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): N,N-Dimethylacetamide (DMAC)

EC Number(s): 204-826-4

CAS Number(s): 127-19-5

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

Version: August 2011

PUBLIC VERSION: *This version does not include the confidential annexes referred to in Parts I and II.*

CONTENTS

TABLES

ABBREVIATIONS AND ACRONYMS

The list includes abbreviations and acronyms used in this report and in the confidential annexes to the report:

ACGIH	American Conference of Governmental Industrial Hygienists
AFMA	American Fiber Manufacturers Association
BEI	Biological Exposure Index
CIRFS	The European Man-Made Fibres Association
CSR	Chemical Safety Report
DCM	Dichloromethane
DMA	Dimethylamine
DMAC	N,N-Dimethylacetamide
DMF	N,N-dimethylformamide
DMI	1,3-Dimethylimidazolidin-2-one
DMPU	Tetrahydro-1,3-dimethyl-1H-pyrimidin-2-one
DMSO	Dimethyl sulfoxide
ECETOC-TRA	Targeted Risk Assessment Tool
ECHA	European Chemicals Agency
EFPIA	European Federation of Pharmaceutical Industries and Associations
ERC	Environmental Release Category
EU	European Union
EUSES	European Union System for the Evaluation of Substances
FRP	Fibre reinforced plastic
GDP	Gross Domestic Product
HVAC	Heating, Ventilation, and Air Conditioning
IOELV	Indicative Occupational Exposure Limit Values
ISO	International Organization for Standardization
LEV	Local exhaust ventilation
MIRAN	Miniature infrared analyzer
MMAc	DMAC metabolite monomethylacetamide
MSDS	Material Safety Data Sheet

NEP	1-Ethylpyrrolidin-2-one
NMP	1-Methyl-2-pyrrolidone
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PAI	Polyamide-imide
PMIA	Poly(m-phenylene isophthalamide)
PPE	Personal Protection Equipment
PROC	Process categories
PU	Polyurethane
PVDF	Polyvinylidene fluoride
RMM	Risk management measure
RPE	Respiratory protective equipment
SDS	Safety Data Sheet
SIDS	Screening Information Dataset
SPERC	Specific Environmental Release Category
STEL	Short Term Exposure Limit
SVHC	Substances of Very High Concern
TMU	Tetramethylurea
TWA	Time weighted average
UK	United Kingdom
US EPA	United States Environmental Protection Agency
VOC	Volatile Organic Carbon

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): N,N-Dimethylacetamide (DMAC)

EC Number(s): 204-826-4

CAS Number(s): 127-19-5

- 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 1B under Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 as well as its corresponding classification under Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 as toxic for reproduction category 2.

Summary of how the substance meets the CMR (1A or 1B) criteria

N,N-Dimethylacetamide is covered by index number 616-011-00-4 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) as toxic for reproduction, Repr. 1B (H360D: “May damage the unborn child”). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is toxic for reproduction, Repr. Cat. 2; R61 (“May cause harm to the unborn child”). Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance: yes

PART I

JUSTIFICATION

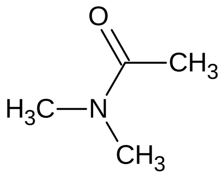
1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	204-826-4
EC name:	N,N-dimethylacetamide
CAS number (in the EC inventory):	127-19-5
CAS number:	127-19-5
CAS name:	Acetamide, N,N-dimethyl-
IUPAC name:	N,N-Dimethylacetamide
Index number in Annex VI of the CLP Regulation	616-011-00-4
Molecular formula:	$C_4 H_9 N O$
Molecular weight:	87.1 g/mol
Synonyms:	Acetdimethylamide DMA DMAA DMAc Dimethylamide acetate N,N-Dimethylethanamide

Structural formula:



1.2 Composition of the substance

Name: N,N-Dimethylacetamide

Description: ---

Degree of purity: 99 – 100 % (according to the information received in the registration dossiers)

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
N,N-Dimethylacetamide EC number 204-826-4		99 – 100 %	According to the information received in the registration dossiers

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks
Information not relevant			Data form the registration dossiers are provided in the confidential Annex 3 of the report

Table 4: Additives

Additives	Typical concentration	Concentration range	Remarks
None			According to the information received in the registration dossiers

1.3 Physico-chemical properties

Table 5: Overview of physicochemical properties

Property	**Value**	**Remarks**	**Reference**
Physical state at 20°C and 101.3 kPa	*liquid*	*Discussion and the value used for Chemical Safety Assessment (CSA) reported in the endpoint summary*	*Bornscheuer, U.; Roempp; Georg Thieme Verlag KG; 2008*
Melting/freezing point	*-20 °C*	*idem*	*Bornscheuer, U.; Roempp; Georg Thieme Verlag KG; 2008*
Boiling point	*163 – 165 °C at 760 Torr*	*idem*	*O'Neil, Maryadele J.; The Merck Index; Merck & Co Inc.; Whitehouse Station, NJ, USA; 14th Edition; 2006*
Relative Density	*0.9429 at 20 °C*		*O'Neil, Maryadele J.; The Merck Index; Merck & Co Inc.; Whitehouse Station, NJ, USA; 14th Edition; 2006*
Vapour pressure (p)	*100 Pa at 28 °C*	*idem*	*Lide, Dacid R.; Handbook of Chemistry and Physics; CRC Press; Boca Raton, London, New York; 88th Edition; 2007-2008*
Water solubility	*> 1000 g/l at 20 °C*	*idem*	*BASF AG; Dampfdruck, Explosionspunkte, Wassermischbarkeit, Flammpunkt nach DIN EN 22719, Zündtemperatur; Department of safety engineering; 2001*
Partition coefficient n-octanol/water (logP value)	*-0.77 at 25 °C*	*idem*	*Lide, Dacid R.; Handbook of Chemistry and Physics; CRC Press; Boca Raton, London, New York; 88th Edition; 2007-2008*

2 HARMONISED CLASSIFICATION AND LABELLING

N,N-Dimethylacetamide (DMAC) is listed by index number 616-011-00-4 in Annex VI, part 3 of Regulation (EC) No 1272/2008 as follows:

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

International Chemical Identification	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
			Hazard Class and Category Code(s)	Hazard state-ment code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment code(s)	Suppl. Hazard statement code(s)		
N,N-Dimethylacetamide	204-826-4	127-19-5	Repr. 1B Acute Tox. 4* Acute Tox. 4*	H360D*** H332 H312	GHS08 GHS07 Dgr	H360D*** H332 H312		Repr. 1B; H360D: C ≥ 5%	

** Indicates that the classification corresponds to the minimum classification for a category*

**** Hazard statements H360 and H361 indicate a general concern for effects on both fertility and development: 'May damage/Suspected of damaging 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.*

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

International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
N,N-Dimethylacetamide	204-826-4	127-19-5	Repr. Cat. 2; R61 Xn; r20/21	T R: 61-20/21 S: 53-45	Repr. Cat. 2: R61: C ≥ 5%	E

Note E: Substances with specific effects on human health (see Chapter 4 of Annex VI to Directive 67/548/EEC) that are classified as carcinogenic, mutagenic and/or toxic for reproduction in categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn). For these substances, the risk phrases R20, R21, R22, R23, R24, R25, R26, R27, R28, R39, R68 (harmful), R48 and R65 and all combinations of these risk phrases shall be preceded by the word 'Also'.

3 ENVIRONMENTAL FATE PROPERTIES

Not relevant for this dossier.

4 HUMAN HEALTH HAZARD ASSESSMENT

Not relevant for this dossier.

5 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for this dossier.

6 CONCLUSIONS ON THE SVHC PROPERTIES

6.1 CMR assessment

N,N-Dimethylacetamide is covered by index number 616-011-00-4 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) as toxic for reproduction category 1B (H360D: “May damage the unborn child”). The 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 (R61: “May cause harm to the unborn child”).

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

PART II

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

The underlying work for development of Part II of this Annex XV report was carried out under contract ECHA/2010/175 SR28 by AMEC[1], supported by COWI[2], IOM[3] and BRE[4]. The technical work on the current project has been led by COWI.

More detailed data on manufacturing, uses and releases are provided in a confidential annex to the report.

EXECUTIVE SUMMARY

Manufacture, Import, and Export

In 2010, DMAC was manufactured by a number of companies in the EU. Actual data on manufacture have been obtained from all manufacturers via consultation. The total manufactured volume was in the range of 15,000-20,000 tonnes. The total import of DMAC into the EU as a substance on its own was in the range of 1,000-2,000 tonnes and the total export was 3,000 – 4,000 tonnes.

Based on the data obtained, the total annual consumption of DMAC in the EU as process chemical and for formulation of mixtures is estimated at 11,000-19,000 tonnes.

DMAC was to some extent imported in mixtures, mainly for the production of fibres, and in articles as residual content (<3%) of fibres and films.

Uses

The main application area for DMAC, representing 65-70 % of the total consumption in the EU, is the use of the substance as solvent, as well as intermediate, in the manufacture of agrochemicals, pharmaceuticals and fine chemicals. DMAC is used in the syntheses of many chemicals and pharmaceuticals and, according to the lead registrant for DMAC, the substance is used by most major producers within these sectors.

The second largest application area, representing 25-30% of the total EU consumption, is as spinning solvent in the production of fibres of various polymers including acrylic, polyurethane-polyurea copolymer and meta-aramid. The major application areas for the fibres are clothing, but the fibres are to some extent also used for technical textiles, e.g. for reinforcement of composite plastic materials. The fibres produced contain residual amounts of DMAC of up to 3%, which is released by the subsequent processing steps.

DMAC is also used as a solvent for production of films of polyimide and possibly other resins representing <2% of the total consumption. The polyimide films are used in a range of industries

[1] 17 Angel Gate, City Road, London, EC1V 2SH, United Kingdom
[2] Parallelvej 2, DK-2800 Kongens Lyngby, Denmark
[3] Riccarton, Edinburgh, EH14 4AP, United Kingdom
[4] Bucknalls Lane, Garston, Watford, WD25 9XX, United Kingdom

including consumer electronics, solar photovoltaic and wind energy, aerospace, automotive and industrial applications. Like the use in production of fibres, the films contain residual DMAC, typically in concentrations of <1%. The DMAC will be released by the subsequent processing steps but may also to some extent end up in the final articles.

Approximately 3-5% of the DMAC is used as solvent in coatings for industrial use. The only use which has been described in detail is the use of the substance in polyamide-imide (PAI) enamels used for electrical wire insulation, but manufacturers of DMAC have indicated that the substance is used for other coatings as well. The DMAC in the PAI enamels is destroyed by the application of the enamels in industrial settings.

Minor uses of DMAC identified by the study are the use of the substance in paint strippers, ink removers, as laboratory chemical, and use in the petrochemical industry. In total these applications account for less than 2% of the total consumption.

Exposure and releases

Worker exposure to DMAC in the EU should be controlled to levels below the Indicative Occupational Exposure Limit Values (IOELVs), which are intended to protect workers from the development of respiratory irritation. Indicative Occupational Exposure Limit Values (IOELVs) of 10 ppm as an 8 hour time weighted average (TWA) and 20 ppm as a 15 minute Short Term Exposure Limit (STEL) have been established in the EU. Comparisons of available exposure data with the IOELV (used as a reference point) in the text below intend to give an indication of the magnitude of exposure associated with the different uses and do not comprise any assessment of the risk related to the toxicity for reproduction of DMAC.

Worker exposure during the manufacture of DMAC appears to be controlled to levels associated with much lower intakes than those associated with the full shift IOELV. The process is entirely enclosed and there is no likelihood of dermal or inhalation exposure.

Worker exposure during the various uses of DMAC is highly variable reflecting a wide range in the scale of processes and degree of enclosure and other risk management measures applied. Most exposures are likely to be within the IOELV and, where processes are contained and effective ventilation is employed, exposures are likely to be a small fraction of the IOELV. The highest levels of exposure are likely to occur during mixing and blending involving DMAC in batch formulation processes where workers may have multiple and/or significant contact with DMAC. The use of appropriate ventilation and personal protective equipment, however, could control exposures associated with formulation to a small fraction of the OELV.

The quantities of residual DMAC present in consumer goods are negligible and no consumer exposure to DMAC is anticipated.

The major release of DMAC to the environment is estimated to be associated with the production and use of fibres which is estimated to account for more than 90% of the total quantified releases to the environment. Residual DMAC in produced fibres (up to 3% of fibre weight) is estimated to be released to the environment. It has however, not been possible to quantify the releases from films (residual content is assumed to be released to the environment), paint strippers and ink removers.

Alternatives

Overall, no information on actual replacement of DMAC with alternative solvents has been obtained. The efforts by industry in reducing the use of the substance have rather focused on improving the recovery rate of DMAC.

For the main uses of DMAC as a solvent in textile fibre processing and as a solvent in the pharmaceutical industry, the most immediate alternatives are themselves classified as toxic to reproduction or carcinogenic or are currently subject to proposals to assign such a classification.

Of the other potential alternatives, two polar aprotic solvents, DMSO and DMI, could potentially be used as alternatives for some applications of DMAC, such as in the production of pharmaceuticals and other chemicals. DMSO is specifically marketed as alternative to DMAC. No comparison with the environmental and health profiles of these potential alternative substances has been made in this report.

These solvents are currently not suggested as solvents for manufacturing of textile fibres of the types for which DMAC is used today. For textile processing, no alternatives with a significantly better environmental and health profile have been suggested by industry or identified in this study.

The use of DMAC as a secondary solvent to dichloromethane in paint strippers seems not to be essential, and paint strippers for similar applications without DMAC are marketed. Indeed, paint strippers based on dichloromethane are due to be phased out for consumer use.

1 MANUFACTURE, IMPORT AND EXPORT

1.1 Manufacturing process

N,N-dimethylacetamide (DMAC) is produced by the reaction of dimethylamine (DMA) and acetic acid in closed systems (OECD, 2001).

1.2 Manufacture, import and export of the substance on its own

According to the OECD SIDS for DMAC, the worldwide production volume of DMAC in the year 2000 was estimated to be between 50,000 and 60,000 tonnes/year (OECD, 2001).

In 2010, DMAC was manufactured in the EU. Actual data on manufacture have been obtained from all manufacturers via consultation. The total manufactured volume was in the range of 15,000-20,000 tonnes. Numbers of companies, manufacturing sites and volumes produced are shown in the confidential annex.

In 2010, DMAC was imported by a number of companies that have submitted registration dossiers under REACH. The total imported volume based on information obtained from importers was in the range of 1,000-2,000 tonnes.

