited. Equipment must be drained prior to cleaning and maintenance and NMP stored in sealed containers. Suitable gloves should be worn where dermal contact is possible.

3.4.2.2 Releases of the substance

Formulation and (re)packing of preparations and mixtures containing NMP

There are limited published data for exposure to NMP during its use in the manufacture of glue and adhesives (Bader et al, 2005). The highest level of exposure was associated with cleaning vessels with a shift mean exposure of 15.5 mgm^{-3} (approximately 4 ppm; Table 14). This task was performed manually in the absence of LEV. Biological monitoring indicated a higher than expected systemic exposure to NMP for this individual that was attributed to poor compliance with RMMs intended to limit dermal exposure. Much lower levels of exposure would be anticipated if LEV was in place and appropriate protective clothing and gloves were used.

Table 14: Inhalation exposure concentrations associated with manufacture of glue / adhesives

Workplace	**Job description**	**NMP in air TWA (mg/m^3)**	**NMP in air peak exposure (mg/m^3)**
Bottling/shipping	Maintenance, foreman	1.0	-
Bottling/shipping	Maintenance	2.8	-
Bottling/shipping	Bottling/shipping	0.9	-
Bottling/shipping	Maintenance, cleaning	2.3	5.9 (42 min)
Production	Mixing, stirrer cleaning	3.4	-
Production	Mixing, stirrer cleaning	6.6	18.7 (19 min)
Production	Vessel cleaning only	15.5	18.0 (42 min), max 85 (5 min)
Both areas, 4 h	Study examiner	-	-
Both areas, 6 h	Study examiner	-	-
Both areas, 8 h	Study examiner	2.8	-

Source: Bader et al (2005)

More recent unpublished measurement data provided by respondents to the questionnaire and exposure estimates in the registrations indicate that both dermal and inhalation exposures associated with the formulation of coatings containing NMP would be expected to be low to moderate for most tasks, provided that appropriate RMMs are employed, although some tasks are associated with moderate exposures. A relatively high level of dermal exposure has been predicted, however, for cleaning and maintenance operations associated with the formulation of coatings at high temperatures (i.e. more than 20^o C greater than ambient). Predicted inhalation concentrations for other tasks associated with the formulation of coatings at high temperatures are higher than for low temperature formulation, although still low in relation to the OEL. Overall it seems likely that inhalation exposures are currently controlled to well below the OEL.

Use of NMP in coatings in industrial settings

Limited recent measurement data provided by respondents to the questionnaire suggest that current inhalation exposures are low to moderate relative to the OEL. Inhalation exposure concentrations predicted in the registrations indicate that exposures associated with high temperature coating processes (>20^{o}C above ambient) are likely to be associated with higher levels of exposure than low temperature processes. Predicted concentrations for all tasks, however, whether preformed at low or high temperature, are low to moderate relative to the OEL.

There are no measured dermal exposure data or information about the actual deployment of RMMs. Some types of coating operation, particularly manual operations such as application by spraying, rollers or brushes, could lead to significant dermal exposure in the absence of appropriate PPE, particularly if undertaken for the entirety of shift. Provided that appropriate PPE is employed, however, dermal exposure levels are predicted to be low to moderate, even if activities are undertaken for the full length of the shift.

Use of NMP in coatings (professional use)

There are no recent measurement data. Inhalation exposure concentrations predicted in the registrations indicate that exposures are likely to range from low to high depending on the activity. All the predicted exposure levels indicate that exposures should be below the OEL provided that appropriate RMMs are employed. This includes ensuring that activities such as spraying, film formation, dipping, immersion or pouring and hand applications are undertaken for less than a full shift and the use of relatively dilute concentrations of NMP in applications with the highest potential levels of exposure. Application by hand or indoor spraying over an entire shift could lead to very high dermal exposures, even if the NMP content of coatings is << 100 % and appropriate gloves are used. Even with the implementation of the recommended RMMs, estimated exposures are higher for some activities than those estimated for industrial coating activities. Estimated inhalation exposures are higher for the high temperature scenario than for the low temperature scenario. This reflects the difficulty of implementing measures such as total containment and extraction in some working environments where coatings would be applied as tasks such as painting buildings are not fixed in space.

Use of NMP in road and construction applications (professional)

There are no recent measurement data. Inhalation and dermal exposure concentrations predicted in the registrations indicate that inhalation exposures are for some activities are likely to be high or very high in relation to the OEL, even when RMMs are employed. Inhalation exposures for other activities are expected to be low. Dermal exposures are predicted to be low to moderate. Predicted exposure concentrations associated with drum/batch transfers in the absence of dedicated facilities and machine application of bitumen cutbacks exceed the OEL. These tasks are also associated with high levels of dermal exposure. The CSR does not provide any specific guidance as to how exposures associated with these tasks should be controlled in order that the OEL is met. In addition to mandatory RPE and protective clothing, it would be desirable to limit the time spent by individual workers on these tasks in order that shift mean exposures remain below the OEL. The relatively high levels of exposure for some tasks may reflect the difficulty of implementing some types of engineering control in a construction environment, particularly for short-lived projects.

3.4.3 Cleaning products

3.4.3.1 Operational conditions of use and existing risk management measures

Formulation of cleaning products containing NMP

The formulation of cleaning products is anticipated to involve similar processes to those involved in the formulation of coatings. It is believed that the RMMs employed would be similar to those employed in the formulation of coatings (above). There is no reason to anticipate that levels of compliance would be significantly different between the two sectors.

Use of cleaning products containing NMP

NMP is used in a wide range of cleaning products including paint strippers and products developed for removing graffiti, amongst others. NMP is also used in industrial tank cleaning, the cleaning of small objects in tanks and the manual cleaning of surfaces. Some industrial cleaning processes are undertaken at elevated temperature. Activities arising from the use of cleaning products containing NMP that could give rise to exposure include transfer from storage, pouring/unloading from drums or containers, mixing/diluting prior to use, cleaning activities (spraying, brushing, dipping, automated and manual wiping) and associated cleaning and maintenance of equipment. Different RMMs are likely to be appropriate for different operations under different circumstances and there is little information about the current deployment of RMMs.

Where cleaning is undertaken on industrial processes, it is possible to contain fluid transfer operations and cleaning operations such as degreasing operations or to employ extract ventilation to minimise inhalation exposures. Professional cleaning should only be undertaken where there is good ventilation, the filling of equipment should be undertaken outdoors and windows and doors should be opened during the manual cleaning of surfaces. In both the industrial and professional use of cleaning agents containing NMP, RPE fitted with a type A or better filter should be used for operations such as the filling/preparation of equipment, use of high pressure washers and manual application via trigger sprays, dipping, rolling, brushing etc. where exposure by inhalation is likely. Gloves should be used to limit dermal contact with NMP. For tasks such as spraying, the use of pressure washers and manual application where extensive exposure to NMP is possible, it is desirable to limit the NMP content of the cleaning agents and the length of time dedicated to these tasks on an individual shift.

The current extent of compliance with the RMMs stipulated in the registration dossier is unknown. Limited information from the questionnaire survey suggests good compliance in industrial settings. One of the respondents, a provider of services in tank cleaning indicated that NMP is stored in a dedicated tank or IBC outdoors and that workers wear protective coveralls, safety glasses with side shields, helmet, chemical resistant gloves, safety shoes, protective coverall and an emergency evacuation mask. Another respondent indicated that when the substance is used in solvent based cleaning products, equipment should be suitable for working in an explosive atmosphere and there is a requirement to provide adequate ventilation by LEV and good general extraction where reasonably practicable. If these are not sufficient to maintain concentrations of particulates and solvent vapour below the OEL, suitable respiratory protection must be worn (a mask fitted with a type A Filter).

3.4.3.2 Releases of the substance

Formulation of cleaning products containing NMP

It is assumed that the processes involved in the formulation of cleaning products will be the same as those in place for the production of coating products and that exposure levels would be similar. There is no reason to anticipate that levels of compliance would be significantly different between the two sectors.

Use of cleaning products containing NMP

Limited recent measurement data provided by respondents to the questionnaire suggest that inhalation exposures for tank cleaning in an industrial environment are low relative to the OEL.

The Concise International Chemical Assessment Document (CICAD, 2001) reviewed a limited quantity of occupational exposure data that suggested that the OEL is likely to be currently met during the use of NMP for paint removal. Personal exposure concentrations of NMP for graffiti removers were reported to be up to 10 mgm^{-3} as both short peak exposure and 8-h time-weighted average in studies published in 1993 and 2000. It was stated that workers in the paint stripping industry are exposed to NMP concentrations up to 64 mgm^{-3} (8-hour time-weighted average TWA) with 1 hour peak concentrations of up to 280 mgm^{-3} based in measurements made in 2000. Given a trend of falling exposure concentrations in most workplace environments through time (Creely et al, 2007), it is anticipated that current levels of exposure would be lower than the levels reviewed in the CICAD.

Some types of cleaning operation, particularly manual operations, could lead to significant dermal exposure in the absence of appropriate PPE.

The stipulated RMM should control exposure to well below the IOELV. It is difficult to assess the extent to which the indicated RMMs are currently in place, although they will in effect become mandatory for these uses of NMP as a result of the development of the ES. It is likely that current use of NMP for industrial cleaning operations is not in conformance with the ES at all locations and that some exposures may exceed those described in the ES. Higher levels of exposure are likely to arise where NMP is used at elevated temperatures.

The predicted levels of inhalation exposure associated with the use of cleaning agents containing NMP at low temperature in an industrial setting or by professionals are low to moderate relative to the OEL. Predicted inhalation exposures associated with some high temperature cleaning operations in an industrial setting are high relative to the OEL. The inhalation exposures associated with using a high pressure washer at high temperatures, contained batch processes, contained automated cleaning processes/closed systems and contained batch processes in an industrial environment are higher than those associated with other industrial cleaning processes or professional cleaning activities. Predicted levels of dermal exposure associated with the use of cleaning agents containing NMP range from low to high but would give intakes less than those associated with the inhalation OEL, provided that appropriate measures are taken to minimise dermal contact.

3.4.4 Agrochemicals

3.4.4.1 Operational conditions of use and existing risk management measures

The RMMs in place for the use of NMP in the formulation of agrochemicals are assumed to be the same as for the formulation of coatings materials.

NMP is used in agrochemicals applied by manual or machine spraying, smokes and fogging and exposure may occur during fluid transfers/pouring from containers, mixing, equipment clean downs and disposal. It is advised that tasks should be limited to less than 4 hours/shift with the exception of spraying and fogging by machine and storage. A protective coverall with 97 % efficiency and a respirator with at least x10 protection are recommended for spraying and fogging by manual application and spraying and fogging by machine should be done from a vented cab supplied with filtered air under positive pressure. Gloves should be used for all tasks where dermal contact is possible, equipment should be drained prior to cleaning and maintenance and NMP must be stored in a closed containers. There is no information about the current deployment of RMMs during the use of NMP in agrochemicals.

3.4.4.2 Releases of the substance

There are no measurement data. Estimated exposures modelled using parameters provided by the European Crop Protection Association reported in the CSR are low to moderate relative to the OEL. The highest levels of predicted exposure are associated with transfer from/pouring from containers, mixing in containers, spraying and fogging (manual operation), small ad hoc operations, cleaning and maintenance of equipment and waste disposal. Predicted dermal exposures range from very low to low based on the use of suitable protective gloves.

3.4.5 Electronic equipment manufacture

3.4.5.1 Operational conditions of use and existing risk management measures

The process involves the automated production of semiconductor devices in batch processes in dedicated equipment (litho track tools) that is either totally or partially enclosed. "Clean room environment" conditions are understood to apply.

The following main processes are understood to be undertaken:

- loading/unloading of wafers to/from automatic enclosed equipment;
- loading/unloading of wafers into partially enclosed equipment;
- maintenance and cleaning of equipment;
- handling and connection of containers;
- sampling.

It is anticipated that a high level of containment and use of ventilation is typical in the electronics sector.

3.4.5.2 Releases of the substance

The electronics industry is highly automated and processes are typically enclosed to prevent product contamination as well as limit operator exposure to a range of hazardous substances.

Limited recent measurement data provided by respondents to the questionnaire indicate that current inhalation exposures range from very low to low in relation to the OEL.

The CICAD reviewed a limited quantity of occupational exposure data. Measurements reported in 1991 indicated that workers in the microelectronics fabrication industry are exposed to up to 6 mgm^{-3} (personal breathing zones; 8-h TWA), well below the OEL. Full-shift NMP air concentrations up to 280 mgm^{-3} were reported for fixed point measurements when warm NMP (80°C) was being handled but it is unclear whether these measurements were representative of personal exposure concentrations. Exposure concentrations have fallen substantially in most industries over the last two decades (Creely et al, 2007) and it seems highly unlikely that personal exposure concentrations in the modern electronics industry exceed the OEL.

The low potential for exposure in the modern electronics industry was confirmed by undertaking a limited modelling exercise using ART. The following assumptions were made in the modelling exercise: activity used NMP at a concentration of 100 % at temperatures above room temperature (25-50^{o}C), involved an open, relatively undisturbed fluid surface (1-3 m^2), was fully enclosed and employed LEV with 10 air changes an hour in the wider work environment. The estimated median exposure was 3.1 mgm^{-3} with an interquartile range of 1.6-6 mgm^{-3}.

No information about dermal exposure in the electronics industry is available. Levels of dermal exposure arising in the electronics industry would be anticipated to be very small because of the requirement to protect the product and also the presence of various other hazardous substances in the workplace (which will also require exposure controls). It seems likely that exposure levels would be of the same order of magnitude as for laboratory work involving NMP. Estimated dermal exposures for laboratory work reported in the CSR are generally very low to low, although very high exposures may arise during the cleaning of equipment in a laboratory setting (see below).

3.4.6 Petrochemical processing

3.4.6.1 Operational conditions of use and existing risk management measures

Little information is available. It is assumed that this use will be confined to large, specialist industrial plants where there is a high level of process containment. It is assumed that NMP and NMP containing formulations are stored in closed containers and transferred between vessels using closed transfer processes. It is also assumed that extract ventilation is in place where activities such as sampling are undertaken where exposure could occur and that gloves/full body coveralls are used as appropriate to limit dermal exposure. Overall the RMMs in place are assumed to be of a similar nature and calibre to those employed during primary production.

3.4.6.2 Releases of the substance

Exposures in the modern petrochemical industry are typically low due to a high level of process automation and enclosure. In the absence of relevant exposure data, exposure concentrations are anticipated to be similar to those associated with primary production and product formulation, assuming similar levels of containment in the absence of relevant exposure data, both dermal and inhalation exposures are anticipated to be low or very low relative to the inhalation OEL.

3.4.7 Functional fluids

3.4.7.1 Operational conditions of use and existing risk management measures

NMP is used as a functional fluid in cable oils, transfer oils, coolants, insulators, refrigerants, and hydraulic fluids in industrial equipment. Exposure may occur during equipment operation, maintenance and related material transfers. It is not known how widely NMP is used in functional fluids or what RMMs are typically in place. It is advised that NMP should be stored in closed containers, enclosed processes are used for fluid transfers (including the use of drum pumps for the manual filling of machines), spillages are avoided through measures such as the clearance of lines used in bulk transfers prior to decoupling, and LEV is employed where NMP is used as a functional liquid in open equipment at elevated temperatures. It is recommended that NMP should be drained from equipment/articles prior to working on off-specification articles or undertaking maintenance. Gloves should be used where dermal contact with NMP is possible: during transfers, during operation of open equipment, during reworking of off specification articles and during maintenance operations. No special precautions are required during the operation of closed equipment containing NMP in functional fluids.

3.4.7.2 Releases of the substance

There are no measurement data available and no information about how widely NMP is used in functional fluids and how frequently workers might be exposed. It seems probable that the volume of NMP used in functional fluids in EU countries is much smaller than that employed for other uses such as coating or cleaning. It seems likely that some workers might be exposed on a daily basis, if they are involved in filling/servicing equipment that employs fluids containing NMP as functional fluids. Other workers may only be intermittently exposed when undertaking equipment maintenance. Under most circumstances, exposures to NMP would be anticipated to be very small except where functional fluids containing NMP are used in open equipment.

Modelled inhalation exposures for the use of NMP in functional fluids in an industrial setting are generally less then the OEL with the exception of where NMP is used in open equipment. The use of NMP in open equipment is predicted to give rise to very high levels of inhalation exposure relative to the OEL, particularly where equipment is operated at high temperatures. In contrast, the professional use of NMP in functional fluids would not be expected to include operation of open equipment and the predicted exposure levels for the professional use of NMP in functional fluids are low to moderate. This is likely to be due to the smaller volumes of fluid involved and lower working temperatures than in some industrial settings. Overall, it is apparent that exposures to NMP in functional fluids are likely to be well below the OEL in most applications but may exceed the OEL where NMP is used in open equipment at elevated temperatures, even if LEV is employed. The CSR exposure estimate assumes the use of extract ventilation but does not provide any guidance on further exposure reduction where NMP is used in this fashion. It would seem prudent to employ RPE and to limit the time spent by workers in the vicinity of open equipment containing NMP at elevated temperatures.

Modelled dermal exposures in both industrial and professional uses are generally low to moderate which reflects the absence of any requirement for direct dermal contact with functional fluids during normal use. Higher dermal exposures are predicted to occur during equipment maintenance.

3.4.8 Use of NMP in laboratories

3.4.8.1 Operational conditions of use and existing risk management measures

Small quantities of NMP are handled in laboratory settings typically within a fume cupboard, on a bench fitted with local exhaust ventilation or under general ventilation. Typical health and safety measures in place in laboratories include the regular maintenance and testing of ventilation systems, careful pouring, replacement of caps/lids on containers after use and wearing suitable gloves. Gloves should be used where dermal exposure is possible (e.g. during fluid transfer operations).

3.4.8.2 Releases of the substance

The predicted inhalation and dermal exposure associated with the use of NMP in laboratories are mostly very low to low consistent with the small quantities of NMP typically employed and the RMMs in place. Very high levels of dermal exposure may, however, occur during the cleaning of equipment. The RMMs stipulated in the ES correspond to common practice in most laboratories and a high level of compliance would be anticipated.

3.4.9 Use of NMP in the preparation of pharmaceuticals

3.4.9.1 Operational conditions of use and existing risk management measures

There is limited information that suggests NMP could be used as a solvent during the preparation of pharmaceuticals as well as being present in some pharmaceutical products (Jouyban et al, 2010). These authors state that NMP is one of the main pharmaceutical co-solvents and that it is an important solvent used in the extraction, purification and crystallisation of drugs. It is not known whether NMP is used in this way within the EU. Manufacturing processes in the pharmaceutical sector are tightly controlled in order to achieve the required level of purity of substances used in drugs. In addition, a high level of containment is generally required as most actives are highly toxic. It is likely that the minimum level of engineering control that is likely to be employed is LEV, but in almost all circumstances a much higher level of containment would be required for process operations. The highest potential exposure might occur during cleaning and maintenance and it is anticipated that the RMMs employed would be similar to those employed for similar operations at plants producing NMP or formulations containing NMP.

3.4.9.2 Releases of the substance

There is no information about the use of NMP as a solvent in the preparation of pharmaceutical substances within the EU. There are no measurement data available. Inhalation exposures are anticipated to be low, probably substantially lower than those associated with the production of NMP or formulations that contain NMP.

No information about dermal exposure is available. Levels of dermal exposure arising in the pharmaceutical industry would be anticipated to be very small because of the requirement to protect the product and also the presence of various hazardous substances in the workplace. It seems likely that inhalation exposure levels would be of the same order of magnitude as for laboratory work involving NMP. Dermal exposures are anticipated to be very low to low.

3.5 Consumer releases and exposure

3.5.1 Overview

The assessment of consumer exposure to NMP has been made using a number of Tier 1 methods. These are based on the methods or models recommended in the REACH Guidance Document for Consumer Exposure Estimation (ECHA, 2010a). For the assessment the NMP content of the consumer product has been assumed to be a maximum of 5 % by weight (i.e. 0.05 g g^{-1}), in line with the existing Annex XVII restriction based on the classification as toxic to reproduction category 1B[12].

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[12] It should be noted that NMP seems to have been used in coating and cleaning products (for example) sold to the public, based on the questionnaire responses, but no information suggesting a higher content than 5 % has been found (higher levels are present in products intended for industrial/professional use). Given that the Cat 1B classification is relatively recent, it may be the case that some of the information provided relates to products which have been withdrawn from the market (or will be soon).

3.5.2 Coatings

3.5.2.1 Background

NMP can be used in various types of paints and coatings that are used by consumers. Scenarios for estimating the consumer exposure from such uses are outlined in Bremmer and van Engelen (2007) and implemented in the ConsExpo v4 model. These sources have been used here to complement the approach given in ECHA (2010a) in order to estimate the realistic worst case exposure of consumers from such uses. It should be noted that the main manufacturer has indicated that they do not support consumer uses of NMP.

3.5.2.2 Inhalation exposure

The Tier 1 approach outlined in ECHA (2010a) assumes the following.

- One event per day.
- 100 % of substance in the consumer product is released at once into a room.
- Default room size – 20 m^3.
- There is no ventilation in the room.
- Amount of product used during the event – X g.
- Weight fraction of substance in product – 0.05 g g^{-1} product (maximum allowable under the existing restriction).

Under these assumptions, the maximum concentration in the air in the room is 2.5×X mg m^{-3}, where X represents the amount of consumer product (paint or coating) (g) used during an event.

In the absence of actual data on usage rates, the suggested values for the amount of consumer product used during an event from the ConsExpo version 4 model has been considered (Bremmer and van Engelen, 2007). These are as follows.

Brush/roller painting, solvent rich paint	1,000 g of paint
Brush/roller painting, high solid paint	1,300 g of paint
Brush/roller painting, waterborne paint	1,250 g of paint
Brush/roller painting, waterborne wall paint	3,750 g of paint

Based on these figures, the amount of paint or coating used per event can be assumed to be in the range 1,000 g to 3,750 g, depending on the paint type. Thus the maximum concentration in air (assuming no ventilation) would be in the range 2,500 mg m^{-3} to 9,375 mg m^{-3}

Assuming a body weight of 60 kg for adult females or 70 kg for adult males (default values from ECHA, 2010a), an inhalation rate of 36 m^3 d^{-1} (default value for females; medium activity) or 62 m^3 d^{-1} (default value for males; medium activity), a respirable fraction for the inhaled substance of 1 and that the consumer is in the room for 2.2 hours d^{-1} during the application of the coating and subsequent clean-up (taken from van Bremmer and Engelen, 2007), the maximum intake of the substance under these conditions would be 138-516 mg kg^{-1} d^{-1} for females and

203-761 mg kg^{-1} d^{-1}. It should be noted that these values represent acute exposure occurring on the day of use only. The annual average (chronic) intake assuming one such event per year would be of the order of 0.38-1.4 mg kg^{-1} d^{-1} for adult females and 0.56-2.1 mg kg^{-1} d^{-1} for adult males.

A more refined estimate of the likely inhalation exposure can be obtained by using a Tier 1 model that incorporates ventilation (as rooms are rarely airtight). The same scenario as above has been modelled using the ConsExpo v4 model. The default ventilation rate assumed in the model is 0.6 h^{-1} and instantaneous release into a 20 m^3 room is assumed. The resulting exposures and doses calculated are as follows (the ConsExpo model assumes by default an adult body weight of 65 kg and a daily inhalation rate for medium activity of 34.7 m^3 d^{-1}).

Table 15: Inhalation exposure for coatings based on ConsExpo

	Concentration in air during event	**Acute daily intake**	**Chronic daily intake**
Solvent rich paint	1,390 mg m^{-3}	67.9 mg kg^{-1}	0.19 mg kg^{-1} d^{-1}
High solid paint	1,800 mg m^{-3}	88.3 mg kg^{-1}	0.24 mg kg^{-1} d^{-1}
Waterborne paint	1,740 mg m^{-3}	84.9 mg kg^{-1}	0.23 mg kg^{-1} d^{-1}
Waterborne wall paint	5,210 mg m^{-3}	255 mg kg^{-1}	1.39 mg kg^{-1} d^{-1}

Note: the chronic daily intake for waterborne wall paints assumes two applications/events per year

For comparison, the OECD SIDS Initial Assessment Report (OECD, 2007) includes the results of a small number of studies which measured NMP in indoor air. From 744 indoor air analyses in Berlin from 1988 to 1999 (mostly from private homes) the arithmetic mean concentration was 15 µg m^{-3}, the median was <2 µg m^{-3}, and the maximum was 302 µg m^{-3}. In Helsinki, samples were taken from personal 48-hour exposure samplers and from residential indoor and outdoor locations and from indoor workplace locations. NMP was only detected in 1 % of the samples: maximum levels found were 42.49 µg m^{-3} (personal exposure), 4.84 µg m^{-3} (outdoor), 90.62 µg m^{-3} (indoor) and 135.78 µg m^{-3} (workplace). There are no details of specific activities using NMP in relation to these studies. These measured concentrations are around a factor of 10,000 or more lower than those predicted above, probably reflecting the conservative nature of the estimates.

It is also worth noting that the predicted concentrations are above the EU OEL in Directive 2009/161/EU of 40 mg m^{-3} as a 8-hour average and 80 mg m^{-3} as a 15 minute average. Although these values do not apply to consumer exposure, and the existing OEL are derived for irritation rather than toxicity to reproduction, the fact that the predicted exposure is well above these values indicates that consumer exposure could be a legitimate concern for this substance.

The ConsExpo model also allows estimates of consumer exposure to aerosols during spray application of paints. The estimated exposure from aerosols is much lower than estimated above from the subsequent evaporation of the solvent. For example the acute daily intake is estimated to be 0.14 mg kg^{-1} d^{-1} for application by spray can and 0.003 mg kg^{-1} d^{-1} for application by pneumatic spray.

Inhalation exposure from the use of writing inks can be considered to be negligible owing to the small volumes involved.

3.5.2.3 Dermal exposure

Although the main source of consumer exposure from use of NMP in coating products would be expected to be from inhalation, dermal exposure is also a possibility through drips, splashes and small spills during use of the coatings and this is considered here[13].

When considering these estimates it should be considered that the exposure levels generated reflect the maximum exposure resulting from the initial contact of the coating with hands. As NMP functions as a solvent in the coating, evaporation from the skin would be expected to occur over a relatively short time frame, resulting in a reduction in the exposure. But it has to be noted as well, that dermal absorption of NMP does also occur, particularly taking into account that in the pharmaceutical application, dermal absorption is the intended function.

The Tier 1 approach outlined in ECHA (2010a) assumes the following.

- Concentration in product – 0.05 g cm^{-3} (assumes the density of the product is approximately 1 g cm^3 and that NMP is present at a maximum of 0.05 g g^{-1} product).
- Thickness of product layer on skin – default 0.01 cm.

Using this approach the total dermal load (the amount of substance on skin per event) can be estimated as 0.5 mg cm^{-2}.

Assuming that the surface area of skin exposed is 731 cm^2 (females) or 840 cm^2 (males) which corresponds to the front and back of the hands (ECHA, 2010a), there is one event per day, an adult body weight of 60 kg (females) or 70 kg (males) and 100 % adsorption, the maximum daily intake can be estimated at around 6 mg kg^{-1} for both males and females during the exposure event. This assumes that the coating is applied to the entire surface of the hand which is highly unlikely. Assuming one such event per year (based on Bremmer and van Engelen (2007)) the average daily intake over the year would be 0.016 mg kg^{-1} d^{-1}.

Dermal exposure from application of coatings by brushing or rolling is also considered in the ConsExpo model. The model uses a parameter called the ‘contact rate’, which is the rate at which the coating is applied to the skin (in units of weight per time) (Bremmer and van Engelen, 2007). The dermal exposure is thought to be dependent on the viscosity of the coating (lower viscosity products such as varnish are assumed to result in higher dermal exposure than higher viscosity products) and the position of the user (for example use of the coating overhead will lead to higher dermal exposure than use on a floor or wall). The recommended values for the contact rate from Bremmer and van Engelen (2007) are summarised below.

Overhead painting – low viscosity	120 mg min^{-1}
Overhead painting – normal viscosity	60 mg min^{-1}
Downward/side painting – all products	30 mg min^{-1}

Bremmer and van Engelen (2007) also note that if, during use of the paint or coating, the amount of paint on the hands is larger (e.g. 1 g or more), then the hand will be cleaned or wiped off. Therefore this limits the potential for dermal exposure.

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[13] NMP has a ‘skin’ notation in Directive 2009/161/EU, indicating the possibility of significant uptake through the skin.

The estimates for dermal exposure obtained using ConsExpo for a number of scenarios are summarised below.

Table 16: Dermal exposure for coatings based on ConsExpo

	Acute dose (during application)	**Chronic dose (average over 1 yr)**
Overhead painting – low viscosity	11.1 mg kg^{-1}	0.030 mg kg^{-1} d^{-1}
Overhead painting – normal viscosity	5.54 mg kg^{-1}	0.015 mg kg^{-1} d^{-1}
Downward/side painting	2.77 mg kg^{-1}	0.0076 mg kg^{-1} d^{-1}

The estimates all assume that the NMP content of the coating is 5 %, the adult body weight is 65 kg, application of the coating occurs for 120 minutes over a day, that there is one event per year and that 100 % of the NMP on the skin is adsorbed.

Dermal exposure from use of writing inks could also possibly occur. If it is assumed that a maximum of 1 cm^2 of the skin will be covered in ink and that the thickness of the ink covering is 0.01 cm the possible dermal intake from use of the ink can be estimated using the Tier 1 approach outlined in ECHA (2010a). Assuming that the ink contains a maximum of 5 % NMP and has a density of approximately 1 and the NMP on the skin is 100 % adsorbed the daily intake from this source can be estimated at 0.008 mg kg^{-1} d^{-1} for adult females or 0.007 mg kg^{-1} d^{-1} for adult males. As use of writing inks could theoretically occur every day of the year these estimates represent chronic exposure values. It should be noted that ink on fingers/skin may lead to either dermal exposure or oral exposure therefore the two routes should not be added to avoid double counting.

