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

[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

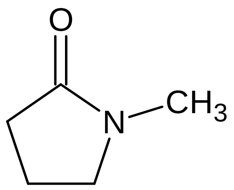
1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

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)

[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]

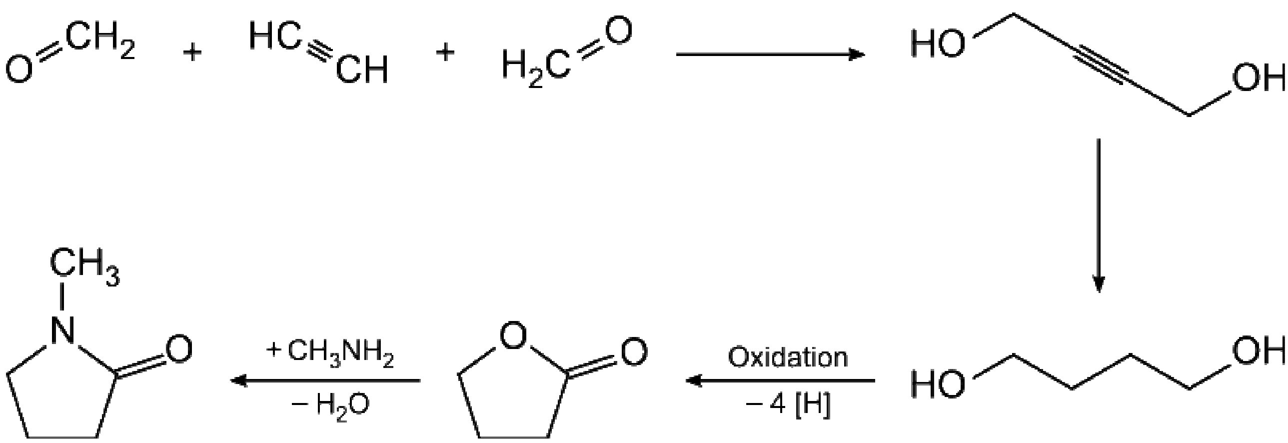
INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

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.

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.

[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.

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

[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 $\geq 20^{o}C$ 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].

[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.

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).

[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)