The total reported export of DMAC based on completed questionnaires was in 2010 was 3,000-5,000 tonnes. The figure includes reported export from all manufacturers. However, it cannot be excluded that some DMAC is exported by companies which has not been identified, but the total is still assumed to be within the indicated range.

Based on the data obtained, the total annual consumption of DMAC in the EU for processes, formulation of mixtures and production of articles is estimated at 10,000-100,000 tonnes. This figure will be used for the following analysis. As further described in Chapter 3, an estimated 93% of the total is used as process chemical (mainly as a solvent).

1.3 Trends

According to the lead registrant, over the past five years the DMAC market has been stagnating with growth below average European GDP. A continuing declining market is expected. This decline is thought to be driven by the classification of DMAC and by lower consumption of fresh DMAC due to recycling of the used substance. Overall, it is anticipated that in the future DMAC will be predominantly used in industrial applications.

One producer of textile fibres indicates that DMAC consumption has been reduced over the last few years due to changes such as process improvements, optimization of recycling of used solvent and capture of fugitive emissions. Another producer of fibres has indicated the intention to reduce DMAC consumption by reducing the DMAC content in the final fibre product.

1.4 Import of the substance in mixtures

Some import of DMAC as a mixture is included in the figures for import of DMAC on its own. This is because some importers have indicated that a certain amount of DMAC is imported in mixtures for use as solvent in textile processing, with no further details.

DMAC is imported as a solvent in an ink eraser pen (as further described in section 2.7). The total import is roughly estimated at < 1 tonne.

It cannot be ruled out that some DMAC is imported in some mixtures such as coatings or paint strippers, but no import has been specifically identified.

1.5 Import of the substance in articles

DMAC is imported as an unintentional residue in polymer films and fibres. Actual import of films of polyimide for use in the electronic industry and elastane fibres has been reported, but DMAC may possibly also be imported in other films and fibres. The DMAC is used as a solvent in the production of films and fibres. In the films the concentration is typically <1% whereas for the fibres concentrations up to 3% are reported although the typical concentration is still below 1 % [5]. It has not been possible to identify any import of fibres, but it cannot be excluded that both import and export of raw fibres takes place (DMAC is basically present in the raw fibres only, as further discussed in section 2.2).

The total import of films with residual DMAC has not been reported, but the total import of DMAC is likely to be in the range of 10-100 tonnes per year, however the basis for the estimate is very uncertain. More information on imported quantities has been requested from the main importer, but none was received within the deadline for data collection.

1.6 Releases from manufacture and transport

1.6.1 Operational conditions of use and existing risk management measures

1.6.1.1 Manufacturing process

N,N-dimethylacetamide (DMAC) is produced by the reaction of dimethylamine (DMA) and acetic acid in closed systems (OECD, 2001). The reaction is at elevated temperature and pressure and the substance is purified by distillation.

1.6.1.2 Operational conditions

Registrants have developed exposure scenarios for the production of DMAC. Respondents to the questionnaire indicate that DMAC is manufactured within a high integrity contained system where little potential for exposure exists (PROC 1). The end product is transferred into vessels/large containers at dedicated automated facilities. Sampling is undertaken using closed loop systems.

Exposure may take place during automated filling, maintenance, and lab analysis.

1.6.1.3 Risk management measures

[5] One of the identified MSDSs indicates the concentration of DMAC as 0-10%. The MSDS use in general the notation with wide ranges, and all available information indicates that the residual DMAC concentration is below 3%.

The key risk management measures (RMMs) are process enclosure and automation of the filling facilities.

One of the respondents to the questionnaire indicated that workers at the filling station wear protective gloves (butyl) and goggles. During maintenance operations workers use protective gloves (butyl), face shields, a respirator fitted with an appropriate filter and a chemical protection suit conforming to the following standards.

- Type 3 EN14605 Liquid tight suit / Type 4 EN14605 Spray tight suit
- Type 5 EN ISO 13982-1 Dry particle suit
- EN14126 Barrier to infective agents
- EN1073-2 Barrier to radioactive particulates - Class 1
- EN1149-1 Anti-static

Another respondent indicated that workers are required to use “adequate respiratory equipment” in case of accidental release, safety glasses or a face shield and protective shield during special activities undertaken as part of plant maintenance.

Indicative Occupational Exposure Limit Values (IOELVs) of 10 ppm as an 8 hour time weighted average (TWA) and 20 ppm as a 15 minute Short Term Exposure Limit (STEL) have been established in the EU. These limits were set to prevent the development of respiratory irritation in workers and do not take account of reproductive toxicity (Scientific Committee on Occupational Exposure Limits, 1994).

1.6.2 Releases of the substance from manufacturing

1.6.2.1 Occupational exposure

Exposure estimations for the manufacturing process are included in the confidential annex.

During the manufacture of DMAC, the process is reportedly entirely enclosed and there is no likelihood of dermal or inhalation exposure.

Automated filling of the product minimises worker exposure during filling. In addition, the use of gloves greatly reduces the potential for incidental dermal contact. Exposures to DMAC are likely to be greatest during maintenance operations. There are no measurements of inhalation exposure concentrations during maintenance work but in the absence of respiratory protection, they would be likely to be substantially greater than during routine process operation. The use of appropriate respiratory protective equipment (RPE) during maintenance work would be expected to reduce exposure levels by a factor of 10 such that worker exposure during maintenance operations may not be substantially greater than during routine operation.

A small quantity of older data describing the exposure of European production workers is provided in the OECD Screening Information Data Set (SIDS) dossier (see Table 1.1), but the relevance of these data to current exposure in the EU is uncertain. It is indicated within the SIDS dossier that production of DMAC was undertaken within a closed system within an acrylic fibre producing plant. Production volumes were reported to be low as DMAC was largely recycled within the fibre production process leading to only a small demand for fresh DMAC to be added during each fibre production cycle. Further information on exposure is provided in the confidential annex.

Table 1.1 Exposure of European production workers (OECD, 2001)

Data source	Activity	Shift mean inhalation concentration – "central tendency" mg/m^3	Shift mean inhalation concentration – "high end" mg/m^3	Dermal dose mg/day Assumes no dermal protection
Monsanto	Manufacturing	1.06	2.49	1.3-3.9
Dupont	Manufacturing	0.14		1,300-3,900
	Tank car/wagon loading	5.27		1,300-3,900
	Drum loading	1.21		1,300-3,900
	Maintenance	<3.5		1,300-3,900

All the measurement data and exposure estimates indicate that levels of inhalation exposure during product are low in relation to the IOELV.

1.6.2.2 Environmental releases

Based on emission factors, further described in the confidential annex (section 3.2 therein), it is estimated that approximate 3.5 tonnes of DMAC is released in the EU from the manufacturing process to waste water directed to sewage treatment plants. Air emissions from the manufacturing process are roughly estimated at approximately 0.5 tonnes. No emission to soil is expected.

1.6.3 Releases of the substance from transport

No data on the releases of the substance by transport have been available. Compared to the releases to the air further down the supply chain the releases from transport are assumed to be small.

1.7 Mass balance and conclusions for manufacture, import and export

In 2010, DMAC was manufactured by a number of companies in the EU. Actual data on manufacture have been obtained from all manufacturers via consultation. The total manufactured volume was in the range of 15,000-20,000 tonnes. The total import of DMAC as a substance on its own was in the range of 1,000-2,000 tonnes and the total export was 3,000 – 5,000 tonnes.

Based on the data obtained, the total annual consumption of DMAC in the EU for processes and manufacturing of mixtures and articles is estimated at 11,000-19,000 tonnes.

The mass balance for the manufacture, import and export of DMAC on its own is illustrated in Figure 1. The import of DMAC includes some small quantities of DMAC imported as mixtures used as a solvent in textile manufacturing.

DMAC was to some extent imported in mixtures, mainly for the manufacturing of fibres, and in articles as residual content (<3%) of fibres and films.

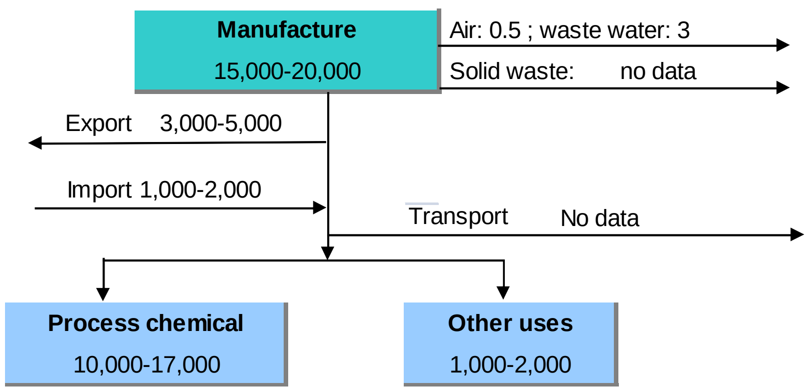


Figure 1 Mass balance for manufacture, import and export of DMAC on its own in 2010

2 USES OF THE SUBSTANCE

2.1 Overview of uses

As part of this study, questionnaires have been sent to manufacturers, importers and downstream users of DMAC. Furthermore, some minor uses have been identified by Internet searches for Material Safety Data Sheets (MSDSs) specifically indicating the presence of DMAC in mixtures and polymers.

Based on the information obtained, the following applications of DMAC in the EU have been identified:

- Process solvent and reagent in the production of agrochemicals, pharmaceuticals and fine chemicals;
- Process solvent for spinning of fibres of various polymers including acrylic, polyurethane-polyurea copolymer (Elastane, Spandex) and poly(m-phenylene isophthalamide) (PMIA, meta-aramid);
- Process solvent in the production of polyimide and polysulphone films;
- Solvent in coatings e.g. polyamide-imide (PAI) enamels (varnishes) used for electrical wire insulation;
- Solvent in paint strippers (paint removers) and ink removers;
- Excipient (carrier ingredient) in human and veterinary pharmaceuticals;
- Laboratory uses.

For some of the uses as solvent, the DMAC will be present as a residue in polymers (e.g. textile fibres) and significant amounts of the substance is released by downstream uses of the polymers.

The total consumption of DMAC for uses within the EU is estimated to be in the range of 11,000-19,000 tonnes in 2010. The estimated breakdown, based on information from manufacturers and importers representing approximately 98% of the market of DMAC is shown in Table 2.1. The indicated number of users and the extent to which the users are industrial, professional or consumers is estimated by the authors to be the most likely based on information obtained from questionnaires.

The substance is nearly 100% used by industrial or professional users. The only identified application where the substance is present in a mixture used by consumers is a pen for removal of ink.

The major use of DMAC is as a process chemical in the production of pharmaceuticals, agrochemicals and fine chemicals. A detailed split on the three application areas has not been available from all manufacturers/importers, but the production of agrochemicals and pharmaceuticals seems to be the main areas and both represent a significant part of the total.

Table 2.1 Estimated distribution of the use of DMAC in the EU in 2010 based on information from questionnaire response

End-use sector	**Application**	**% of total**	**Number of companies**	**End users**
Production of agrochemicals, pharmaceuticals and fine chemicals	Process solvent in the synthesis of active agrochemical and pharmaceutical substances	65-70	100-1000	100% industrial
Textile industry, plastics industry, automotive industry	Spinning solvent in the production of fibres of acrylic, polyurethane-polyurea copolymer and meta-aramid	25-30	1-10 (manufacturing of fibres) 101-1000 (manufacturing of textiles)	100 % industrial
Electrical component industry Possibly other sectors	Solvent in coatings	3-5	11-100	100% industrial
Polymer industry	Solvent for polyimide and other resins in film production	<2	no data	100% industrial
Metal industry	Solvent in paint strippers	<1	10-100	100% industrial/professional
Offices	Solvent in ink removers	<1	no data	partly professional, partly consumers
Laboratories	Laboratory chemical	0.3-0.6	no data	100% professional
Other *		<1		

* Includes petrochemical industry. Further information on the use has been requested from manufacturers of DMAC, but no data has been received.

According to the OECD SIDS, around the year 2000, DMAC was principally used as solvent for dissolution in the man-made fibre production industry (OECD, 2001). As indicated in Table 2.1, this is not the situation in the EU today, where the majority of DMAC is used as a process solvent in the production of agrochemicals, pharmaceuticals and fine chemicals.

According to Honnert and Grzebyk (2010), the main application of DMAC in France in 2008 was as a solvent in the manufacturing of acrylic, polyurethane and aramide fibres. This application accounted for the majority of the identified consumption of 1,510 tonnes DMAC in France. In total, 67 companies in France registered the use of DMAC for the study.

Other minor application areas mentioned on manufacturers' websites are (Taminco, 2011):

- Solvent in the production of x-ray contrast media.
- Solvent in the production of cellophane (cellulose film).
- Solvent for cellulose fibres in several applications.

Specific information confirming the consumption of DMAC for these areas has not been obtained.

The OECD SIDS (2001) quotes US EPA (1995) for the following applications: DMAC may be used as a solvent for production of X-ray and photographic products (10-20%), reactor solvent for cosmetic and pharmaceutical intermediates (10-20%), aramid fibres (10-20%), polyimide films and polymers (<10%), resins and polymers (<10%), miscellaneous organic chemicals (<10%), and liquid treatment fibres (<10%); and solvent in production of photo-resist stripping compounds (<10%) (US EPA Use and Exposure Profile, 1995). Of these applications, the uses as photo-resist liquid treatment fibres and stripping compounds has not been identified in the EU.

In Canada, the reported uses of DMAC, apart from applications identified in the EU, includes photoresist stripping in the production of electronic components and sealant applications in aircraft (Environment Canada, 2009). Photoresist stripping is the removal of unwanted photoresist layers from the semiconductor wafers. 1-methyl-2-pyrrolidone (NMP) is widely used for this application (ECHA, 2011b).

2.2 Use # 1 – Use as a solvent in man-made fibre production

2.2.1 Functions of the substance

As indicated in Section 2.1, one of the principal uses of DMAC in the EU is as a solvent in the production of man-made fibres used in textile production. DMAC acts as the solvent in the polymerization reaction and helps transfer the polymer through the spinning process to produce very fine fibres.

The solvent is recovered and recycled in the process and the consumption of DMAC is related to the solvent losses due to acid hydrolysis during recovery, environmental releases, residuals in the fibres and DMAC disposed of as waste from the process.

2.2.2 Applications

DMAC is used in the spinning of man made fibres. DMAC is used as a solvent for spinning of fibres of various polymers including acrylic, polyurethane-polyurea copolymer (Elastane, Spandex) and poly(m-phenylene isophthalamide) (PMIA, meta-aramid).

Man-made fibres come in two main forms: continuous filament, used for weaving, knitting or carpet production; and staple, discontinuous lengths of fibre which can be spun into yarn or incorporated in unspun uses such as fillings or nonwovens. The DMAC is mainly used for the manufacturing of continuous filament fibres.