3.5.2.4 Oral exposure

The Tier 1 approach outlined in ECHA (2010a) assumes the following.

- Concentration in product – 0.05 g cm^{-3} (assumes the density of the product is approximately 1 g cm^3 and that NMP is present at a maximum of 0.05 g g^{-1} product).
- Volume of product per event in contact with mouth – V cm^3.
- Fraction of product in contact with mouth that is ingested – 1 (default).
- Body weight – 60 kg (adult females) or 70 kg (adult males).
- Number of events per day – n.

For use in coatings, oral exposure of consumers can be assumed to be negligible (volume of product in contact with mouth and number of events are assumed to be 0).

For writing inks, contact with the mouth would appear to be a possibility (e.g. sucking pens or fingers covered with ink etc.). Assuming that the volume of ink in contact with the mouth is 0.01 cm^3 and there is one such event per day, the total daily intake from this source could be estimated as 0.008 mg kg^{-1} d^{-1} for adult females or 0.007 mg kg^{-1} d^{-1} for adult males. It should be noted that ink on fingers may lead to either dermal exposure or oral exposure therefore the two routes should not be added to avoid double counting.

3.5.3 Cleaning products

3.5.3.1 Background

NMP can be used by consumers in certain cleaning products such as paint removers, cleaners and degreasers. Scenarios for estimating the consumer exposure from such uses are outlined in Burg et al. (2007) and implemented in the ConsExpo v4 model. These sources have been used here to complement the approach given in ECHA (2010a) in order to estimate the realistic worst case exposure of consumers from such uses.

3.5.3.2 Inhalation exposure

The Tier 1 approach outlined in ECHA (2010a) assumes the following.

- One event per day.
- 100 % of substance in the consumer product is released at once into a room.
- Default room size – 20 m^3.
- There is no ventilation in the room.
- Amount of product used during the event – X g.
- Weight fraction of substance in product – 0.05 g g^{-1} product (maximum allowable under the existing restriction).

Under these assumptions, the maximum concentration in the air in the room is 2.5×X mg m^{-3}, where X represents the amount of consumer product (g) used during an event.

In the absence of actual data on usage rates, the suggested values for the amount of consumer product used during an event from the ConsExpo version 4 model has been considered (Burg et al., 2007). These are as follows.

Paint remover	1,000 g of product (based on a paint removal from a door)
Glue remover	2,000 g of product (based on glue removal from a stair carpet)
Sealant/foam remover	100 g of product (based on a bathroom sealant)

Based on these figures, the amount of paint or coating used per event can be assumed to be in the range 100 g to 2,000 g, depending on the actual usage. Thus the maximum concentration in air (assuming no ventilation) would be in the range 250 mg m^{-3} to 5,000 mg m^{-3}. Burg et al. (2007) recommends that a more appropriate room sizes for the glue removal and sealant/foam removal scenarios would be 30 m^3 and 10 m^3 respectively rather than default of 20 m^3 and this would result a the range of maximum air concentrations of between 500 and 3,330 mg m^{-3}.

Assuming a body weight of 60 kg for adult females or 70 kg for adult males (default values from ECHA, 2010a), an inhalation rate of 36 m^3 d^{-1} (default value for females; medium activity) or 62 m^3 d^{-1} (default value for males; medium activity), a respirable fraction for the inhaled substance of 1 and that the consumer is in the room during the event for either 1 hours d^{-1} (for the paint remover), 4 hours d^{-1} (for the glue remover) or 3 hours d^{-1} (for the sealant/foam remover; 2 hours during application and removal of the cleaning product plus a further hour; all values taken from Burg et al, 2007), the maximum intake of the substance under these conditions would be 38-333 mg kg^{-1} d^{-1} for females and 55-491 mg kg^{-1} d^{-1}. It should be noted that these values represent acute exposure occurring on the day of use only. The annual average (chronic) intake assuming one such event per year would be of the order of 0.10-0.91 mg kg^{-1} d^{-1} for adult females and 0.15-1.3 mg kg^{-1} d^{-1} for adult males.

A more refined estimate of the likely inhalation exposure can be obtained by using a Tier 1 model that incorporates ventilation (as rooms are rarely airtight). The same scenario as above has been modelled using the ConsExpo v4 model. The default ventilation rates assumed in the model are 0.6 h^{-1} for the paint remover, 1.5 h^{-1} for the glue remover and 2 h^{-1} for the sealant/foam remover, and instantaneous release into a room of volume 20 m^3 (paint remover), 30 m^3 (glue remover) or 10 m^3 (sealant/foam remover) is assumed. The resulting exposures and doses calculated are as follows (the ConsExpo model assumes by default an adult body weight of 65 kg and a daily inhalation rate for medium activity of 34.7 m^3 d^{-1}).

Table 17: Inhalation exposure for cleaning products based on ConsExpo

	Concentration in air during event	**Acute daily intake**	**Chronic daily intake**
Paint remover	1,880 mg m^{-3}	41.8 mg kg^{-1}	0.11 mg kg^{-1} d^{-1}
Glue remover	554 mg m^{-3}	49.3 mg kg^{-1}	0.034 mg kg^{-1} d^{-1}
Sealant / foam remover	83.1 mg m^{-3}	5.54 mg kg^{-1}	0.076 mg kg^{-1} d^{-1}

Note: the chronic daily intake assumes 1 event per year for the paint remover, 1 event every four years for the glue remover and 5 events per year for the sealant/foam remover.

The ConsExpo model also allows estimates of consumer exposure to aerosols during spray application. However for volatile substances the estimated exposure from aerosols is much lower than estimated above from the subsequent evaporation of the solvent and so can be neglected.

3.5.3.3 Dermal exposure

Although the main source of consumer exposure from use of NMP in cleaning products would be expected to be from inhalation, dermal exposure is also a possibility during application and removal of the cleaning agent, particularly if gloves are not used. When considering these estimates it should be considered that the exposure levels generated reflect the maximum exposure resulting from the initial contact of the cleaning product with hands. As NMP functions as a solvent in the cleaning product, evaporation from the skin would be expected to occur over a relatively short time frame, resulting in a reduction in the exposure. However, also fast dermal absorption is expected.

The Tier 1 approach outlined in ECHA (2010a) assumes the following.

- Concentration in product – 0.05 g cm^{-3} (assumes the density of the product is approximately 1 g cm^3 and that NMP is present at a maximum of 0.05 g g^{-1} product).
- Thickness of product layer on skin – default 0.01 cm.

Using this approach the total dermal load (the amount of substance on skin per event) can be estimated as 0.5 mg cm^{-2}.

Assuming that the surface area of skin exposed is 731 cm^2 (females) or 840 cm^2 (males) which corresponds to the front and back of the hands (ECHA, 2010a), there is one event per day, an adult body weight of 60 kg (females) or 70 kg (males) and 100 % adsorption, the maximum daily intake can be estimated at around 6 mg kg^{-1} for both males and females during the exposure event. This assumes that the cleaner is applied to the entire surface of the hand which is highly unlikely. Assuming one such event per year the average daily intake over the year would be 0.016 mg kg^{-1} d^{-1}.

Dermal exposure from application and removal of cleaning products is also considered in the ConsExpo mode (Burg et al., 2007). For paint removers, the approach assumes that dermal exposure can occur during application of the paint remover and also particularly during removal of the paint. It is assumed that both palms of the hand (surface area 430 cm^2) can come into contact with the product during removal of the paint. However, as the applied product is usually allowed to soak for around 15 minutes before removal, much of the solvent will be lost by evaporation before removal. The dermal load of the product is estimated at 0.5 g during the process.

For glue removers, the method outlined in Burg et al. (2007) assumes that dermal exposure can occur over 4 hours continual use of the product and that the dermal contact rate with the product is 30 mg min^{-1}. The surface area that comes into contact with the product is assumed to be 230 cm^2 (corresponding to the surface area of the fingers of both hands).

For sealant/foam removers the approach assumes that dermal exposure can occur to around 0.1 g of product as a result of removal of the sealant by hand (or picking up bits of dropped sealant). The exposed surface area is taken to be 5 cm^2 (corresponding to the fingers of one hand).

The estimates for dermal exposure obtained using ConsExpo are summarised below.

Table 18: Dermal exposure for cleaning products based on ConsExpo

	Acute dose (during application)	Chronic dose (average over 1 yr)
Paint remover	0.39 mg kg^{-1}	0.0011 mg kg^{-1} d^{-1}
Glue remover	5.54 mg kg^{-1}	0.0038 mg kg^{-1} d^{-1}
Sealant / foam remover	0.077 mg kg^{-1}	0.0011

The estimates all assume that the NMP content of the coating is 5 % and the adult body weight is 65 kg. The frequency of events is assumed to be 1 per year for the paint remover, 1 every four years for the glue remover and 5 per year for the sealant/foam remover.

3.5.3.4 Oral exposure

The Tier 1 approach outlined in ECHA (2010a) assumes the following.

- Concentration in product – 0.05 g cm^{-3} (assumes the density of the product is approximately 1 g cm^3 and that NMP is present at a maximum of 0.05 g g^{-1} product).
- Volume of product per event in contact with mouth – V cm^3.
- Fraction of product in contact with mouth that is ingested – 1 (default).
- Body weight – 60 kg (adult females) or 70 kg (adult males).
- Number of events per day – n.

For use in cleaning products, oral exposure of consumers can be assumed to be assumed to be negligible (volume of product in contact with mouth and number of events are assumed to be 0).

3.5.4 Summary of consumer exposure estimates

The consumer exposure estimates obtained are summarised in the table below.

Table 19: Summary of consumer exposure estimates

Scenario	**Calculation method**	**Exposure route**	**Estimated exposure dose (internal)**	
			Acute (on day of event) **(mg kg^{-1})**	**Chronic** **(mg kg^{-1} d^{-1})**
Coatings	ECHA (2010a) – Tier 1 (no ventilation)	Inhalation	138-516 (females) 203-761 (males)	0.38-1.4 (females) 0.56-2.1 (males)
		Dermal	6 (females) 6 (males)	0.016 (females) 0.016 (males)
		Oral	Negligible	Negligible
		Total	144-522 (females) 209-767 (males)	0.40-1.4 (females) 0.58-2.1 (males)
Coatings – brush/roller application, solvent rich paint	ConsExpo v4 (includes ventilation)	Inhalation	67.9	0.19
		Dermal	2.77-11.1	0.0076-0.030
		Oral	Negligible	Negligible
		Total	70.7-79	0.18-0.22
Coatings – brush/roller application, high solid paint	ConsExpo v4 (includes ventilation)	Inhalation	88.3	0.24
		Dermal	2.77-11.1	0.0076-0.030
		Oral	Negligible	Negligible
		Total	91.0-99.4	0.25-0.27
Coatings – brush/roller application, waterborne paint	ConsExpo v4 (includes ventilation)	Inhalation	84.9	0.23
		Dermal	2.77-11.1	0.0076-0.030
		Oral	Negligible	Negligible
		Total	87.7-96.0	0.24-0.26
Coatings – brush/roller application, waterborne wall paint	ConsExpo v4 (includes ventilation)	Inhalation	255	1.39
		Dermal	2.77-11.1	0.0076-0.030
		Oral	Negligible	Negligible
		Total	258-266	1.40-1.42
Writing inks	ECHA (2010a) – Tier 1 (no ventilation)	Inhalation	Negligible	Negligible
		Dermal[a]	0.008 (females) 0.007 (males)	0.008 (females) 0.007 (males)
		Oral[a]	0.008 (females) 0.007 (males)	0.008 (females) 0.007 (males)
		Total	0.008 (females) 0.007 (males)	0.008 (females) 0.007 (males)

Scenario	**Calculation method**	**Exposure route**	**Estimated exposure dose (internal)**	
			Acute (on day of event) **(mg kg^{-1})**	**Chronic** **(mg kg^{-1} d^{-1})**
Cleaning products	ECHA (2010a) – Tier 1 (no ventilation)	Inhalation	38-333 (females) 55-491 (males)	0.10-0.91 (females) 0.15-1.3 (males)
		Dermal	6 (females) 6 (males)	0.016 (females) 0.016 (males)
		Oral	Negligible	Negligible
		Total	44-339 (females) 61-497 (males)	0.12-0.93 (females) 0.17-1.3 (males)
Cleaning products – paint remover	ConsExpo v4 (includes ventilation)	Inhalation	41.8	0.11
		Dermal	0.39	0.0011
		Oral	Negligible	Negligible
		Total	42.2	0.11
Cleaning products – glue remover	ConsExpo v4 (includes ventilation)	Inhalation	49.3	0.034
		Dermal	5.54	0.0038
		Oral	Negligible	Negligible
		Total	54.8	0.038
Cleaning products – sealant/foam remover	ConsExpo v4 (includes ventilation)	Inhalation	5.54	0.076
		Dermal	0.077	0.0011
		Oral	Negligible	Negligible
		Total	5.6	0.077

a) The scenario of ink may lead to either dermal exposure or oral exposure and therefore the two routes should not be added to avoid double counting.

All these estimates assumed a maximum NMP content of 5 % by weight. The actual exposure estimates are all directly proportional to the NMP content of the consumer product and so can readily be scaled to other NMP contents (i.e. a NMP content of 1 % by weight would result in exposure estimates a factor of 5 times lower than presented in the table above.

The above estimates also assume that NMP is 100 % absorbed following inhalation, oral or dermal exposure. According to the OECD SIDS Initial Assessment Report (OECD, 2007), NMP is well absorbed following inhalation (40-60 %), oral (approx. 100 %) and dermal (approx. 100 % depending on conditions). Therefore this assumption appears to be appropriate for oral and dermal exposure but may result in an overestimate of the actual internal dose resulting from inhalation exposure.

It should also be noted that the possibility for combined exposure exists. For example, the use of a paint remover containing NMP may subsequently be followed by use of a paint/coating containing NMP.

3.6 Environmental releases and exposure

Estimates of the emissions of NMP to the environment have been made based on an overall usage in the EU of 10,000 to 50,000 tonnes and the breakdown between use areas from OECD (2007) (see Section 2). Emission factors have been taken from the Specific Environmental Release Categories (SpERCs)[14].

The results are in the table below.

Table 20: Summary of environmental release estimates

Application	**Fraction**	**Release to air (t/year)**	**Release to waste water (t/year)**
Coatings (industrial)	10 %	98 - 490	20 - 100
Coatings (professional)	10 %	980 - 4900	10 - 50
Cleaning	20 %	600 - 3000	0.2 - 1
Agrochemicals	15 %	750 - 3750	0 - 0
Electrical equipment	20 %	600 - 3000	0.2 - 1
Petrochemical processing	10 %	5 - 25	10 - 50
Pharmaceuticals	15 %	37.5 - 187.5	30 - 150
Total		3071 - 15353	70 - 352

Notes:

Coatings – products containing NMP are used in industrial settings and by professionals. In these calculations an even split between these has been assumed. (ESVOC SpERC 4.3a.v1 and 8.3b.v1 respectively).

Cleaning – the most appropriate description of use appears to be industrial use as a solvent in cleaning agents (ESVOC SpERC 4.4a.v1).

Agrochemicals – the SpERCs available for agrochemicals (ECPA SpERC 1 and 2) assume 100 % release either to air or to soil depending on the nature of the use; for these calculations 50 % for each has been assumed (hence there are releases of 750 - 3750 t/y to soil in addition to those in the table).

Electrical equipment – the use here appears to be largely in electronics, and has been categorised as industrial use as a solvent in cleaning agents, ESVOC SpERC 4.4a.v1.

Petrochemical production – this has been categorised as solvent use in chemical production, ESVOC SpERC 1.1.v1.

Pharmaceuticals – this has been categorised as solvent use in larger-scale laboratory-type situations, ESVOC SpERC 4.24.v1.

The identification of the relevant SpERC for each use is not straightforward. There is thus some uncertainty in these values related to this. There are also other areas of uncertainty. The 50:50 split between industrial and professional use in coatings is arbitrary, and different splits could produce significantly different emissions. The situation is similar for the releases from use in agrochemicals. A proportion of the use in the electrical equipment manufacture area appears likely to be under well controlled conditions and hence the emissions to air from this area may be over-estimated. The same may be true for the use in cleaning (and possibly for use on coatings).

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[14] See http://www.cefic.be/en/reach-for-industries-libraries.html.

3.7 Natural or unintentional formation

No information is available to suggest that NMP is formed naturally or unintentionally.

4 CURRENT KNOWLEDGE ON ALTERNATIVES

4.1 Introduction

This section provides a compilation of some of the information available from the consultation undertaken on alternatives to NMP.

Firstly, information provided by manufacturers and importers is presented, including issues in replacement of NMP.

This is followed by information on replacement of NMP in specific uses, including coatings, electronics and cleaning products. No information was available on alternatives for other applications.

4.2 Manufacturers and importers

The majority of companies that provided information in the form of questionnaire responses were importers of the substance, although information was also provided by EU manufacturers. Key issues that have been highlighted in relation to potential replacement of NMP include:

- NMP is a powerful organic solvent which is very well established in the industry. It is widely available and, for certain industries such as the semiconductor industry, NMP is available at the required purity level to meet the stringent requirements that are reportedly in place. NMP has a higher loading capacity than alternatives being considered. In order to replace NMP it may be necessary to move to corrosive alternatives with lower loading capacities, which could lead to increase in volumes used and waste generated, which would also increase costs.

- NMP has been the solvent of choice for solvent-based coating systems, in some cases because of its unique dissolving properties for binder polymers that are required for adhesion to metal substrate and the high temperature properties.

- Downstream users are gradually replacing solvent-based systems with multi-layer water based systems (these can be higher quality and longer lasting but more difficult in application and still containing a solvent fraction including NMP). This trend has been driven in some cases by local and regional regulations and by environmental considerations.

- It was indicated by manufacturers/importers that the greatest volumes of NMP-based products are used in a limited number of industrial applications with dedicated equipment for application and curing.

- Requalification of alternative substances would reportedly be very costly and resource intensive on customers and could take 1-2 years in some cases (some downstream users have indicated longer timescales).

- A number of companies stated there were no suitable alternatives identified to NMP. Furthermore, potential alternatives identified by certain companies may not be suitable for all similar processes.

- It has been highlighted that there is no real other universal solvent currently available, particularly given that the most technically suitable alternative for most applications (NEP, see below) may also be shortly classified as reprotoxic. Other solvents are reportedly restricted to more narrow ranges of application due to technical reasons or physicochemical hazards (flammability). Research on alternatives for NMP and NEP is understood to be ongoing.

4.3 Downstream Users

4.3.1 Coatings

4.3.1.1 Overview

Approximately 80 % (28 companies out of 34) of the downstream users that provided information via questionnaires use NMP in formulations (mixtures/preparations). The majority of these (approximately 91 %) use NMP as a solvent in coatings.

4.3.1.2 N-ethylpyrrolidone (NEP)

Introduction

The main alternative available on the market to NMP is N-ethylpyrrolidone (NEP) (EC Number 220-250-6, CAS Number 2687-91-4).

Most of the users noted that NEP is currently being reviewed for reproduction toxicity and pending the results of the upcoming initiative for a possible new classification and labelling of NEP.

There are differences of opinion amongst companies, presumably due to the different applications in which NMP-based coatings are used and the differing levels of research done into alternatives. Several users noted that NEP was not a suitable alternative to NMP, whilst others noted that NEP is so far the only feasible alternative. The picture is clearly mixed, therefore, as to the extent to which NEP can be used as an alternative in technical terms.

Considerations on use of NEP

A selection of the responses provided by companies in relation to their potential use of NMP is provided below:

- One company has tested NEP for substitution and is currently introducing this into their products. Furthermore, a number of other companies indicated that they have already replaced NMP and it is understood that several of these have used NEP as an alternative.

- A number of companies noted that whilst it is their preference to substitute, R&D for alternative solvents will be dependant on their raw-material suppliers.

- One company’s suppliers of additives and resins suggested using NEP as an alternative. They noted that no other practical alternative to replacing NMP by their suppliers had been identified as NMP is already a replacement for previously used substances. The company has undertaken a study for replacing NMP with NEP which has been approved. Whilst they note that the only logical substitute for them is NEP, they also note that it may be classified as a reprotoxic substance (1B) in the next few years.

- One company which uses NMP in certain coating formulations as a solvent and also as a thinning solvent noted that a project to investigate using NEP has been suspended following advice from NEP registrant consortium that NEP may be classified as a reprotoxic substance.
- One company noted that an alternative coating polymer system they are considering may not have the same level of chemical resistance as the current coating technology.
- Alternative coating formulations have been checked by another company. No 1:1 substitute has yet been found. The coating would reportedly have to be completely reformulated to eliminate NMP.
- One company noted that they anticipated the reprotoxic category classification and likely restrictions, and so phased out their use of NMP, substituting it with NEP. Many of the former users of NMP have also switched to NEP, following the reprotoxic classification. The company noted that NEP and NMP have unique properties that are difficult to replace. Replacement of NMP was relatively easy by switching to NEP; if NEP also needs to be replaced, finding as suitable an alternative will be difficult for many companies.
- One company noted that by replacing NEP with N-propyl pyrrolidone, this would result in the reduction of the wetting ability on increasing the alkyl chain length, which would not be a satisfactory solution. (This highlights the relatively suitability of NEP as a replacement for various applications but indicates that longer alkyl chain length derivatives may not be so suitable.)
- One company which uses NMP for high performance paints for cookware noted that no alternative was found with similar properties with a lower hazard risk potential.
- One company noted that the main reasons NEP was not used were its cost and that it has a similar risk potential as NMP.

In most responses, NEP is already commercially used and has been widely adopted for use in coating solvents.

Time required for replacement

One company estimated that process redesign would require approximately one man-day per formulation or approximately two years to introduce alternative.

With regards additional work required if alternatives are to be used, it was noted that because of the current review of NEP as a reprotoxic substance, further research is required for other substances. One company noted that the coated aerosols will be required to be pack-tested by the brand-owners who fill them (taking 1 -2 years). One company noted that line trials will be required at each customer for each individual product, including re-design of exhaust ventilation layout and line configuration of application line.

With regards to time required before alternatives could replace the substance (years), some companies had already introduced NEP as an alternative, others noted a timeframe of between 1-3 years, with the majority stating 2-3 years, which in some cases would include line trails.

Cost implications

Most companies noted that the cost of using NEP is significantly higher than for NMP. One company indicated that the cost could be 10 % higher than NMP; another noted a 15 % difference.

Conclusions

In general, many companies noted that substituting NMP with NEP was no longer considered a suitable option.

Overall, a number of former users of NMP have switched to using NEP, following the reprotoxic classification of NMP. However, for a number of companies substitution with NEP has largely occurred, and now the main concern is that if NEP is also subject to the same classification and control measures/restrictions as NMP then there will be no other feasible alternative available with a lower risk.

As well as the potential future classification of NEP in relation to reprotoxic effects, other technical constraints noted were: reduction in wetting ability and reduced solvency (but this was noted as tolerable); higher curing temperature required (CO_2-balance is negative), and higher raw material costs (15 %).

With regards to product redesign or process changes required to use NEP, the majority of responses where this was being considered as an alternative noted that there would be significant adjustments to paint formulations, which would require new customer approvals. Some noted that they expect process redesign, but that this had not been identified yet.

It should be noted that a CLH dossier may be published in the near future in relation to potential reprotoxic effects for NEP.

Whilst companies that have provided information generally indicate that NMP could be replaced within a period of up to three years, it is clear that in case neither NMP nor NEP were to be available, more significant and time-consuming efforts could be required in order to find a replacement.

4.3.1.3 Alternatives using water borne coatings

In the case of waterborne parquet varnish, one company investigated replacing NMP with other solvents including methyl diproxitol butyldiglycol. Difficulties noted were not enough open time and levelling properties, and they concluded that they needed to use NMP to have a commercially viable product on the market, and therefore a suitable alternative has not been identified.

Another company considering replacing NMP with waterborne polyurethane dispersion paint without solvents noted that this is commercially available with a replacement cost of approximately €800,000 (the company currently uses around 100 tonnes of NMP and has investigated formulation across over a thousand formulations).

4.3.1.4 Dimethyl sulfoxide (DMSO)

One company has undertaken a study for the use of DMSO as alternative. This substance is not currently used commercially. The technical constraints noted for the use of this substance were that the melting point is too high. In addition, DMSO has slower evaporation and other mixing properties. They anticipated that there would be process redesign and additional work required if this alternative was to be used, but this had not yet been identified.

Another company which uses NMP for printing as part of a formulated screen ink, noted that DMSO has been shown to have higher environmental and/or health risk than NMP. One company suggested that DMSO is of much greater concern than NEP, owing to the ability to dissolve and transport other substances through gloves and skin, potentially increasing systemic exposures to other substances.

4.3.1.5 Hydrocarbon solvent

For one company, use of a new solvent would require a lengthy qualification process for customers and supply chains to re-qualify new products. In some applications, reformulation and additional process development may be required to ensure the end product meets customers' performance requirements.

4.3.1.6 Ketone solvents

These solvents are commercially available and are already in place, but it is understood that they are not considered as technically effective as NMP.

4.3.1.7 Glycolethers (DPM)

One company has used these as alternatives, but noted they are not sufficiently effective unlike solvents. It is expected that the product, wherein NMP is used, has to be approved according to the Biocidal Products Directive (BPD) Product Type 8 and that the time frame for replacing NMP would be at least 3-4 years. The company expects that a new product will need to be formulated and that this will be costly.

4.3.1.8 Dimethylformamide (DMF) and dimethylacetamide (DMAC)

One company noted that DMF and DMAC could be used as solvents but these were classified as toxic under the Dangerous Substances Directive before NMP. They report that these are not currently commercially available. One main technical constraint noted was the specialist engineering polymers used by the company are only soluble in a few solvents. They suggest that no process redesign would be required if DMF and DMAC were accepted by the EU and their customers. Some additional work would be required, with possible reformulation to ensure viscosity and application characteristics remain the same. They expect the time required would be one year to replace NMP with an alternative. They note that DMF and DMAC would be a less expensive option, but that any other solvent that might be used would be more expensive.

4.3.1.9 Other Alternatives:

One company that used NMP in the production of polymer dispersions for floor finishes containing PU PU/AC, started work to replace NMP with other solvents in the dispersion production 8 years ago. Alternatives have reportedly been implemented over the past 5-6 years for their products, with only one product and a few tonnes of NMP remaining (previously they used 160 t/y NMP). The choice of substitute was a very different substance; details of the substance used were not provided, but they noted that dispersions were being produced without the use of solvents, stating that there was no requirement for NMP in waterborne polyurethane and polyurethane/acrylate copolymer floor finishes. They noted no technical constraints to using the alternatives. It reportedly took 2-3 years for the company to replace NMP.

Alcoxy alkyl amide is used in some mixtures. Use of this substance would require potentially 1 year of R&D work and 3-4 years of customer qualifications according to one of the companies responding.

Gamma butyrolactone (CAS 96-48-0) can reportedly be used in polyimide precursor coatings. Tests undertaken by one company showed that the solubility of this substance was not good enough for polyamic acids and R&D could not find any safer solvents on the market with a high enough solubility to replace NMP.

One company noted that N-ethyl-2-pyrrolidone (CAS 2687-91-4) and 1,3-Dimethyl-2-imidazolidinone (CAS 80-73-9) were considered as alternatives. However, the costs of using these substances were 10 times that of NMP, and therefore not considered as viable.

One company importing NMP in inks noted that 2-Pyrrolidone (CAS 616-45-5) is currently under consideration but has been not yet been tested as an alternative in finished inks. According to the company, this seems to pose only a moderate technical risk; although they noted that further work was pending in relation to the classification from the REACH Article 10 registration and/or the C&L public inventory from the C&L notification process.

4.3.2 Electronics

One electronics company which uses NMP in mixtures for removal of photoresist in the semiconductor manufacturing process noted that other solvent alternatives are available for the sector, notably polyimides, which are solvent based alternatives and are under evaluation. These can be used as photoresist strippers and casting solvents for polyimide resin based formulations. These substances are reportedly not yet commercially available and have not yet been fully tested.

Key problem areas in replacing NMP that have been highlighted include:

- Replacement of NMP for many downstream users depends on R&D of raw-material suppliers to find an alternative.
- There are concerns that alternatives pose higher or equivalent health or environmental hazards. Many of the alternatives that could be considered to be technical feasible (DMSO, Sulfolane, GBL, PGMEA, Ethyl lactate, glycol ethers) have reportedly been shown to have higher risks.
- Alternatives may be available but process performance must be verified to be equivalent in several cases.
- For some firms, replacement requires development of alternative processes and process requalification. Replacements may be possible for certain chemicals; however, reformulation and requalification of the process could take anywhere from 1 to 4 years.
- Process requalification would be required for the entire supply chain in some instances. In some cases, identifying alternatives for NMP will not just require changing the solvent, but also identifying and qualifying new resins.

- Finding and qualifying substitutes is complex, requires partnerships within the supply chain and is process, technology and company specific.
- Downstream customer approval of the process change may also be required and is a lengthy process. In semiconductor manufacture, the replacement of NMP depends on the use of NMP (e.g. is it a straight solvent, part of a wet clean formulation, a casting solvent for resist).
- The main technical constraints noted were that product qualification is required and there may be an impact on product characteristics. Some companies noted that converting to alternative substances is a very risky, costly and time consuming process for the end user. Alternatives are also generally considered to be more expensive.
- It has also been highlighted that replacement may affect supply line stability.
- One consultee suggested that restrictions and disproportionate bans on chemicals within the EU may mean that semiconductor manufacturing and supplier industries will be hampered from further innovating.
- R&D studies were performed by one company in 2006, but the stability of the formulations with these solvents was not viable, so it is not suitable to use within the semiconductor processes where the company products were used.
- Other alternatives noted for use in polyimide precursor coatings in the semi-conductor industry were:
    - N-formyl piperidine (CAS 2591-86-8);
    - Dimethylpropionamide (CAS 758-96-3);
    - 1,3 dimethyl-2-imidazolidinone (CAS 80-73-9);
    - 1,1,3,3 Tetramethylurea (CAS 632-22-4).
- It is of note that, as with use in coatings, several companies noted NEP as a potential alternative to NMP and that the industry has highlighted concerns with this substance also potentially being classified as a reproductive toxin in the future.