The fibres are to some extent used in combination with other fibres. The elastane is typically mixed with cotton or polyester fibres, whereas the meta-aramid fibres may be used in combination with fibre glass e.g. for protective clothing and gloves.

Whereas the main part of the fibres is used for production of clothing, a part of fibres are used as technical textiles for other applications.

Examples of applications of technical textiles of meta-aramid and polyacrylonitril fibres described on the websites of producers of the fibres include:

- Fibreglass/meta-aramid nonwoven (felt) fabrics used for aerospace composites where light weight, strength and stability are crucial (BGF, 2011)
- Surface tissue made of polyacrylonitril used in fibre reinforced plastics (FRP-applications). The surface tissue is used to reduce fibre print through of glass fibres in the surface which means a

better surface quality (Lantor, 2011). The surface tissue is for instance used in the production of truck cabins of fibre reinforced plastics.

- Meta-aramid fibres are used in different systems where properties typical of textiles should be adapted to high ambient temperatures. An example is filters for hot gas filtration (Dupont, 2011b).
- Paper made from synthetic meta-aramid polymer in two physical forms: short fibres (floc) and microscopic fibrous binder particles (fibrids) (Aramid, 2011). The paper is widely used in two major end uses including (i) insulation for electrical equipment applications in liquid and dry transformers, motors, and generators and (ii) structural composites. (Aramid, 2011).

2.2.2.1 Sectors of use and description of the supply chain

The European Man-Made Fibres Association (CIRFS) is the representative body for the European man-made fibres industry. Man made fibres are produced from a variety of polymers.

In 1997, fibre production using DMAC in Europe was estimated as (OECD, 2001):

- 410,000 t/year of acrylic fibre,
- 25,000 t/year polyurethane elastane yarns, and
- 4,000 t/year meta-aramid fibres.

CIRFS has been asked to provide updated information on the quantities of fibres produced by the use of DMAC but updated data have not been obtained. The production of acrylic fibres in Europe in 2009 is reported to be 562,000 tonnes (CIRFS, 2011), but data for the other fibres have not been available. It is not indicated to what extent the acrylic fibres are produced by the use of DMAC.

Man made fibres are used for various end-uses and go through a number of processing steps before the fibres ultimately end up with the consumer in the form of a piece of clothing or in different technical products.

DMAC is only used intentionally in the first stage of the supply chain of the fibres, the polymerization reaction. However, a small residual amount of DMAC (typically 0.1-1%) remains as an impurity in the fibres used downstream in the supply chain.

After the spinning, the fibres are typically further processed by companies within the textile industry.

The involved processes may include:

- Fibre processing: rewinding, knitting, beaming, warping, etc.
- Fabric processing: dyeing, heat setting, washing, etc.
- Textile processing: cutting, sewing, etc.

The different processes within the fibre processing and fabric processing may take place in separate, specialised companies or the entire process from fibre to final fabric may be undertaken by one integrated company.

The further processing of the final fabric, i.e. the manufacturing of clothing, carpets, household textiles and a wide range of technical products are typically undertaken by other companies.

The DMAC would typically be present as a residue at significant concentration only in the first steps of the fibre processing. As further discussed in the section 2.2.4, the residual DMAC evaporates during the processing of the fibres and the concentrations in the final fabric are below the detection limit.

The supply chain of DMAC is consequently considered to consist of the production of the fibres and the processing of the fibres. The supply chain for fibre and fabric processing is quite complex, and is here considered as one stage. In reality, for some products the supply chain could consist of different companies involved e.g. in knitting and dyeing. Information on the number of exposed workers has not been available.

Table 2.2 Supply chain of DMAC used as solvent in man-made fibre production

Stage	Stage in supply chain	Sector	Number of companies (total)	Spatial distribution	Remark
1	Production of man-made fibres	Man-made fibre industry SU5 Manufacture of textiles, leather, fur	1-10	Even across Europe	
2	Fibre and fabric processing	Textile and clothing industry SU5 Manufacture of textiles, leather, fur	101-1000	Even across Europe	Residual DMAC in the fibres used as raw material at this stage is typically 0.1-1 % but can be up to 3%
3-5	Production of textiles and clothing Production of composites for the automotive, construction and aeronautics sectors Users of filters in different sectors Not considered a part of the supply chain of DMAC For the further stages in the supply chain of fibres DMAC is not present in significant quantities	SU5 Manufacture of textiles, leather, fur SU12 Manufacture of plastics products, including compounding and conversion SU17 General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment	>1000	Even across Europe	Residual DMAC in the fabric is typically below detection limit

2.2.2.2 Use in mixtures

DMAC is used as solvent on its own for this application area.

2.2.3 Processes involved in the production of fibres

DMAC is used in production of polymers from monomers in continuous and batch processes. DMAC acts as the solvent in the polymerization reaction and helps transfer the polymer through the spinning process to produce very thin fibres.

The process is described by the respondents to the questionnaire as “Use as carrier solvent in fibre production” covered by SU 3 (Industrial uses: Uses of substances as such or in preparations at industrial sites) and PROC 3 (Use in closed batch process (synthesis or formulation)).

The following overall description of the process is largely extracted from the description provided on the website of the American Fiber Manufacturers Association (AFMA, 2011).

In their initial state, the fibre-forming polymers are solids and therefore must be first converted into a fluid state for extrusion. This is usually achieved by melting, if the polymers are thermoplastic synthetics (i.e., they soften and melt when heated), or by dissolving them in a suitable such as DMAC solvent if they are non-thermoplastic polymers. The process is sometimes referred to as dope preparation.

The fibres are produced by pressing the liquid through the spinneret. The spinnerets used in the production of most produced fibres are similar, in principle, to a bathroom shower head. A spinneret may have from one to several hundred holes. The tiny openings are very sensitive to impurities and corrosion. As the filaments emerge from the holes in the spinneret, the liquid polymer is converted first to a rubbery state and then solidified. This process of extrusion and solidification of endless filaments is called spinning, not to be confused with the textile operation of the same name, where short pieces of staple fibre are twisted into yarn. There are basically four methods of spinning filaments of fibres: wet, dry, melt, and gel spinning.

DMAC is primarily used for wet and dry spinning.

Wet spinning is used for fibre-forming substances that have been dissolved in a solvent. The spinnerets are submerged in a chemical bath and as the filaments emerge they precipitate from solution and solidify. Because the solution is extruded directly into the precipitating liquid, this process for making fibres is called wet spinning. Acrylic, rayon, aramid, modacrylic and spandex can be produced by this process.

Dry spinning is also used for fibre-forming substances in solution. However, instead of precipitating the polymer by dilution or chemical reaction, solidification is achieved by evaporating the solvent in a stream of air or inert gas.

According to information obtained from producers of fibres, dry spinning is today used for production of polyurethane based fibres (spandex, elastane) whereas wet spinning is used in the production of acrylic fibres.

In order to reuse the DMAC in the process, the DMAC is removed by evaporation with subsequent extraction. The extracted DMAC is then condensed and recovered in a set of distillation columns.

In the case of a wet process, the separation/purification process involves the transference of a water/solvent solution through heat-exchangers, columns and between vessels at dedicated facilities.

According to a supplier of DMAC recovery plants, the plant would normally include the following units: distillation unit; squeezing column unit and DMAC stripping unit. The overall recovery yield is reported to be up to 99.5% in relation to the purity of the initial feed. The technology can achieve a purity of 99.99% of the recovered DMAC (MFC, 2011).

The DMAC is consequently reused as a solvent many times in the process. The remaining 0.5-1% from each cycle is evaporated from the process, remains in the fibres as residue, is discharged with waste water or is disposed of with waste from the process. Whereas, the quantity of DMAC leaving the process for each cycle is relatively small, the overall DMAC flow in the process is that all DMAC consumed for the production of the fibres ultimately is released to the environment, ends up in the fibres (and from the fibres to the environment) or is disposed of as waste as described further in section 2.2.7.

2.2.4 Residues in fibres and textiles

According to information from a producer of the fibres, the residual DMAC in the fibres is typically between 0.1 and 0.5% although there are reports of up to 3% as an impurity in the raw fibre. One of the MSDSs report a range of up to 10%, although levels this high are not thought to occur in practice (it is assumed to be a generic/standardised range).

Examples of residual content of DMAC in fibres according the MSDSs of the fibres are shown in Table 2.3.

During the downstream processing of the fibre, residual DMAC may be volatized and exhausted by the air handling system or washed off during wet processing steps.

Whereas the concentration in the fibres is low, the total quantities involved may be significant. If 500,000 tonnes of fibres are produced per year and the average residual content is 0.3%, in total the fibres would contain 1,500 tonnes DMAC. This estimate is quite well in accordance with information from producers of fibres indicating that a significant amount of the DMAC used ultimately ends up in the fibres.

According to the OECD SIDS (2001), textile articles may contain up to 30% elastanes (e.g. Spandex). These textiles are subjected to a hot-wet treatment during production, e.g. dyeing or bleaching. This reduces the residual DMAC content to below 0.001%. For consumers, the residual amount does not represent a risk (OECD. 2001).

This information has been confirmed by information provided by producers for this study.

One producer of fibres reports the following residual concentrations:

- Raw fibre: typically 0.1-0.5%; a few grades may contain up to 2%
- Greige fabric (first stage of fabric production): below 0.1%
- After further hot and/or wet processing steps: below 0.05%.
- Baby diapers containing the fibres: non detectable

Another producer of fibres reports that the produced fibres contain 0.1-2% (w/w) as residue. Tests show that after the subsequent dyeing process, undertaken by companies at the next stage in the supply chain, the residual amount of DMAC will be reduced to less than 0.1% (w/w). For the specific company, 95% of the produced fibres were subsequently dyed. No data have been provided to illustrate the extent to which the DMAC is released to the air or released to water by the dyeing process. For the remaining 5% of the supplied fibres, which are not dyed, washing tests done according to DIN EN ISO 6330 in a Washcator at 60°C, leads to the result that under the washing conditions, used in the domestic home (40°C), no release of the residual DMAC is expected. The company reached the conclusion that that the residual DMAC is fixed in the fibres and under usual conditions of washing and cleaning in domestic households, there is no release of DMAC. Data on DMAC in the final textile is not reported, and another explanation could be that the DMAC is released to the air from the processing of the fibres into fabric/textiles as demonstrated by other producers of textiles.

A producer of textiles has undertaken measurements to detect the concentration of the substance in the yarn during the different production steps, but could not detect the substance, either in the greige fabric after knitting or at the end of the process after dyeing and washing.

For technical applications, the fibres are typically processed into a kind of fabric. The MSDS for the fabrics (surface tissue or needle felt) indicated that the fabric contains residual DMAC at the same levels as reported for the fibres, as indicated in the table below.

Table 2.3 Examples of residual content of DMAC in fibres and textiles according to MSDSs

Name of product	Type of product	Percentage DMAC in product	Website (assessed June 2011)
D7760 and D7780	Surface tissue in FRP-applications (Fibre reinforced plastics) of polyacrylonitrile	<0.7% (as residual solvent	http://www.lantor.nl/files_cms/bestand/73151.pdf
Leacril	Acrylic fibre for textile use	>0.7%	http://www.mef.it/en/acrilico/AcrilicoSchede%20SicurezzaInglese.htm
Nomex® Fibers	Meta -aramid fibres	1 - 3%	http://www.minifibers.com/MSDS/MSDS_Nomex.pdf
Nomex® paper and pressboard	Paper of meta-aramid fibres	0.1-0.5 %	http://www.mueller-ahlhorn.com/fileadmin/Downloads/public/en/Material%20data%20sheets%20OW/Electrical%20insulation%20materials/Nomex%C2%AE/Nomex_MSDS.pdf
Sontara Spunlaced fabrics	Meta-aramid fibres	0-10%	http://www.conservationresources.com.au/html/home/help_info/downloads/Sontara_MSDS.pdf
Fiberglass/Meta-aramid nonwoven	Needle felt	< 3%	http://www.bgf.com/MSDSpdf/tm013.pdf

2.2.5 Processes involved in the processing and reprocessing of fibres

Residual DMAC can evaporate during the first stages of the processing of the fibres, such as transfer and filling operations, rewinding and beaming, spinning of yearn, and knitting/weaving.

Reprocessing of fibre transfer and filling operations is described by one producer as opening of the carton boxes, manual stocking operations and manual waste run operations.

By the rewinding the fibre is unwound from the bobbins on which it is provided from the fibre producer. By the beaming, the warp yarns is winded onto a beam usually in preparation for slashing, weaving, or warp knitting. The process is also called warping. After this step the fabric is typically produced by weaving or knitting.

The processes are open processes where the fibres/yarns are processed on large machinery. The DMAC evaporates from the yarns into the rooms and is then mainly removed by the exhaust/ ventilation air and released to the environment.

As indicated above, the greige fabric contains DMAC in concentrations below 0.1%. The further processing steps include wet processes where the fabric is dyed and/or washed. After these steps the concentration is typically below 0.05-0.1%.

A specific process reported by producers of fibres and reported in the questionnaires is the reprocessing of yarn which is returned on beams from customers or waste from the production. Residual DMAC in these yarns would typically be released to the air.

2.2.6 Service life of final products

As described above, the residual content of DMAC in the final textile product is reported to be below the detection limit.

The market actors have been requested to provide information on any applications where the fibres are used by consumers without prior further processing steps, and consequently where the consumers could be exposed to residual DMAC. It has not been possible to identify any such applications, but it cannot be excluded that it exists.

2.2.7 Quantities involved

According to data from manufacturers and importers of DMAC, representing 98% of the market, use as a solvent in fibre processing is the second largest application area and account for 25-30% of the current use of DMAC in the EU. The total quantities involved are in the range of 3,000-6,000 tonnes. The recycling efficiency for the DMAC used in the fibre manufacturing is about 99%, i.e. the DMAC is reused more than 99 times for dissolving the polymers used for the spinning.

In 1997, 429,000 tonnes of fibres were produced by use of DMAC in the EU, as reported by the OECD (2001). No data on the actual volumes of fibre production in the EU involving DMAC as a solvent have been available.

The use of DMAC for the fibre production does not necessary follow the volume of produced fibres as the total consumption is very dependent on the recycling efficiency which has increased over time.

The available information indicates that that the use of DMAC may be reduced by reducing the residual content of the fibres, whereas the quantities of fibres produced by the use of DMAC seem to be stagnant.

2.3 Use #2 – Use as a solvent and intermediate in production of pharmaceuticals, agrochemicals and fine chemicals

2.3.1 Function of the substance

The major use of DMAC in the EU is as a process solvent in the synthesis of fine chemicals, agrochemicals and pharmaceuticals.

DMAC is a dipolar, aprotic solvent with high solving power for high molecular-weight polymers (aprotic = cannot donate hydrogen). The solvent can be used for a wide range of organic and inorganic compounds and is miscible in water, ethers, esters, ketones and aromatic compounds (Taminco, 2011). The polar nature of DMAC enables it to act as a combined solvent and reaction catalyst in many reactions (Taminco, 2011).

DMAC has properties quite similar to N-methyl pyrrolidone (NMP) and can be considered a ‘direct’ alternative to this solvent; and visa versa. The properties of NMP have been described in the stakeholder consultation for NMP in May 2011 (ECHA, 2011a).

The physical properties of these dipolar, aprotic solvents that make them an attractive choice from a chemistry perspective in the synthesis of Active Pharmaceutical Ingredients (API) include:

- Generally high solubility of many APIs and intermediates, which often have very poor solubility in less polar solvents. This facilitates processes that require minimal solvent quantities, compared with the much larger volumes of other solvents that may be required.
- Offers sufficient solubility of many inorganic reagents (e.g. acids and bases) that facilitates chemical reactions that would not be practicable or robust in many other organic solvents.
- Reaction rates of certain reactions (e.g. nucleophilic substitution) are substantially enhanced due to the solvent polarity.
- The use of these solvents can be essential (due to their relatively low acidity) when strong bases are employed as these materials would be completely consumed by side reactions if protic solvents were used (Protic = has a hydrogen atom bound to an oxygen).
- Water miscibility – for example facilitating precipitation, and subsequent isolation, of products from reaction liquors through the addition of water as an anti-solvent.
- High boiling points. The boiling point of DMAC of 166ºC is lower that the boiling point of NMP (202ºC) but still allows reactions to be carried out at much higher temperatures than would be achievable in many organic solvents, without the need to operate under pressure (often not operationally feasible in typical pharmaceutical reactors, and inherently of greater operational hazard). An additional benefit is that the potential for solvent emissions associated with processing is less than those associated with many other solvents.

DMAC is reported to be used as intermediate for synthesis of some chemicals, but no details about this use have been obtained.

DMAC is to some extent used as excipient (carrier ingredient) in human and veterinary pharmaceuticals due to its polar, aprotic characteristics.

2.3.2 Applications

Within the sector of agrochemicals, DMAC is used in the production of pesticides, fertilizers, and other agricultural chemicals. More detailed information has on the use has been requested from industry, but not been obtained.

Within the pharmaceutical sector DMAC is used as a solvent and as a reagent (intermediate) in the production of various pharmaceuticals (Taminco, 2011). It is reported to be used as a solvent in the production process of antibiotics like cephalosporins (such as cefadroxil, cefalexin and cefradine) and as a solvent in the production of novel contrast media (Taminco, 2011).

As further discussed in section 2.3.2.2, DMAC is used as a carrier ingredient is some pharmaceuticals and veterinary agents.

2.3.2.1 Sectors of use and description of supply chain

According to the lead registrant, DMAC is used as a process solvent by most major manufacturers of fine chemicals, agrochemicals and pharmaceuticals. As the solvent is in general not included in mixtures the supply chain has one stage only. A minor part is used as an intermediate in the same sectors.

Table 2.4 Supply chain of DMAC used as solvent in manufacturing of agrochemicals, pharmaceuticals and fine chemicals.

Stage	Supply chain stage	Sector	Number of companies (total)	Spatial distribution	Remark
1	Production of agrochemicals, pharmaceuticals and fine chemicals	Agrochemical industry, pharmaceutical industry (human and veterinary), fine chemicals industry, industry	100-1000 (estimated)	Even across Europe	

2.3.2.2 Use in mixtures

As mentioned above, DMAC appears in general to be used as a solvent in the processes and not included in mixtures.

Product summaries indicate that DMAC is used as an excipient (carrier ingredient) of different human and veterinary pharmaceuticals. The concentration of DMAC is not indicated. A search on products summaries in Denmark revealed that DMAC is listed as an excipient in a number of pharmaceuticals including Selsun dandruff shampoo and Busilvex® cytocide. Examples of DMAC in veterinary products include Florkem and Alamycin Prolongatum veterinary injection fluids. A search on the UK reviews in the electronic Medicines Compendium (eMC), which contains information about UK licensed medicines, gave two search results: Amsidine and Busilvex® (ECM, 2011).The result indicates that DMAC is used as an expedient in some pharmaceuticals, but the use is not widespread.

2.3.2.3 Processes involved

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

For the production of agrochemicals it is reported that the substance is only handled as a solvent, i.e. in liquid phase. The substance is mixed with the reactants and at the end of the reaction separated from the products by different means, i.e. filtration or distillation. Solvent for re-use is always purified by distillation prior to re-use.

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

2.3.3 Quantities involved

Production of agrochemicals, pharmaceuticals and fine chemicals is the major application area for DMAC. According to information obtained from producers and importers of the substance representing 98% of the market, this application area represents approximately 65-70% of the total consumption, corresponding to a total consumption in the range of 7,000-13,000 tonnes.

A detailed breakdown of the total volume on the use in different sectors has not been made available by all manufacturers/importers, but based on the most detailed questionnaire responses it is roughly estimated that the majority is used in the agrochemical and the pharmaceutical sectors, with the pharmaceutical sector accounting of more than half of the total.

As consequence of the classification of DMAC (toxic to reproduction, category 1B), existing regulation under the Solvent Emissions Directive (Directive 1999/13/EC as amended by Directive 2004/42/EC) means that use of DMAC within pharmaceutical manufacturing is restricted to those applications where there is no feasible alternative.

2.4 Use #3 – Use as a solvent in enamels and other coatings

2.4.1 Function of the substance

DMAC is used in solvents for some types of coatings.

2.4.2 Applications

According to the lead registrant for DMAC, the use of DMAC in coatings is restricted to the industrial sector. DMAC is not present in paints or other coatings for consumer use.

The only identified use of DMAC in coatings in the EU is the use of the substance as solvent in polyamide-imide (PAI) enamels (varnishes) used for electrical wire insulation. One manufacturer of DMAC has furthermore indicated that DMAC is used for some coatings, but detailed information on the uses has not been provided. It has not been possible to identify any MSDSs for coatings containing DMAC.

For PAI enamels, the polymer content is typically 30%, with the polymer dissolved in various solvents. The average concentration of the DMAC in the PAI enamels is 10%. PAI is a high strength plastic with the highest strength and stiffness of any thermoplastic up to 275°C (based on a questionnaire response). PEI-based enamel is one of the most important insulating enamels in electrical engineering and widely used for enamels on wires used for producing of electrical parts such as electrical motors, transformers, alternators, etc. These electrical parts are used for a wide range of applications in vehicles, electrical appliances, electrical tools, etc. Wires with PAI enamel are suitable for use in applications up to 220ºC.

Unlike the use of DMAC in fibres and some type of films, the DMAC is not present as residues in the coated wires as further described below.

2.4.2.1 Sectors of use and description of supply chain

The DMAC is used for the formulation of PAI enamels (and probably other coatings) by formulators within the paint and coating industry.

PAI enamels where DMAC is used as solvent are used by producers of insulated wires. Further downstream in the supply chain of the coated wires the DMAC is not present at measurable concentrations.

The supply chain for PAI enamels is shown on the table below.

Table 2.5 Supply chain of DMAC used for PAI enamels for wire insulation

	Stage in supply chain	Sector	Number of companies	Remark
1	Formulation of PAI enamels	Paint and coatings industry SU10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)	1-10	
2	Application of PAI enamel on electrical wire: insulating film formation in oven	Electro technical industry SU16: Manufacture of computer, electronic and optical products, electrical equipment SU3: Industrial uses: Uses of substances as such or in preparations* at industrial sites	11-100	The applied enamels contain on average 10% DMAC as a solvent
3	Automotive industry equipment suppliers (alternators), electrical motors producers for various applications, electrical transformer producers Not considered here a part of the supply chain of DMAC	Electro technical industry, automotive industry	101-1000	DMAC is not present in the insulated wires at measurable concentration

2.4.2.2 Use in mixtures

As regards the use in coatings, DMAC is formulated into coating products by coating producers. These mixtures are reported to be used in the industrial sector only.

In polyamide-imide (PAI) enamels used for electrical wire insulation, the average concentration of the DMAC in the enamels is 10%.

2.4.2.3 Processes involved

The key processes involved include coatings formulation and coatings application.

Formulation of coating

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

The following processes have been reported for the formulation of coatings containing DMAC.

- Road tanker unloading into a storage tank*
- Storage*
- Transfer by pump to reactor*
- Sampling
- Transfer to blender*
- Filtration
- Packaging

The processes indicated with (*) are in closed circuit with no exposure to personnel.

Application of coating

The application of PAI enamel on electrical wire involves insulating film formation in an enamelling oven equipped with VOC (Volatile Organic Carbon) catalytic oxydization devices. According to producers, due to the elevated temperatures by the processing, DMAC is not present in measurable quantities in the final wire coating and DMAC emissions from the enamelled wire cannot be detected.

Concerning the use of DMAC in coatings the “Information on Registered Substances” at ECHA’s website indicates the following processes for the application of DMAC in coatings:

Industrial spraying

- Transfer of substance or mixtures (charging/discharging) from to vessels/large containers at dedicated (and non-dedicated) facilities; Industrial setting
- Roller application or brushing
- Treatment of articles by dipping and pouring

2.4.2.4 Use in articles

DMAC is not assumed to be present in enamelled articles, as it is used as a solvent in coatings applied at elevated temperatures, meaning that the DMAC evaporates following application of the coating.

2.4.3 Quantities involved

The use of DMAC as solvent in coatings is estimated to account for 2-5% of the total use of DMAC in the EU, corresponding to 100-1,000 tonnes.

It appears that the used DMAC is nearly 100% destroyed by the treatment of off-gas from the applications.

According to the available information, the quantity used is increasing.

2.5 Use #4 – Use as a solvent in production of films

2.5.1 Function of the substance

DMAC is a good solvent for polyimide resins used in film production (Taminco, 2011). It is also reportedly the ideal solvent for the production of dialyser membranes, based on polysulphones (Taminco, 2011).

Films of meta-aramide are reported in the literature, but no actual uses of meta-aramide films have been identified during the course of the present analysis (paper of meta-aramide is described in section 2.2).

Similarly with the textile fibres, residual DMAC from the production of the films is present in the films used by downstream users.

2.5.2 Applications

2.5.2.1 Sectors of use and description of supply chain

Polyimide films are produced by companies within the polymer industry. No actual production within the EU has been identified.

Imported polyimide films are used for a variety of applications due to their unique combination of electrical, thermal, chemical and mechanical properties that withstand extreme temperature, vibration and other demanding environments. Polyimide films are used in a range of industries including consumer electronics, solar photovoltaic and wind energy, aerospace, automotive and industrial applications (Dupont, 2011a). Examples of applications include substrates for flexible printed circuits, transformer and capacitor insulation and bar code labels, wire and cable tapes, formed coil insulation, motor slot liners, magnet wire insulation.

Polyimide track-etched membranes are used for the detection of microorganisms in the pharmaceutical, cosmetic, and food industries.

Dialyser membranes based on polysulphones are used in the medical sector. Though no actual use of DMAC for the production of polysulphones has been identified in this study.

One producer of DMAC has indicated that the substance is used for polymer production, but it was not possible to obtain further details on the use within the timeframe of this study.

Table 2.6 Supply chain of DMAC used for films

	Stage in supply chain	Sector	Number of companies	Remark
1	Production of polyimide and polysulphone films	Plastics industry	no data	
2	Use of polyimide films for production of components	Producers of electrical and electronic components	101-1000 (estimated)	Residual DMAC in the films used at this stage is reported to be < 1 %
3	Production of electrical and electronic equipment	Producers of electrical and electronic equipment	> 1000 (estimated)	Residual DMAC in the film at this stage is expected to be below the detection limit of the applied analysis methods

2.5.2.2 Service life of produced articles

According to a producer of films, DMAC is a residual unintended impurity from the production of film articles (films which are produced outside of the EU).

According to the MSDSs of polyimide film and membranes, the residual content of DMAC in the films is <1%.

Similarly to the textile fibres, it is expected that the residual DMAC will be released further down the supply chain or (applying for the case of the films) from the finished electronic equipment.

More information on the fate of the DMAC further down the supply chain has been requested from a major producer of films, but no data have been obtained.

Table 2.7 Examples of residual content of DMAC in films according to MSDSs

Name of product	Type of product	Percentage DMAC in product	Website (assessed June 2011)
It4ip tm polyimide track-etched membrane	Porous film	<1%	http://www.it4ip.be/uploads/images/PDF/MSDS_002%20MSDS%20PI%20MEMBRANE%20v02.pdf
KaptonTM	Polyamide films	< 1%	http://msds.dupont.com/msds/pdfs/EN/PEN_09004a2f800897ec.pdf
ipPORE TM	Porous polyimide track-etched membrane	< 1%	http://www.it4ip.be/uploads/images/PDF/MSDS_002%20MSDS%20PI%20MEMBRANE%20v02.pdf

2.5.3 Quantities involved

The reported consumption of DMAC for polymers (apart from textiles) is <1% of the total EU consumption, corresponding to 10-100 tonnes per year. The data does allow for a detailed breakdown of application areas.

DMAC will be present in imported films, but no data on total quantities of DMAC in imported films have been reported by importers.

No data on the trends in DMAC use for this application area has been obtained.

2.6 Use # 5 – Use as a solvent in paint strippers

2.6.1 Function of the substance

DMAC is a powerful solvent and is used in mixtures applied for removal of paint. The function of DMAC is to dissolve cured paint and varnishes.

2.6.2 Applications

DMAC is used in cleaning products (paint strippers or paint removers) for dissolvation and removal of paint. The substance is used in the cleaning agents in conjunction with other solvents.

The paint strippers identified are mainly used in industrial settings.

2.6.2.1 Sectors of use and description of supply chain

The paint strippers are formulated and marketed by companies specialised in cleaning products for the industrial and commercial sectors.

The products are marketed together with other products for cleaning in various industrial sectors, and it is expected that the main end-use sector is metal industry; the products may also be used in other industrial sectors.