4.3.3 Cleaning products

Of the organisations classified as downstream users of NMP which provided information, three use NMP in cleaning solvents and three in paint remover solvents.

The following points are some key findings:

- One company noted that an alternative solvent could not be found with the same cleaning results as NMP.
- One company undertook a 4 year laboratory trial programme to find an alternative to NMP (2005-2009) in paint remover, but a suitable alternative was not found with the same solvent strength. The company also trialled NEP (CAS 2687-91-4), with the outcome that NEP was found to be a less effective solvent with a significantly higher cost. They also found that the adding and mixing process using NEP was slower and longer than that for NMP.

- One company using NMP in surface cleaners and photoresist remover is considering an analogous preparation free of NMP, with similar capabilities, but which has not yet been tested in the field.

4.4 Conclusions

Overall, it appears that the industry has already undertaken significant efforts to identify replacements for NMP. It is clear that some companies have been successful in doing this, given the number of companies that have indicated that they have removed NMP from their formulations. It is also clear that much work to identify alternatives is ongoing, largely as a result of the classification of NMP as a reproductive toxicant.

For the main uses of NMP in coatings, electronics and cleaning products, the most frequently identified potential alternative is NEP. Whilst there would still be challenges in replacing NMP with NEP (due to customer approvals, further testing, etc.), it appears that this substance has the greatest potential in technical and economic terms as a replacement for NMP. In particular, whilst it certainly does not appear to be a drop-in substitute for all applications, it seems to have the broadest spectrum of uses in which it could be used to replace NMP.

However, many of the companies responding have highlighted the potential future classification of NEP as a reproductive toxicant. Understandably, therefore, there is a concern that this may not be a suitable alternative in the long term.

There is a variety of other alternatives that have been tested by companies providing information for the current assessment. Some of these seem to be suitable, at least for some applications, although a greater number of respondents have expressed concerns regarding their technical suitability as replacements. However, none of these seem to be able to replace NMP in as many applications as NEP and it is clear that some companies do not currently have a solution identified in the event that they are no longer able to use NMP or NEP.

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In addition to the above, significant additional information was received from companies and other organisations.

A. ANNEX 1: INFORMATION ON USES FROM OECD SIDS DATASET

Table 21: INFORMATION ON USES FROM OECD SIDS DATASET

Type	Category	Details
Industrial	Agricultural industry	Crop protection agents
Industrial	Chemical industry: used in synthesis	Extraction of hydrocarbons, and as a solvent in the synthesis of acetylene.
Industrial	Chemical industry: used in synthesis	Used in the extraction of unsaturated/aromatic compounds, the purification of acetylenes, olefins, and diolefins, gas purification, and aromatic extraction from feedstocks
Industrial	Chemical industry: used in synthesis	Initial product for chemical syntheses.
Industrial	Electrical/electronic engineering industry	Cleaning, de-fluxing, edge bead removal, photoresist stripping.
Industrial	Fuel industry	Petroleum processing
Industrial	Fuel industry	Petrochemical processing. Lube oil processing, natural and synthetic gas purification. Auto fuel system cleaners (30-40 % NMP).
Industrial	Paints, lacquers and varnishes industry	Used in paint removers and stripping paints to reduce paint viscosity, and to improve the wettability of paint systems.
Industrial	Paints, lacquers and varnishes industry	Paint industry
Industrial	Paper, pulp and board industry	Printing ink industry
Industrial	Polymers industry	Spinning agent for polyvinyl chloride
Industrial	Other: coatings	High temperature coating, urethane dispersions, acrylic and styrene latexes
Industrial	Other: microelectronics industry plastic solvent applications	
Use	Intermediates	Must not be used in cosmetics products
Use	Pesticides	
Use	Pharmaceuticals	As a penetration enhancer for a more rapid transfer of substances through the skin
Use	Photochemicals	
Use	Solvents	N-Methylpyrrolidone has a fairly mild, amine-like odor, and is miscible with water and most organic solvents. It has a good solvency for cellulose ethers, butadiene, acrylonitrile copolymers, polyamides, polyacrylonitrile, waxes, polyacrylates, vinyl chloride copolymers, and epoxy resins.
Use	Solvents	Solvent for resins, acetylene, etc.
Use	Solvents	Solvent for carbon dioxide removal in ammonia generators, polymer preparation and processing acetylene. Solvent for extraction of BTX aromatics and butadiene
Use	Solvents	Approved as a solvent for slimicide application to food packaging materials

Type	**Category**	**Details**
Use	Solvents	Agricultural chemicals: Solvent for herbicide, pesticide and fungicide formulations. Found in herbicides, fungicides, and pesticides (<7 % NMP).
Use	Surface active agent	Pigment dispersant
Use	Other: extracting agent	
Use	Other: formulation agent	
Use	Other: gas scrubber absorption aid	
Use	Other: gas scrubbing	Acetylene recovery [illustration of BASF process given]
Use	Other: industrial and consumer cleaners	Paint removers, floor strippers, graffiti remover, industrial degreasing, injection head and cast-molding equipment cleaning. Sources such as the National Environmental Trust (2004) indicate that products purchased by consumers which may contain NMP include household cleaning agents, adhesives and sealants. The U.S. National Institutes of Health Household Products Database indicates that NMP is found in various paint removers (40-70 % NMP), various floor cleaners (10 % NMP)
Use	Other: substitute for methylene chloride	
Use		The Swiss Product Register from April 2005 states a total number of 2432 registered NMP-containing products on the Swiss market: 2018 products for industrial and 414 products for consumer use. The number of products containing NMP concentrations of 0.1, 1, 10, 50 and 100 % are given with 278, 417, 907, 286 and 130 for industrial use and with 34, 108, 209, 56 and 7 for consumer use, respectively. Products containing the highest NMP concentrations of up to 100 % are reported for cleaning agents, hardeners, paints, dyes, lacquers, sealing masses, photographic chemicals, fungicides, products for galvanization and solvents. Most of the NMP-containing products are used for paints, dyes, lacquers (39 %), followed by cleaning agents (14 %), glues, surfaces, cements, sealing masses (11 %), auxiliary material (11 %) and solvents, degreasers, diluters, (paint) strippers (9 %)
Use		The Danish Product Register of 2004 includes 809 products with a total quantity of 609 tons NMP per year. The total number of products containing NMP concentrations of 0-2 %, 2-20 %, 20-50 % and 50-100 % are 401, 270, 74 and 64 respectively. NMP is used in a variety of materials including adhesives, cleaning agents, colouring agents, construction materials, agricultural chemicals and solvents
Use		The Swedish Products Register of 2003 quantifies the total number of registered NMP-containing products on the Swedish market with 471, resulting in a total volume of 1,264 tons NMP per year. The total number of consumer products is given with 73, containing the following concentrations (weight percentage) of NMP: 0 – 2 % (29 products), 2 – 20 % (32), 20 – 80 % (11) and 80 – 100 % (1). The total number and corresponding production quantity of products containing 0 – 2 %, 2 – 20 %, 20 – 80 % and 80 – 100 % NMP is reported to be 128 (21 tons/year), 250 (403 tons/year), 62 (260 tons/year) and 31 (580 tons/year), respectively (Swedish Products Register, 2003).

Source: OECD (2009)

B. ANNEX 2: INFORMATION FROM NATIONAL PRODUCT REGISTERS

Latvia

Table 22: Imports to Latvia of NMP on its own and in mixtures (Latvian MSCA, 2010)

Year	Substance as such (NMP in t)	In mixtures (NMP in t)
2003	0.4	2.5
2004	-	3.8
2005	6.6	3.8
2006	4.2	28.5
2007	10.8	36.5
2008	-	32.1
2009	-	17.7

Table 23: Imports to Latvia of specific product types for recent years (quantities in tonnes) (Latvian MSCA, 2010)

Trade name	Category	Conc (%)	2003	2004	2005	2006	2007	2008	2009
'ASTIN' TRAIPU LIKVIDĒŠANAS SALVETES	Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	2.5		1					
ACTICIDE SR 1335	Wholesale of non-agricultural intermediate products, waste and scrap	40 - 40					0.2	0.6	
AQUIDOL D1900	Manufacture of furniture; manufacturing n.e.c.	2.5 - 5					0.58	1.61	2.17
ATEPOL B-U-73	Manufacture of man-made fibres	1 - 5					0.4	0.2	
ĀTRI ŽŪSTOŠĀ PARKETA LAKA	Painting and glazing	6.1			0.17	0.12			
BETONGLAKK	Agents involved in the sale of timber and building materials, General construction of buildings and civil engineering works	1 - 5						0.05	
BYK-410	Manufacture of paints, varnishes and similar coatings, printing ink and mastics	30 - 50		0.4	0.4	0.4			
BYK-410 STROMBERG-BALTICA	Wholesale of non-agricultural intermediate products, waste and scrap	48 - 48				0.7		0.2	0.2
BYK-420	Wholesale of non-agricultural intermediate products, waste and scrap	48 - 48				0.2		0.4	0.7
CELCO PROF BEST LAKA	General construction of buildings and civil engineering works, Retail sale of hardware, paints and glass, Wholesale of wood, construction materials and sanitary equipment	1 - 5				0.1			
CELCO PROF SOLIDO - KRĀSA	Painting and glazing	1 - 5						0.09	
CELCO PROF SOLIDO - LAKA	Painting and glazing, Wholesale of wood, construction materials and sanitary equipment	1 - 5			0.78				
DETAĻU MAZGĀŠANAS LĪDZEKLIS G08	Maintenance and repair of motor vehicles	1 - 5		0.1					
DRYMAX	Manufacture of paints, varnishes and similar coatings, printing ink and mastics	30 - 60					0.18	0.2	
KRĀSA PRINTERIM ARIZONINK	Wholesale trade and commission trade, except of motor vehicles and motorcycles	0 - 10				0.09			

Trade name	**Category**	**Conc (%)**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**
KRĀSA PRINTERIM MUTINK TOUCAN	Wholesale trade and commission trade, except of motor vehicles and motorcycles	0 - 10				0.06			
KRĀSA PRINTERIM XAAR	Wholesale trade and commission trade, except of motor vehicles and motorcycles	0 - 10				0.49	1.01		
LAKA OLYMPIA	Painting and glazing	5 - 10				5.2	4.8	1.66	
LAKA SYNTEKO BEST 1643-45	Painting and glazing	1 - 5				0.16			
LAKA SYNTEKO EXTRA 1609-11	Painting and glazing	5 - 10				0.02			
LAKA SYNTEKO PRO 1625-27	Painting and glazing	1 - 5				0.39	0.05		
MAKROFLEX REMOVER	Joinery installation	50-100	0.23						
MAPECOAT W 65, DIVKOMPONENTU KOMPONENTE B	Agents involved in the sale of timber and building materials, General construction of buildings and civil engineering works	0 - 0.2						1.58	0.27
MR. MUSCLE OVEN	Wholesale of other household goods	1 - 4	0.49	0.48	0.49				
NEOCRYL XK-98	Manufacture of paints, varnishes and similar coatings, printing ink and mastics	6.9				5.3			
NEOPAC E-106	Manufacture of paints, varnishes and similar coatings, printing ink and mastics	6.9				6.6	23.1	21	3.2
NEOPAC E-111	Manufacture of paints, varnishes and similar coatings, printing ink and mastics	1.7				1.1	3.2		
PRIME ECO PENR	Other wholesale, Other retail sale in specialized stores	3 - 15						0.59	7.84
PRIME ECO PENR CLEANING FLUID	Other wholesale, Other retail sale in specialized stores	3 - 10						0.01	0.22
PRIME ECO PENR V2,0	Other wholesale, Other retail sale in specialized stores	3 - 15							0.01
PRIME PRJ3	Other wholesale, Other retail sale in specialized stores	3 - 15						0.34	0.44
PRIME PRSD	Other wholesale, Other retail sale in specialized stores	0 - 10						0.01	0.07
PRIME PRTO	Other wholesale, Other retail sale in specialized stores	0 - 10							0.15
PROTECT	Industrial cleaning	6 - 6				0.18	0.36	0.38	0.18

Trade name	**Category**	**Conc (%)**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**
HOUSEHOLD SPRAY									
SPANSCOUR GR	Manufacture of textiles	10 - 20				0.24			
SPANSCOUR YP	Manufacture of textiles	10 - 20				2.28	2.16	1.44	0.96
SPECTRAINK	Other wholesale, Other retail sale in specialized stores	0 - 10						0.63	0.32
SYNTEKO BEST - LAKA	Painting and glazing, Wholesale of wood, construction materials and sanitary equipment	1 - 5	1.07	1.16	1.95	0.34			
SYNTEKO BEST 2 KOMPONENTU	General construction of buildings and civil engineering works, Retail sale of hardware, paints and glass, Wholesale of wood, construction materials and sanitary equipment	1 - 5				3.77	0.42		
SYNTEKO EXTRA	General construction of buildings and civil engineering works, Retail sale of hardware, paints and glass, Wholesale of wood, construction materials and sanitary equipment	5 - 10				0.17			
SYNTEKO EXTRA 20, 90 - LAKA	Painting and glazing, Wholesale of wood, construction materials and sanitary equipment	5 - 10	0.73	0.61		0.38			
VIENKOMPONENTA ŪDENĪ ŠĶĪSTOŠA DILUMIZTURĪGA LAKA KOKA GRĪDAS LAKOŠANAI, SYNTEKO EXTRA	Floor and wall covering	5 - 10				0.24			
XAAR	Other wholesale, Other retail sale in specialized stores	0 - 10							0.8
XAAR-128	Other wholesale, Other retail sale in specialized stores	0 - 10						0.66	
XAAR-500	Other wholesale, Other retail sale in specialized stores	0 - 10						0.43	0.15
Total			2.52	3.75	3.78	28.52	36.45	32.09	17.67

Malta

The following uses were reported to the Maltese MSCA (2010):

- One company imports and distributes around 200 kg of NMP per year for cleaning electronic components.
- Another company imports a mixture, consisting of NMP, utilized in automatic paint spraying equipment with Local Extraction Ventilation.
- Finally a third company imports a mixture with traces of NMP, used as a wafer adhesive (microelectronics).

Norway

Table 24: Declaration of chemical products for Norway (Norway MSCA, 2010)

Product type	2008 (tonnes)	2009 (tonnes)
Additives for paint and varnishes	0.01	
Adhesives	0.16	0.07
Biocide	0.41	0.87
Cleaning/washing agents	1.78	2.56
Fire extinguishing agents	0.52	0.28
Paint and varnish removers	28	15
Paint, lacquers and varnishes	9.53	6.34
Plant protection - agricultural pesticides	22.5	
Printing inks	0.32	0.18
Solvents	10.85	2.92
Total	**74.07**	**28.22**

Sweden

Table 25: Imports and exports of NMP in Sweden in tonnes (Swedish MSCA, 2010)

Product type	Imported to Sweden (2008)	Exported from Sweden (2008)
As a raw material (NMP 'as such')	164	47
In chemical products	290	80

Table 26: Imports and manufacture of products containing NMP in Sweden in 2008 (Swedish MSCA, 2010)

Product type	Imported (NMP in t)	Manufactured (NMP in t)
Paints and varnishes	102	54
Paint and varnish removers	3	127
Binders	69	-
Pesticides	39	-
Glues	37	< 1
Raw material for paint	20	< 0.1
Cleaning agents	4	11
Raw material for textile industry	8	-
Lubricants	< 1	2
Polishing agent	1	< 1
Car care products	< 1	-
Other types of products	6	1

United Kingdom

Data collected between 2003 and 2004 (which therefore may not be representative of the current market) indicates that NMP was used on at least four sites as a paint stripper for graffiti removal and seven sites as a solvent in degreasing tanks specifically in the aerospace industry.

C. ANNEX 3: CONFIDENTIAL INFORMATION ON MANUFACTURE, IMPORT AND SALES

D. ANNEX 4: ESTIMATES OF ENVIRONMENTAL EMISSIONS (CONFIDENTIAL)

E. ANNEX 5: ESTIMATES OF OCCUPATIONAL RELEASES AND EXPOSURE (CONFIDENTIAL)

Report on the State of the Art for N-Methyl-2-pyrrolidone in the Production of Lithium-ion Battery Cells

Report on the state of the art for N-Methyl-2-pyrrolidone in the production of lithium-ion battery cells

Executive Summary

This report describes the current state of the art for lithium-ion battery cell production and the need to use N-Methyl-2-pyrrolidone (NMP) as a solvent in cathode manufacturing.

First, the physical and chemical properties as well as the environmental and health risks of NMP are presented. In order to assess the possibility of elimination or substitution, the current technological status of cathode production is described with focus on the use of NMP as a solvent. For the evaluation of an elimination of NMP and thus a solvent-free cathode production, the dry coating process and the production of the All-Solid-State batteries are explained. Both technologies show promising results due to stable coatings with good electrochemical properties. However, the coatings have only been produced on a laboratory scale so far. The implementation of these technologies on an industrial scale is currently not possible due to process sequences and process times. The substitution of NMP in industrial scale by water or other organic solvents is currently not feasible, either. There are three main problems when using a water-based mixing process: Agglomeration of the NMC particles, decreased wetting behaviour of the slurry on the aluminium foil and limited stability of NMC due to the formation of LiOH groups on the NMC particle surface. As a result, cathode production on an industrial scale must be performed according to the current state of technology with NMP as the solvent, as there are currently no alternatives. The report demonstrates that remaining health and environmental risks can be managed by certain precautions. Taking the current status of cell chemistry technologies and production technologies into account, it is estimated that a technology change in industrial battery cell production could take place within the next 5-10 years.[1]

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[1] Assessment of the Chair of Production Engineering of E-Mobility Components, RWTH Aachen University, 2019.

Contents

1 Characteristics of NMP

1.1 Physical and Chemical characteristics

N-Methyl-2-pyrrolidone is a colourless hygroscopic, air and light sensitive organic liquid with a mild amine smell. It is soluble in water as well as in most organic solvents including alcohols, ethers, aromatics, and chlorinated hydrocarbons. It has a relatively low vapour pressure of 0.7 mbar at 25 °C and therefore evaporates slowly.[2]

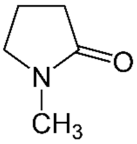

Figure 1: Structural formula of N-Methyl-2-pyrrolidone.

NMP is a very weak base, a 10% aqueous solution shows a pH value of 7.7 to 8.0, the compound is chemically very stable. The lactam ring can only be opened with strong acids and bases, resulting in 4-*N*-Methylaminobutyric acid. NMP is only stable to oxygen to a limited extent, with oxidation starting at the 5-position and *N*-Methylsuccinimide being formed via various intermediate stages. NMP forms flammable vapour-air mixtures above the flash point of 91 °C. The explosion range lies between 1.3 vol.% as the lower explosion limit and 9.5 vol.% (393 $g \cdot m^3$) as upper explosion limit. A correlation of the lower explosion limit with the vapour pressure function results in a lower explosion point of 79 °C. The limiting oxygen concentration at 200 °C is 8.1 vol.%. The limiting gap width was determined to be 0.93 mm. This results in an assignment to explosion group IIA. The ignition temperature is 265 °C. The substances therefore falls into temperature class T3. NMP decomposes at a temperature above 300 °C, producing carbon monoxide, carbon dioxide, nitrous gases and hydrogen cyanide. The conductivity is at $2 \cdot 10^{-6}$ $S \cdot m^{-1}$.[3] An overview of the physical and chemical properties is given in Table 1.

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[2] O. Ajayi, E. Harriman, N-Methyl Pyrrolidone: Chemical Profile, Technical Report No. 36, 1996, The Massachusetts Toxics Use Reduction Institute, University of Massachusetts Lowell

[3] Technical Data Sheet, NMP, Hefei TNJ Chemical Industry Co., Ltd, 2019.

Table 1: Overview of physical and chemical properties of N-Methyl-2-pyrrolidone (99%).[4]

Name	*N*-Methyl-2-pyrrolidone 1-Methylpyrrolidin-2-one *N*-Methylpyrrolidone *N*-Methylpyrrolidinone Pharmasolve
CAS number	872-50-4
Molecular formula	C_5H_9NO
Molecular weight	99.133 $g{\cdot}mol^{-1}$
Density	1.0300 $g{\cdot}cm^{-3}$ at 25 °C
Viscosity	1.67 mPa at 20 °C
Melting point	-24 °C
Boiling point	202 °C
Flash point	91 °C
Autoignition temperature	346 °C
Explosion limits	1.3 vol.% (lower) 9.5 vol.% (upper)
Vapour pressure	0.7 mbar
Vapour density	3.4 (Reference: Air = 1.0)
Surface tension	40.7 $mN{\cdot}m^{-1}$
Solubility in	Water (1000 $g{\cdot}cm^{-3}$), ethanol, acetone, diethylether, ethyl acetate, chloroform, benzene
Vapour pressure	0.7 mbar at 25 °C
pH (100 $g{\cdot}L^{-1)}$	7.7-8.0

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[4] Safety Data Sheet, ThermoFisher Scientific, 2019

1.2 Environmental and health impacts

The following chapter lists the hazard information for NMP in tabular form.

Table 2: Hazard Statements of N-Methyl-2-pyrrolidone (99%).[5]

Pictograms	 Irritant  Health hazard
Skin Corrosion/irritation	Category 2 H315 – Causes skin irritation
Serious Eye Damage/Eye Irritation	Category 2 H319 – Causes serious eye irritation
Reproductive Toxicity	Category 1B H360D – May damage the unborn child
Specific target organ toxicity	Category 3 H335 – May cause respiratory irritation
Toxicity	Threshold Limit Value estimated at 100 ppm[6]
Special hazards	Combustible material. Containers may explode when heated. Keep product and empty container away from heat and sources of ignition.

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[5] Safety Data Sheet, ThermoFisher Scientific, 2019.

[6] O. Ajayi, E. Harriman, N-Methyl Pyrrolidone: Chemical Profile, Technical Report No. 36, 1996, The Massachusetts Toxics Use Reduction Institute, University of Massachusetts Lowell (value for 8 working hours).

Table 3: Toxicological parameters of N-Methyl-2-pyrrolidone (99%).[7]

Toxicity	Threshold Limit Value estimated at 100 ppm[8]
LD 50 Oral	3914 $mg \cdot kg^{-1}$ (Rat)
LD 50 Dermal	8 $g \cdot kg^{-1}$ (Rabbit)
LC 50 Inhalation	>5.1 $mg \cdot L^{-1}$ (Rat) 4hr
Fresh water PNEC[9]	0.25 $mg \cdot L^{-1}$
Fresh water sediment PNEC	0.805 $mg \cdot kg^{-1}$
Marine water PNEC	0.025 $mg \cdot L^{-1}$
Marine water sediment PNEC	0.0805 $mg \cdot kg^{-1}$
Food chain PNEC	0.00167 $g \cdot kg^{-1}$
Microorganisms in sewage	10 $mg \cdot L^{-1}$
Soil (Agriculture)	0.138 $mg \cdot kg^{-1}$
Hazardous Combustion products	Carbon monoxide (CO), carbon dioxide (CO_2), nitrogen oxides (NOx), peroxides

Table 4: Precautionary Statements of N-Methyl-2-pyrrolidone (99%).[10]

Skin Corrosion/irritation	P302 + P352 – Wash with plenty of soap and water
Serious Eye Damage/Eye Irritation	P337 + P313 – Get medical advice / attention
Reproductive Toxicity	P312 – Call a Poison Centre or doctor / physician if you feel unwell
Specific target organ toxicity	P304 + P340 – Remove to fresh air and keep at rest in a position comfortable for breathing
Personal precautions, protective equipment and emergency procedure	Use personnel protective equipment. Ensure adequate ventilation. Keep people away from and upwind of Spill/leak. Evacuate personnel to safe areas. Remove all sources

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[7] Safety Data Sheet, ThermoFisher Scientific, 2019.
[8] O. Ajayi, E. Harriman, N-Methyl Pyrrolidone: Chemical Profile, Technical Report No. 36, 1996, The Massachusetts Toxics Use Reduction Institute, University of Massachusetts Lowell (value for 8 working hours).
[9] Predicted No Effect Concentration.
[10] Safety Data Sheet, ThermoFisher Scientific, 2019.

other	P280 – Wear protective gloves / protective clothing / eye protection / face protection P332 + P313 – If skin irritation occurs: Get medical advice / attention

Studies in rats on the toxic effect of NMP show a negative influence on the foetus in pregnancy and suggest mutagenic effect.[11],[12] In summary, it must be assumed that NMP is mutagenic and causes skin, eye and respiratory irritations.

Nevertheless, there will be no environmental impact from NMP as long as the quantities of NMP released are kept below the levels shown in Table 5.

Table 5: Environment impact of N-Methyl-2-pyrrolidone (99%).[13]

	Threshold value	Environmental compartment	Exposure duration
PNEC[14]	5 $mg \cdot L^{-1}$	water	Intermittent release
PNEC	0.25 $mg \cdot L^{-1}$	Fresh water	Short term (one time)
PNEC	0.025 $mg \cdot L^{-1}$	Seawater	Short term (one time)
PNEC	10 $mg \cdot L^{-1}$	Sewage treatment plant (STP)	Short term (one time)
PNEC	1.09 $mg \cdot kg^{-1}$	Fresh water sediment	Short term (one time)
PNEC	0.109 $mg \cdot kg^{-1}$	Seawater sediment	Short term (one time)
PNEC	0.07 $mg \cdot kg^{-1}$	Soil	Short term (one time)

Based on different studies, NMP has been classified as readily biodegradable under aerobic conditions, as under various conditions at least 95% of NMP was biodegraded within a maximum of 2 weeks.[15,16]

As the calculated bio-concentration factor of NMP is 0.16, only a minor potential for bioaccumulation is to be expected (cf. Table 6).

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[11] Hass et al., Developmental Toxicity of Inhaled N-Methylpyrrolidone in the Rat, Pharmacology & Toxicology, 76, 406-409, 1995.

[12] Saillenfait et al., Development toxicity of N-methyl-2-pyrrolidone administered orally to rats, Food and Chemical Toxicology, 40, 1705-1712, 2002.

[13] Safety Data Sheet, Roth, P052, 2019.

[14] Predicted No Effect Concentration.

[15] N-Methyl Pyrrolidone: Chemical Profil, Technical Report No. 36, University of Massachusetts Lowell, 1996.

[16] N-Methyl-2-Pyrrolidone, Concise International Chemical Assessment Document 35, World Health Organization, 2001.

Table 6: Rough estimation of bioconcentration factor values.[17]

BCF	
<1	Non-bioaccumulative
1-10	Weakly bioaccumulative
10-100	Moderately bioaccumulative
100-1000	bioaccumulative
1000-5000	Highly bioaccumulative
>5000	Very high bioaccumulative

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[17] www.bgbau.de, 2020.

2 Applications and advantages in LiB production

N-Methyl-2-pyrrolidone (NMP) is typically used in the manufacturing process of lithium-ion batteries as a solvent for cathode slurries to obtain a stable suspension. In a mixing process, the cathode active material and conductive additives, the binder (typically PVDF) and the solvent NMP are mixed together for producing the so-called slurry. $LiCoO_2$ (LCO), $LiMn_2O_4$ (LMO), LiFePO4 (LFP) and $LiNi_xMn_yCo_zO_2$ (NMC) are typical cathode materials that are used in the production of lithium-ion batteries.[18] First, the solids are premixed dry, then the solids are dispersed homogeneously in the solvent and agglomerates are dissolved. Depending on the slurry components, this process step can be carried out in different types of mixers with different mixing tools. To avoid air inclusions in the slurry, mixing is usually done under vacuum, which requires a closed system. The slurry is then transferred via a sealed pump system to the coating plant and is applied to the electrode carrier foil by a coating tool such as a slot die. The used composite structure of the active material, binders, and conductive additives coated on the current collector foil requires careful control of colloidal chemistry, adhesion, and solidification. The use of NMP requires a closed system for all process steps to prevent contamination of the environment with NMP. After the coating process, the NMP is totally removed from the cathode material during the subsequent drying process. With the help of suitable exhaust air systems, NMP can be collected and can be purified for reuse.

As NMP has the properties listed above, handling requires dedicated safety standards and contact with strong oxidizing agents, strong acids, strong bases, heat, flames, sparks hot surfaces and sources of ignition should be avoided. The flammable vapours of NMP require all processing equipment during the production of electrodes to be explosion proof, meaning all spark-producing electrical components need to be shielded against vapour concentrations.

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[18] Li et al. Cathode Manufacturing for Lithium-Ion Batteries, Handbook of Battery Materials, Wiley-VCH-Verlag, 2011.

3 Evaluation Approach

Because *N*-Methyl-2-pyrrolidone (NMP) has the described harmful properties, the long-term goal should be to eliminate or at least replace NMP with a less hazardous solvent in battery cell production. Therefore, chapter 3.1 investigates LIB production technologies that help to eliminate the usage of NMP. If elimination is not possible, a substitution of NMP by other solvents in LIB cell production is discussed in the following chapter. An extensive literature research was carried out to highlight the state-of-the-art research on solvents in LIB production. Finally, a remaining risk assessment will be conducted for processes using NMP as a solvent.

3.1 Elimination

Commercial Li-ion battery electrodes are manufactured by coating a metal foil (current collector) with a slurry as described in chapter 2 (Applications and advantages in LiB production). In order to assess whether NMP can be eliminated in the LIB production, solvent-free manufacturing technologies are considered. Studies using pulsed laser and sputtering[19] deposition have shown that dry particle deposition is possible in general, but these processes are not suitable for commercial applications due to prolonged manufacturing time.[20,21,22,23] A solvent-free dry spray manufacturing process was also carried out in a study on a laboratory scale with promising results, which, however, must be further developed and evaluated for industrial production.[24] From similar technology development activities, one can say that this will take at least 5-10 years until this technology is ready for mass production.