Table 2.8 Supply chain of DMAC used for PAI enamels for wire insulation

	Stage in supply chain	Sector	Number of companies	Remark
1	Formulation of paint strippers	Cleaning products for the industrial & commercial sectors SU10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)	1-100	
2	Application of the paint stripper for removal of paint and varnish Companies specialized in paint stripping	Metal industry (main sector) SU3: Industrial uses: Uses of substances as such or in preparations at industrial sites	no data	The applied paint stripper contain typically 1-5% DMAC as a solvent

2.6.2.2 Use in mixtures

In regard to the use for dissolving paint, DMAC is formulated into paint stripper products by producers of cleaning products for the industrial sector. According to information from Material Safety Data Sheets (MSDSs), the concentration in the products is in the range of 0.1-2.5% for one product and 1-5% for two other products. Examples of products on the German market are shown in the table below.

The substance is used in combination with other solvents such as dichloromethane (CAS-No 75-09-2) and light aromatic naphtha (CAS-No. 64742-95-6). The main solvent in the paint strippers is dichloromethane, accounting for more than 50% of the formulations.

Table 2.9 Examples of paint strippers with DMAC

Name of product	Application	Percentage DMAC in product	Website (assessed June 2011)
Leyco-strip 2	Paint stripper	0.1-2.5%	http://www.zetolan.com/England/Safety%20data%20sheets/LEYCO-STRIP%202.PDF
Sinco Stripper	Paint stripper (cold conditions)	: ≥ 1 - < 5 %	http://www.singoli.de/downloads/sinco-stripper-sdb.pdf
ABF flüssig	Paint stripper (cold conditions)	: ≥ 1 - < 5 %	http://www.nita-vertrieb.de/images/produkte/abbeizer/abf_fluessig_sicherheitsdatenblatt.pdf

2.6.2.3 Processes involved

The key processes involved include paint stripper formulation and the application of the paint strippers.

This formulation of paint strippers and the application of DMAC in paint strippers are not covered by any of the CRSs prepared by manufacturers or importers of DMAC.

Formulation of the paint stripper

Formulation of cleaning products of this type will typically involve similar stages as used for the formulation of paint, such as bulk transfer of the substance (e.g. from IBCs, tanker or drums, though sometimes in closed pipelines); mixing, which may be in open systems; and filling of the cleaning agent into drums/cans.

The following processes are expected based on experience with similar processes:

- Unloading into a storage tank
- Storage
- Transfer by pump to reactor
- Sampling
- Transfer to blender
- Packaging

Application of paint strippers
The identified paint strippers are basically applied in two different ways.

One type of paint stripper is reported to be used in dipping baths at temperatures of around 20 ºC (Leyco, 2011; Nita-Vertrieb, 2011). Iron parts with cured paint and varnish are put into a basket and submerged into the bath in order to dissolve the paint or varnish. The dipping baths indicated in the technical data sheet for the product are open baths. The time taken to remove the surface coating depends upon the type of varnish, its strength and the temperature of the dip. The burning coating materials become detached, splinter or float from the metal. It is recommended by the supplier that a false floor be built in the reservoir, so that the varnish residue can be removed occasionally without having to remove the liquid. After cleaning, parts are removed from the dip; they should be thoroughly hosed down with clean water (Leyco, 2011).

Another type of paint stripper is sold in smaller quantities and is indicated to be applied by hand with a brush or bristle on the item and the paint is afterwards removed with a scraper (Singoli, 2011). The product is marketed for professional users.

According to Commission Regulation No 276/2010 of 31 March 2010, paint strippers containing dichloromethane in a concentration equal to or greater than 0.1 % by weight shall not be placed on the market for supply to the general public or to professionals after 6 December 2011 and not be used by professionals after 6 June 2012. By way of derogation from the general restriction, Member States may allow on their territories and for certain activities the use, by specifically trained professionals, of paint strippers containing dichloromethane and may allow the placing on the market of such paint strippers for supply to those professionals. It has not been investigated whether the paint strippers with DMAC would be used for applications that would be allowed by some Member States.

2.6.3 Quantities involved

No information on DMAC quantities used for paint strippers has been obtained from manufacturers and importers, indicating that the total quantities involved are small. Information has been requested from formulators of paint strippers, but no quantitative information was obtained within the timeframe of this study.

2.7 Use # 6 – Use as a solvent in ink removers

2.7.1 Function of the substance

DMAC is used as solvent to stabilise the erasing property of erasing liquid. The erasing liquid is contained in ink removers, which are applied via an erasing pen.

2.7.2 Applications

2.7.2.1 Sectors of use and description of supply chain

The erasing pens are expected to be used in offices and by the general public.

2.7.2.2 Use in mixtures

It is indicated, by one market actor, that the mixture used in the erasing pens is produced in Europe and then exported outside Europe to be filled into the pens. The pens containing the mixture are afterwards imported into the EU. Information on the formulation of the mixture has not been obtained. Some info on the concentration of DMAC is provided in the confidential annex of this report.

2.7.2.3 Processes involved

No data have been available on the formulation process for the mixture for the pen.

The pen is used by applying the mixture on the ink to be erased. It is expected that the DMAC evaporates following application.

2.7.2.4 Use in articles

The DMAC is present in a mixture inserted in an erasing pen used for removal of ink.

2.7.3 Quantities involved

The total quantities of DMAC are reported by one company importing the article to be < 0.01 tonnes, but similar products could likely be imported by other companies for similar applications. The total imported quantity is roughly estimated to be <1 tonne.

The company which has reported the import of the pen indicated that the provider of the pens has been asked to identify an alternative and that the import will cease by mid 2012.

2.8 Other uses

2.8.1 Use in laboratories

According to market information obtained from manufacturers and importers, the use of the substance in laboratories appears to be in the range of 10-1,000 tonnes per year.

This use has not been investigated further and no specific information has been received from industry on this use.

2.8.2 Petrochemical applications

One manufacturer of DMAC has indicated that a small amount of DMAC is used for petrochemical applications. Further information on the use has been requested, but data has not been obtained within the timeframe of this study.

2.8.3 Cellulose fibres

According to one manufacturer's technical data sheet, a mixture of DMAC with lithium chloride is a useful solvent for cellulose fibres in several applications (Taminco, 2011). No actual use of DMAC for this application in the EU has been identified.

2.8.4 Other uses in mixtures

According to information from Member States (Annex 1), DMAC has, apart from uses mentioned elsewhere, been registered in the Nordic product registers in sealants (Finland), putty (Sweden) and adhesives (Finland). According to the online database of the Nordic product registers, SPIN, in 2010 a total of 0.2 tonnes DMAC was registered in 10 mixtures in the category "adhesives, binding agents" in Finland. No quantitative data was available from the other countries (Denmark, Sweden and Norway).

One manufacturer indicates on its website that DMAC may be used as a "booster solvent in coating and adhesive formulations".

These uses have not been confirmed by information obtained from stakeholders.

Through a search for MSDSs via the Internet, one MSDS for an adhesive marketed in the USA was identified (see the table below). No indication of actual marketing of this product in the EU has been obtained.

Table 2.10 Example of other uses of DMAC in mixtures according to MSDSs

Name of product	Application	Percentage DMAC in product	Website (assessed June 2011)
TRANSILON K14 cement	Adhesive	2.5 - 10	http://www.forbo-siegling.com/us/pages/information/download/fms071903_materialsafetydatasheet_transilon-cement-k14_en.pdf

2.9 Conclusions on the uses of DMAC

The main application area for DMAC, representing 65-70 % of the total consumption in the EU, is the use of the substance as solvent and intermediate in the production of agrochemicals, pharmaceuticals and fine chemicals. DMAC is used in the syntheses of many chemicals and pharmaceuticals and according to the lead registrant for DMAC the substance is used by most major producers within these sectors.

The second largest application area, representing 25-30% of the total EU consumption is as spinning solvent in the production of fibres of various polymers including acrylic, polyurethane-polyurea copolymer and meta-aramid. The major application areas for the fibres are clothing, but the fibres are to some extent also used for technical textiles e.g. for reinforcement of composite plastic materials. The fibres produced contain residual amounts of DMAC of up to 3% which is apparently released by the subsequent processing steps.

DMAC is also used as a solvent for production of films of polyimide and possibly other resins representing <2% of the total consumption. The polyimide films are used in a range of industries including consumer electronics, solar photovoltaic and wind energy, aerospace, automotive and industrial applications. Like the use in production of fibres, the films contain residual DMAC, typically in concentrations of <1%. The DMAC will mainly be released by the subsequent processing steps, but may also to some extent end up in the final articles.

Approximately 3-5% of the DMAC is used as solvent in coatings for industrial use. The only use which has been described in detail is the use of the substance in polyamide-imide (PAI) enamels (varnishes) used for electrical wire insulation, but manufacturers of DMAC have indicated that the substances is used for other coatings as well. The DMAC in the PAI enamels is anticipated to be destroyed during the application of the enamels at elevated temperatures, in industrial settings.

Minor uses of DMAC identified by the study are the use of the substance in paint strippers, ink removers, as laboratory chemical, and use in the petrochemical industry. In total these applications account for less than 2% of the total consumption.

3 RELEASES FROM USES

3.1 Occupational releases and exposure

3.1.1 Overview

3.1.1.1 Data availability

The exposure assessment described in this section of the report and in the confidential annex is largely based on the information provided in the CSRs (in confidential annex), questionnaires to manufacturers and users, some information from the Screening Information Data Set (SIDS) Dossier (OECD; EC 2001), and a small number of published studies of workplace exposure that were identified through a search of PubMed – a comprehensive database of the medical literature that is maintained by the US National Library of Medicine. Some additional modelling using the Advanced REACH Tool was undertaken as part of this assessment in order to provide exposure estimates for uses not covered in the CSRs.

Exposure scenarios

Exposure assessments have been undertaken for manufacture and for the following uses identified in section 2.1 of this report above:

- Formulation in mixtures
- Use as an intermediate in the industrial production of chemicals
- Process solvent in the production of agrochemicals, pharmaceuticals and fine chemicals;
- Process solvent for spinning of fibres of various polymers including acrylic, polyurethane-polyurea copolymer (Elastane, Spandex) and poly(m-phenylene isophthalamide) (PMIA, meta-aramid);
- Process solvent in the production of polyimide and polysulphone films;
- Solvent in coatings e.g. polyamide-imide (PAI) enamels (varnishes) used for electrical wire insulation;
- Solvent in paint removers (paint strippers) and ink removers;
- Excipient (carrier ingredient) in human and veterinary pharmaceuticals;
- Laboratory uses.

The uses described in most of the CSRs are highly generic and some of the registered uses cover more than one of the more specific uses identified above. Most of the uses and assessments are common to more than one of the CSRs, but there are some differences in the recommended Risk Management Measures RMMs and exposure estimates. Several of these generic uses encompass a range of different degrees of process enclosure and automation and scale of process giving rise to potentially very different levels of exposure arising from individual categories of use. The registered uses are shown in the confidential annex.

3.1.1.2 Exposure Limits

The EU has derived Indicative Occupational Exposure Limit (OEL) Values (IOELVs) of 10 ppm (36 mg/m^3) as an 8 hour Time Weighted Average (TWA) and 20 ppm (72 mg/m^3) as a short term (15 minute) average. The IOELV (which are intended to protect workers from the development of respiratory irritation) has been adopted by most EU member states, but France has set OELs at lower levels: 2 ppm as an 8 hour TWA and 10 ppm as a 15 minute average. The IOELV equates to an approximate inhaled intake of 360 mg over an 8 hour shift or 5.14 mg/kg/day. There are no dermal exposure standards but a Biological Exposure Index (BEI) has been derived by the American Conference of Governmental Industrial Hygienists (ACGIH) and adopted by the German authorities. The BEI provides a measure of total systemic exposure (combining dermal and inhalation exposure) and is based on measurement of the DMAC metabolite monomethylacetamide (MMAc) in urine in end of shift samples. The BEI of 30 mg MMMCc/g creatinine is believed to be equivalent to inhalation exposure to 10 ppm.

Note: Comparisons of available exposure data with the IOELV (used as a reference point) in the current Annex XV report intend to give an indication of the magnitude of exposure associated with the different uses and do not comprise any assessment of the risk related to the toxicity for reproduction of DMAC.

3.1.2 Formulation of mixtures

3.1.2.1 Operational conditions and existing risk management measures

The following processes are identified for the use of DMAC for formulation of mixtures in the “Information on Registered Substances” at ECHA’s website:

PROC 5: Manufacture or formulation of chemical products or articles using technologies related to mixing and blending of solid or liquid materials, and where the process is in stages and provides the opportunity for significant contact at any stage.

- PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated facilities; Industrial setting.
- PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities; Industrial setting.

Information related to the exposure scenarios developed by registrants, including RMM, is provided in the confidential annex of the report.

3.1.2.2 Releases of the substance from formulation of mixtures

Releases of the substance from formulation of mixtures and occupational exposure are described in the confidential annex.

A small quantity of older data describing the exposure of European workers exposed to DMAC during the formulation of mixtures for use in the man-made fibres industry is provided in the SIDS dossier (as set out in the table below), but the relevance of these data to current exposure in the EU is uncertain. These limited data suggest that it is possible that some inhalation exposure concentrations during formulation may exceed workplace exposure limits. No information is provided about whether LEV or other protective measures were in force.

Table 3.1 Exposure to DMAC(OECD, 2001)

Data source	Activity	Shift mean inhalation concentration – "central tendency" mg/m^3	Shift mean inhalation concentration – "high end" mg/m^3	Dermal dose mg/day Assumes no dermal protection
Monsanto	Pigment operators	9.30	51.35	1300-3900
	Batch operators/sampling	9.30	51.35	1300-3900

3.1.3 Use #1 - Use as a solvent in man-made fibre production

3.1.3.1 Operational conditions of use and existing risk management measures

DMAC is used in the spinning of polymers including acrylic, polyurethane-polyurea copolymer (Elastane, Spandex) and poly(m-phenylene isophthalamide) (PMIA, meta-aramid). Further details on operational conditions are provided in the confidential annex.

Exposure to DMAC may occur during its use as a solvent during fibre production or during the further processing of fibres to form textiles. In addition to these two scenarios, exposure to DMAC is theoretically possible during the further processing of textiles containing residual DMAC to create garments or other textile based articles.

Information about exposure during the production and use of fibres is available from questionnaire responses.

Fibre production

The production of the polymer solution and fibre spinning is generally undertaken in closed systems and LEV is employed where emissions of DMAC are likely. Workers are generally required to wear appropriate gloves, protective clothing, eye protection and respiratory protection where direct contact with DMAC is possible. Employers may take additional precautions to minimise the exposure of pregnant women, including temporary change of workplace. Air and biological monitoring can provide important information about the effectiveness of RMMs in order to ensure that exposures are maintained at the lowest practicable levels.