In addition to that, the usage of environmentally hazardous solvents can be avoided by a complete technological change, for example the use of All-Solid-

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[19] Sputtering: Sputter deposition is a physical vapor deposition method of thin film deposition. This involves ejecting material from a target that is a source onto a substrate

[20] Yan et al., Li-rich Thin Film Cathode Prepared by Pulsed Laser Deposition, Sci. Rep., 3, 3332, 2013.

[21] Koike et al., Preparation and performance of higly porous layered LiCoO2 films for lithium batteries, J. Power Sources, 174, 976-980, 2007.

[22] Bagetto et al., Fabrication and characterization of Li-Mn-Ni-O sputtered thin film high voltage cathodes for Li-ion batteries, J. Power Sources, 211, 108-118, 2012.

[23] Chiu, Lithium cobalt oxide thin films deposited at low temperature by ionized magnetron sputtering, Thin Solid Films, 515, 4614, 2007.

[24] Ludwig et al., Understanding Interfacial-Energy-Driven Dry Powder Mixing for Solvent-Free Additive Manufacturing of Li-ion Battery Electrodes, Adv. Mater. Interfaces, 2017 (1700570).

State batteries. For the production of the cathode in All-Solid-State batteries theoretically different materials like LFP, NMC and LCO can be used. In practice only LCO as cathode material in combination with LLZO as electrolyte shows sufficient stability and performance. These two materials are converted separately into a homogenous melt by means of twin screw extruder and are then calendered to a composite. By using this method, no solvent is required in the production of the cathode material. The cathode/electrolyte composite and the anode, usually metallic lithium, are pressed together by rolls. Alternatively, the All-Solid-State battery can be combined by high-frequency sputtering of the cathode and electrolyte powder and subsequent sintering. Both processes do not require a solvent, consequently NMP can be eliminated with the application of this technology. Nevertheless, challenges in material compatibility and industrial manufacturability – as sputter deposition methods usually show very low tact times – inhibit the entry into industrial production for All-Solid-State batteries.[25]
In our estimation, the developments of the technologies listed here for the elimination of NMP as a solvent in cathode production require a further 5-10 years before they can be carried out on an industrial scale.[26]

3.2 Substitution

For a substitution of NMP as solvent of the active material for the cathode, the properties of the solvents must be compared with each other. Due to the low costs, environmental compatibility as well as non-flammability, the use of water as a solvent in cathode production mostly with regard to lithium ion phosphate (LFP) as active material is often discussed.[27,28] This is due to the much higher stability of LFP to water compared to other cathode materials such as NMC. The lower specific capacity of LFP (165 mAh·g^{-1}) in comparison to NMC (NMC 111: 180 mAh g^{-1}; NMC 811: >200 mAh·g^{-1}) as well as the lower average voltage (LFP: 3.4 V; NMC: 3.7 V) and high quality demands from automotive

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[25] Heimes et al., Production of All-Solid-State battery cells, Printed by PEM of RWTH Aachen and VDMA, 2018.

[26] Assessment of the Chair of Production Engineering of E-Mobility Components, RWTH Aachen University, 2019.

[27] Li et al., Superior Performance of $LiFePO_4$ Aqueous Dispersions via Corona Treatment and Surface Energy Optimization, J. Electrochem. Soc., 159 (8), 2012.

[28] Daniel, Lithium Ion Batteries and Their Manufacturing Challenges, The National Academies of Science, Engineering, and Medicine, 2015.

industry have limited its adoption into the electric vehicle market.[29,30,31] Nevertheless, solutions for water-based cathode production methods are repeatedly discussed, which is why the challenges of water-based NMC coating are briefly explained in the following. Water is a polar solvent and has hydrophilic properties, whereas NMP is a non-polar organic solvent with hydrophobic properties. When water is used, the cathode active material tends to agglomerate. In addition, the surface wetting of the aluminium foil with the water-based slurry is significantly worse due to the higher surface tension of water ($70\ mN \cdot m^{-1}$) compared to NMP($40\ mN \cdot m^{-1}$).[32] The poorer surface wetting leads to reduced adhesion of active material coating. This in turn leads to decreased battery performance and can even lead to battery failure if the active material coating becomes detached.

Laboratory-scale studies showed that the surface charge and thus the hydrophilicity of the active material particles can be influenced by modification with functional groups, for example by using phosphoric acid to apply a nanometre thick $LiPO_4$ coating[33]. This can prevent agglomeration formation but the modification, however, is costly and time-consuming. In addition, phosphoric acid as a corrosive chemical also poses a certain risk potential.[34] In the production of phosphoric acid, rock phosphate (apatite) is also reacted with another acid, such as sulphuric or hydrochloric acid. This process therefore also has a potential risk. Thus, the total amount of environmentally harmful chemicals used would not be minimized by substitution with water. The agglomeration of the active material NMC in water could most probably also be prevented by the addition of stabilizing agents. However, since this has been investigated on a laboratory scale and certainly not on an industrial scale, these are assumptions that need to be investigated in more detail.[35] Another aspect of using water as solvent to coat the cathode with NMC is the chemical stability of NMC to water. The Lithium-Oxygen species present in NMC (Li_2O, Li_2O_2) already react with water from the ambient air

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[29] Li et al., 30 Years of Lithium-Ion Batteries, Adv. Mater., 30, 2018 (1800561).

[30] Nitta et al., Li-ion battery materials: present and future, Mater. Today, 18, 2015.

[31] Thackeray et al., The Quest for Manganese-Rich Electrodes for Lithium Batteries: Strategic Design and Electrochemical Behaviour, Energy & Fuels, 2, 2019.

[32] Li et al. Cathode Manufacturing for Lithium-Ion Batteries, Handbook of Battery Materials, Wiley-VCH-Verlag, 2011.

[33] Jo et al., An effective method to reduce residual lithium compounds on Ni-rich $Li[Ni_{0.6}Co_{0.6}Mn_{0.2}]O_2$ active material using a phosphoric acid derived Li3PO4 nanolayer, Nano Research, 8(5), 1464-1479, 2014.

[34] Safety Data Sheet, Fisher Science, S25470B, 2020.

[35] Li et al., Superior Performance of LiFePO4 Aqueous Dispersions via Corona Treatment and Surface Energy Optimization, J. Electrochem. Soc., 159 (8), 2012.

to form LiOH on the particle surface. It is assumed that a water-based NMC coating will react with water in the same way. The formed LiOH layer causes large irreversible capacity decrease during the initial cycle. During the successive charge-discharge cycles, the water is released again, resulting in decomposition of the $LiPF_6$ electrolyte salt and formation of HF.[36] Furthermore, a recent study from 2019 confirmed the influence of contamination with water in particular on NMC 111 und NMC 811. Here, the properties of wet and dry NMC 111 and NMC 811 are compared, whereby a higher influence of the water by decreasing the electrochemical performance of NMC 811 can be determined.[37] This is supported by previous studies which found a higher water affinity for high-nickel cathodes.[38]
In spite of the studies on the limited water stability of NMC, there are a few studies on water-based cathode materials, e.g. about ultra-thick NMC 111 coatings. However, the approach described there was carried out exclusively on a laboratory scale with NMC 111 and tested on coin cells. Therefore, the technologies developed there have to be further evaluated for a transfer into industrial production and for larger cell designs.[39]

A further possibility of substituting NMP in LIB production is the usage of organic solvents with comparable physical and chemical properties.

The solvents dimethylacetamide (DMAc), dimethylformamide (DMF) and dimethyl sulfoxide (DMSO) listed in Table 7 were identified as possible substituents.

Table 7: Physical and chemical characteristics of identified organic solvents which could be used to substitute NMP.

Parameters	Solvents			
	NMP	DMAc	DMF	DMSO
Flammability	Moderate	Moderate	Highly	Moderate
Flash Point [°C]	93	63	57.7	89
Toxicity	Toxic	Less toxic than DMF	More toxic	Non-toxic
Vapour pressure [hPa; 20°C]	0.32	3.3	3.77	0.556

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[36] Hou et al., Surface/Inerfacial Structure and Chemistry of High-Energy Nickel-Rich Layered Oxide Cathodes: Advances and Perspectives, Small, 13, 2017 (1701802).

[37] Sicklinger et al., Ambient Storage Derived Surface Conatmination of NMC811 and NMC111: Performance Implications and Mitigation Strategies, J. Electrochem. Soc., 166 (12), 2019.

[38] You et al., Stable surface chemistry against ambient air of modified high-nickel cathodes for lithium-ion batteries, Angew. Chem. Int. Ed., 57, 6480, 2018.

[39] Ibing et al., Journal of Power Sources 423, 183-191, 2019.

Acute Permeability Constant [$g \cdot m^{-2} h^{-1}$]	171 (fast in skin penetration)	107 (slow in skin penetration)	98 (slower in skin penetration)	176 (faster in skin penetration)
Threshold Limit Values established	100 ppm	10 ppm	10 ppm	None established
Environmental Fate	Moderately biodegradable	Half-life of less than one day in the air	Not readily biodegradable, half-life of one year or more	Biodegradable and environmentally safe

Since toxicity and environmental fate are one of the main criteria for selecting suitable substitutesfor NMP, only the use of DMSO can improve LIB production.
DMSO is chemically stable and has a high relative permittivity[40] of 46.7[41], high oxidation potential and high boiling temperature, why DMSO is discussed both as solvent in cathode production and as electrolyte in lithium-ion batteries.[42] However, DMSO in combination with NMC can form by-products, such as Li_2CO_3. Like LiOH, Li_2CO_3 act as an insulating layer to inhibit lithium ion conductivity and impairs the electrochemical properties, especially during long-term cycles.[43]
The results of a study in laboratory scale has shown a possible substitution of NMP by using DMSO. Nevertheless, the cathodes were only examined in small coin cells.[44] Publications about scale-up or larger cathode production with DMSO as solvent could not be found.
Studies on the substitution of NMP in other industrial applications, for example as solvent for cleaning polyurethane resin from parts and equipment in the production of urethane foam products, have shown that certain properties of the solvent are also required in this case. However, since these properties do not correspond to those of NMP in LIB production, the studies are not explained in detail here.[45]
Finally, it has to be mentioned that there are only few publications on reagents for the substitution of NMP as a solvent in cathode production, which obviously reflects the difficulty of substituting NMP.

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[40] Permittivity is a material property that affects the Coulomb force between two point charges in the material. Relative permittivity is the factor by which the electric field between the charges is decreased relative to vacuum.

[41] https://roempp.thieme.de/roempp4.0/do/data/RD-04-01767, 15.12.2019.

[42] Kim et al., Lithium-ion batteries: outlook on present, future, and hybridized technologies, J. Mater. Chem. A., 7, 2942-2964, 2019.

[43] Hou et al., Surface/Inerfacial Structure and Chemistry of High-Energy Nickel-Rich Layered Oxide Cathodes: Advances and Perspectives, Small, 13, 2017 (1701802).

[44] Bankole et.al., Environmental Compatible Dimethyl Sulfoxide: an Alternative to N-methylpyrrolidone for Electrochemical Performance of Recycled $LiMn_{1/3}Ni_{1/3}Co_{1/3}O_2$ in Lithium-Ion Battery, Russ J Electrochem, 2013, DOI: 10.1134/S1023193514030021

[45] Case Study: NMP Replacement Solution, JR Hess Company, 2016.

In order to eliminate or substitute NMP from cathode production in long term, UKBIC should track the technology development of lithium-ion battery production in the future and should check where new technologies can be integrated into the manufacturing environment.

3.3 Remaining Risk assessment

As explained in the previous chapters, it is not possible to eliminate or substitute NMP in lithium-ion battery production according to the current state of research and technology. Therefore, the following section explains the prevention of hazard minimisation and safety enhancement in the cathode production of lithium-ion batteries.

In order to avoid contamination with NMP and especially for the health protection of the workers, cathode production is carried out in a closed system. This means that the mixing process of the active material, NMP and additives should be performed in an air-tight vessel and the slurry should be transferred to the coating head using a sealed pump system. By equipping the cathode coaters with a solvent recovery system, the NMP can be removed directly from the plant and can be collected by condensation. For example, the use of a recirculation fan and the control of the supply air flow by dampers as well as a 3-stage condenser is a suitable extraction system for NMP. Small amounts of NMP can also be collected in a carbon filter where the air is cleaned to a residual of $<0{,}5\ g \cdot m^{-3}$.The NMP is finally professionally transported and disposed of in a closed system.

The cathode production with NMP as solvent is performed successfully and safely at various established cell manufacturers (CATL, Custom Cells, etc.) in the described process. As cathode production uses NMP emission values below $10\ g \cdot h^{-1}$, these hazard prevention methods are be considered sufficient.[46]

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[46] The Solvent Emissions Directive – For the Environmental Permitting (England and Wales) Reguslations 2010, Version 3.0.

4 Current regulations in Europe

Different regulations apply to Europe, which are listed below and briefly explained.

The **Directives 2010/75/EU of the European Parliament and the Council of 24 November 2010 on industrial emissions** contain the regulations for the approval of an installation. In *L334/18 (5)* it is said, that to ensure the prevention and control of pollution, each installation should operate only if it holds a permit or in case of certain installations and activities using organic solutions, only if it holds a permit or is registered. For this purpose, it was stipulated in *L334/19 (15)* that is it important to provide sufficient flexibility to competent authorities to set emission limit values that ensure that, under normal operating conditions, emissions do not exceed the emission levels associated with the best available techniques. To this end, the competent authority may set emission limits that differ from the emission levels associated with the best available techniques in terms of the values, periods of time and reference conditions applied, so long as it can be demonstrated, through the results of emission monitoring, that emissions have not exceeded the emission levels associated with the best available techniques. Compliance with the emission limit values that are set in permits results in emissions below those emission limit values. In addition, it is said in the section *L334/18 (16)* that in order to take into account certain specific circumstances where the application of emission levels associated with the best available techniques would lead to disproportionately high costs compared to the environmental benefits, competent authorities should be able to set emission limit values deviating from those levels. Such deviations should be based on an assessment taking into account well-defined criteria. The emission limit values set out in this Directive should not be exceeded. In any event, no significant pollution should be caused and a high level of protection of the environment taken as a whole should be achieved. If the installation contains the best available techniques in accordance with *L334/23 (10)* and the operator demonstrates to the competent authority that for an individual installation the emission limit value for fugitive emissions is not technically and economically feasible, the competent authority may allow emissions to exceed that emission limit value provided that significant risks to human health or the environment are not to be expected and that the operator demonstrates to the competent authority that the best available techniques are being used *(L334/44, Article 59).*

As described above, both the use of the best available technique an no substitutability of the NMP applies in this case, to that the emission limit values could be adjusted.

In addition, **EUROBAT** (Association of European Automotive and Industrial Battery Manufactures) has published a recommendation on the usage of NMP in the lithium-ion battery industry. In the key recommendations it is said that no alternatives are available today for the battery industry use. The advice given by **RAC/SEAC** in November to EU Commission to opt for restriction for NMP (reduced occupational limit) as the best risk management option, is perfectly suitable for the batteries manufacturing. Furthermore, the implementation harmonized OHS requirements has also taken place by already implemented the valid OEL-value for NMP of 40 $mg\cdot m^{-3}$ as derived by SCOEL as the appropriate protection measure for industrial use.

NMP was added to the **Federal Toxics Release Inventory (TRI)** and **Toxics Use Reduction Act (TURA)** list of reportable chemicals on November 30, 1994 for the 1995 reporting year. An Environmental Protection Agency NMP-specific assessment began in response to information indicating that exposure to NMP could present a significant risk of reproductive and developmental harm to humans. The Final Assessment concludes that such a reproductive and developmental risk does exist. **EU-Commission Directive 2006/15/EC** of 7 February 2006 establishing a second list of indicative occupational exposure limit value in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.[47]

The **UK-EH40** containing the workplace exposure limits (WELs) for use with the Control of Substances Hazardous to Health Regulations (COSHH) 2002 (as amended) and were updated by September 2006 official press release and October 2007 Supplement.[48] Furthermore **IRE-2010 Code of Practice for the Safety, Health and Welfare at Work** (Chemical Agents) published regulations in 2001 by the Health and Safety Authority.[49] The data of the mentioned regulations are shown in Table 8.

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[47] Safety Data Sheet, ThermoFisher Scientific, 2019

[48] Safety Data Sheet, ThermoFisher Scientific, 2019

[49] Safety Data Sheet, ThermoFisher Scientific, 2019

Table 8: Exposure limits of the EU, UK and IRE for N-Methyl-2-pyrrolidone (99%) uptake through the skin.[50]

	European Union	**United Kingdom**	**Ireland**
STEL[51] [ppm]	20 ppm 15 min	20 ppm 15 min	20 ppm 15 min
STEL [mg·m^3]	80 mg·m^{-3} 15 min	80 mg·m^{-3} 15 min	80 mg·m^{-3} 15 min
TWA[52] [ppm]	10 ppm 8 hr	10 ppm 8 hr	10 ppm 8 hr
TWA [mg·m^3]	40 mg·m^{-3} 8 hr	40 mg·m^{-3} 8 hr	40 mg·m^{-3} 8 hr

Furthermore, NMP was included in 2018 in **REACh Annex XVII** and may only be marketed and used from May 2020 if compliance with certain exposure limits can be ensured.

Although NMP is classified as hazardous in the above regulations, we support the approval of the use of NMP in the small emission values and under the described safety measures in the process equipment.[53]

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[50] Safety Data Sheet, ThermoFisher Scientific, 2019

[51] Short-Term Exposure Limit

[52] Time Weighted Averages

[53] 1-Methyl-2-pyrrolidone, Registration Dossier – European Chemicals Agency, 2020.

5 Summary and Outlook

In this report, based on the current industrial production process and state of research, the elimination or substitution of NMP within the manufacturing process of lithium-ion batteries is considered to be not feasible in the near future. .

In Summary, it can be stated that an elimination through new technologies is currently not possible due to the reasons elaborated in this report. A substitution of NMP by a more environmentally friendly solvent can only be implemented if LFP is used as cathode material. However, LFP has a lower specific capacity and average voltage compared to NMC, making it unsuitable for use in the future electric vehicle market. It should also be noted that the TRL level for NMP is the highest possible at TRL9. The TRL levels for processes with other solvents in the cathode production, however, are all below TRL5, which indicates that the process is not yet fully developed and may involve unknown risks. One reason for this is that the processes have currently only been evaluated on a laboratory scale.
Since the cathode production with NMP as a solvent is an established process, the environmental risk can be management by certain precautions named in this report.

The intent of the UK Battery Industrialisation Centre is to develop and establish manufacturing technologies of lithium ion batteries associated with the automotive or other industries. It is well understood and similar to that experienced within the Pharmaceutical and Aerospace industries where confidence in any change to a known industrial process is inherently time consuming due to the certification and approval principles. This applies directly to the present research into the elimination or substitution of NMP within the Lithium Ion battery industry.

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Concise International Chemical Assessment Document 35

N-Methyl-2-pyrrolidone

Concise International Chemical Assessment Document 35

N-METHYL-2-PYRROLIDONE

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First draft prepared by Dr Bengt Åkesson, Department of Occupational & Environmental Health, University Hospital, Lund, Sweden

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World Health Organization
Geneva, 2001

The **International Programme on Chemical Safety (IPCS)**, established in 1980, is a joint venture of the United Nations Environment Programme (UNEP), the International Labour Organization (ILO), and the World Health Organization (WHO). The overall objectives of the IPCS are to establish the scientific basis for assessment of the risk to human health and the environment from exposure to chemicals, through international peer review processes, as a prerequisite for the promotion of chemical safety, and to provide technical assistance in strengthening national capacities for the sound management of chemicals.

The **Inter-Organization Programme for the Sound Management of Chemicals (IOMC)** was established in 1995 by UNEP, ILO, the Food and Agriculture Organization of the United Nations, WHO, the United Nations Industrial Development Organization, the United Nations Institute for Training and Research, and the Organisation for Economic Co-operation and Development (Participating Organizations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen cooperation and increase coordination in the field of chemical safety. The purpose of the IOMC is to promote coordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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FOREWORD

Concise International Chemical Assessment Documents (CICADs) are the latest in a family of publications from the International Programme on Chemical Safety (IPCS) — a cooperative programme of the World Health Organization (WHO), the International Labour Organization (ILO), and the United Nations Environment Programme (UNEP). CICADs join the Environmental Health Criteria documents (EHCs) as authoritative documents on the risk assessment of chemicals.

International Chemical Safety Cards on the relevant chemical(s) are attached at the end of the CICAD, to provide the reader with concise information on the protection of human health and on emergency action. They are produced in a separate peer-reviewed procedure at IPCS. They may be complemented by information from IPCS Poison Information Monographs (PIM), similarly produced separately from the CICAD process.

CICADs are concise documents that provide summaries of the relevant scientific information concerning the potential effects of chemicals upon human health and/or the environment. They are based on selected national or regional evaluation documents or on existing EHCs. Before acceptance for publication as CICADs by IPCS, these documents undergo extensive peer review by internationally selected experts to ensure their completeness, accuracy in the way in which the original data are represented, and the validity of the conclusions drawn.

The primary objective of CICADs is characterization of hazard and dose–response from exposure to a chemical. CICADs are not a summary of all available data on a particular chemical; rather, they include only that information considered critical for characterization of the risk posed by the chemical. The critical studies are, however, presented in sufficient detail to support the conclusions drawn. For additional information, the reader should consult the identified source documents upon which the CICAD has been based.

Risks to human health and the environment will vary considerably depending upon the type and extent of exposure. Responsible authorities are strongly encouraged to characterize risk on the basis of locally measured or predicted exposure scenarios. To assist the reader, examples of exposure estimation and risk characterization are provided in CICADs, whenever possible. These examples cannot be considered as representing all possible exposure situations, but are provided as guidance only. The reader is referred to EHC 170[1] for advice on the derivation of health-based guidance values.

While every effort is made to ensure that CICADs represent the current status of knowledge, new information is being developed constantly. Unless otherwise stated, CICADs are based on a search of the scientific literature to the date shown in the executive summary. In the event that a reader becomes aware of new information that would change the conclusions drawn in a CICAD, the reader is requested to contact IPCS to inform it of the new information.

Procedures

The flow chart on page 2 shows the procedures followed to produce a CICAD. These procedures are designed to take advantage of the expertise that exists around the world — expertise that is required to produce the high-quality evaluations of toxicological, exposure, and other data that are necessary for assessing risks to human health and/or the environment. The IPCS Risk Assessment Steering Group advises the Co-ordinator, IPCS, on the selection of chemicals for an IPCS risk assessment, the appropriate form of the document (i.e., EHC or CICAD), and which institution bears the responsibility of the document production, as well as on the type and extent of the international peer review.

The first draft is based on an existing national, regional, or international review. Authors of the first draft are usually, but not necessarily, from the institution that developed the original review. A standard outline has been developed to encourage consistency in form. The first draft undergoes primary review by IPCS and one or more experienced authors of criteria documents to ensure that it meets the specified criteria for CICADs.

The draft is then sent to an international peer review by scientists known for their particular expertise and by scientists selected from an international roster compiled by IPCS through recommendations from IPCS national Contact Points and from IPCS Participating Institutions. Adequate time is allowed for the selected experts to undertake a thorough review. Authors are required to take reviewers' comments into account and revise their draft, if necessary. The resulting second draft is submitted to a Final Review Board together with the reviewers' comments.

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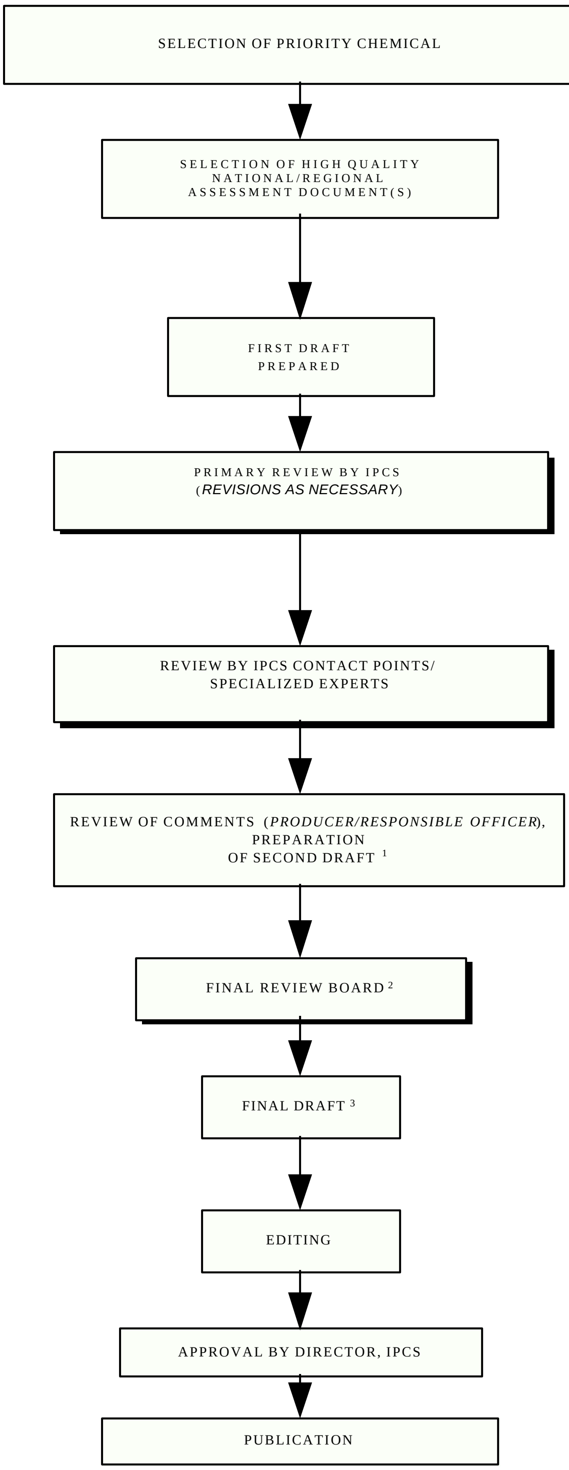
[1] International Programme on Chemical Safety (1994) *Assessing human health risks of chemicals: derivation of guidance values for health-based exposure limits.* Geneva, World Health Organization (Environmental Health Criteria 170).

CICAD PREPARATION FLOW CHART



1 Taking into account the comments from reviewers.
2 The second draft of documents is submitted to the Final Review Board together with the reviewers' comments.
3 Includes any revisions requested by the Final Review Board.

A consultative group may be necessary to advise on specific issues in the risk assessment document.

The CICAD Final Review Board has several important functions:

- to ensure that each CICAD has been subjected to an appropriate and thorough peer review;
- to verify that the peer reviewers’ comments have been addressed appropriately;
- to provide guidance to those responsible for the preparation of CICADs on how to resolve any remaining issues if, in the opinion of the Board, the author has not adequately addressed all comments of the reviewers; and
- to approve CICADs as international assessments.

Board members serve in their personal capacity, not as representatives of any organization, government, or industry. They are selected because of their expertise in human and environmental toxicology or because of their experience in the regulation of chemicals. Boards are chosen according to the range of expertise required for a meeting and the need for balanced geographic representation.

Board members, authors, reviewers, consultants, and advisers who participate in the preparation of a CICAD are required to declare any real or potential conflict of interest in relation to the subjects under discussion at any stage of the process. Representatives of nongovernmental organizations may be invited to observe the proceedings of the Final Review Board. Observers may participate in Board discussions only at the invitation of the Chairperson, and they may not participate in the final decision-making process.

1. EXECUTIVE SUMMARY

This CICAD on *N*-methyl-2-pyrrolidone was based primarily on a review prepared for the Nordic Expert Group (Åkesson, 1994) and on a review of human health concerns prepared by the United Kingdom's Health and Safety Executive (HSE, 1997). For data on environmental fate and behaviour, no comprehensive document of the same status was identified. Instead, HSDB (1997) was used as an additional source document. Supplementary unvalidated data, mainly ecotoxicological, were found in IUCLID (1995), and some additional articles were identified in the open literature (searched through July 1998). Information concerning the nature and availability of the source documents is presented in Appendix 1. Information on the peer review of this CICAD is presented in Appendix 2. This CICAD was considered at a meeting of the Final Review Board, held in Stockholm, Sweden, on 25–28 May 1999. Participants at the Final Review Board meeting are listed in Appendix 3. After the Final Review Board meeting, advice was sought from a consultative group, consisting of Dr B. Heinrich-Hirsch, BgVV, Germany, Mr Frank Sullivan, Consultant, United Kingdom, Dr Robert Chapin, National Institute of Environmental Health Sciences, USA, Dr Gary Kimmel, US Environmental Protection Agency, USA, and Professor Rolf Hertel, BgVV, Germany (Chair), regarding the interpretation of data on the reproductive toxicity of *N*-methyl-2-pyrrolidone. Based on the advice from this group, the author, in collaboration with the Secretariat, revised the relevant sections of the document. The revised CICAD was approved as an international assessment by the members of the Final Review Board in a mail ballot. The International Chemical Safety Card for *N*-methyl-2-pyrrolidone (ICSC 0513), produced by the International Programme on Chemical Safety (IPCS, 1993), has also been reproduced in this document.

N-Methyl-2-pyrrolidone (NMP) (CAS No. 872-50-4) is a water-miscible organic solvent. It is a hygroscopic colourless liquid with a mild amine odour. NMP is used in the petrochemical industry, in the microelectronics fabrication industry, and in the manufacture of various compounds, including pigments, cosmetics, drugs, insecticides, herbicides, and fungicides. An increasing use of NMP is as a substitute for chlorinated hydrocarbons.

NMP may enter the environment as emissions to the atmosphere, as the substance is volatile and widely used as a solvent, or it may be released to water as a component of municipal and industrial wastewaters. The substance is mobile in soil, and leaching from landfills is thus a possible route of contamination of groundwater.

In air, NMP is expected to be removed by wet deposition or by photochemical reactions with hydroxyl radicals. As the substance is completely miscible in water, it is not expected to adsorb to soil, sediments, or suspended organic matter or to bioconcentrate. NMP is not degraded by chemical hydrolysis. Data from screening tests on the biodegradability of NMP show that the substance is rapidly biodegraded.

In rats, NMP is absorbed rapidly after inhalation, oral, and dermal administration, distributed throughout the organism, and eliminated mainly by hydroxylation to polar compounds, which are excreted via urine. About 80% of the administered dose is excreted as NMP and NMP metabolites within 24 h. A probably dose-dependent yellow coloration of the urine in rodents is observed. The major metabolite is 5-hydroxy-*N*-methyl-2-pyrrolidone.

Studies in humans show comparable results. Dermal penetration through human skin has been shown to be very rapid. NMP is rapidly biotransformed by hydroxylation to 5-hydroxy-*N*-methyl-2-pyrrolidone, which is further oxidized to *N*-methylsuccinimide; this intermediate is further hydroxylated to 2-hydroxy-*N*-methylsuccinimide. These metabolites are all colourless. The excreted amounts of NMP metabolites in the urine after inhalation or oral intake represented about 100% and 65% of the administered doses, respectively.

NMP has a low potential for skin irritation and a moderate potential for eye irritation in rabbits. Repeated daily doses of 450 mg/kg body weight administered to the skin caused painful and severe haemorrhage and eschar formation in rabbits. These adverse effects have not been seen in workers occupationally exposed to pure NMP, but they have been observed after dermal exposure to NMP used in cleaning processes. No sensitization potential has been observed.

In acute toxicity studies in rodents, NMP showed low toxicity. Uptake of oral, dermal, or inhaled acutely toxic doses causes functional disturbances and depressions in the central nervous system. Local irritation effects were observed in the respiratory tract when NMP was inhaled and in the pyloric and gastrointestinal tracts after oral administration. In humans, there was no irritative effect in the respiratory system after an 8-h exposure to 50 mg/m^3.

There is no clear toxicity profile of NMP after multiple administration. In a 28-day dietary study in rats, a compound-related decrease in body weight gain was observed in males at 1234 mg/kg body weight and in females at 2268 mg/kg body weight. Testicular degeneration and atrophy in males and thymic atrophy in females were observed at these dose levels. The no-observed-adverse-effect level (NOAEL) was 429 mg/kg body weight in males and 1548 mg/kg body weight in females. In a 28-day intubation study in rats, a dose-dependent increase in relative liver and kidney weights and a decrease in lymphocyte count in both sexes were observed at 1028 mg/kg body weight. The NOAEL in this study was 514 mg/kg body weight. In another rat study, daily dietary intake for 90 days caused decreased body weights at doses of 433 and 565 mg/kg body weight in males and females, respectively. There were also neurobehavioural effects at these dose levels. The NOAELs in males and females were 169 and 217 mg/kg body weight, respectively.

The toxicity profile after exposure to airborne NMP depends strongly on the ratio of vapour to aerosol and on the area of exposure (i.e., head-only or whole-body exposure). Because of higher skin absorption for the aerosol, uptake is higher in animals exposed to aerosol than in those exposed to vapour at similar concentrations. Studies in female rats exposed head only to 1000 mg/m^3 showed only minor nasal irritation, but massive mortality and severe effects on major organs were observed when the females were whole-body exposed to the same concentration of coarse droplets at high relative humidity. Several studies in rats following repeated exposure to NMP at concentrations between 100 and 1000 mg/m^3 have shown systemic toxicity effects at the lower dose levels. In most of the studies, the effects were not observed after a 4-week observation period.

In rats, exposure to 3000 mg NMP/m^3 (head only) for 6 h/day, 5 days/week, for 13 weeks caused a decrease in body weight gain, an increase in erythrocytes, haemoglobin, haematocrit, and mean corpuscular volume, decreased absolute testis weight, and cell loss in the germinal epithelium of the testes. The NOAEL was 500 mg/m^3.

There are no data in humans after repeated-dose exposure.

NMP did not show any clear evidence for carcinogenicity in rats exposed to concentrations up to 400 mg/m^3 in a long-term inhalation study.

The mutagenic potential of NMP is weak. Only a slight increase in the number of revertants was observed when tested in a *Salmonella* assay with base-pair substitution strains. NMP has been shown to induce aneuploidy in yeast *Saccharomyces cerevisiae* cells. No investigations regarding mutagenicity in humans were available.

In a two-generation reproduction study in rats, whole-body exposure of both males and females to 478 mg/m^3 of NMP vapour for 6 h/day, 7 days/week, for a minimum of 100 days (pre-mating, mating, gestation, and lactation periods) resulted in a 7% decrease in fetal weight in the F_1 offspring. A 4–11% transient, non-dose-dependent decrease was observed in the average pup weight at all exposure levels tested (41, 206, and 478 mg/m^3).

When NMP was administered dermally, developmental toxicity was registered in rats at 750 mg/kg body weight. The observed effects were increased preimplantation losses, decreased fetal weights, and delayed ossification. The NOAEL for both developmental effects and maternal toxicity (decreased body weight gain) was 237 mg/kg body weight.

Inhalation studies in rats (whole-body exposure) demonstrated developmental toxicity as increased pre-implantation loss without significant effect on implantation rate or number of live fetuses at 680 mg/m^3 and behavioural developmental toxicity at 622 mg/m^3. In an inhalation study (whole-body exposure), the NOAEL for maternal effects was 100 mg/m^3, and the NOAEL for developmental effects was 360 mg/m^3.

Several further studies on the reproductive effects of NMP have been performed, but these have not been published and are not generally available. For the information of the reader, a short synopsis of these studies is presented in section 8.7.3 of this document. However, the studies are not used in the evaluation of the health effects of NMP.

A tolerable inhalation concentration, 0.3 mg/m^3, based on mortality and organ damage, is expected to be protective against any possible reproductive toxicity. Similarly, an oral tolerable intake of 0.6 mg/kg body weight per day, based on a 90-day study, is expected to provide adequate protection against possible reproductive effects. Because of non-existent data on the exposure of the general population and very limited information on occupational exposure, no meaningful risk characterization can be performed.

It is not possible to perform a quantitative ecotoxicological risk assessment on the basis of the present data. However, based on the biodegradability shown, the lack of expected bioconcentration (based on a log octanol–water partition coefficient of −0.38), and the indicated low acute toxicity to aquatic organisms as well as birds, it is tentatively concluded that NMP should not pose a significant environmental risk.

2. IDENTITY AND PHYSICAL/CHEMICAL PROPERTIES

N-Methyl-2-pyrrolidone (CAS No. 872-50-4) is also known as NMP, 1-methyl-2-pyrrolidone, *N*-methyl-pyrrolidone, and 1-methyl-2-pyrrolidinone. NMP is a colourless liquid with a mild amine odour. It is a basic and polar compound with high stability. It is only slowly oxidized by air and is easily purified by fractional distillation. NMP is hygroscopic. The substance is completely miscible with water. It is highly soluble in lower alcohols, lower ketones, ether, ethyl acetate, chloroform, and benzene and moderately soluble in aliphatic hydrocarbons.

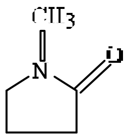
Additional physical/chemical properties are presented in Table 1 as well as in the International Chemical Safety Card (ICSC 0513) reproduced in this document.

Table 1: Some physical/chemical properties of NMD.[a]

Property	Value
Relative molecular mass	99.13
Density	1.028 g/cm^3
Melting point	!23 to !24.4 °C
Boiling point	202°C at 101.3 Pa
Vapour pressure	39 Pa at 20 °C 45 Pa at 25 °C
Henry's law constant	1.6 × 10^{-3} Pa@m^3/mol at 25 °C[b]
log K_{ow}	!0.38
Conversion factors (20 °C, 101.3 kPa)	1 ppm = 4.12 mg/m^3 1 mg/m^3 = 0.24 ppm

[a] From Åkesson (1994), except where otherwise noted.
[b] Hine & Mookerjee (1975).

The chemical structure of NMP is illustrated below:



3. ANALYTICAL METHODS

3.1 Measurement of NMP

Sampling of NMP in air may be performed on solid sorbent or in absorption solution. NMP is desorbed from the solid adsorbent and extracted from the absorption solution by an organic solvent. Analysis of NMP in a liquid phase is performed by gas chromatographic methods, employing flame ionization detection (FID) or nitrogen–phosphorus detection (NPD). The detection limits of these methods (15 min, 0.2 litres/min) correspond to NMP air concentrations of 0.1 mg/m^3 (FID) and 0.01 mg/m^3 (NPD) (Blome & Hennig, 1984; Andersson & Andersson, 1991; Åkesson & Paulsson, 1997).

NMP in biological samples may, after matrix modulating steps, be determined by high-performance liquid chromatographic methods (Wells & Digenis, 1988; Midgley et al., 1992; Wells et al., 1992). Alternatively, NMP in blood and urine may be extracted by an organic solvent and analysed with gas chromatographic methods, using a nitrogen–phosphorus or mass spectrometric detector. The detection limits for NMP in blood and urine samples are 0.04 and 0.1 µmol/litre (0.004 and 0.01 mg/litre), respectively (Åkesson & Paulsson, 1997).

No evaluated analytical method for NMP in water samples is reported.

3.2 Measurement of NMP metabolites

Analysis of 5-hydroxy-*N*-methyl-2-pyrrolidone (5-HNMP), *N*-methylsuccinimide (MSI), and 2-hydroxy-*N*-methylsuccinimide (2-HMSI) may be performed, with or without derivatization steps, with gas chromatographic methods, using mass spectrometric detection in electron impact or chemical ionization mode. The detection limits in blood are 0.05, 0.01, and 0.03 µmol/litre (0.005, 0.001, and 0.003 mg/litre), respectively, and in urine, 2, 0.03, and 2 µmol/litre (0.2, 0.003, and 0.2 mg/litre), respectively (Jönsson & Åkesson, 1997a,b,c).

The NMP metabolites in plasma or urine, summed or separately, may be used as biological NMP exposure indicators. The plasma concentration of 5-HNMP at termination of exposure is preferred, as 5-HNMP is the major metabolite with a suitable half-life (Åkesson & Jönsson, 2000a).

4. SOURCES OF HUMAN AND ENVIRONMENTAL EXPOSURE

NMP is mainly used as a solvent for extraction in the petrochemical industry, as a reactive medium in polymeric and non-polymeric chemical reactions, as a remover of graffiti, as a paint stripper in the occupational setting, and for stripping and cleaning applications in the microelectronics fabrication industry. It is also used as a formulating agent in pigments, dyes, and inks and in insecticides, herbicides, and fungicides. NMP is further used as an intermediate in the pharmaceutical industry, as a penetration enhancer for topically applied drugs, and as a vehicle in the cosmetics industry.

There are no known natural sources of NMP.

NMP may enter the environment as a fugitive emission during its production or use (ISP, undated; Barry, 1987; Priborsky & Mühlbachova, 1990; HSDB, 1997). It may also be released to the environment as a component of municipal and industrial wastewaters.

5. ENVIRONMENTAL TRANSPORT, DISTRIBUTION, AND TRANSFORMATION

The vapour pressure of NMP (39–45 Pa; see Table 1) suggests that the substance will volatilize from dry surfaces. Its Henry's law constant has been calculated to be 1.6×10^{-3} $Pa \cdot m^3/mol$ (Hine & Mookerjee, 1975). Based on this value, substantial volatilization from water is not expected. According to a simple fugacity calculation (corresponding to Mackay's Level I fugacity model: Mackay, 1979; Mackay & Paterson, 1981, 1982), more than 99% of NMP released into the environment will partition to water (assuming equilibrium distribution).

In the atmosphere, NMP is expected to undergo a rapid gas-phase reaction with hydroxyl radicals, with an estimated half-life of 5.2 h (Atkinson, 1987). Reaction with (tropospheric) ozone is expected to be an insignificant route of removal from the atmosphere (Levy, 1973; Farley, 1977). Because of its high solubility in water, NMP may undergo atmospheric removal by wet deposition (HSDB, 1997).

A calculated adsorption coefficient (K_{oc}) of 9.6 indicates that NMP is highly mobile in soil (Swann et al., 1983). Soil thin-layer chromatography also indicates a high mobility in soil, R_f values being 0.65–1.0 in four different soils (Shaver, 1984). The calculated adsorption coefficient further indicates that adsorption to sediments or suspended organic matter in aquatic environments should be insignificant (HSDB, 1997). The dissipation of NMP showed half-lives of about 4 days in clay, 8 days in loam, and 12 days in sand (Shaver, 1984).

Unvalidated data on hydrolytic half-lives (IUCLID, 1995) suggest that NMP is not degraded by chemical hydrolysis. According to Åkesson (1994), NMP is a highly stable compound.

Screening studies using activated sludge indicate that NMP is biodegraded aerobically after a lag phase of a few days. A 95% degradation after 2 weeks was shown in a static die-away system, and an average 7-day biodegradability of 95% was shown in a semicontinuous activated sludge (SCAS) system. A stable carbonyl compound was identified as a biodegradation product (Chow & Ng, 1983).

In a test conducted according to Guideline 301C of the Organisation for Economic Co-operation and Development (modified MITI-I test), 73% of an initial concentration of 100 mg NMP/litre was degraded within 28 days of incubation by the non-adapted activated sludge (MITI, 1992). From this result, NMP has been classified as readily biodegradable under aerobic conditions.

After 24 h, NMP underwent 94% removal by 1-day acclimatized sludge, measured by chemical oxygen demand (COD) (Matsui et al., 1988). In a flow-through biological treatment system with a retention time of 18 h, NMP underwent >98% removal (Rowe & Tullos, 1980). In an inherent biodegradability study (SCAS test), NMP was removed to >98% as measured by COD after 24 h (Matsui et al., 1975). In another inherent biodegradability study, removal of COD was >90% after 8 days, with a 3- to 5-day acclimation period (Zahn & Wellens, 1980).

From NMP's calculated bioconcentration factor of 0.16 (HSDB, 1997) and its low log octanol–water partition coefficient (K_{ow}) of -0.38 (see Table 1), only a minor potential for bioaccumulation is to be expected.

6. ENVIRONMENTAL LEVELS AND HUMAN EXPOSURE

6.1 Environmental levels

NMP has been qualitatively detected in US drinking-water supplies (Lucas, 1984). The substance was identified in leachate from a municipal landfill in Ontario (Lesage, 1991).

In a survey of 46 US industrial effluent samples, NMP was detected in 1 of the samples (Bursey & Pellizzari, 1982). In shale retort water, NMP was found at concentrations of 3 mg/litre (Dobson et al., 1985) and up to 10.1 mg/litre (Syamsiah et al., 1993). The substance was identified in wastewater from the petrochemical industry in Japan (Matsui et al., 1988). It was also detected in the raw effluent from a textile finishing plant in the USA (Gordon & Gordon, 1981).

In a German investigation of three different biologically treated wastewaters (domestic wastewater, wastewater from a lubricating oil refinery, and wastewater from an oil reclaiming facility), NMP was qualitatively identified in the domestic wastewater (Gulyas et al., 1993).

No information was found on levels in ambient air, in soil, or in biota.

6.2 Occupational exposure

NMP concentrations in air in the personal breathing zones of graffiti removers are reported to be up to 10 mg/m^3, both short peak exposure (Anundi et al., 1993) and 8-h time-weighted average (TWA) (Anundi et al., 2000). Workers in the microelectronics fabrication industry are exposed to up to 6 mg/m^3 (personal breathing zones; 8-h TWA), and samples collected in the work area revealed full-shift NMP air concentrations up to 280 mg/m^3 when warm NMP (80 °C) was being handled (Beaulieu & Schmerber, 1991). In the paint stripping industry, workers are exposed to NMP concentrations up to 64 mg/m^3 (personal breathing zones; 8-h TWA), and 1-h peak samples revealed concentrations up to 280 mg/m^3 (Åkesson & Jönsson, 2000c).

7. COMPARATIVE KINETICS AND METABOLISM IN LABORATORY ANIMALS AND HUMANS

In rats, NMP is rapidly absorbed via inhalation, ingestion, and dermal administration and widely distributed throughout the body (Midgley et al., 1992; Ravn-Jonsen et al., 1992). The peak plasma concentration after administration of a mixture of [2-^{14}C]-NMP and [5-^{14}C]-2-pyrrolidone by gastric intubation (112/75 mg/kg body weight in 0.6 ml distilled water) occurred after 2 h; after application to the skin (2.5/1.67 mg/cm^2 skin on 9 cm^2 in 150 µl isopropanol), the peak plasma concentration occurred after 1 h for males and 2 h for females. Following dermal application of the two compounds, the plasma concentrations showed little variation 1–6 h after administration, indicating that the absorption through the skin during this period was relatively constant (Midgley et al., 1992). The percutaneous absorption, expressed as the total excretion in urine, faeces, and expired air, was 69% in males and 78% in females. The levels of total radioactivity in plasma were markedly higher in female rats than in male rats for 12 h after the application, reflecting a greater percutaneous absorption in females (Midgley et al., 1992). The percutaneous absorption of NMP may differ when NMP is applied as pure NMP or as an NMP solution. In a dermal absorption study in the rat, the absorbed amounts of applications of pure NMP, 30% NMP in water, and 30% NMP in (R)-(+)-limonene were 31%, 3.5%, and 72%, respectively (Huntingdon Life Sciences, 1998). In rats exposed whole body by inhalation to 618 mg NMP/m^3 for 6 h, the NMP concentration in the blood increased from 0 to 4 h after termination of the exposure (Ravn-Jonsen et al., 1992). Such an increase is due to a percutaneous uptake of adsorbed NMP on fur and skin when the animals are whole-body exposed to aerosol NMP. When a solution of 10% NMP as a penetration enhancer was studied for 24 h *in vitro*, the skin permeability of NMP was 4 times higher in rats than in humans (Bartek et al., 1972; Priborsky & Mühlbachova, 1990).

After intravenous administration to rats, there is a rapid distribution to all major organs. The plasma NMP level declined 5–30 min after administration and was only slightly decreased from then on up to 2 h. Six hours after administration of radiolabelled NMP, the highest accumulation of radioactivity occurred in the liver, small and large intestines, testes, stomach, and kidneys, although the thymus and bladder had the highest concentrations when expressed per gram of tissue. After 24 h, the radioactivity was still measurable in the liver and intestines. The rapid distribution phase is followed by a slow terminal elimination phase (Wells & Digenis, 1988).

In rats whole-body exposed to 618 mg NMP/m^3 by inhalation for 6 h, NMP passed through the placenta, and the concentrations in fetal and maternal blood were similar 6 h after the start of exposure. The elimination of NMP from the blood was faster in non-pregnant than in pregnant rats (0.21 versus 0.11 mg/kg body weight per hour, respectively) (Ravn-Jonsen et al., 1992).

Following intravenous administration in rats, the main pathway for biotransformation of NMP is by hydroxylation. The major metabolite excreted in urine, 70–75% of the dose, is identified as 5-HNMP. Two other minor polar metabolites (15% and 9%) were not identified

(Wells & Digenis, 1988; Wells et al., 1992). Formation of carbon dioxide is of minor importance. The almost identical metabolism for NMP administered by dermal and oral routes indicates that little first-pass metabolism occurs (Midgley et al., 1992). Twelve hours after an orally or percutaneously administered dose, all of the NMP in plasma was in the form of the polar metabolites (Midgley et al., 1992).

All studies of NMP exposure of rats report discoloration (yellow-orange-brownish) of urine. The coloration, noted at 100 mg/m^3 and higher concentrations, was probably dose related, but has not been studied further. It may be due to a coloured unidentified metabolite or to an effect in the body (e.g., in the liver).

The half-life of NMP in plasma is 7–10 h. The urinary excretion of NMP and NMP metabolites accounted for about 70% of the dose within 12 h and 80% within 24 h (RTI, 1990; E.I. du Pont de Nemours and Company, 1995a). Only a minor part is excreted into the urine as the mother compound (<1%). There is minor biliary excretion of about 2%. The elimination of NMP in expired air is also minimal (1–2%). No conjugated metabolites were found in the urine (Wells & Digenis, 1988).

In humans, as in rats, NMP is rapidly absorbed via inhalation (Åkesson & Paulsson, 1997), ingestion (Åkesson & Jönsson, 1997), and dermal administration (Ursin et al., 1995; Åkesson & Jönsson, 2000b). An uptake of about 90% by the inhalation route was found when the difference between inhaled and exhaled NMP concentrations was calculated. NMP is rapidly biotransformed by hydroxylation to 5-HNMP, which is then further oxidized to MSI; MSI is in turn hydroxylated to 2-HMSI. The peak plasma concentrations after an 8-h exposure to NMP occurred at the termination of exposure for NMP, at 2 h post-exposure for 5-HNMP, at 4 h post-exposure for MSI, and at 16 h post-exposure for 2-HMSI. The half-lives in plasma after a short period of distribution were 4 h, 6 h, 8 h, and 16 h, respectively. The detected amounts in urine after inhalation were as follows: NMP (2%), 5-HNMP (60%), MSI (0.1%), and 2-HMSI (37%). The recovery was about 100%. After oral administration, the amounts detected in urine were as follows: NMP (1%), 5-HNMP (67%), MSI (0.1%), and 2-HMSI (31%), corresponding to 65% of the administered dose. There was no tendency for coloration in any of the urine samples collected, and none of the synthesized metabolites was coloured (Åkesson & Jönsson, 1997, 2000a,b). In a 6-h topical single-application study with administration of 300 mg NMP in volunteers (six per sex), the NMP concentration in plasma reached a maximum 3 h after application in both males and females. Twenty-four per cent and 22% of the dose in males and females, respectively, were recovered in urine as NMP and NMP metabolites (Åkesson & Jönsson, 2000b). The permeability rate of NMP through living human skin, adjusted for the permeability rate of ^{3}H-labelled water, was 171 ± 59 g/m^3 per hour (Ursin et al., 1995).

The NMP metabolites in plasma or urine, summed or each metabolite separately, may be used as biological NMP exposure indicators. The plasma concentration of 5-HNMP at termination of exposure is preferred, as 5-HNMP is the major metabolite with a suitable half-life (Åkesson & Jönsson, 2000a).

8. EFFECTS ON LABORATORY MAMMALS AND *IN VITRO* TEST SYSTEMS

8.1 Single exposure

Studies in rodents indicate that NMP has low acute toxicity. No deaths occurred in rats (five per sex) when head-only exposed by inhalation for 4 h to 5100 mg/m^3 of a vapour/aerosol mixture with mass median aerodynamic diameter (MMAD) of 4.6 µm (respirable fraction 87%) (LC$_{50}$ >5100 mg/m^3). During the exposure, symptoms such as rapid, irregular respiration, shortness of breath, decreased pain reflex, and slight bloody nasal secretion were observed. Post-exposure, rapid respiration, slightly bloody fur around the nose, and yellow urine excretion were registered. From 4 days post-exposure, no symptoms were observed. Examination of the lungs 14 days post-exposure showed darkening of lungs, indicating irritation (BASF, 1988). Three separate 4-h whole-body exposures (aerosol, thermal vaporization, and saturated vapour) displayed an approximate lethal concentration of 1700 mg/m^3 in rats (E.I. du Pont de Nemours and Company, 1977).

Oral LD$_{50}$s for rats, mice, guinea-pigs, and rabbits ranged from 3900 to 7900 mg/kg body weight (Ansell & Fowler, 1988), and dermal LD$_{50}$s for rats and rabbits ranged from 4000 to 10 000 mg/kg body weight (Bartsch et al., 1976). Non-surviving rats in an acute oral toxicity study showed irritation of the pyloric and gastrointestinal tracts and darkening of kidneys, liver, and lungs (LD$_{50}$ 4150 mg/kg body weight) (Ansell & Fowler, 1988). At sublethal doses (one-eighth of the LD$_{50}$), ataxia and diuresis were recorded in survivors (Clark et al., 1984).

8.2 Irritation and sensitization

Skin irritation tests in New Zealand White rabbits (*n* = 6) exposed to 0.5 ml NMP were performed (Draize et al., 1944). The test sites were occluded for 24 h and then examined for skin reactions. Only slight erythema was observed. When the examination was repeated 72 h and 7 days after the start of exposure, no effects were observed. The tests showed a low potential for skin irritation and resulted (for both intact and abraded skin and averaged reading from 24 and 72 h) in a primary irritation index of 0.5 (out of a maximum 8) (BASF, 1963; Ansell & Fowler, 1988). Repeated daily dermal administration of 450 mg/kg body weight to rabbits caused painful and severe haemorrhage and eschar formation after four doses; the reaction to a dose of 150 mg/kg body weight per day was less marked (BASF, 1993a). Aqueous solutions of NMP were tested for primary skin irritation in 10 male albino guinea-pigs. Twenty-four hours after application, slight erythema was observed in two guinea-pigs with the 50% solution and in 0 with the 5% solution. After 48 h, no effects were registered (E.I. du Pont de Nemours and Company, 1976b). Dry skin at the application site was found in rats at dermal doses of 500–2500 mg/kg body weight and per 25 cm^2 of skin (Becci et al., 1982).

Sensitization potential tests, defined as the increase of response at challenge after a series of four intradermal injections (0.1 ml of 1% NMP in 0.9% saline solution; one injection per week), were performed in 10 male albino guinea-pigs. Two weeks after the intradermal injections, the animals were exposed to aqueous solutions of NMP. About 0.05 ml each of a 5% and a 50% (vol/vol) solution were applied and lightly rubbed in to the shaved intact shoulder skin. Nine guinea-pigs that did not have intradermal injections of NMP were used as control animals. No sensitization was found when the animals were examined after 24 and 48 h. After 24 h, there was slight erythema at the 50% solution test sites in 6 out of 10 challenged guinea-pigs and in 4 out of 9 controls. No effects were observed when animals were examined after 48 h. The 5% NMP solution caused no irritation (E.I. du Pont de Nemours and Company, 1976b).

Primary eye irritation tests (Draize et al., 1944) were performed in New Zealand White rabbits ($n = 9$). Intraocular applications of 0.1 ml NMP into one eye (the other eye served as untreated control) caused conjunctival effects, such as corneal opacity, iritis, and conjunctivitis. The effects faded within 21 days after the application. When the exposed eye was washed out 30 s after the application (performed in three of the nine exposed rabbits), the effects faded within 14 days. The primary irritation index scores for unwashed/washed eye were 41/35, 40/26, 34/18, 8/1, 4/0, and 0/! after 1, 2, 3, 7, 14, and 21 days post-exposure, respectively. The tests in the rabbits indicated a moderate potential for eye irritation (Ansell & Fowler, 1988).

8.3 Short-term exposure

8.3.1 *Inhalation*

Concentration-related signs of lethargy and irregular respiration were observed at all dose levels in rats exposed to 100, 500, or 1000 mg NMP/m^3 (mainly aerosol; >95% of the droplets <10 µm) for 6 h/day, 5 days/week, for 4 weeks using whole-body exposure. At the two lowest exposure levels, these signs were reversible within 30–45 min post-exposure. No signs of pathological lesions were observed at these dose levels. At 1000 mg/m^3, there was excessive mortality. In dead animals, myelotoxic effects in terms of bone marrow hypoplasia and atrophy and/or necrosis of the lymphoid tissue in thymus, spleen, and lymph nodes were found. In surviving animals, these findings were not observed at 14 days post-exposure (Lee et al., 1987).

In a series of inhalation toxicity studies, female rats were exposed to 1000 mg NMP/m^3, 6 h/day, 5 days/week, for 2 weeks (Table 2). The head-only exposure, independent of aerosol fraction and humidity, caused no effects other than slight nasal irritation and coloured urine (BASF, 1992, 1995g). Whole-body exposure (coarse droplets and high relative humidity) caused massive mortality, apathy, decreased body weight and body weight gain, irritation in the nasal region, and severe effects on organs and tissues (BASF, 1995d,f,g). Whole-body exposure (fine droplets and low or high relative humidity) caused no deaths and less severe effects (BASF, 1995a,c,e). It should be noted that NMP may exist in various proportions of vapour and aerosol depending on the concentration, temperature, and atmospheric humidity. The maximum vapour phase at room temperature is 1318 mg/m^3 in dry air (0% relative humidity), 412 mg/m^3 at normal humidity (60% relative humidity), and 0 mg/m^3 in wet air (100% relative humidity).

Ten female rats per dose level were exposed whole body to 0 or 1000 mg NMP/m^3 (coarse/dry; MMAD 4.7–6.1 µm; 10% relative humidity) for 6 h/day, 5 days/week, for 4 weeks. There were no deaths. The body weights were decreased, and apathy, ruffled fur, and respiratory irritation were observed (BASF, 1995b).

8.3.2 *Oral*

Rats (10 per sex) were intubated 5 days/week for 4 weeks with 0, 257, 514, 1028, or 2060 mg NMP/kg body weight per day. In males, a dose-dependent decrease was observed in body weight at 1028 and 2060 mg/kg body weight (11% and 16%, respectively), and a decrease in relative and absolute testes weight was

Table 2: Inhalation toxicity in female rats exposed to 1000 mg NMP/m^3 for 2 weeks.[a]

Exposure characterization[b]	Area	Effects observed	Reference
Fine/dry (<3 µm 10% RH)	Whole body	No deaths. Slight decrease in body weight gain ($P < 0.05$). Slight decrease in lymphocytes. Slight increase in neutrophils.	BASF, 1995c
Fine/dry (3.8–4.4 µm; 35% RH)	Nose only	No deaths.	BASF, 1992
Coarse/wet (4.8 µm; 70% RH)	Whole body	Nine deaths. Congestion in nearly all organs, lesions in spleen and lungs. Surviving rat recovered in 2 weeks.	BASF, 1995f
Coarse/wet (4.4–4.5 µm; 70% RH)	Head only	No deaths. Nasal irritation.	BASF, 1995g
Coarse/wet (4.4–4.5 µm; 70% RH)	Whole body	Nine deaths. Serious lesions in spleen (depletion and necrosis of lymphocytes) and bone marrow (panmyelophthisis and gelatinous bone marrow). In the surviving rat: Body weight and absolute organ weight different from means of the control group.	BASF, 1995g
Coarse/wet (5.1–5.2 µm; 70% RH)	Whole body	Eight deaths. Apathy, irregular respiration, convulsions, tremor, and poor general health state. Pulmonary oedema and multifocal purulent pneumonia. Necrotic alterations in liver. Cell depletion in bone marrow and necrosis in spleen. Ulceration in the glandular stomach. Increased adrenal weight. In the surviving rats: No significant gross or microscopic findings.	BASF, 1995d
Fine/dry (<3 µm; 10% RH)	Whole body	No deaths. Sensory irritation (significant changes: respiratory rate decreased, minute volume lower, inspiration time longer).	BASF, 1995a
Fine/wet (>3 µm; 70% RH)	Whole body	No deaths. Slight ($P = 0.05$) decrease in white cells and lymphocytes and increase in liver weight. Increased relative lung weight. Nasal irritation symptoms.	BASF, 1995e

[a] Female rats ($n = 10$) were exposed to 1000 mg NMP/m^3 with an exposure schedule of five 6-h exposures per week for 2 weeks. A control group of 10 female rats was exposed to air.