One questionnaire respondent used DMAC in fibre production until 2009. The RMMs that were in place are tabulated below:

Table 3.2 RMMs in fibre production

Process	RMMs
Dope Preparation	Closed system, enclosure of specific equipment plus use of LEV, use of gloves, and where necessary RPE, during sampling or unusual procedures
Spinning	LEV, use of covers and enclosing doors to isolate the areas where DMAC vapours may be emitted, requirement for gloves, RPE and protective suit for workers starting up production
Solvent recovery	Closed process undertaken in outdoor area. Use of gloves, and where necessary RPE, during sampling maintenance or unusual procedures

Fibre re-processing (further processing of fibres)

The residual DMAC in fibre prior to further processing is small. One respondent to the questionnaire indicated that the DMAC content of polyacrylonitrile product is <2%. The RMMs in place are similar to those involved in primary production with both general ventilation being employed at plant level and LEV in place at processes where DMAC is likely to be emitted. Further information is provided in the confidential annex.

Downstream use of textiles

Elastane (spandex) has been used to make a range of textile products like swimsuits, underwear and socks for a very long time. It is also used in the production of absorbent hygiene products such as baby diapers and incontinence products.

Respondents to the questionnaire indicate that the quantities of residual DMAC present in fibres in these products are very small. For example, the maximum quantity present in diapers is reportedly 0.1 ppb (0.0000001%) compared with a theoretical worst case estimate of 0.005%.

3.1.3.2 Releases of the substance

Fibre production

Information on DMAC measurements in the workplace is provided in the confidential annex.

Air measurement and biological monitoring data presented by respondents to the questionnaire indicate that both exposure levels are well below the IOELV or the equivalent level of total exposure by combined routes as expressed in terms of the Biological Exposure Index.

There are also older published data that describe exposure to DMAC during fibre production. In a study of workers producing acrylic fibres, Perbellini et al (2003) reported that environmental concentrations of DMAC were consistently less than 1.5 ppm. In a study of workers employed in the production of spandex fibre and polyurethane, Tanaka et al. (2002) reported that median exposure concentrations were less than 2 ppm, but the 90^{th} percentile was about 20 ppm with a maximum measured concentration of 28 ppm. A US study of workers involved in acrylic fibre production, Spies et al (1995) reported exposure concentrations of 1.9 ppm in workers identified as having the greatest potential exposure compared with 1.3 ppm for those that were not specifically handling DMAC. Given that exposure concentrations in most industries have greatly reduced over the last 30 years (Creely et al, 2007), it is likely that current exposures are generally lower than in the early 1990s. The SIDS dossier indicates that North American workers involved in spinning acrylic fibre were exposed to concentrations of DMAC of less than 5 ppm.

The SIDS dossier contains a summary of workplace exposure data submitted by Monsanto and DuPont on approximately 135 workers. It is stated that preparation, drawing and drying of the tows take place in closed or semi-closed units fitted with air extraction equipment (see the table below). The inhalation exposures were within the IOELV but the estimates of dermal exposure are high in relation to the inhaled intake that would be associated with the IOELV.

Table 3.3 Summary of workplace exposure data submitted for the OECD SIDS by Monsanto and DuPont (OECD, 2001)

Data source	Activity	Shift mean inhalation concentration – "central tendency" mg/m^3	Shift mean inhalation concentration – "high end" mg/m^3	Dermal dose mg/day Assumes no dermal protection
Monsanto	Senior operators	7.02	35.53	650-1,960
	Spinning operators	7.02	35.53	1,300-3,900
	Utility operators	7.02	35.53	1,300-3,900
	Jet room personnel Dye room personnel	7.02	35.53	650-1,950

In conclusion it seems likely that current inhalation exposures to DMAC during fibre production are well within the IOELV and combined inhalation and dermal exposures are likely to be well below the intake associated with IOELV, provided that appropriate PPE is employed.

Textile production using fibres produced using DMAC

Fibres produced using DMAC contain small quantities of residual DMAC giving rise to the potential for exposure during textiles production. Further data are provided in the confidential annex. Air monitoring data provided by respondents to the questionnaire indicate that the levels of DMAC that were present in workplace air were well within the IOELV but they are not directly informative as to workers' personal inhalation exposure.

Biological monitoring provides a measure of combined uptake of DMAC by dermal contact and inhalation. Reported levels of the DMAC metabolite MMAc in urine are within the biological exposure limit (30 mg/g creatinine, 1 mg/L is approximately equivalent to 1 mg/g creatinine).

Some limited older exposure measurements and estimates are described in the SIDS dossier which indicated that the proportion of DMAC remaining in the raw acrylic fibres delivered to downstream users was <0.5% by weight. Measurements undertaken at textile converters indicated that inhalation exposures were within the IOELV. Exposure concentrations associated with working with a Ring Spinning or Open-End Spinning system were reported to be <0.1 ppm, and <5 ppm for tow processing at the carding machines. The inhalation exposure associated with spinning elastane containing DMAC was estimated using EASE as 1-3 ppm (3.6-10.9 mg/kg/day). Dermal exposure from hand contact with acrylic fibres containing DMAC was considered not to occur with dry skin. For sweaty skin, the maximum daily potential exposure was estimated in the SIDS dossier as approximately 0.01 mg/kg. In comparison the inhaled dose associated with 8 hours exposure to the OEL is about 250 mg or 3.4 mg/kg/shift. The estimated direct dermal uptake during manual operations with spools on which elastane is wound containing residual amounts of DMAC (0.1-3%

by weight) over a period of 8 days was 0.0015 mg on sweaty hands or 0.000025 mg/kg body weight.

In conclusion, exposures during the further processing of fibres containing small quantities of residual DMAC may be higher than during primary fibre production, but are still relatively low in comparison to the intake associated with the IOELV.

Downstream use of textile

Elastane (spandex) is used to make a range of textile products like swimsuits, underwear and socks for a very long time and also in the production of absorbent hygiene products e.g. baby diapers and incontinence products.

According to the OECD SIDS (2001) consumer exposure is negligible, which is further supported by migration tests with simulated sweating on textile articles containing residual DMAC.

Respondents to the questionnaire indicate that the quantities of residual DMAC present in fibres in these products are very small. For example, the maximum quantity present in diapers is reportedly 0.1 ppb (0.0000001%) compared with a theoretical worst case estimate of 0.005%.

The extremely low DMAC content of textiles means that combined inhalation and dermal exposure to DMAC during the downstream use of textile is anticipated to be <0.001 mg/kg/day.

3.1.4 Use #2 – Use as a solvent and intermediate in production of pharmaceuticals, agrochemicals and fine chemicals

3.1.4.1 Use as a solvent

Operational conditions of use and existing risk management measures

DMAC is used as a solvent in continuous or batch processes that may use either dedicated or multipurpose equipment that may be either technically controlled or manually operated. The uses covered in this section include use as a solvent as an aid in chemical reactions and also as a “solvent” in the applications of paints, lubricants in metal working fluids and anti-set off agents in polymer moulding/casting. There is substantial variation in the degree of process enclosure and automation. The following processes are identified in the “Information on Registered Substances” at ECHA’s website:

PROC 1: Use in closed process, no likelihood of exposure; Industrial setting.

PROC 2: Use in closed, continuous process with occasional controlled exposure (e.g. sampling); Industrial setting.

PROC 3: Use in closed batch process (synthesis or formulation); Industrial setting.

PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises.

PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated facilities; Industrial setting.

PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities; Industrial setting.

Releases of the substance

The exposure estimates provided in the CSRs are shown in the confidential annex.

One respondent to the questionnaire indicated that no DMAC was detected in 6 routine measurements made in 1997 and 1998 during the use of DMAC as a process solvent during chemicals manufacture. The processes included Includes PROC 3, 4, 8a and 8b. The limit of detection ranged from 0.07 to 0.22 mg/m^3.

In conclusion, exposure levels are likely to be widely variable depending on process design, the extent of containment and ventilation employed. Exposures are believed to be within the IOELV and are likely to be a small fraction of the IOELV where processes are contained and effective ventilation is employed.

3.1.4.2 Use as an intermediate

Operational conditions of use and existing risk management measures

DMAC is used as an intermediate in a wide range of processes undertaken on various scales that include both continuous and batch processes using either dedicated or multipurpose equipment that may be technically controlled or manually operated. There is substantial variation in the degrees of process enclosure and automation. More information regarding exposure scenarios, including RMM, is provided in the confidential annex.

Releases of the substance from use as an intermediate

Information on predicted releases from use as an intermediate is provided in the confidential annex.

3.1.4.3 Use as excipient in human and veterinary pharmaceuticals

Operational conditions of use and existing risk management measures

Exposure during formulation of these products is covered under the “formulation of mixtures” above. It is anticipated that production would involve a small scale batch process and that a relatively high level of containment would be employed in order to protect the product and also to minimise potential exposure to potent pharmaceutical actives.

Releases of the substance

Exposure during formulation of these products is covered under the “Formulation of mixtures” above. It is anticipated, however, that actual levels of exposure would be lower than the estimates provided above. Handling within a fume cupboard, for example, would reduce exposures by at least a factor of ten.

3.1.5 Use #3 – Use as a solvent in enamels and other coating

Exposure during formulation of these products is covered under the “Formulation of mixtures” in section 3.1.2.

3.1.5.1 Operational conditions of use and existing risk management measures

DMAC is used as a solvent in some coatings that may be applied in an industrial setting by spraying, roller application/brushing or dipping. Exposure may also occur during transfers of DMAC or mixtures containing DMAC to and from large containers using either dedicated or non-dedicated facilities. Processes involving DMAC would normally be contained and LEV employed where releases are possible.

One of the questionnaire respondents is involved in the formulation of enamel coatings for wire. Once the wires have been enamelled, the coating contains no residual DMAC. The coated wires are used in a variety of electrical applications including in vehicles (in alternators), electrical motors and electrical transformers. Two separate uses were identified for the purposes of exposure assessment, as shown in the table below.

Table 3.4 Function of DMAC

Use	Function of DMAC
PROC 1,3,5,8a,9	DMAC is used as one of the solvents in the production of PAI enamels
PROC 2, 3, 5, 7, 8a, 10, 13	PAI enamels are applied during enamelling with the use of enamelling ovens with VOC catalytic oxidation devices. The process evaporates and burns the solvents and no DMAC remains in the enamelled wire

LEV is reportedly used wherever releases of DMAC are possible. All operators wear solvent-resistant gloves and protective clothing. Respiratory protection is used for the filter sockets change operation.

3.1.5.2 Releases of the substance

One of the questionnaire respondents provided the results of workplace monitoring undertaken in 2009-10 which is shown in the table below. The exposure measurements are low in comparison to the IOELV with the highest exposures being associated with specific tasks that are undertaken for only short periods during the working day. Shift mean exposures for workers undertaking these tasks would be much lower (at least a factor of 10 lower) than these peak exposures.

Table 3.5 Workplace concentrations

Task	Workplace concentration mg/m^3	Comments
Sampling on blender	1.68	Average of 3 measurements for operation that takes “some minutes”
Filtration sockets change	2.6	Average of 3 measurements, 10 minute operation, operator uses RPE
Packaging - filtration	0.093	
Filtration sockets change	1.68	10 minute operation

3.1.6 Use #4 – Use as a solvent in production of films

3.1.6.1 Operational conditions of use and existing risk management measures

Imported polyimide and polysulphone films are used in a variety of applications within the EU (above), but there is no evidence that these materials are produced within the EU. None of the CSRs refer to the production of polyimide or polysulphone films, although it is possible that this use falls within the exposure scenario: “the industrial use as a solvent”.

None of the questionnaire responses concern production of these films. Given the absence of evidence for polyimide or polysulphone film production within the EU, no exposure assessment has been undertaken for film production.

The DMAC content of imported films is small (reported as being <1% or less than an unspecified detection limit) and it is not known whether any specific RMMs are applied during the industrial processing of these films.

3.1.6.2 Releases of the substance

Given that the DMAC content of imported films is very small, no substantial exposure to DMAC would be anticipated to arise during the industrial use of these films in manufacturing processes. There are no exposure data. It seems likely that inhalation and dermal exposure levels would be very low in relation to the IOELV or BEI.

3.1.7 Use #5 and #6 – Use as solvent in paint strippers and ink removers

3.1.7.1 Operational conditions of use and existing risk management measures

Exposure during formulation of these products is covered under the “Formulation of mixtures” in section 3.1.2. Exposure during use is not addressed by any of the CSRs. Paint strippers that contain DMAC are largely used in an industrial setting and can be applied by dipping or brushing. Paint strippers containing DMAC may also be applied by brushing during professional use. Paint strippers are generally used at room temperature and have a DMAC contact of up to 5%. It is uncertain what RMMs might be routinely applied during the use of DMAC for paint stripping.
DMAC is used in eraser pens designed for ink removal. This use is expected to be discontinued during 2012.

3.1.7.2 Releases of the substance

Exposure during formulation of these products is covered under the "Formulation of mixtures" in section 3.1.2. Exposures during use will depend on the circumstances of use (such as volume of mixture used, area covered, whether inside or outside and room size) and the RMMs applied.
Estimates of inhalation exposure to fumes arising from paint stripper (containing 5% DMAC) derived using ART indicate that exposure levels are likely to be low in relation to the IOELV.

Table 3.6 Estimates of inhalation exposure from paint strippers

Method of application	Assumptions	Median exposure estimate mg/m^3	Interquartile range mg/m^3
Dipping at industrial sites	No containment or LEV, Surface area of bath 1-3 m^2	0.00025	0.00012-0.005
Professional application by brush	Used in unventilated indoor space, rate of surface coverage 1-3 m^2/hour	0.025	0.012-0.051

Dermal contact with paint stripper could be extensive during use depending on the viscosity of the stripper and whether protective clothing and gloves are used. In the absence of protective clothing or gloves and assuming exposure of the hands and forearms, the EASE model indicates that the dermal exposure associated with dipping objects is likely to be of the order of 3-30 mg/kg/day. The dermal exposure associated with application by brushing is likely to be of the order of 150-430 mg/kg/day. The use of suitable protective clothing and gloves would be expected to reduce exposure levels by at least a factor of ten.

Exposure to DMAC during the use of erasing pens containing DMAC is likely to be extremely small given the small volumes used on each occasion and the low frequency of exposure.

3.1.8 Other uses

3.1.8.1 Laboratory uses

Operational conditions of use and existing risk management measures

A description of operational conditions and RMMs applied, based on information from the CSRs, is included in the confidential annex.

Releases of the substance

There are no modelled exposure data. Description of data from the CSRs is provided in the confidential annex.

The use of LEV would be anticipated to reduce inhalation exposure by at least 50% and handling within a fume cupboard would reduce exposure by at least a factor of 10. Similarly the use of appropriate gloves would be expected to significant reduce the extent of dermal exposure.