[b] RH = relative humidity.

observed in nine animals at 2060 mg/kg body weight. The histological examination showed adverse effects on seminiferous tubule epithelium and formation of multinucleate giant cells and clumping of sloughed-off cells. In both sexes, a dose-dependent increase in relative liver and kidney weights and a decrease in body weight gain were observed at 1028 and 2060 mg/kg body weight, and lymphocyte count decreased following exposure to 1028 and 2060 mg/kg body weight. At 2060 mg/kg body weight, testes weights decreased in nine males, and histological changes in the testes were observed. At 2060 mg/kg body weight, symptoms of general toxicity, such as tremor, restlessness, ruffled fur, and defensive reactions, were registered (BASF, 1978a). The NOAEL and lowest-observed-adverse-effect level (LOAEL) in this study were 514 and 1028 mg NMP/kg body weight, respectively.

In a repeated-dose toxicity study (Malek et al., 1997), rats (five per sex) were given 0, 2000, 6000, 18 000, or 30 000 mg NMP/kg diet for 28 days. The mean daily NMP doses were 0, 149, 429, 1234, and 2019 mg/kg body weight in males and 0, 161, 493, 1548, and 2268 mg/kg body weight in females. Compound-related decreases in body weight and body weight gain were observed in male rats at 18 000 and 30 000 mg/kg diet and in female rats at 30 000 mg/kg diet. In males at 18 000 and 30 000 mg/kg diet, the mean body weight on test day 28 was reduced by 17% and 33%, respectively, compared with the control value, and the body weight gain was reduced by 40% and 72%, respectively. In females at 30 000 mg/kg diet, the mean body weight on test day 28 was reduced by 14% compared with the control value, and the body weight gain was reduced by 52%. The decreases in body weight and body weight gain were correlated with lower food consumption. In males at 18 000 and 30 000 mg/kg diet, food consumption was reduced by 19% and 31%, respectively, and food efficiency was reduced by 26% and 59%, respectively. In females at 30 000 mg/kg diet, food consumption was reduced by 23%, and food efficiency was reduced by 36%. Microscopic lesions associated with decreased food consumption and depressed body weights were present in male rats at 18 000 and 30 000 mg/kg diet and in female rats at 30 000 mg/kg diet. These histological alterations included hypocellular bone marrow in both sexes, testicular degeneration and atrophy in males, and thymic atrophy in females. Based on this study, the NOAEL was found to be 6000 mg/kg diet (429 mg/kg body weight) in male rats and 18 000 mg/kg diet (1548 mg/kg body weight) in female rats.

In a repeated-dose toxicity study (Malek et al., 1997), mice (five per sex) were given 0, 500, 2500, 7500, or 10 000 mg NMP/kg diet for 28 days. The mean daily NMP dose was 0, 130, 720, 2130, and 2670 mg/kg body weight in males and 0, 180, 920, 2970, and 4060 mg/kg body weight in females. Swelling of epithelium of distal renal tubuli was observed in two out of five males at 7500 mg/kg diet, in four out of five males at 10 000 mg/kg diet, and in three out of five females at 10 000 mg/kg diet. There were no compound-related effects on body weight or food consumption at any dose level. Based on this study, the NOAEL was found to be 2500 mg/kg diet (720 mg/kg body weight) in male mice and 7500 mg/kg diet (2970 mg/kg body weight) in female mice.

8.4 Medium-term exposure

8.4.1 Inhalation

In a medium-term exposure study, rats (10 per sex per dose level) were exposed (head only) to 0, 500, 1000, or 3000 mg NMP/m^3 for 6 h/day, 5 days/week, for 13 weeks. These groups were sacrificed and examined at the end of exposure. An additional two satellite groups (10 rats per sex per dose level) were identically exposed to 0 or 3000 mg/m^3 and sacrificed after 13 weeks of exposure and a 4-week post-exposure period to obtain information on the reversibility of possible effects. The generated NMP atmospheres consisted of a large proportion (82–92%) of respirable aerosol particles (MMAD 2.1–3.5 µm; relative humidity 52–61%). Dark yellow discoloration of the urine was found at all levels, and nasal irritation as shown by crust formation on nasal edges at 1000 mg/m^3 was observed at the end of the exposure period. At 3000 mg/m^3, non-specific clinical symptoms and irritation of the respiratory tract were registered. In male rats, body weight was significantly decreased (34%) and absolute testes weight was decreased. Cell loss in germinal epithelium of testes in 4 out of 10 male rats was noted. Slight increases in erythrocytes, haemoglobin, haematocrit, and mean corpuscular volume were observed. In female rats, the number of polymorphonuclear neutrophils increased and the number of lymphocytes decreased. Examination of the satellite group at the end of the 4-week post-exposure observation period showed a significant lower body weight gain in males compared with the controls. The testes effects registered in the 3000 mg/m^3 group sacrificed at the end of exposure were also registered in the satellite group at the end of the 4-week post-exposure observation period. The NOAEL was 500 mg NMP/m^3 for both male and female rats (BASF, 1994).

8.4.2 Oral

Rats (10 per sex) were administered 0, 3000, 7500, or 18 000 mg NMP/kg diet for 90 days. The mean daily NMP dose was 0, 169, 433, and 1057 mg/kg body weight in males and 0, 217, 565, and 1344 mg/kg body weight in females. A decrease in body weight and body weight gain was correlated with lower food consumption and food efficiency and was observed in both males and females at dose levels of 7500 mg/kg diet (6% and 15% in males and females, respectively) and 18 000 mg/kg diet (28% and 25% in males and females, respectively). Compound-related adverse effects were observed in males in 3 out of 36 neurobehavioural parameters. Increased foot splay was observed at 7500 and 18 000 mg/kg diet. This effect was not reversed in the recovery group. A higher incidence of low arousal and slight palpebral closure was observed in males at 18 000 mg/kg diet, suggesting a sedative effect of NMP. The NOAEL for this study was 3000 mg NMP/kg diet (equivalent to mean doses of 169 mg/kg body weight in males and 217 mg/kg body weight in females) (E.I. du Pont de Nemours and Company, 1995b).

Dogs (six per sex per dose level) administered NMP at doses of 0, 25, 79, or 250 mg/kg body weight per day in the diet for 90 days showed no statistically significant adverse effects. A dose-dependent decrease in body weight gain and an increase in platelet count and megakaryocytes within a normal range were observed. At the exposure termination, no significant differences between high-dose and control groups were reported (Becci et al., 1983). The NOAEL for dietary exposure in dogs in this study is 250 mg/kg body weight per day.

8.5 Long-term exposure and carcinogenicity

In a 2-year inhalation study, Charles River CD rats (120 per sex per dose level) were exposed (whole body) to NMP vapour concentrations of 0, 40, or 400 mg/m^3 for 6 h/day, 5 days/week. Ten rats per sex were subjected to haematology and blood and urine chemistry analysis after 1, 3, 6, 12, and 18 months of exposure. Ten rats per sex were sacrificed after 3, 12, and 18 months. All surviving rats were killed at the end of 24 months of exposure and subjected to a gross examination. All vital organs and tissues were subjected to microscopic examination. Respiratory tract toxicity was observed at 400 mg/m^3 as a minimal inflammation in the lung. Male rats exposed to 400 mg/m^3 for 18 months showed higher haematocrit and higher alkaline phosphatase levels in serum than were observed in the control group. There was no such difference after 24 months of exposure. At the 400 mg/m^3 dose level, male rats excreted larger urine volumes, and both males and females excreted dark yellow urine. The 2-year study showed a 6% reduction in the mean body weight in male rats at the 400 mg NMP/m^3 dose level (statistical significance not reported). NMP was reported to have no oncogenic potential (Lee et al., 1987).

8.6 Genotoxicity and related end-points

8.6.1 In vitro

NMP has been tested in bacterial mutagenicity assays in the dose range of 0.01–1000 µmol/plate (0.99 µg/plate to 99 mg/plate) with and without metabolic activation by Aroclor-induced rat liver S9. In the direct plate incorporation in *Salmonella typhimurium* strains TA97, TA98, TA100, TA102, and TA104 at highest dose, signs of cytotoxicity (decreased number of revertants or bacterial lawn thinning) were observed. In strains TA102 and TA104 without activation, a minor and no dose-related increase in the number of revertants were observed. When using a preincubation method in strains TA98 and TA104, no effects were registered (Wells et al., 1988). Also, in another preincubation test in strains TA98, TA100, TA1535, and TA1537 (NMP dose levels up to 10 mg/plate) with and without Aroclor-induced rat or hamster liver S9, no mutagenic activity was observed (Mortelmans et al., 1986). Other studies, also using *Salmonella typhimurium* strains for testing the mutagenicity of NMP, reported no mutagenic activity (BASF, 1978b; Maron et al., 1981).

Two assays in yeast show that NMP may induce aneuploidy. Incubation of *Saccharomyces cerevisiae* strain D61.M with NMP in the dose range of 77–230 mmol/litre (7.6–23 g/litre) caused a dose-related effect. Concentrations of 179 mmol/litre (18 g/litre) and higher were toxic and decreased the level of survival by more than 50% (Mayer et al., 1988). The decrease in survival was shown to be the same when NMP was used at a concentration of 2.44% for incubation of the same yeast strain (Zimmermann et al., 1988).

Negative results were obtained in a study of the ability of NMP to induce unscheduled DNA synthesis in rat primary hepatocyte cultures (GAF, 1988) and in a study of the mutagenic activity of NMP in L5178Y mouse lymphoma cells (E.I. du Pont de Nemours and Company, 1976a).

8.6.2 In vivo

In a micronucleus test, NMRI mice (both sexes) were orally administered a single dose of 950, 1900, or 3800 mg NMP/kg body weight. Irregular respiration, colored urine, and general poor health were observed. No clastogenic effects or aneuploidy were observed when mice were examined at 24, 48, and 72 h after dose administration. Positive controls displayed clastogenic and aneugenic activity. Thus, no mutagenic activity with NMP was found (Engelhardt & Fleig, 1993).

In a bone marrow chromosomal aberration study, Chinese hamsters (both sexes) were exposed to a single oral dose of 1900 or 3800 mg NMP/kg body weight. Irregular respiration, coloured urine, and general poor health were observed. At 16 (only high dose level) and 24 h after administration, bone marrow samples were taken. Structural and numerical chromosomal alterations were found in positive control animals but not in NMP-exposed animals, indicating no mutagenic activity with NMP (Engelhardt & Fleig, 1993).

Signs of toxicity were reported in two older studies: a micronucleus test in Chinese hamsters (both sexes) (BASF, 1976) exposed for 6 weeks (6 h/day, 5 days/week) to 3300 mg NMP/m^3 and a germ cell genotoxic activity test (a dominant lethal test) in male NMRI mice (BASF, 1976) with intraperitoneal administration of 391 mg NMP/kg body weight (once per week for 8 consecutive weeks). The inhalation study displayed a slight but non-significant increase in structural chromosomal aberrations in the bone marrow. In the intraperitoneal study, a significantly increased post-implantation loss was observed (relative to the control animals). The studies were not performed to current regulatory standards and could not be fully evaluated for NMP mutagenic activity.

8.7 Reproductive toxicity

The reproductive toxicity of NMP in rats is summarized in Table 3.

8.7.1 Effects on fertility

8.7.1.1 Inhalation

In a two-generation reproduction study, rats (10 males and 20 females per dose level) were exposed whole body to 0, 41, 206, or 478 mg/m^3 of NMP vapour (relative humidity 40–60%) for 6 h/day, 7 days/week, for a minimum of 14 weeks (P_0 generation). The P_0 generation was 34 days old at exposure onset. At 119 days of age, one male and two females from the same exposure

Table 3: Reproductive toxicity of NMP in rats.

		Toxicity			
Species; type of study	**Exposure**	**Fetal**	**Maternal**	**NOAEL/LOAEL**	**Reference**
Rat; two-generation; inhalation (whole body), 6 h/day, 7 days/week	0 mg/m^3 41 mg/m^3 206 mg/m^3 478 mg/m^3	None None None Pup body weight decrease (4–11%)	None None None Decrease in response to sound	Reproductive toxicity: NOAEL = 206 mg/m^3; LOAEL = 478 mg/m^3 Maternal toxicity: NOAEL = 206 mg/m^3; LOAEL = 478 mg/m^3	Solomon et al., 1995
Rat; testes and semen toxicity study; inhalation (whole body); 6 h/day, 7 days/week; <90 days	0 mg/m^3 618 mg/m^3	None None	None None	Reproductive toxicity: NOAEL = 618 mg/m^3	Fries et al., 1992
Rat; two-generation study; inhalation (whole body)	0 mg/m^3 478 mg/m^3	None Fetal body weight decrease (mean 7%)	None None	Developmental toxicity: LOAEL = 478 mg/m^3	Solomon et al., 1995
Rat; developmental toxicity; inhalation (whole body); days 4–20, 6 h/day	0 mg/m^3 680 mg/m^3	None Increased preimplantation loss but no effect on number of implantations per dam or number of live fetuses; delayed ossification	None None	Developmental toxicity: LOAEL = 680 mg/m^3 Maternal toxicity: NOAEL = 680 mg/m^3	Hass et al., 1995
Rat; developmental toxicity; inhalation (whole body); days 7–20, 6 h/day	0 mg/m^3 622 mg/m^3	None Decreased body weight; neuro-behavioural effects	None None	Developmental toxicity: LOAEL = 622 mg/m^3 Maternal toxicity: NOAEL = 622 mg/m^3	Hass et al., 1994
Rat; developmental toxicity; inhalation (whole body); days 6–15, 6 h/day	0 mg/m^3 100 mg/m^3 360 mg/m^3	None None None	None None Lethargy and irregular respiration during the first 3 days of exposure	Developmental toxicity: NOAEL = 360 mg/m^3 Maternal toxicity: NOAEL = 100 mg/m^3; LOAEL = 360 mg/m^3	Lee et al., 1987
Rat; range-finding developmental toxicity study; dermal; days 6–15	0 mg/kg body weight per day 500 mg/kg body weight per day 1100 mg/kg body weight per day 2500 mg/kg body weight per day	– – – –	None None Massive resorption; decreased body weight gain Lethal	Maternal toxicity: NOAEL = 500 mg/kg body weight per day; LOAEL = 1100 mg/kg body weight per day	Becci et al., 1982
Rat; developmental toxicity study; dermal; days 6–15	0 mg/kg body weight per day 75 mg/kg body weight per day 237 mg/kg body weight per day 750 mg/kg body weight per day	None None None Increased resorption, delayed ossification	None None None Decreased body weight gain	Developmental toxicity: NOAEL = 237 mg/kg body weight per day; LOAEL = 750 mg/kg body weight per day Maternal toxicity: NOAEL = 237 mg/kg body weight per day; LOAEL = 750 mg/kg body weight per day	Becci et al., 1982

group were allowed to mate. The P_0 males were exposed for >100 days (pre-mating and mating periods), and the females were exposed for >106 days (pre-mating, mating, gestation, and lactation periods). At the end of the mating period, 50% of the P_0 males were sacrificed and examined for adverse reproductive effects. The other 50% of the P_0 males were examined 21 days later (recovery period). From the delivered offspring, exposed from day 4 postpartum, one male and one female per litter were examined for adverse reproductive effects on day 21 postpartum. The remaining offspring were designated as the F_1 generation. At the end of the weaning period, the P_0 dams were sacrificed and examined for adverse effects on reproduction. In parallel, the sex-specific effects of exposure to 0 and 478 mg/m^3 vapour for 6 h/day, 7 days/week, for a minimum of 14 weeks were studied by cross-mating of exposed and unexposed males and females from the F_1 generation for production of an F_2 generation. No effects on body, testes, or ovarian weights or on reproductive ability were recorded. A 4–11% decrease in pup weight of the F_1 offspring whose parents both inhaled NMP was observed from day 1 to day 21 postpartum, but not at day 28 postpartum. This effect was not clearly dose related and reached statistical significance for the low and high, but not for the intermediate, exposure groups (Solomon et al., 1995).

In a reproduction study, male rats (12 per dose level) were exposed whole body to 0 or 618 mg NMP/m^3 (vapour; <50% relative humidity) for 6 h/day, 7 days/week, for 90 days. There were no abnormal histopathological changes or differences in testis weights when rats were examined at the termination of exposure and 90 days later. Nor were there any abnormalities of the semen, sperm cell morphology, or cell concentration (Fries et al., 1992).

8.7.2 Developmental toxicity

8.7.2.1 Inhalation

In the two-generation reproductive toxicity study of Solomon et al. (1995), a developmental toxicity study was performed in rats. Groups of 10 males and 20 females were whole-body exposed to 0 or 478 mg NMP/m^3 for 6 h/day, 7 days/week, for a minimum of 14 weeks. Exposed males were then mated with exposed females, and non-exposed males were mated with non-exposed females (controls). For the developmental toxicity evaluation, the pregnant females were sacrificed on day 21. No effects on pregnancy rate, numbers of viable litters, corpora lutea, implantations, fetal deaths, resorptions, litter size, or incidence of fetal malformations or variations were found. A 7% decrease (P # 0.05) in mean fetal weight in the exposed group was observed.

In a developmental study, pregnant rats (27 in the control group and 28 in the exposed group) were exposed whole body to 0 or 680 mg NMP/m^3 (vapour; <50% relative humidity) for 6 h/day on days 4–20 of gestation. The dose was chosen to correspond to the "worst-case" level of human exposure. No clinical signs of maternal toxicity were seen. The number of dams with preimplantation loss was increased in the exposed group. Preimplantation loss was observed in 20 out of 23 litters compared with 11 out of 20 litters in the control group ($P < 0.05$); no significant effect on the number of implantations per dam or the number of live fetuses was observed. Compared with the control group ($P < 0.05$), there was also an increase in the incidence of delayed ossification of the skull, cervical vertebrae 4 and 5, sternebrae, and metatarsal and digital bones in the exposed animals. No increased incidence of malformations was found (Hass et al., 1995).

In a neurobehavioural teratology study, pregnant rats were exposed whole body to 0 or 622 mg NMP/m^3 (vapour; <50% relative humidity) for 6 h/day on days 7–20 of gestation. The dose was chosen to minimize maternal toxicity and offspring mortality, based on earlier experience in the laboratory. Maternal weight development during days 7–20 was 15% slower among the exposed dams (no statistical analysis reported). In the exposed group, a lower body weight of the pups and slight delay in achieving some developmental milestones in the preweaning period were observed. While most of the behavioural tests gave similar results for the exposed and control animals, an occasionally increased latency in Morris swimming maze and a statistically borderline impairment in operant behaviour with delayed spatial alternation were noted among the exposed offspring (Hass et al., 1994).

In a developmental toxicity study, pregnant rats (25 per dose level) were exposed whole body to 0, 100, or 360 mg NMP/m^3 for 6 h/day on days 6–15 of gestation. The exposure consisted of a mixture of aerosol/vapour of unknown particle size distribution. No effects of the NMP exposure on the outcome of pregnancy, embryonal growth rate, or development in vital organs and skeletons of the fetuses were found. Nor were there abnormal clinical signs or pathological lesions in the maternal rats. During the first 3 days, lethargy and irregular respiration were observed in the dams exposed to 100 mg/m^3 (Lee et al., 1987).

8.7.2.2 Dermal

In a range-finding study of developmental toxicity, pregnant rats (3–5 per exposure level) were exposed to daily dermal doses of 0, 500, 1100, or 2500 mg NMP/kg body weight during days 6 through 15 of gestation. At the highest dose level, all dams died or aborted before day 20 of gestation. The dose level of 1100 mg/kg body weight caused a depression in dam body weight gain and was embryolethal; 65 out of 66 fetuses were resorbed. A daily dermal dose of 500 mg/kg body weight had no adverse effect on pregnancy, dam body weights, implantations, or gestation (Becci et al., 1982).

In a developmental toxicity study, pregnant rats (about 22 per dose level) were administered daily dermal NMP doses of 0, 75, 237, or 750 mg/kg body weight during days 6 through 15 of gestation. At the highest dose, maternal and developmental toxicity were shown: on day 20 of gestation, decreased dam body weight gain, increased resorption of fetuses, and decreased fetal body weight, as well as skeletal abnormalities, including missing sternebrae, fused/split/extra ribs, incomplete closing of the skull, incomplete ossification of vertebrae, fused atlas and occipital bones, and reduced or incomplete hyoid bone, were observed. No increase was observed in the incidence of soft tissue anomalies. The NOAEL in dams and fetuses was 237 mg/kg body weight per day. The lower maternal body weight observed may be explained by increased resorption rate and decreased fetal body weight (Becci et al., 1982).

8.7.3 Additional studies

A number of studies that are not available in the open literature and therefore are not usable as a basis for risk assessment in this CICAD are reported in this section as supporting data for the developmental effects of NMP.

In a multigeneration reproduction study, rats were exposed in the diet to NMP at doses of 50, 160, or 500 mg/kg body weight per day. The first parental generation (P_1) was exposed during a period prior to mating, gestation, lactation, and weaning of the litter (F_{1a}) and during a period prior to a second mating, gestation, lactation, and weaning of the litter (F_{1b}). The second parental generation ($P_2 = F_{1b}$) was exposed from day 21 postpartum as the P_1 generation until the first litter (F_{2a}) and the second litter (F_{2b}) were delivered. The highest dose level caused decreased parental body weight and food consumption and a concomitant reduction in survival and growth rates in the offspring. The data from the 50 and 160 mg/kg body weight per day experiments with slightly lower male fertility and female fecundity indices do not clearly demonstrate a NOAEL (EXXON, 1991).

In a pre-test of developmental toxicity, five pregnant rabbits per dose level were exposed to 0, 300, 1000, or 2000 mg NMP/m^3 (vapour/aerosol; MMAD 3.8–4.0 µm) for 6 h/day on days 7–19 post-insemination. Maternal toxicity was expressed as prolonged clotting time, decreased plasma protein content, and increased liver weight at both 1000 and 2000 mg/m^3. In the main study, pregnant rabbits (15 per dose level) exposed head only for 6 h/day to 0, 200, 500, or 1000 mg NMP/m^3 (vapour/aerosol; MMAD 2.7–3.5 µm) on days 7–19 post-insemination showed no signs of maternal toxicity. At 1000 mg/m^3, a slight fetal toxicity was seen as increased occurrence of skeletal variations (accessory 13th ribs) (BASF, 1993b). The two studies show NOAELs for developmental and maternal toxicity of 500 mg/m^3 (BASF, 1991).

In a developmental study, pregnant rats (25 per dose level) were given daily NMP doses of 0, 40, 125, or 400 mg/kg body weight by oral gavage on days 6–15 of gestation. Maternal and fetal toxicity were observed at the highest dose level compared with controls. The toxicity was indicated as maternal body weight gain decrement, reduced fetal body weights, and increased incidence of fetal stunting at 400 mg/kg body weight (EXXON, 1992).

In another developmental toxicity study (GAF, 1992), orally administered doses of 55, 175, or 540 mg NMP/kg body weight per day in pregnant rabbits (20 per dose level) on days 6–18 of gestation caused maternally decreased body weight gain at 175 and 540 mg/kg body weight per day. Developmental toxicity was shown as post-implantation loss, altered fetal morphology, and increased incidences of cardiovascular and skull malformations at 540 mg/kg body weight per day.

An oral daily dose of 997 mg NMP/kg body weight administered to rats by gavage on days 6–15 of gestation showed no maternal toxicity but increased the incidence of resorptions (95%) and caused malformations in 8 out of 15 surviving fetuses. Other adverse effects observed were fetal mortality, reduced placental and fetal weights, and reduced fetal lengths. No adverse effect was observed at 332 mg NMP/kg body weight, but a minor decrease in placental weight was observed. Reported maternal toxicity data were unsatisfactory (US EPA, 1988).

Oral daily doses of 0, 1055, or 2637 mg/kg body weight on days 11–15 of gestation in mice caused an increase in resorption rate, increased incidence of runts, diminished fetal weight and length, and an increased rate of malformations such as cleft palate at the higher dose level. The lower dose level caused no observable embryotoxicity. Both developmental and maternal toxicity are insufficiently reported, and the exposure covers only a part of organogenesis (US EPA, 1988).

The maternal toxicity in rabbits after dermal application was studied in a range-finding study. Pregnant rabbits (15 per dose level) were exposed daily to dermal doses of 0, 400, 600, or 800 mg/kg body weight (as 40% aqueous solution). There was maternal toxicity, expressed as prolonged clotting time at 800 mg/kg body weight (BASF, 1993a).

In a developmental toxicity study, 15 pregnant rabbits per dose level were exposed daily by dermal application to 0, 100, 300, or 1000 mg NMP/kg body weight for 6 h/day on days 7–19 post-insemination. The application doses were made as 40% aqueous solution. There were no signs of maternal toxicity. At 1000 mg/kg body weight per day, a slight fetal toxicity was seen as increased occurrence of skeletal variation (accessory 13th ribs) (BASF, 1993a).

An intraperitoneal daily dose to mice of 0, 630, or 1570 mg/kg body weight on days 11–15 of gestation caused increased resorption rate, increased incidence of runts, diminished fetal weight and length, and an increased rate of malformations such as cleft palate at the high level. No maternal toxicity was observed. The low dose level caused no observable embryotoxicity. No information on maternal toxicity is given in this study; thus, evaluation of the results is difficult (US EPA, 1988).

NMP doses of 14–166 mg/kg body weight singly or repeatedly intraperitoneally administered to mice during various phases of pregnancy caused increased post-implantation loss and a reduced body weight of the fetuses. Morphological defects such as exencephaly, open eyelids, microphthalmia, cleft palate, oligodactyly, shortened or kinked tails, fusions and curvature of neck and chest vertebrae, and fusion of sternebrae and ribs were observed. The LOAEL for repeated doses was 74 mg/kg body weight administered on days 7–11 of gestation. No information on maternal toxicity is given in this study; thus, evaluation of the results is difficult (Schmidt, 1976).

8.8 Immunological and neurological effects

Effects on the immune system (thymic atrophy in female rats, decreased leukocyte count in both sexes) have been described in studies performed in rats after a 28-day oral administration at high dose levels (see section 8.3).

9. EFFECTS ON HUMANS

A 23-year-old laboratory technician was occupationally exposed to NMP during her first 20 weeks of pregnancy. The uptake via the lungs was probably of minor importance, as the NMP was handled at room temperature. Hand rinsing of glassware with NMP and cleaning up of an NMP spill in week 16 of pregnancy may have brought about a much larger uptake through the skin. During the 4 days following the spill, malaise, headache, and nausea were experienced. Examination of the pregnancy at week 14 showed no signs of delayed development; however, at week 25, signs of delayed fetal development were observed, and at week 31, a stillborn fetus was delivered. Stillbirth in this period of pregnancy is unusual. However, as the level of exposure is unknown, it is impossible to establish if exposure to NMP is the causative factor (Solomon et al., 1996; Bower, 1997).

A total of 15 24-h exposures in a repeated-insult patch test in human subjects (*n* = 50) caused minor to moderate transient irritations. No signs of contact sensitization were observed. Direct contact of skin with NMP caused redness, swelling, thickening, and painful vesicles when NMP was used as a cleaner (Leira et al., 1992) or as a paint stripper (Åkesson & Jönsson, 2000c).

Workers exposed to NMP in working areas with air concentrations up to 280 mg/m^3 reported severe eye irritation and headache. With the methods of assessing the exposure level (sampling on charcoal and tracer gas method) and the response (observation and informal interview), it is impossible to develop a concentration–response relationship (Beaulieu & Schmerber, 1991). Six volunteers exposed to 10, 25, or 50 mg/m^3 during 8 h in a chamber study registered their symptoms, before the start of exposure and then every 2 h for 16 h, in a questionnaire on a scale from 0 to 10 (0 = no symptoms and 10 = not tolerated). The volunteers displayed none of the following symptoms: eye or respiratory tract irritation; hacking cough, nose secretion, or blockage, sneezing, itching, or dryness in the mouth and throat, or other symptoms in upper airways; itching, secretion, smarting pain, visual disturbances, or other symptoms such as headache, dizziness, and nausea; and other symptoms. Two volunteers reported detecting an odour at 50 mg/m^3. There were no significant differences in the spirometric data displayed by the forced expiratory volume in 1 s, vital capacity, and the highest forced expiratory capacity measured before or after any level of exposure. There were no acute changes in the nasal cavity assessed by continuous acoustic rhinometry. Even though the effects observed in this study were not very pronounced, the possibility of undetected effects still remains (the number of volunteers was only six) (Åkesson & Paulsson, 1997).

No epidemiological studies were located.

10. EFFECTS ON OTHER ORGANISMS IN THE LABORATORY AND FIELD

10.1 Aquatic environment

In a static test on the acute toxicity of NMP to the freshwater guppy (*Poecilia reticulata*), a 96-h LC_{50} value of 2670 mg/litre was determined, based on the nominal concentration (Weisbrod & Seyring, 1980).

Unvalidated study results reported in IUCLID (1995) indicate that NMP has low acute toxicity to fish, crustaceans, algae, and bacteria (short-term LC_{50} or EC_{50} values >500 mg/litre). No data on the long-term toxicity of NMP to aquatic organisms have been identified.

10.2 Terrestrial environment

No recent and evaluated data on the toxicity of NMP to terrestrial species were found. However, some older results from short-term studies on birds were found in IUCLID (1995). According to these data, the acute toxicity following a single oral dose as well as the subacute toxicity following dietary exposure are low (LD_{50} >2000 mg/kg body weight and LC_{50} >5000 mg NMP/kg diet, respectively).

11. EFFECTS EVALUATION

11.1 Evaluation of health effects

11.1.1 Hazard identification and dose–response assessment

Data on the effects of exposure to NMP in humans are scanty. The toxicity evaluation is therefore based on animal data.

NMP is efficiently absorbed from the respiratory and gastrointestinal tracts as well as through the skin and is rapidly distributed to all organs. A relatively large proportion of the administered NMP dose was recovered in the testis after intravenous administration.

The acute toxicity of NMP is low. The air concentration of NMP causing acute toxicity in whole-body-exposed rats was less than one-third of that causing acute toxicity in head-only-exposed rats.

In a chamber study, a single exposure of volunteers did not cause irritation-related symptoms in eyes or the respiratory tract at exposures up to 50 mg inhalation and in the pyloric and gastrointestinal tracts after oral administration.

Dermal irritation has been observed in humans after exposure to liquid NMP used as a cleaner or paint stripper. A low potential for skin irritation was reported in a repeated-insult patch test in humans, as well as in a primary skin irritation study in rabbits. NMP was negative for skin sensitization in humans and animals and caused moderate eye irritation in animals.

NMP did not show carcinogenic potential in a 2-year inhalation study in rats. No genotoxic potential of NMP was reported in a series of *in vitro* and *in vivo* studies.

In a repeated whole-body exposure study in which rats were exposed to 1000 mg NMP/m^3 for 2 weeks, there was extensive mortality, and autopsy revealed myelotoxicity and atrophy of lymphoid tissue.

Inhalation exposure to NMP did not induce changes in the male reproductive tract or semen quality in rats. Administration of NMP parenterally or at maternally toxic doses to experimental animals induced fetal toxicity and teratogenicity.

One study by inhalation reported a slight decrease in fetal weight in the absence of clinical signs of maternal toxicity at an exposure level of 478 mg/m^3 and a non-dose-dependent, transient minor decrease in pup weight at exposure levels of 41, 206, and 478 mg/m^3 (Solomon et al., 1995). A transient decrease in pup weight, late arrival at some of the measured postnatal development milestones, and impaired results in some of a large number of functional neurobehavioural tests were observed in rats after exposure to 622 mg NMP/m^3, a concentration that was accompanied by a minor decrease in maternal weight gain (Hass et al., 1994). Another study reported preimplantation loss with no significant effect on the number of implantations per dam or the number of live fetuses and an increase in the incidence of skeletal variations and delayed ossification, but no increased incidence of malformations, at an exposure level of 680 mg/m^3, which did not induce clinical toxicity in dams (Hass et al., 1995). No effects of exposure to NMP at the highest concentration tested, 360 mg/m^3, on the outcome of pregnancy, embryonal growth rate, or development in vital organs and skeletons of the fetuses were observed in a further study in rats (Lee et al., 1987).

In a range-finding study on dermal exposure to NMP with few animals, all dams died or aborted before day 20 of gestation at a daily dose level of 2500 mg/kg body weight; 1100 mg/kg body weight caused resorption of 65 of 66 fetuses and a depression in dam body weight gain. A daily dermal dose of 500 mg/kg body weight had no adverse effect on pregnancy, dam body weights, implantations, or gestation. In a follow-up study with a proper number of experimental animals, a dose of 750 mg/kg body weight during days 6–15 of gestation decreased dam body weight gain, increased resorption of fetuses, decreased fetal body weight, and induced skeletal abnormalities and delayed/incomplete ossification, but there was no increase in the incidence of soft tissue anomalies. No effects were observed at the lower dose levels studied, 75 and 237 mg/kg body weight per day (Becci et al., 1982).

In studies not published in the open literature, skeletal variations, reduced fetal weight, and, at exposure levels toxic to dams, soft tissue terata have been observed. These studies cannot be assessed, as few details have been provided.

11.1.2 Criteria for setting tolerable intakes/ concentrations or guidance values for N-methyl-2-pyrrolidone

At high and maternally toxic exposure levels, NMP clearly induces adverse developmental effects, including terata. However, at exposure levels close to the NOAEL for maternal toxicity, effects are minor or, as in the case of the reported possible neurobehavioural toxicity, need confirmation by independent studies. With respect to the risk assessment, however, tolerable intakes and tolerable concentrations derived from either reproductive toxicity studies or studies on other end-points are very similar.

The NOAEL from the 4- to 13-week repeated-dose inhalation exposure studies, based on mortality, effects on haematopoietic and lymphatic organs, and nasal irritation, is 500 mg/m^3 (BASF, 1994). Thus, the tolerable concentration (TC) can be calculated as follows:

$$\begin{aligned} \text{TC} &= [500 \text{ mg/m}^3 \times (6/24) \times (5/7)] / 300 \\ &= 0.3 \text{ mg/m}^3 \end{aligned}$$

where:

- 500 mg/m^3 is the NOAEL,
- 6/24 and 5/7 adjust the intermittent exposure in the animal experiment to continuous human exposure, and
- 300 is the combined uncertainty factor. In the absence of specific data on NMP, the uncertainty factors are the default values, i.e., 10 for species differences, 10 for interindividual variation in humans, and 3 for adjustment from a 90-day study to a lifelong exposure (IPCS, 1994).

Considering 400 mg/m^3 as a LOAEL in the Lee et al. (1987) long-term study, a very similar tolerable concentration would be obtained.

In the reproductive studies, effects on offspring, mostly accompanied by changes in the mother, have generally been observed at exposure levels of 500 mg/m^3, and a no-effect level has been reported at 360 mg/m^3 (Lee et al., 1987). A TC may be thus be derived as follows:

$$\begin{aligned} \text{TC} &= [360 \text{ mg/m}^3 \times (6/24)] / 100 \\ &= 0.9 \text{ mg/m}^3 \end{aligned}$$

For dermal exposure, using the reproductive toxicity NOAEL of 237 mg/kg body weight per day as the starting point (Becci et al., 1982), a TC may be derived as follows:

$$\begin{aligned} \text{TC} &= 237 \text{ mg/kg body weight per day} / 100 \\ &= 2.37 \text{ mg/kg body weight per day} \end{aligned}$$

For oral exposure, a NOAEL from the 90-day study by E.I. du Pont de Nemours and Company (1995b), 169 mg/kg body weight per day, leads to the following TC:

$$\begin{aligned} \text{TC} &= 169 \text{ mg/kg body weight per day} / 300 \\ &= 0.6 \text{ mg/kg body weight per day} \end{aligned}$$

using the same default uncertainty factors as for the 90-day inhalation study above.

11.1.3 Sample risk characterization

Because of non-existent data on the exposure of the general population and very limited information on occupational exposure, a meaningful risk characterization cannot be performed.

11.1.4 Uncertainties of the health effects evaluation

Reproductive effects have been observed following inhalation exposure to NMP. However, the calculated TC, based on other effects in experimental animals, is also protective against reproductive effects. The dermal and oral tolerable intakes have been calculated using different end-points, the former a reproductive toxicity study and the latter a 90-day toxicity study. These studies give very similar tolerable intakes. As absorption via the skin and gastrointestinal tract are both very effective, it is again not important from the risk characterization point of view whether full weight is given to the reproductive toxicity studies.

There is an important discrepancy between the tolerable daily intake via inhalation and the tolerable intakes via other routes of exposure. The inhalation TC of 0.3 mg/m^3 will lead to a total daily dose by inhalation of [0.3 mg/m^3 × 20 m^3/day] / 64 kg = 0.1 mg/kg body weight per day (where 20 m^3 is the diurnal volume of respiration, and 64 kg the weight of the average human), i.e., approximately 5–15% of that by other routes. The reasons for the disproportionately high inhalation toxicity of NMP are not known. This disproportionate inhalation toxicity is also apparent in the oral/dermal LD_{50} / short-term LC_{50} values. LD_{50} values (oral, dermal, rat) are in the order of 5000 mg/kg body weight, but 2-week exposure (6 h/day × 5 days/week) to 1000 mg NMP/m^3 (calculated total dose in the order of 300 mg/kg body weight) led to the death of 9 out of 10 animals.

The inhalation toxicity of NMP is quite variable depending on the conditions of exposure; there is no apparent explanation for this discrepancy either.

Reliable analysis of the hazards and risks due to inhalation exposure to NMP requires further experimental work.

11.2 Evaluation of environmental effects

Water and air are considered to be the most relevant compartments for NMP, since the substance may be released both as volatile emissions to the atmosphere and as a component of wastewater, municipal as well as industrial. Since the substance shows high mobility in soil, leaching from landfills is a possible route of contamination of groundwaters. NMP is expected to be removed from air by wet deposition or by reaction with hydroxyl radicals. The substance is not transformed by chemical hydrolysis but is rapidly biodegraded under aerobic conditions. The substance is not expected to bioconcentrate.

Very few reliable ecotoxicological data were found. However, the available results from short-term tests on aquatic species (fish, crustaceans, algae, and bacteria) and terrestrial species (birds) indicate that NMP has low acute toxicity.

Also, very few data on measured concentrations in the environment were identified. The available ecotoxicological data should not be used for a quantitative risk assessment until fully evaluated. As a tentative conclusion, however, based on the biodegradability of the substance, the absence of bioconcentration tendency, and the indicated low acute aquatic toxicity, NMP is not expected to present a significant risk to the environment.

12. PREVIOUS EVALUATIONS BY INTERNATIONAL BODIES

No previous evaluations were identified.

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APPENDIX 1 — SOURCE DOCUMENTS

Åkesson (1994): *N-Methyl-2-pyrrolidone (NMP)*, Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals, *Arbete och hälsa*, 40:1–24

Copies of the *Arbete och hälsa* document on NMP (ISSN 0346-7821; ISBN 91-7045-288-1), prepared by the Nordic Expert Group, may be obtained from:

National Institute of Working Life
Publications Department
S-171 84 Solna
Sweden

In the peer review procedure of documents prepared in the series Criteria Documents from the Nordic Expert Group (focused on human health only), one member of the Nordic Expert Group serves as a primary reviewer for the first draft. A second draft is forwarded to all members of the Nordic Expert Group, who in turn consult appropriate specialists to review the document. The specialists are chosen either because they have an extended knowledge of the substance itself or because they are specialists in the critical effect area of the substance evaluated. The second review is performed by a review board, including the Nordic Expert Group participants with the ad hoc experts, for further comments. The review board meeting is repeated if necessary.

HSE (1997): *N-Methyl-2-pyrrolidone: Risk assessment document EH72/10*, Sudbury, Suffolk, HSE Books

The authors' draft version is initially reviewed internally by a group of approximately 10 Health and Safety Executive experts (mainly toxicologists, but also scientists from other relevant disciplines, such as epidemiology and occupational hygiene). The toxicology section of the amended draft is then reviewed by toxicologists from the United Kingdom Department of Health. Subsequently, the entire risk assessment document is reviewed by a tripartite advisory committee to the United Kingdom Health and Safety Commission, the Working Group for the Assessment of Toxic Chemicals (WATCH). This committee is composed of experts in toxicology and occupational health and hygiene from industry, trade unions, and academia.

The members of the WATCH committee at the time of the peer review were:

Mr Steve Bailey (Confederation of British Industries)
Professor Jim Bridges (University of Surrey)
Dr Ian Guest (Confederation of British Industries)
Dr Alastair Hay (Trades Union Congress)
Dr Jenny Leeser (Confederation of British Industries)
Dr Len Levy (Institute of Occupational Hygiene, Birmingham)
Dr Mike Molyneux (Confederation of British Industries)
Mr Alan Moses (Confederation of British Industries)
Dr Ron Owen (Trades Union Congress)
Mr Jim Sanderson (Independant Consultant)
Dr Mike Sharratt (University of Surrey)

HSDB (1997): *Hazardous substances data bank*, Bethesda, MD, National Library of Medicine

The version of HSDB used for this CICAD is included in the CD-ROM CHEM-BANK (February 1998), published by:

Silver Platter Information Inc.
100 River Ridge Drive
Norwood, MA 02062-5043
USA

HSDB is also available on CD-ROM from the Canadian Centre for Occupational Health and Safety (CCINFOdisc D2) and on-line by Data-Star, DIMDI, STN International, and TOXNET.

HSDB is built, reviewed, and maintained on the National Library of Medicine's Toxicology Data Network (TOXNET). HSDB is a factual data bank, referenced and peer reviewed by a committee of experts (the Scientific Review Panel). All data extracted from HSDB to this CICAD were preceded by the symbol denoting the highest level of peer review.

The date for the last revision or modification of the record on NMP was November 1997.

APPENDIX 2 — CICAD PEER REVIEW

The draft CICAD on *N*-methyl-2-pyrrolidone was sent for review to institutions and organizations identified by IPCS after contact with IPCS national contact points and Participating Institutions, as well as to identified experts. Comments were received from:

A. Aitio, World Health Organization, Switzerland

M. Baril, Institut de Recherche en Santé et en Sécurité du Travail du Québec, Canada

R. Benson, US Environmental Protection Agency Region VIII, USA

R. Cary, Health and Safety Executive, United Kingdom

R.S. Chhabra, National Institute of Environmental Health Sciences, USA

P. Edwards, Department of Health, United Kingdom

T. Fortoul, National University of Mexico, Mexico

E. Frantik, National institute of Public Health, Czech Republic

R. Hertel, Federal Institute for Health Protection of Consumers and Veterinary Medicine, Germany

R. Montaigne, European Chemical Industry Council (CEFIC), Belgium

D. Willcocks, National Industrial Chemicals Notification and Assessment Scheme, Australia

P. Yao, Chinese Academy of Preventive Medicine, People’s Republic of China

APPENDIX 3 — CICAD FINAL REVIEW BOARD

Stockholm, Sweden, 25–28 May 1999

Members

Mr H. Abadin, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Atlanta, GA, USA

Dr B. Åkesson, Department of Occupational and Environmental Health, University Hospital, Lund, Sweden

Dr T. Berzins (*Chairperson*), National Chemicals Inspectorate (KEMI), Solna, Sweden

Mr R. Cary, Health and Safety Executive, Bootle, Merseyside, United Kingdom

Dr R.S. Chhabra, General Toxicology Group, National Institute of Environmental Health Sciences, Research Triangle Park, NC, USA

Dr S. Dobson (*Rapporteur*), Institute of Terrestrial Ecology, Monks Wood, Abbots Ripton, Huntingdon, Cambridgeshire, United Kingdom

Dr H. Gibb, National Center for Environmental Assessment, US Environmental Protection Agency, Washington, DC, USA

Dr R.F. Hertel, Federal Institute for Health Protection of Consumers and Veterinary Medicine, Berlin, Germany

Dr G. Koennecker, Chemical Risk Assessment, Fraunhofer Institute for Toxicology and Aerosol Research, Hanover, Germany

Dr A. Nishikawa, National Institute of Health Sciences, Division of Pathology, Tokyo, Japan

Professor K. Savolainen, Finnish Institute of Occupational Health, Helsinki, Finland

Dr J. Sekizawa, Division of Chem-Bio Informatics, National Institute of Health Sciences, Tokyo, Japan

Ms D. Willcocks (*Vice-Chairperson*), Chemical Assessment Division, National Occupational Health and Safety Commission (Worksafe Australia), Sydney, Australia

Professor P. Yao, Institute of Occupational Medicine, Chinese Academy of Preventive Medicine, Ministry of Health, Beijing, People’s Republic of China

Observers

Dr N. Drouot (representing the European Centre for Ecotoxicology and Toxicology of Chemicals [ECETOC]), Elf Atochem, DSE-P Industrial Toxicology Department, Paris, France

Ms S. Karlsson, National Chemicals Inspectorate (KEMI), Solna, Sweden

Dr A. Löf, National Institute of Working Life, Solna, Sweden

Dr A. Poole (representing the European Chemical Industry Council [CEFIC]), Dow Europe S.A., Horgen, Switzerland

Dr K. Ziegler-Skylakakis, Institute for Toxicology, GSF - National Research Center for Environment and Health, Neuherberg, Oberschleissheim, Germany

Secretariat

Dr A. Aitio, Programme for the Promotion of Chemical Safety, World Health Organization, Geneva, Switzerland

Ms M. Godden, Health and Safety Executive, Bootle, United Kingdom

Ms L. Regis, Programme for the Promotion of Chemical Safety, World Health Organization, Geneva, Switzerland

Dr P. Toft, Division of Health and Environment, World Health Organization, Regional Office for the Americas/Pan American Sanitary Bureau, Washington, DC, USA

Dr M. Younes, Programme for the Promotion of Chemical Safety, World Health Organization, Geneva, Switzerland

N-METHYL-2-PYRROLIDONE

0513

April 1997

CAS No: 872-50-4
RTECS No: UY5790000
UN No:
EC No: 606-021-00-7

1-Methyl-2-pyrrolidinone
1-Methyl-2-pyrrolidone
N-Methylpyrrolidone
C_5H_9NO
Molecular mass: 99.1

TYPES OF HAZARD/ EXPOSURE	ACUTE HAZARDS/SYMPTOMS	PREVENTION	FIRST AID/FIRE FIGHTING
FIRE	Combustible. Gives off irritating or toxic fumes (or gases) in a fire.	NO open flames.	Powder, alcohol-resistant foam, water spray, carbon dioxide.
EXPLOSION	Above 96°C explosive vapour/air mixtures may be formed.	Above 96°C use a closed system, ventilation.	
EXPOSURE		**PREVENT GENERATION OF MISTS!**	
Inhalation	Headache.	Ventilation.	Fresh air, rest. Refer for medical attention.
Skin	MAY BE ABSORBED! Dry skin. Redness.	Protective gloves. Protective clothing.	Remove contaminated clothes. Rinse skin with plenty of water or shower.
Eyes	Redness. Pain. Blurred vision.	Safety spectacles.	First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then take to a doctor.
Ingestion		Do not eat, drink, or smoke during work.	Rinse mouth. Do NOT induce vomiting. Refer for medical attention.

SPILLAGE DISPOSAL	PACKAGING & LABELLING
Collect leaking and spilled liquid in sealable containers as far as possible. Absorb remaining liquid in sand or inert absorbent and remove to safe place (extra personal protection: filter respirator for organic gases and vapours).	Xi Symbol R: 36/38 S: (2-)41

EMERGENCY RESPONSE	STORAGE
NFPA Code: H2; F1; R0.	Separated from oxidants, rubber, plastics, aluminium, light metals. Dry. Ventilation along the floor.

IPCS
International
Programme on
Chemical Safety

Prepared in the context of cooperation between the International Programme on Chemical Safety and the European Commission

SEE IMPORTANT INFORMATION ON THE BACK.

IMPORTANT DATA

Physical State; Appearance
COLOURLESS HYGROSCOPIC LIQUID, WITH CHARACTERISTIC ODOUR. TURNS YELLOW ON EXPOSURE TO HEAT.

Chemical Dangers
The substance decomposes on heating or on burning producing toxic fumes including nitrogen oxides, carbon monoxide. Attacks aluminium, light metals, rubber, plastic.

Occupational Exposure Limits
TLV not established.
MAK: 20 ppm; 80 mg/m^3; skin (1996).

Routes of Exposure
The substance can be absorbed into the body by inhalation and through the skin.

Inhalation Risk
A harmful contamination of the air will not or will only very slowly be reached on evaporation of this substance at 20°C, on spraying however much quickly.

Effects of Short-term Exposure
The substance irritates the eyes and the skin. Swallowing the liquid may cause aspiration into the lungs with the risk of chemical pneumonitis.

Effects of Long-term or Repeated Exposure
Repeated or prolonged contact with skin may cause dermatitis. Animal tests show that this substance possibly causes toxic effects upon human reproduction.

PHYSICAL PROPERTIES

Boiling point: 202°C
Melting point: -24°C
Relative density (water = 1): 1.03
Solubility in water: very good
Vapour pressure, Pa at 25°C: 66
Relative vapour density (air = 1): 3.4
Relative density of the vapour/air-mixture at 20°C (air = 1): 1.00
Flash point: 96°C o.c.
Auto-ignition temperature: 270°C
Explosive limits, vol% in air: 0.99-3.9

ENVIRONMENTAL DATA

NOTES

N-Methyl-2-pyrrolidone enhances the skin permeability for other substances. Insufficient data are available on the effect of this substance on human health, therefore utmost care must be taken.

ADDITIONAL INFORMATION

RÉSUMÉ D’ORIENTATION

Ce CICAD relatif à la *N*-méthyl-2-pyrrolidone (NMP) repose principalement sur deux mises au point, l’une préparée à l’intention du Groupe d’experts nordiques (Åkesson, 1994) et l’autre rédigée par le *Health and Safety Executive* du Royaume-Uni au sujet des effets que ce composé pourrait avoir sur la santé humaine (HSE, 1997). En ce qui concerne les données sur le devenir et le comportement de cette molécule dans l’environnement, on n’a pas repéré de document de niveau équivalent. On a donc utilisé l’HSDB (1997) à titre de source documentaire complémentaire. D’autres données non validées, principalement de nature écotoxicologiques, ont été trouvées dans IUCLID (1995) et d’autres articles ont été repérés dans les publications accessibles (dépouillement jusqu’à fin juillet 1998). On trouvera à l’appendice 1 des indications sur la nature des sources documentaires existantes. Les renseignements concernant l’examen du CICAD par des pairs font l’objet de l’appendice 2. Ce document a été examiné lors de la réunion du Comité d’évaluation finale qui s’est tenue à Stockholm (Suède) du 25 au 28 mai 1999. La liste des participants à cette réunion figure à l’appendice 3. Après la réunion, on a demandé l’avis d’un groupe consultatif composé de B. Heinrich-Hirsch (BgVV , Allemagne), Frank Sullivan (Consultant, Royaume-Uni), Robert Chapin (*National Institute of Environmental Health Sciences*, Etats-Unis), Gary Kimmel (*US Environmental Protection Agency*, Etats-Unis) et Rolf Hertel (BgVV, Allemagne, Président), pour l’interprétation des données sur la toxicité génésique de la *N*-méthyl-2-pyrrolidone. Sur la base des avis émis par ce groupe et avec l’aide du Secrétariat, l’auteur a révisé les sections correspondantes du document. Le CICAD révisé a été approuvé en tant qu’évaluation internationale par les membres du Comité d’évaluation finale, qui se sont exprimés par correspondance. La fiche d’information internationale sur la sécurité chimique (ICSC 0513) relative à la *N*-méthyl-2-pyrrolidone, établie par le Programme international sur la sécurité chimique (IPCS, 1993), est également reproduite dans ce document.

La *N*-méthyl-2-pyrrolidone (NMP) (No CAS 872-50-4) est un solvant organique miscible à l’eau. Elle se présente sous la forme d’un liquide hygroscopique incolore dégageant une légère odeur d’amine. On l’utilise dans l’industrie pétrochimique et dans la fabrication de composants microélectroniques; elle entre également dans la composition de divers produits tels que pigments, cosmétiques, médicaments, insecticides, herbicides et fongicides. Elle est en outre de plus en plus utilisée en remplacement des hydrocarbures chlorés.

La NMP peut pénétrer dans l’environnement soit sous la forme d’émissions dans l’atmosphère car le composé est volatil et très largement utilisé comme solvant, soit en étant déversée dans l’eau avec les eaux usées municipales et industrielles dont elle est un constituant. Elle est mobile dans le sol et elle peut venir contaminer les eaux souterraines par lessivage des décharges.

Elle s’élimine vraisemblablement de l’atmosphère par dépôt humide ou à la faveur de réactions photochimiques avec les radicaux hydroxyles. Etant totalement miscible à l’eau, elle ne devrait pas être adsorbée aux particules du sol, aux sédiments ou aux matières organiques en suspension, ni subir une bioconcentration. La NMP n’est pas décomposée par hydrolyse chimique. Les essais de biodégradabilité montrent que la NMP subit une biodégradation rapide.

Chez le rat, le composé est rapidement résorbé après inhalation, ingestion ou application cutanée; il se répartit dans l’organisme puis est éliminé après hydroxylation en dérivés polaires qui sont excrétés par voie urinaire. La dose initiale est excrétée dans les 24 h à environ 80 % sous la forme de NMP et de métabolites. Chez les rongeurs, on observer une coloration jaune des urines, qui est probablement liée à la dose. Le principal métabolite est la 5-hydroxy-*N*-méthyl-2-pyrrolidone.

Les études sur l’Homme donnent des résultats analogues. On a montré que la pénétration percutanée était très rapide. La NMP subit une transformation rapide en 5-hydroxy-*N*-méthyl-2-pyrrolidone, qui est ensuite oxydée en *N*-méthyl-succinimide, cet intermédiaire subissant à son tour une hydroxylation en 2-hydroxy-*N*-méthyl-succinimide. Tous ces métabolites sont incolores. On a constaté qu’après inhalation ou ingestion, la quantité de métabolites excrétés dans les urines représentait respectivement 100 % ou 65 % de la dose administrée.

Chez le lapin, la NMP n’a qu’un faible pouvoir irritant pour peau et elle est modérément irritante pour la muqueuse oculaire. Des doses quotidiennes répétées de 450 mg par kg de poids corporel appliquées sur la peau de lapins ont provoqué des hémorragies et des escarres graves et douloureuses. Ces effets indésirables ne sont pas observés chez les travailleurs exposés à de la NMP pure, mais on les a constatés après exposition cutanée à de la NMP utilisée pour le nettoyage. Aucun pouvoir sensibilisateur n’a été constaté.

Les études toxicologiques effectuées sur des rongeurs révèlent une faible toxicité aiguë. L’administration de doses toxiques aiguës par voie orale, percutanée ou respiratoire provoque des troubles fonctionnels et une dépression du système nerveux central. Une irritation locale a été observée au niveau des voies respiratoires après inhalation ainsi qu’au niveau du pylore et de l’ensemble des voies digestives après ingestion. Chez l'Homme, on n'a pas constaté d'irritation des voies respiratoire après exposition à 50 mg/m^3 pendant 8 h.

Après administration de doses multiples, le profil toxicologique de la NMP ne se dégage pas clairement. Lors d'une étude alimentaire de 28 jours sur des rats, on a observé chez les mâles une diminution du gain de poids liée à l'administration du composé pour une dose de 1234 mg/kg de poids corporel (p.c.), le même phénomène se produisant chez les femelles à la dose de 2268 mg/kg p.c. A ces doses, on a également observé une dégénérescence testiculaire chez les mâles et une atrophie du thymus chez les femelles. La dose sans effet indésirable observable (NOAEL) était de 429 mg/kg p.c. pour les mâles et de 1548 mg/kg p.c. pour les femelles. Dans une étude de 28 jours au cours de laquelle de la NMP a été administrée par intubation à des rats, on a constaté une augmentation, liée à la dose, du poids relatif du foie et des reins et une diminution du nombre des lymphocytes chez les deux sexes à la dose de 1028 mg/kg p.c. La NOAEL obtenue dans cette étude était égale à 514 mg/kg p.c. Lors d'une autre étude sur des rats, la prise quotidienne de NMP avec la nourriture pendant 90 jours a provoqué une diminution du poids corporel à la dose de 433 mg/kg p.c. chez les mâles et de 565 mg/kg p.c. chez les femelles. Des effets neurocomportementaux ont également été observés à ces doses. La NOAEL était respectivement égale à 169 et à 217 mg/kg p.c. pour les mâles et les femelles.

Après exposition à de la NMP présente dans l'air, le profil de toxicité dépend fortement du rapport vapeurs/aérosol et de la région exposée (par ex. tête seule ou totalité du corps). Comme l'aérosol est plus absorbé par voie percutanée, la NMP est davantage résorbée, à concentration égale, lorsque l'animal est exposé à un aérosol que lorsqu'il est exposé à des vapeurs. Chez des femelles dont seule la tête était exposée à une concentration de 1000 mg/m^3, on n'a constaté qu'une légère irritation nasale, mais à la même concentration, la mortalité a été massive avec de graves lésions au niveau des principaux organes lorsque ces femelles avaient le corps entièrement exposé à de grosses gouttelettes dans un milieu présentant une forte humidité relative. Plusieurs études sur des rats ont montré qu'à des concentrations comprises entre 100 et 1000 mg/m^3, une exposition répétée à la NMP provoquait des effets toxiques généraux aux doses les plus faibles de cette fourchette. Dans la plupart des études, les effets ne se sont pas manifestés au bout de 4 semaines d'observation.

Chez des rats exposés (tête seulement) à une concentration de 3000 mg/m^3, 6 h par jour, 5 jours par semaine, pendant 13 semaines, on a observé une diminution du gain de poids, une augmentation des érythrocytes, du taux d'hémoglobine, de l'hématocrite et du volume globulaire moyen, une réduction du poids des testicules et une perte cellulaire dans l'épithélium germinal des testicules. La NOAEL était de 500 mg/m^3.

On ne dispose d'aucune donnée concernant une exposition répétée chez l'Homme.

On n'a pas observé de signes clairs de cancérogénicité chez des rats exposés à des concentrations de NMP allant jusqu'à 400 mg/m^3 lors d'études d'inhalation de longue durée.

Le pouvoir mutagène de la NMP est faible. On n'a observé qu'une légère augmentation des mutants réverses lors d'un test sur salmonelles avec des souches présentant une substitution des paires de bases. Il a été montré que la NMP produisait une aneuploïdie dans des cellules de levure (*Saccharomyces cerevisiae*). Aucune étude portant sur des effets mutagènes chez l'Homme n'est disponible.