3.2 Environmental releases of DMAC

The emissions of DMAC to the environment have been estimated for each of the main use areas (including manufacture) described in the previous sections, and the results are presented in Table 3.7. The background data for the estimates are provided in the confidential annex.

The estimates are based on an analysis of the available information on releases, which includes site-specific measurements, EUSES and ERCs/SPERCs. As such there is uncertainty in the figures, but it is not possible to quantify this uncertainty with the current information. The ranges in some values relate to the uncertainty in the amounts used in these areas.

Sources of emission in the manufacturing, other chemicals manufacture, fibre production and formulation of mixtures are considered to be point sources.

The releases from the production and use of the fibres are estimated to account for more than 90% of the total quantified atmospheric emission. A major part of the DMAC used as solvent in the production of fibres is ultimately emitted to the atmosphere either from fibre manufacturing or from downstream processing. Based on the available data it is assumed that all residual DMAC in the fibres is released to the environment by the subsequent processing steps. Information from several downstream users suggests that the DMAC present as a residual content in the fibres would be released to air by the first stages of the further processing of the fibres.

Very different information has been obtained from producers as concerns the outflow from the fibre production process. Whereas one company indicates that nearly 100% of the DMAC ends up in different waste steams, another indicates that a significant amount of the DMAC is released to the atmosphere, and one company indicates that a significant part ends up in waste water, as further described in the Confidential Annex. The differences are to some extent linked to the different processes applied by those companies.

During the application of coatings, DMAC is reported to be evaporated by the heating. The evaporated DMAC is burned and transformed to CO_2, NO_2. According to a producer of enamels, no releases to atmosphere take place during this process.

The available information has not allowed for a quantification of releases from films, paint strippers and ink removers. It is assumed that the majority of residual DMAC in films (<1% of film weight) is released to the environment, but detailed data on the total residual DMAC content in films have not been identified.

For the other use areas, in particular for paint removers and laboratory use, there are likely to be professional users and the sites of use will be more diffuse. Use of ink eraser pens is likely to be by consumers.

The water emissions are assumed to be directed to a waste water treatment plant. The subsequent fate in the plant is estimated to be 32.5% to surface water, with 67.4% degraded and negligible amounts to air and sludge.

For each use, details of the relevant parts of the life-cycle stage that are assumed to contribute to releases are set out in the confidential annex.

Table 3.7 Estimated releases of DMAC to the environment

	Emissions (t/yr)	
Use	Air	Waste water
Manufacture	0.46	3.16
Chemical production	120	84
Production and use of fibres	1896	20.8
Coatings	0.075-0.2	0
Films	?	?
Paint stripper	?	?
Ink remover	?	?
Laboratory use	25-150	25-150
Total	2041-2166	133-258

3.3 Natural or unintentional formation

No information is available to suggest that DMAC is formed naturally or unintentionally

3.4 Conclusions on releases

Worker exposure to DMAC in the EU should be controlled to levels below the Indicative Occupational Exposure Limit Values (IOELVs), which are intended to protect workers from the development of respiratory irritation. Indicative Occupational Exposure Limit Values (IOELVs) of 10 ppm as an 8 hour time weighted average (TWA) and 20 ppm as a 15 minute Short Term Exposure Limit (STEL) have been established in the EU. Comparisons of available exposure data with the IOELV (used as a reference point) in the text below intend to give an indication of the magnitude of exposure associated with the different uses and do not comprise any assessment of the risk related to the toxicity for reproduction of DMAC.

Worker exposure during the manufacture of DMAC appears to be is controlled to levels associated with much lower intakes than those associated with the full shift IOELV. The process is entirely enclosed and there is no likelihood of dermal or inhalation exposure.

Worker exposure during the various uses of DMAC is highly variable reflecting a wide range in the scale of processes and degree of enclosure and other risk management measures applied. Most exposures are likely to be within the IOELV and where processes are contained and effective ventilation is employed, exposures are likely to be a small fraction of the IOELV. The highest levels of exposure are likely to occur during mixing and blending involving DMAC in batch formulation processes where workers may have multiple and/or significant contact with DMAC. The use of appropriate ventilation and personal protective equipment, however, could control exposures associated with formulation to a small fraction of the OELV.

The quantities of residual DMAC present in consumer goods are negligible and no consumer exposure to DMAC is anticipated.

The major release of DMAC to the environment is estimated to be associated with the production and use of fibres which is estimated to account for more than 90% of the total quantified releases to the environment. Residual DMAC in produced fibres (up to 3% of fibre weight) is estimated to be released to the environment. It has however, not been possible to quantify the releases from films (residual content is assumed to be released to the environment), paint strippers and ink removers

4 CURRENT KNOWLEDGE ON ALTERNATIVES

4.1 Overview

This section provides a compilation of some of the information available from the consultation undertaken on alternatives to DMAC.

DMAC is primarily used as a solvent and many of the same alternative solvents have been indicated by the manufacturers and downstream users.

Firstly, general information on classification of potential alternatives and application areas, for which the alternatives have been considered, is presented.

This is followed by information on replacement of DMAC in specific uses, including textile processing, pharmaceutical industry, coatings and paint strippers. No information was available on alternatives for other applications.

4.2 List of alternatives considered

DMAC is a dipolar, aprotic solvent with high solving power for high molecular-weight polymers. The solvent can be used for a wide range of organic and inorganic compounds and is miscible in water, ethers, esters, ketones and aromatic compounds. The polar nature of DMAC enables it to act as a combined solvent and reaction catalyst in many reactions.

Potential alternative solvents which have specifically been considered as part of the consultation or in the literature are shown in Table 4.1. The table indicates the actual classification of the substances. The extent to which alternatives provide a better environmental and health profile than DMAC is a key element in the considerations regarding substitution but is outside the scope of the current study.

Four of the alternatives are classified as toxic to reproduction or carcinogenic: **NMP**, **DMF**, **DCM**, and **DMPU**. NMP and DMF have both been mentioned as potential alternatives for a number of the application areas of DMAC. However, due to their classification, these substances are of less to industry interest as possible alternatives to DMAC.

Four of the considered alternatives are not classified: NEP, TMU, DMSO, and DMI.

France has recently submitted a proposal for classification of **NEP** as toxic to reproduction (France, 2011). According to comments from industry, quoted in the Annex XV report for NMP, several companies noted NEP as a potential alternative to NMP, but the industry highlighted concerns with this substance also potentially being classified as a reproductive toxin in the future (ECHA, 2011b).

According to comments provided by industry on the Annex XV report for NMP, Safety Data Sheets for **TMU** state that this substance is toxic for reproduction (ECHA. 2011b). As an example, the SDS from TCI Europe NV assigns the R-phrase "R63 - Possible risk of harm to the unborn child" to the substance (TCI, 2010a). The same is indicated in the SDS from the reference catalogue from the Joint Research Centre's Institute for Reference Materials and Measurements (JRC, 2004).

DMSO, like DMAC, is a polar aprotic solvent and is marketed by one supplier as “the safe and competitive alternative to other polar aprotic solvents” (Arkema, 2011). As one of the most promising alternatives, the substance is described in more detail in the next section.

Table 4.1 DMAC and potential alternative solvents and their classification

Abbr./name	Chemical name	EC No /CAS No	Classification **	Risk phrases	Application areas for which the alternative have been considered
DMAC	N,N-dimethylacetamide	204-826-4 127-19-5	Repr. Cat. 2; R61 Xn; R20/21	R61: May cause harm to the unborn child. R20/21: Harmful by inhalation and in contact with skin.	
NMP	1-methyl-2-pyrrolidone	212-828-1 872-50-4	Repr. Cat. 2; R61 Xi; R36/37/38	R61: May cause harm to the unborn child R36/37/38: Irritating to eyes, respiratory system and skin	Fibres, pharmaceuticals, polyimid films, enamels
DMF	N,N-dimethylformamide	200-679-5 68-12-2	Repr. Cat. 2; R61 Xn; R20/21 - Xi; R36	R61: May cause harm to the unborn child. R20/21: Harmful by inhalation and in contact with skin. R36: Irritating to eyes.	Fibres, pharmaceuticals, polyimid films
DMPU	tetrahydro-1,3-dimethyl-1H-pyrimidin-2-one	230-625-6 7226-23-5	Repr. Cat. 3; R62 - Xn; R22 - Xi; R41	R22: Harmful if swallowed. R41: Risk of serious damage to eyes. R62: Possible risk of impaired fertility.	Pharmaceuticals
DCM	dichloromethane	200-838-9 75-09-2	Carc. Cat. 3; R40	R40: Limited evidence of a carcinogenic effect.	Pharmaceuticals
NEP	1-ethylpyrrolidin-2-one	220-250-6 2687-91-4	Not classified *	-	Fibres
DMI	1,3-dimethylimidazolidin-2-one	201-304-8 80-73-9	Not classified	-	Fibres, pharmaceuticals
DMSO	dimethyl sulfoxide	200-664-3 67-68-5	Not classified	-	Pharmaceuticals, polyimid films
TMU	tetramethylurea	211-173-9 632-22-4	Not classified	-	Pharmaceuticals
Sulfolane	tetrahydrothiophene 1,1-dioxide	204-783-1 126-33-0	Xn; R22	R22: Harmful if swallowed.	Pharmaceuticals
Acetone	acetone	200-662-2 67-64-1	F; R11 - Xi; R36 - R66 - R67	R11: Highly flammable. R36: Irritating to eyes. R66: Repeated exposure may cause skin dryness or cracking. R67: Vapours may cause drowsiness and dizziness.	Pharmaceuticals
Acetonitrile	acetonitrile	200-835-2 75-05-8	F; R11 - Xn; R20/21/22 - Xi; R36	R11: Highly flammable. R20/21/22: Harmful by inhalation, in contact with skin and if swallowed. R36: Irritating to eyes.	Pharmaceuticals

* France has submitted a proposal for classification of NEP as toxic to reproduction, Repr. Cat. 2; R61 (France, 2011).

** Classification according to Table 3.2 of Regulation (EC) No 1272/2008.

According to comments provided by industry to the Annex XV report for NMP, no information on the reprotoxic properties of **DMI** was found at the time of the evaluation, but the industry found it reasonable to assume that DMI is also reprotoxic based on the chemical similarity with NMP and the other solvents in this group (ECHA. 2011b). DMI is a polar aprotic solvent marketed for some of the same application areas as DMAC and is described in more detail in the next section.

4.2.1 Dimethyl sulfoxide, DMSO

DMSO is a polar aprotic solvent, not classified, and marketed as alternative to DMAC, NMP and other polar aprotic solvents" (Arkema, 2011a). For this reason it is described in more detail here.

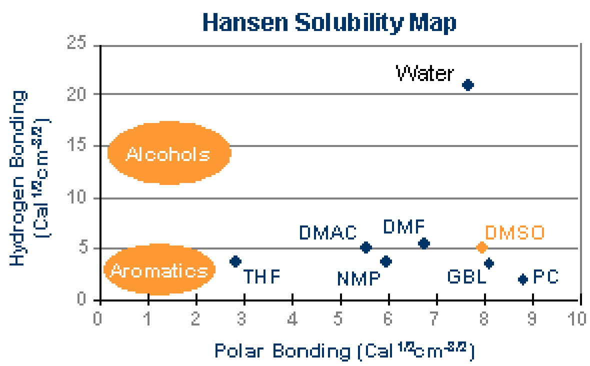
The applications of DMSO include (Arkema, 2011):

- Reaction solvent for active substances synthesis and in synthesis of agrochemicals;
- Alternative to dichloromethane and NMP in paint strippers;
- Photoresist stripping and cleaning agent in electronic industry;
- Solvent for the formulation of polymers such as polyethersulfones, polyurethanes for coatings;
- Other applications including cleaning, aromatic extraction and reagent.

DMSO is not specifically mentioned as solvent for the manufacturing of textile fibres.

DMSO is readily available and the global DMSO manufacturing capacity is estimated to be 80,000 tonnes (ECHA, 2011a).

It is a powerful organic solvent which is well established in the industry, with dissolving properties for binder polymers including PVDF, PAI, PUs, and acrylics. The polar bonding of DMSO is higher than the polar bonding of DMAC while the hydrogen bonding is the same as indicated in the solubility map below. The boiling point of DMSO (189 °C) is slightly higher than the boiling point of DMAC (166ºC).



Source: http://www.arkema.com

As mentioned in the Annex XV report for NMP, one company suggested that DMSO is of 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 (ECHA, 2011b). One manufacturer of DMSO notes on its website that DMSO is as well absorbed and excreted in the urine as NMP, however the data shows that the permeability of these two substances is higher than the permeability of DMAC. The permeability of DMSO is 176 $mg/m^2/h$, whereas it is 107 $mg/m^2/h$ for DMAC (Arkema, 2011a).

According to comments provided by the pharmaceutical industry on the Annex XV report for NMP, DMSO is a potentially reactive chemical and thermal instability can be induced by a range of chemicals / impurities. They indicate that many incidents have been reported involving this solvent and that from a safety point of view alone alternative solvents should be investigated before choosing DMSO as a reaction solvent (ECHA. 2011a).

According to information from a manufacturer of DMSO (Arkema, 2011b), for each chemical reaction involving DMSO, the thermal stability of the mixture has to be checked. In presence of some materials, self accelerating exothermic decompositions can occur at lower temperature:

- Some strong bases like sodium hydride or potassium terbutoxide should be used with great care in presence of DMSO.
- Some acids can cause a rapid decomposition of DMSO.

Whilst DMSO certainly is not a drop-in substitute for all applications, it has a broad spectrum of uses. The extent to which the thermal instability of the substance limits the use of DMSO as an alternative to DMAC has not been investigated in detail, but from the available information, DMSO seems to be a potential alternative with a better health profile than DMAC at least for some of the applications of DMAC.

4.2.2 1,3-dimethylimidazolidin-2-one, DMI

According to a manufacturer of this substance, the dissolving power of DMI for organic and inorganic compounds in addition to its accelerating effect as an aprotic polar solvent, makes it an exceptionally effective reaction solvent (Mitsui, 2011). The boiling point of 225 ºC is higher than the boiling points of NMP and DMAC.

The applications of DMI include (Mitsui, 2011):

- Reaction solvent. It is effective for various nucleophilic substitution reactions such as the synthesis of phenylether derivatives, amino compounds and fluorobenzene derivatives used as intermediates in agrochemicals, medicines, dyestuffs and monomers of high performance resins.
- Solvent for various polymers. Among various applications mentioned, it is used in the formation of polyimide and polysulfone films and in the stretching of polyetherketone film, treatment of DMI makes films more uniform.
- Detergent and surface treatment agent.
- Dyestuff, pigments, electric material and petroleum products.