Lors d'une étude sur la reproduction portant sur deux générations de rats, l'exposition du corps entier des mâles et des femelles à vapeurs de NMP à la concentration de 478 mg/m^3 6 heures par jour, 7 jours par semaine pendant au moins 100 jours (avant l'accouplement, pendant l'accouplement, pendant la gestation et pendant la lactation) a provoqué une diminution de 7 % du poids des foetus dans la génération F_1. Une diminution passagère, non liée à la dose, de 4 à 11 % du poids corporel moyen des ratons s'est produite à toutes les concentrations étudiées (41, 206 et 478 mg/m^3).

L'administration de NMP à des rats par application cutanée a eu un effet toxique sur leur développement à la dose de 750 mg/kg p.c. Les effets suivants ont été observés : perte avant la nidation, diminution du poids foetal et retard à l'ossification. La NOAEL relative aux effets sur le développement et à la toxicité pour les mères (diminution du gain de poids) était de 237 mg/kg p.c.

Des études d'inhalation sur des rats (exposition du corps entier) ont mis en évidence des effets toxiques sur le développement se traduisant par une augmentation des pertes avant la nidation sans conséquence pour le taux de nidation ou le nombre de foetus vivants à la concentration de 680 mg/m^3 et des effets toxiques comportementaux à la concentration de 622 mg/m^3. Lors d'une étude d'inhalation (exposition du corps entier), la NOAEL relative aux effets toxiques sur les mères a été évaluée à 100 mg/m^3, la NOAEL relative aux effets sur le développement étant égale à 360 mg/m^3.

Plusieurs autres études ont été consacrés aux effets de la NMP sur la reproduction, mais elles n'ont pas été publiées et en général, elles ne sont pas disponibles. Un résumé en est donné à titre d'information à la section 8.7.3 du présent document.

Ces études n’ont cependant pas été prises en compte pour l’évaluation des effets sanitaires de la NMP.

En se basant sur la mortalité et les lésions observées au niveau des organes, une dose tolérable par inhalation de 0,3 mg/m^3, devrait assurer contre tout risque d’effets toxiques sur la reproduction. Il devrait en être de même avec une dose tolérable par ingestion de 0,6 mg par kg p.c., basée sur les résultats d’une étude de 90 jours. Comme il n’existe aucune donnée sur l’exposition de la population générale et que les informations sur l’exposition professionnelle sont très limitées, on ne peut pas procéder à une caractérisation valable du risque.

Il est impossible d’évaluer quantitativement le risque écotoxicologique sur la base des données actuelles. Cependant, compte tenu de la biodégradabilité du composé, du fait qu’il ne subit pas de bioconcentration (selon le coefficient de partage [log K_{ow}] = $-0{,}38$), et qu’il est peu toxique pour les organismes aquatiques ainsi que les oiseaux, on peut provisoirement conclure que la NMP ne devrait pas constituer un risque environnemental important.

RESUMEN DE ORIENTACIÓN

Este CICAD sobre la *N*-metil-2-pirrolidona se basó fundamentalmente en un estudio preparado por el Grupo de Expertos Nórdicos (Åkesson, 1994) y en un examen de los problemas relativos a la salud humana preparado por la Dirección de Salud y Seguridad del Reino Unido (HSE, 1997). Para los datos relativos al destino y el comportamiento en el medio ambiente, no se identificó ningún documento amplio del mismo nivel. En su lugar, se utilizó el HSDB (1997) como documento original adicional. En IUCLID (1995) se encontraron datos complementarios no validados, fundamentalmente ecotoxicológicos, y en la bibliografía abierta se identificaron algunos artículos (búsqueda hasta julio de 1998). La información relativa al carácter y a la disponibilidad de los documentos originales figura en el apéndice 1. La información sobre el examen colegiado de este CICAD se presenta en el apéndice 2. Este CICAD se examinó en una reunión de la Junta de Evaluación Final, celebrada en Estocolmo (Suecia) del 25 al 28 de mayo de 1999. La lista de participantes en esta reunión figura en el apéndice 3. Tras la reunión de la Junta de Evaluación Final, se pidió asesoramiento a un grupo consultivo formado por el Dr. B. Heinrich-Hirsch, BgVV (Alemania), el Sr. Frank Sullivan, consultor (Reino Unido), el Dr. Robert Chaplin, Instituto Nacional de Ciencias de la Salud Ambiental (EE.UU.), el Dr. Gary Kimmel, Agencia para la Protección del Medio Ambiente de los Estados Unidos (EE.UU.) y el profesor Rolf Hertel, BgVV (Alemania) (Presidente), con respecto a la interpretación de los datos sobre la toxicidad reproductiva de la *N*-metil-2-pirrolidona. Sobre la base del asesoramiento de este grupo, el autor, en colaboración con la Secretaría, revisó las secciones correspondientes del documento. Los miembros de la Junta de Evaluación Final aprobaron el CICAD revisado como evaluación internacional en una votación por correo. La Ficha internacional de seguridad química (ICSC 0513) para la *N*-metil-2-pirrolidona, preparada por el Programa Internacional de Seguridad de las Sustancias Químicas (IPCS, 1993), también se reproduce en el presente documento.

La *N*-metil-2-pirrolidona (CAS Nº 872-50-4) es un disolvente orgánico miscible con el agua. Es un líquido incoloro higroscópico con un ligero olor a amina. Se utiliza en la industria petroquímica y en la microelectrónica, así como en la fabricación de varias sustancias, entre ellas pigmentos, productos de cosmética, medicamentos, insecticidas, herbicidas y fungicidas. Se está registrando un creciente uso de la *N*-metil-2-pirrolidona como sustitutivo de los hidrocarburos clorados.

La *N*-metil-2-pirrolidona puede incorporarse al medio ambiente mediante emisiones a la atmósfera, puesto que la sustancia es volátil y se utiliza ampliamente como disolvente, o bien puede liberarse al agua como componente de las aguas residuales municipales e industriales. La sustancia es móvil en el suelo y, por consiguiente, la lixiviación a partir de los vertederos es una posible vía de contaminación del agua freática.

En el aire, cabe suponer la eliminación de la *N*-metil-2-pirrolidona mediante deposición húmeda o por reacciones fotoquímicas con radicales hidroxilo. Puesto que la sustancia es totalmente miscible con el agua, no es previsible su adsorción en el suelo, los sedimentos o la materia orgánica suspendida ni su bioconcentración. La *N*-metil-2-pirrolidona no se degrada por hidrólisis química. Los datos de las pruebas de detección sobre su biodegradabilidad ponen de manifiesto que la sustancia se biodegrada con rapidez.

Tras la administración a ratas por inhalación o por vía oral o cutánea, la *N*-metil-2-pirrolidona se absorbe con rapidez, se distribuye por todo el organismo y se elimina sobre todo mediante hidroxilación a compuestos polares, que se excretan en la orina. Alrededor del 80% de la dosis administrada se excreta como *N*-metil-2-pirrolidona y sus metabolitos en un plazo de 24 horas. En los roedores se observa una coloración amarilla de la orina, probablemente dependiente de la dosis. El principal metabolito es la 5-hidroxi-*N*-metil-2-pirrolidona.

En los estudios con personas, se observan resultados comparables. Se ha comprobado que la penetración a través de la piel humana es muy rápida. La *N*-metil-2-pirrolidona se biotransforma con rapidez por hidroxilación a 5-hidroxi *N*-metil-2-pirrolidona, que se oxida nuevamente a *N*-metil-succinimida. Todos estos metabolitos son incoloros. La concentración de metabolitos de la *N*-metil-2-pirrolidona excretados en la orina tras la inhalación o la ingesta por vía oral es de alrededor del 100% y el 65% de las dosis administradas, respectivamente.

La *N*-metil-2-pirrolidona tiene en los conejos un potencial de irritación cutánea bajo y un potencial de irritación ocular moderado. La administración cutánea de dosis diarias repetidas de 450 mg/kg de peso corporal produjo en los conejos hemorragia grave dolorosa, así como la formación de escara. Estos efectos adversos no se han detectado en trabajadores ocupacionalmente expuestos a la *N*-metil-2-pirrolidona pura, pero se han observado tras la exposición cutánea a la utilizada en procesos de limpieza. No se ha observado potencial de sensibilización.

En estudios de toxicidad aguda en roedores, la *N*-metil-2-pirrolidona mostró una toxicidad baja. La administración oral, cutánea o por inhalación de dosis muy tóxicas provoca trastornos funcionales y depresión del sistema nervioso central. Tras la administración por inhalación y por vía oral de *N*-metil-2-pirrolidona se observaron efectos de irritación local, respectivamente, en las vías respiratorias y en los tractos pilórico y gastrointestinal. En las personas, no se observó ningún efecto irritante en el sistema respiratorio tras una exposición de ocho horas a 50 mg/m^3.

No hay un perfil claro de toxicidad de la *N*-metil-2-pirrolidona después de una administración múltiple. En un estudio de alimentación de 28 días con ratas, se observó una disminución del aumento del peso corporal relacionada con el compuesto a 1234 mg/kg de peso corporal en los machos y a 2268 mg/kg de peso corporal en las hembras. A estos niveles de dosis se detectó degeneración y atrofia testicular en los machos y atrofia del timo en las hembras. La concentración sin efectos adversos observados (NOAEL) fue de 429 mg/kg de peso corporal en los machos y de 1548 mg/kg de peso corporal en las hembras. En un estudio de intubación de 28 días en ratas, se observó un aumento dependiente de la dosis del peso relativo del hígado y el riñón y una disminución del recuento de leucocitos en ambos sexos a 1028 mg/kilo de peso corporal. La NOAEL en este estudio fue de 514 mg/kg de peso corporal. En otro estudio realizado en ratas, la ingesta diaria con los alimentos durante 90 días provocó una disminución del peso corporal a concentraciones de 433 y 565 mg/kg de peso corporal en las hembras y los machos, respectivamente. A esos niveles de dosis también se observaron efectos en el neurocomportamiento. La NOAEL de los machos y las hembras fue de 169 y 217 mg/kg de peso corporal, respectivamente.

El perfil de la toxicidad tras la exposición a la *N*-metil-2-pirrolidona suspendida en el aire depende considerablemente de la razón vapor:aerosol y de la superficie de exposición (es decir, exposición sólo de la cabeza o de todo el cuerpo). Debido a la mayor absorción cutánea del aerosol, a concentraciones semejantes la asimilación de los animales expuestos al aerosol es superior a la de los expuestos al vapor. En estudios con ratas hembras con la cabeza solamente expuesta a 1000 mg/m^3, sólo se observó una ligera irritación nasal, pero se registró una mortalidad masiva y efectos graves en los órganos principales tras la exposición de todo el cuerpo de las hembras a la misma concentración de gotas gruesas con una humedad relativamente alta. Varios estudios en ratas después de una exposición repetida a concentraciones de *N*-metil-2-pirrolidona de 100 a 1000 mg/m^3 han puesto de manifiesto efectos de toxicidad sistémica a los niveles de dosis más bajos. En la mayoría de los estudios no se observaron estos efectos tras un período de observación de cuatro semanas.

En ratas, la exposición a 3000 mg de *N*-metil-2-pirrolidona/m^3 (sólo en la cabeza) seis horas al día, cinco días a la semana, durante 13 semanas provocó una disminución del aumento del peso corporal, un incremento de los eritrocitos, la hemoglobina, el hematocrito y el volumen corpuscular medio, una reducción del peso absoluto de los testículos y pérdida celular en el epitelio germinal de los testículos. La NOAEL fue de 500 mg/m^3.

No hay datos en las personas después de una exposición a dosis repetidas.

En un estudio de inhalación prolongado, la *N*-metil-2-pirrolidona no mostró ningún signo claro de carcinogenicidad en las ratas expuestas a concentraciones de hasta 400 mg/m^3.

El potencial mutagénico de la *N*-metil-2-pirrolidona es débil. Sólo se observó un ligero aumento del número de revertientes cuando se sometió a prueba en una valoración de *Salmonella* con cepas con un par de bases sustituidas. Se ha demostrado que la *N*-metil-2-pirrolidona induce aneuploidía en las células de levadura de *Saccharomyces cerevisiae*. No se dispone de investigaciones relativas a la mutagenicidad en el ser humano.

En un estudio de reproducción de dos generaciones en ratas, la exposición de todo el cuerpo, tanto de machos como de hembras, a 478 mg/m^3 de vapor de *N*-metil-2-pirrolidona seis horas al día, siete días a la semana, durante un mínimo de 100 días (períodos de preacoplamiento, acoplamiento, gestación y lactación) produjo una disminución del 7% en el peso fetal de las crías F_1. Se observó una reducción transitoria no dependiente de la dosis del 4% al 11% en el peso medio de las crías a todos los niveles de exposición sometidos a prueba (41, 206 y 478 mg/m^3).

Tras la administración cutánea de *N*-metil-2-pirrolidona a ratas, se registró toxicidad en el desarrollo a 750 mg/kg de peso corporal. Los efectos observados fueron un aumento de las pérdidas antes de la implantación, una reducción del peso fetal y un retraso de la osificación. La NOAEL tanto para los efectos en el desarrollo como para la toxicidad materna (reducción del aumento del peso corporal) fue de 237 mg/kg de peso corporal.

En estudios de inhalación en ratas (exposición del cuerpo completo), a 680 mg/m^3 se observó toxicidad en el desarrollo mediante el aumento de las pérdidas antes de la implantación, sin un efecto significativo en la tasa de implantación o el número de fetos vivos, y a 622 mg/m^3 toxicidad en el desarrollo del comportamiento. En un estudio de inhalación (exposición del cuerpo completo), la NOAEL para los efectos maternos fue de 100 mg/m^3 y para los efectos en el desarrollo de 360 mg/m^3.

Se han realizado varios estudios más sobre los efectos reproductivos de la *N*-metil-2-pirrolidona, pero no se han publicado ni están en general disponibles. Para información del lector, en la sección 8.7.3 de este documento se presenta una breve sinopsis de estos estudios. Sin embargo, los estudios no se utilizan para la evaluación de los efectos de la *N*-metil-2-pirrolidona en la salud.

Cabe prever que la inhalación de una concentración tolerable, de 0,3 mg/m^3, basada en la mortalidad y en los daños de los órganos, no protegerá de una posible toxicidad reproductiva. Igualmente, se supone que una ingesta oral tolerable de 0,6 mg/kg de peso corporal al día, basada en un estudio de 90 días, proporcionará una protección adecuada contra posibles efectos reproductivos. Debido a la falta de datos sobre la exposición de la población general y a la información muy limitada sobre la exposición ocupacional, no se puede realizar una caracterización válida del riesgo.

No es posible realizar una evaluación cuantitativa del riesgo ecotoxicológico a partir de los datos presentes. Sin embargo, teniendo en cuenta la biodegradabilidad observada, la falta de bioconcentración prevista (basada en un log del coeficiente de reparto octanol-agua de −0,38) y la baja toxicidad aguda indicada para los organismos acuáticos, así como para las aves, se puede llegar a la conclusión provisional de que la *N*-metil-2-pirrolidona no debería representar un riesgo importante para el medio ambiente.

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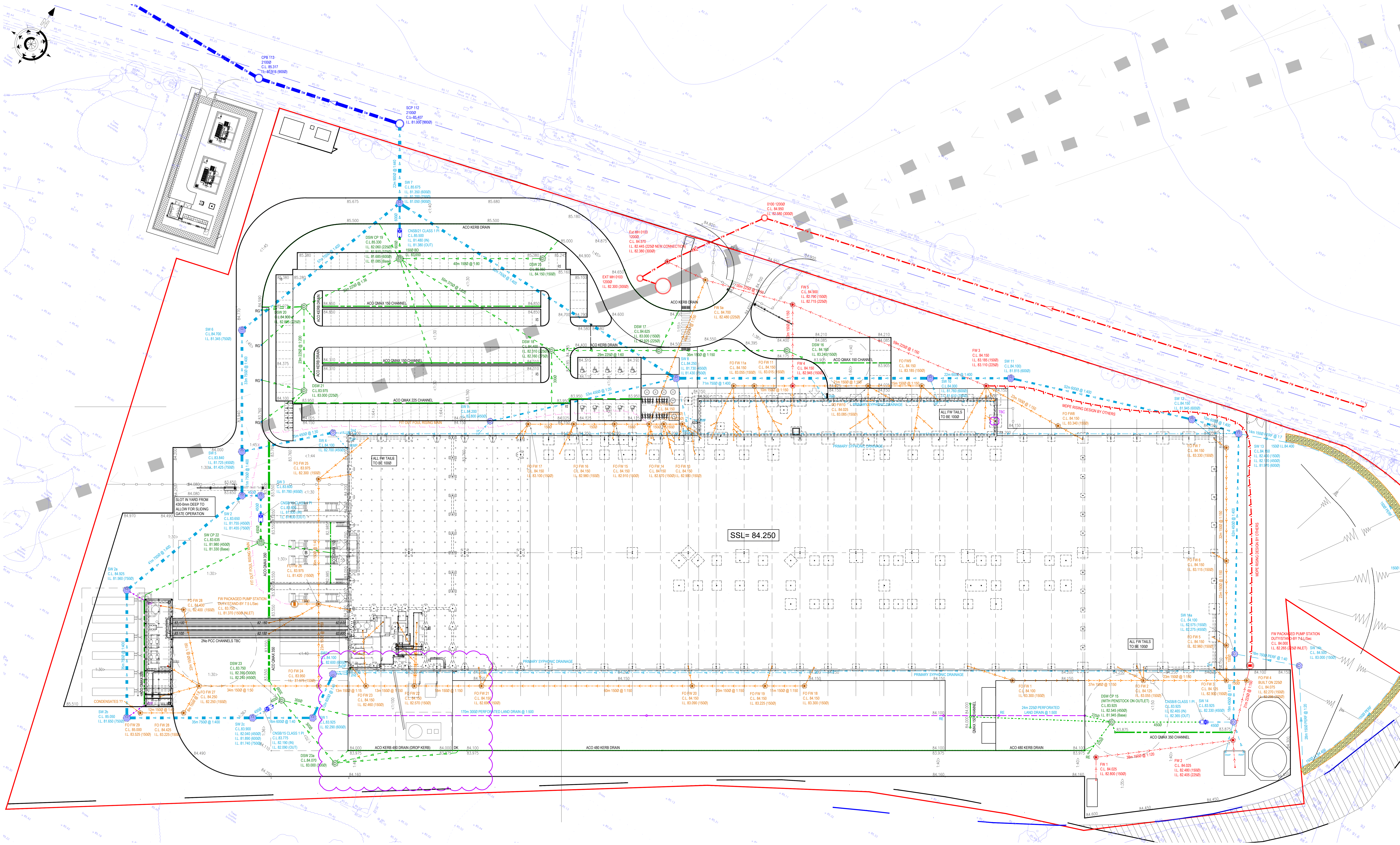
APPENDIX 3.7

SITE DRAINAGE DRAWING



SURFACE WATER FIT OUT REQUIREMENTS SHOWN IN PURPLE
FOUL WATER FIT OUT REQUIREMENTS SHOWN IN OCHRE/BROWN

DRAINAGE LAYOUT
Scale 1:400

FIT OUT - POP UP POSITIONS TO BE SET OUT TO ARCHITECTS DRAWING NOT THIS DRAWING

SAFETY, HEALTH AND ENVIRONMENTAL INFORMATION

IN ADDITION TO THE HAZARDS/RISKS NORMALLY ASSOCIATED WITH THE TYPES OF WORK DETAILED ON THIS DRAWING, NOTE THE ADDITIONAL RISKS:

CONSTRUCTION
IT IS CONSIDERED THAT THE PROPOSED WORKS ARE WITHIN THE SCOPE OF A COMPETENT CONTRACTOR AND AS SUCH NO UNUSUAL HAZARDS HAVE BEEN IDENTIFIED, WITH THE EXCEPTION OF THE FOLLOWING:-
THE CONTRACTOR TO PROVIDE METHOD STATEMENTS TO HIGHLIGHT & MINIMISE
RISKS FOR ELEMENTS OF WORK INDICATED ON THIS DRAWING MAINLY WORKING AT DEPTH & THE REQUIRED TEMPORARY SUPPORT FOR EARTHWORKS

MAINTENANCE/CLEANING/OPERATION
JETTING OF PIPEWORK/MANHOLES TO BE BY UNDERTAKEN AT REGULAR INTERVALS (APPROX 6 MONTHS) BY SPECIALIST

DECOMMISSIONING/DEMOLITION

NO SPECIAL REQUIREMENTS

IT IS ASSUMED THAT ALL WORKS WILL BE CARRIED OUT BY A COMPETENT CONTRACTOR WORKING, WHERE APPROPRIATE, TO AN APPROVED METHOD STATEMENT

DRAINAGE NOTES

1. THIS DRAWING TO BE READ IN CONJUNCTION WITH ALL RELEVANT ARCHITECTS, ENGINEERS AND SPECIALISTS DRAWINGS AND SPECIFICATIONS.
2. ALL DRAINAGE WORK TO BE CARRIED OUT IN ACCORDANCE WITH BS 8301, BS 8005 AND THE BUILDING REGULATIONS.
3. ALL PIPES ARE TO HAVE SURROUND IN ACCORDANCE DRAINAGE DETAILS, UNLESS NOTED OTHERWISE.
4. FOR EXACT LOCATION OF RAIN WATER AND FOUL WATER OUTLETS, REFER TO ARCHITECTS DRAWINGS.
5. SURFACE WATER DRAINS SHALL BE either
H.D.P.E. RIDGIDRAIN TWINWALL CARRIER PIPE BY `POLYPIPE PLC'
(OR SIMILAR APPROVED) TO B.S EN 1401-1
OR P.C.C. PIPES TO B.S 5911
OR VITRIFIED CLAY TO B.S EN 295
6. FOUL WATER DRAINS SHALL BE VITRIFIED CLAY TO B.S. EN 295 OR P.C.C PIPES TO B.S. 5911 (CLASS H)
7. ALL GRP UNDERGROUND TANKS ARE TO BE BEDDED ON AND ENCASED IN 225mm GEN3 CONCRETE WITH 20mm AGG. CONCRETE STRICTLY IN ACCORDANCE WITH THE MANUFACTURERS INSTRUCTIONS.
8. ROAD GULLY OUTLET PIPE INVERT LEVELS TO BE 600mm BELOW TOP OF GRATING LEVEL.
9. ALL MANHOLE AND INSPECTION CHAMBER COVERS, FRAMES AND SLOT DRAINS DRAINS IN TRAFFICKED AREAS SHALL COMPLY TO EITHER B.S. 497 : PART 1 HEAVY DUTY COVERS TO MA60. OR B.S. EN 124 GRADE D400 (11.5 TONNE WHEEL LOADING)
10. FOR DRAINAGE CONSTRUCTION AND PIPE BED DETAILS REFER TO DRAWING No. 4008-52 & 53.
11. ALL DRAINAGE BRANCHES TO BE 100mm FOR FOUL WATER & 150mm FOR SURFACE WATER UNLESS MARKED OTHERWISE.
12. ALL SOIL & VENT STACKS TO HAVE RODDABLE ACCESS 150mm ABOVE GROUND FLOOR SLAB LEVEL WITH REMOVABLE ACCESS PLATES.
13. ALL SLOTDRAIN DRAINAGE TO HAVE SUMP UNITS AT OUTLETS OF RUNS & HAVE RODDING ACCESS POINTS EVERY 30m THEREAFTER.
14. ALL SHALLOW DRAINAGE (<900mm COVER) AND DRAINAGE BELOW FLOOR SLAB TO BE INCASED IN MIN 150mm CONCRETE SURROUND.
15. ALL CONCRETE SURROUNDS FOR THE DRAINAGE TO BE CLASS DC2 (SULPHATE RESISTING) OR IN LINE WITH GROUND INVESTIGATIONS

LEGEND.

1200mmØ MANHOLE & DRAIN RUN
FOUL WATER - RED
CLEAN SURFACE WATER - BLUE
DIRTY SURFACE WATER - GREEN
FOUL WATER FIT-OUT - OCHRE/BROWN
SURFACE WATER FIT-OUT - PURPLE

1500mmØ MANHOLE & DRAIN RUN
COLOURS AS ABOVE

1800mmØ MANHOLE & DRAIN RUN
COLOURS AS ABOVE

EXISTING SURFACE WATER
MANHOLE & DRAIN RUN

ACO QMAX/GATIC SLOTDRAIN OR SIMILAR

BEANY KERBDRAIN OR SIMILAR

CLASS 1 BYPASS PETROL INTERCEPTORS (CONDER REFERENCES) OR SIMILAR EA APPROVED MANUFACTURER

DP PRIMARY SYPHONIC DOWNPIPE

RWP RAIN WATER PIPE

PACKAGED PUMP STATION
(BLUE - SURFACE WATER - DUTY/ASSIST)
(RED - FOUL WATER - DUTY/STAND-BY)

FW EXISTING FOUL WATER SEWER

SW EXISTING SURFACE WATER SEWER

1:400	0	4m	8m	12m	16m	20m	24m	28m	32m	36m	40m
1:1	0	10mm	20mm	30mm	40mm	50mm	60mm	70mm	80mm	90mm	100mm

BUCKINGHAM
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REV	DATE	DESCRIPTION	CHK	DRN
L	22.07.19	DRAINAGE REVISED TO FIT OUT AREA	TC	CE
K	20.06.19	FIT OUT RUNS OMMITTED	TC	CE
J	17.06.19	ADDED SW DRAINAGE	TC	CE
H	07.06.19	POP UPS ADDED TO OFFICE AREA	TC	CE
G	06.06.19	COACH DROP OFF ADDED	TC	CE
F	23.05.19	FIT OUT REQUIREMENTS ADDED	TC	CE
E	23.04.19	MANHOLES MOVED	TC	CE
D	16.04.19	FW CONNECTION REVISED/FW5 MOVED	TC	CE
C	12.04.19	SW10 REVISED	TC	CE
B	08.04.19	SW9 & SW12 REVISED	TC	CE
A	05.04.19	ISSUED FOR CONSTRUCTION	TC	CE
P2	20.03.19	LAND DRAIN ADDED	TC	CE
P1	05.03.19	PRELIMINARY ISSUE	TC	CE

NOTE: Where a "P" revision applies, this drawing is NOT to be used for construction

T. R. COLLIER & ASSOCIATES.
CONSULTING ENGINEERS
Rochester House 275 Baddow Road
Chelmsford Essex CM2 7QA
Telephone 01245 500360
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PROJECT
UKBIC WHITLEY SOUTH
COVENTRY

TITLE
DRAINAGE LAYOUT

ARCHITECT
pHp ARCHITECTS

DRAWN	DESIGNED	CHECKED
CE	TC	TC
DATE	**SCALE**	**STATUS**
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SECTION 4

ADDITIONAL INFORMATION FOR PART B APPLICATION

Part B Permit

Additional information for Part B application to WDC

Author – Tony Richardson

Contents - Report

1 Introduction

This document is to supplement the UKBIC EPR Part B application submitted on 20/01/2020.

The previous letter from WDC EHO dated 27th November included a 'Notice for Information'. The required information has been submitted within the Part B application and summarised below.

2 Notice for Information

There were four points within the Part A(2) application Notice for Information dated 27th November 2019 of which are briefly detailed below and indicated where they are referenced within the application bundle.

1. *Fully justify why N Methyl-2-pyrrolidene solvent (NMP) must be used as the solvent, why UKBIC cannot use another less hazardous solvent and explain what steps UKBIC have taken to actively seek an alternative.*

The three documents initially sent with the Part A(2) application were deemed insufficient by the WDC EHO therefore a supplementary report was commissioned.

The Aachen Report – '*Report on the state of the art for N-Methyl-2-pyrrolindone in the production of the lithium-ion battery cells'*. Details the current position of the use of NMP and addresses the process UKBIC considered within the scope of elimination and substitution of the substance. The report was commissioned by UKBIC and instructed Aachen University to generate an academic assessment of the use of NMP within the Lithium-ion battery manufacturing environment globally.

Aachen University are leaders within Europe within the field of intellectual understanding of the current state of the Li battery manufacturing field. The university are the primary technical advisors for the German equivalent off the UK Battery Industrialisation Centre of which is in the process of being constructed and commissioned.

2. *Describe the UKBIC ongoing research programme to develop alternatives to the use of NMP solvent in the battery cell manufacture programme.*

As described to the WDC EHO, it is not within the scope of UKBIC to research or develop alternatives to the use of NMP. A defined role of UKBIC is to mirror acknowledged industrial processes and to remain abreast of respective developments in the field of NMP elimination or substitution. UKBIC are therefore not in a position of developing alternatives to NMP.

3. *Details of all alternative abatement technologies UKBIC have considered to control the emission of NMP vapour from the installation, together with an expert analysis of the effectiveness, merits and drawbacks of each technology in the context of the proposed installation.*

Within the Supporting document for the environmental permit, the selection of alternative abatement technologies is detailed in Section 5.3.1 – Abatement Selection for BAT

This section within the report addresses the respective options for the abatement: The report covers the advantages and disadvantages, recycling/recovery options, operational considerations, raw material and energy consumption as well as the respective emissions; Air, Noise and Odour.

4. *Report of the assessment by a competent person of the actual health risk to off-site receptors arising from the abated emission to air of NMP from the installation employing the applicants proposed abatement technology and the applicants proposed point of discharge. The method of assessment to be agreed between the applicant UKBIC and the regulator.*

Following the meeting at WDC on 17th December 2019 where representatives from Atkins Environmental consultants joined via tele-conference, it was agreed to generate an expert report detailing the actual health risk to off-site receptors.

The report titled '*Atkins Technical report – NMP Emissions Assessment: This is based on the Environment Agency screening assessment utilising the conservative anticipated emissions for the UKBIC abatement system.*

3 Summary

The 'Notice for Information' received from WDC EHO on 27th November was associated with the initial Part A(2) application. The information requested has been included within the Part B application as detailed in section 2 above.

I have also supplemented the Part B application with a two-page process steps presentation as requested by Mr Peter Lawson and two copies of the Emissions Facility Plan drawing that were not included within the original application bundle.

We believe this satisfies the requirement for the respective aspects of the application that Mr Peter Lawson deemed insufficient.

Date	Created by	Version	Amendments	Signed	Approved
21/01/2020	T Richardson	V1	Initial version		*C Mitchell*