DMI is not specifically mentioned as a solvent for the manufacturing of textile fibres.

DMI is not classified under Regulation (EC) No 1272/2008. As mentioned above, industry found it reasonable to assume that DMI is also reprotoxic based on the chemical similarity with NMP and the other solvents in this group (ECHA. 2011b). The toxicity data provided on the manufacturer’s website do not include data on toxicity to reproduction. The SDS from TCI Europe NV assigns the following R-phrases: R21/22 - Harmful in contact with skin and if swallowed; R36/38 - Irritating to eyes and skin (TCI, 2010b).

In an evaluation of DMI as a possible alternative to textile fibres (see next section), limited availability and higher cost have been indicated as a disadvantage of DMI.

4.3 Use #1 – Use as a solvent in man-made fibre production

4.3.1 Alternative solvents

Different alternative solvents for textile fibres have been considered by the industry.

DMF may be used for some types of fibres. According to one producer, DMF has been widely used for elastane production in China, but the Chinese government has directed the producers to eliminate the use of DMF in the manufacturing of elastane by the end of 2011. Due to its classification, DMF is not considered a viable alternative by the textile producers.

Three other solvents considered as alternatives in the production of fibres by industry (specific details are provided in the confidential annex) are listed in Table 4.2 below. For NMP and NEP the main constraints are the higher boiling point (the boiling point of DMAC is 166ºC) and the fact that the substances do likely not provide an improved hazard profile. Whereas the required polymer can be produced, the high boiling point significantly affects spinning and solvent recovery processes and will affect product properties.

DMI is not classified, but as mentioned above its hazard profile has still not been evaluated. It is used for other fibres, but according to the industry does not produce a useful polymer fibre with the polymer concerned. According to the fibres producer, DMAC has been used for 50 years for the specific fibre and no alternative has been found to be more suitable for this fibre, using criteria that include performance, manufacturability, human health and environmental impact, among others.

Several fibre producers of the three main types, acrylic, elastane, meta-aramid fibres, have indicated that alternatives to DMAC are not available. According to one producer, replacement of DMAC would require major changes in three processes that would have to readjusted or reinvented: dope preparation, extrusion/spinning process and the water/solvent separation process.

NMP and NEP are also mentioned by a producer of another type of fibre, who also mentions the high boiling point and the classification as main constraints for the use of these solvents. The producer furthermore mentions that other polar aprotic solvents potentially capable of dissolving the polymers are limited by the achievable maximum polymer solids, polymer solution viscosity stability, economic supply and recovery, and uncertainties in health and environmental effects.

No information on the possible use of DMSO in fibre production has been obtained.

Table 4.2 Alternative solvents considered as reported by one producer of fibres*

	NMP **1-methyl-2-pyrrolidone**	**NEP** **1-ethylpyrrolidin-2-one**	**DMI** **1,3-dimethylimidazolidin-2-one**
Commercially used currently	Yes, with a different spinning process	No	Not for this fibre
Technical constraints on use of the alternative	Higher boiling point than DMAC (204°C)	Higher boiling point and higher costs (298°C)	Very limited availability and higher cost
Other constraints on use of the alternative	Its classification as a category 1B reprotoxin	Likely to become classified category 1B reprotoxin	DMI is manufactured through a proprietary process and has limited availability. Moreover its hazard profile is unknown
Product redesign or process changes required to use the alternative	Current facilities are not designed for this alternative product	Current facilities are not designed for this alternative product	None possible. This product does not produce useful polymer
Additional work required if alternative is to be used	Would require the development of new process technology and build new plant and require requalification in critical to human life and safety critical products	Would require the development of new process technology and build new plant and require requalification in critical to human life and safety critical products	None possible. This product does not produce useful polymer
Time required before the alternative could replace the substance of interest (years)	Not evaluated as direct replacement is not feasible for current technology and the substance does not provide an improved hazard profile	Not evaluated as direct replacement is not feasible for current technology and the likely the substance does not provide an improved hazard profile	Not evaluated as cannot produce a useful polymer

* Fibre type indicated in Confidential Annex

4.3.2 Alternative spinning method

One producer mentions wet spinning as an alternative production technology which has been used historically in the production of elastane. The producer mentions that wet spinning still requires the use of organic solvents such as DMAC or DMF. By the wet spinning process, the majority of the solvent used is extracted into a relatively large volume of water, from which the solvents must be recovered in an energy intensive process. Little, if any, commercially available elastane is currently made via wet spinning as a result of the higher energy consumption and poorer overall product performance, while still using the same solvents as in the dry spinning process.

4.4 Use #2 – Use as a solvent and intermediate in production of pharmaceuticals, agrochemicals and fine chemicals

The following information on alternatives to DMAC in the production of pharmaceuticals is, unless otherwise indicated, based on the comments from the trade organisation EFPIA and pharmaceutical companies on the Annex XV report for NMP (ECHA, 2011a). EFPIA has confirmed that the information applies to alternatives to DMAC as well as to DMAC itself (EFPIA, 2011). The main difference between DMAC and NMP is the difference in volatility. Furthermore, information has been requested from a major producer of agrochemicals, but no data have been received within the deadline.

Due to the classification of DMAC as toxic to reproduction, its use in the pharmaceutical industry is limited by the Solvent Emissions Directive (European Community Directive 1999/13/EC). The Directive requires specific industries, including the pharmaceutical manufacturing industry, to replace as far as possible substances or mixtures which contain VOCs classified as carcinogens, mutagens, or toxic to reproduction by less harmful substances or mixtures within the shortest possible time.

In cases where it is not possible to substitute DMAC, the Solvent Emissions Directive requires an emission limit value of ≤ 2 mg/m^3 for discharges where the mass flow is more than 10 g/h.

According to industry, a key point of consideration for the pharmaceutical industry is the regulatory implications that may be associated with changing the solvent used in any stage of a commercial manufacturing process that is registered with the appropriate regulatory health authorities. Changes to such processes invariably require extensive redevelopment of processes and associated interaction/authorisation from health authorities in order to ensure product quality, efficiacy and that patient safety is not compromised. Typically, changing a commercial process would necessarily involve a long lead time, large amounts of work and significant associated costs.

There are a number of solvents that could potentially be used in place of DMAC in some manufacturing syntheses of active pharmaceutical ingredients (API). The most common ‘direct’ alternatives used within the pharmaceutical industry are NMP and DMF, but these solvents carry essentially the same health hazard as DMAC (R61: May cause harm to the unborn child.). According to the comments, the risk associated with using NMP would be lower than the risk associated with using DMF or DMAC as the latter substances have higher volatility (i.e. higher vapour pressure and lower boiling point) than NMP, meaning that the risk of worker or environmental exposure through use of these solvents is generally higher. According to EFPIA DMF is not a suitable alternative due to the lower boiling point and thermal instability of DMF (EFPIA, 2011).

According to a major user of DMAC for synthesis of agrochemicals, DMAC is used exclusively as a solvent in industrial synthesis. The whole synthesis has been optimized for this solvent, which was chosen due to its physico-chemical properties. Potential alternatives are not as suitable based on their physico-chemical properties.

Other alternative polar aprotic solvents exist, a number of which are listed and commented on below. As can be seen from the comments from EFPIA on these solvents, there are other limitations associated with these alternatives which may prevent their use in specific circumstances. Whilst a more detailed, circumstance-specific, consideration is of course required in the context of a particular chemical process, these comments serve to illustrate that finding a feasible alternative to NMP (or DMF, DMAC) may be difficult.

- DMSO: According to EFPIA, DMSO is a potentially reactive chemical and thermal instability can be induced by a range of chemicals / impurities. Many incidents have been reported involving this solvent. From a safety point of view alone they suggest that alternative solvents should be investigated before choosing DMSO as a reaction solvent. This can also be the case with other aprotic solvents such as DMF or dichloromethane (DCM). As described in the previous section, for each chemical reaction involving DMSO, they indicate that thermal stability of the mixture has to be checked. The extent to which DMSO may be used as an alternative to DMAC for certain reactions would need a more detailed evaluation.

- DCM: In addition to the potential reactive hazards noted in the previous bullet, DCM presents significant health hazards as a Category 2 carcinogen (under Regulation (EC)1272/2008).
- Sulfolane: Sufolane has a high melting point (range ~ 20-26ºC) and consequently may often prove operationally impracticable.
- Acetone and acetonitrile: Neither of these solvents possesses the high solvating power of NMP, DMF and DMAC, nor the high boiling point to facilitate higher temperature reactions. The boiling points of the two substances are 56ºC and 83ºC, respectively).
- DMPU, DMI and TMU. These solvents are relatively new and have been the subject of recent evaluation within one of EFPIA's member companies. Whilst they appear to offer some opportunity as alternatives to NMP (and possibly DMAC), their commercial availability is currently questionable, and security of supply for a manufacturing process could present a risk. DMPU is classified reprotoxic (Table 4.1) and, as discussed above, SDSs for TMU state that this substance is toxic for reproduction. No information on the reprotoxic properties of DMI was found at the time of the evaluation. As discussed in section 4.2.2, safety data sheets do not indicate that DMI is toxic to reproduction and further assessment would be needed to determine whether DMI is a suitable alternative.

In summary, alternatives to DMAC exist, but the main alternatives are themselves classified as toxic to reproduction or carcinogenic. Two polar aprotic solvents, DMSO and DMI, could potentially be used as alternatives for some applications of DMAC, but industry indicates that the technical feasibility, the supply situation and their environmental and health properties would need a further assessment.

4.5 Use #3 – Use as a solvent in enamels and other coatings

According to a producer of enamel based on polyamide imide (PAI), NMP can be used as an alternative solvent in these enamels. DMAC has a better solvent effect, which allows less solvent to be used for the same polymer content (in insulating wire coating) for the customer.

A major global producer of PAI powders indicates that these powders are soluble in dipolar aprotic solvents such as DMAC, NMP, DMSO and DMF (Solvay, 2011). Solutions of these systems can be sprayed into coatings, cast into films, spun into fibres and cast or spun into specialty membranes. High strength, high temperature capable adhesives can also reportedly be formulated from these PAI powders.

Of the solvents mentioned, DMSO is the only one which is not classified, as discussed above. No information on actual experience with DMSO as an alternative to the specific applications of DMAC has been obtained.

The requirements of the Solvent Emissions Directive mentioned above for the pharmaceutical industry also applies to winding wire coating (such as any coating activity of metallic conductors used for winding the coils in transformers and motors), and the relevant thresholds of that Directive apply accordingly.

4.6 Use #5 – Use as a solvent in production of films

No information on alternatives to the specific use of DMAC in paint strippers has been obtained from formulators of the mixtures.

In the paint strippers, DMAC is a secondary solvent, used in concentrations below 5%. The main solvent in the paint strippers is dichloromethane (CAS No 75-09-2). A large number of paint strippers based on dichloromethane without DMAC are available on the market.

In an impact assessment of potential restrictions on the marketing and use of dichloromethane in paint strippers for the European Commission reach the conclusion that a number of alternatives to dichloromethane are available for chemical paint stripping (RPA, 2007). Furthermore, the real-life example of Austria, Denmark and Sweden, where the use of dichloromethane-based paint strippers is already restricted, suggests substitution of these products is feasible.

The alternatives evaluated were:

- NMP (CAS No. 872-50-4);
- benzyl alcohol (CAS No. 100-51-6);
- dimethyl sulphoxide (CAS No. 67-68-5);
- 1,3-dioxolane (CAS No. 646-06-0);
- sodium hydroxide (CAS No. 1310-73-2); and
- dibasic esters (CAS Nos. 106-65-0, 1119-40-0, 627-93-0, and 95481-62-2).

As concerns the technical suitability of alternatives, the study concludes that technically suitable alternatives to DCM-based paint strippers are generally available on the market, but it is neither possible nor feasible to select a specific substance or technique as being the most appropriate for paint stripping. This is because each of the paint stripping formulations and techniques considered has unique advantages and disadvantages. For some applications, the introduction of an alternative substance or technique (as a result of any restrictions) may be simple and ‘seamless’, while for other applications, it may be more complicated.

According to Commission Regulation No 276/2010 of 31 March 2010, paint strippers containing dichloromethane in a concentration equal to or greater than 0.1 % by weight shall not be placed on the market for supply to the general public or to professionals after 6 December 2011 and not be used by professionals after 6 June 2012. By way of derogation from the general restriction, Member States may allow on their territories and for certain activities the use, by specifically trained professionals, of paint strippers containing dichloromethane and may allow the placing on the market of such paint strippers for supply to those professionals.

It has not been investigated whether the paint strippers with DMAC would be used for applications that would be allowed by some Member States. As DMAC is not included in the majority of paint strippers for similar applications, the substance is not considered essential in the strippers.

4.7 Other uses

An importer of ink eraser pens containing DMAC indicates that they have asked the producer of the mixture to deliver to the supplier of the eraser pen an alternative mixture which does not contain this substance. It is expected that the mixture containing DMAC will be replaced from mid 2012.

An importer of polyimide films with residual DMAC content reports that no alternatives are available for the manufacturing of polyimide films.

Specific information on alternatives has not been obtained for other uses of DMAC.

4.8 Conclusions on alternatives

Overall, no information on actual replacement of DMAC with alternative solvents has been obtained. The efforts in reducing the use of the substance have rather focused on improving the recovery rate of DMAC.

For the main uses of DMAC as a solvent in textile fibre processing and as a solvent in the pharmaceutical industry, the most immediate alternatives are themselves classified as toxic to reproduction or carcinogenic or are currently subject to proposals to assign such a classification.

Of the other potential alternatives, two polar aprotic solvents, DMSO and DMI, could potentially be used as alternatives for some applications of DMAC, such as in the production of pharmaceuticals and other chemicals. DMSO is specifically marketed as alternative to DMAC. No comparison with the environmental and health profiles of these potential alternative substances has been made in this report.

These solvents are currently not suggested as solvents for manufacturing of textile fibres of the types for which DMAC is used today. For textile processing, no alternatives with a significantly better environmental and health profile have been suggested by industry or identified in this study.

The use of DMAC as a secondary solvent to dichloromethane in paint strippers seems not to be essential, and paint strippers for similar applications without DMAC are marketed. Indeed, paint strippers based on dichloromethane are due to be phased out for consumer use.

5 REFERENCES

AFMA. 2011. Synthetic and Cellulosic Fiber Formation Technology. American Fiber Manufacturers Association / Fiber Economics Bureau. Accessed May 2011 at: http://www.fibersource.com/f-tutor/techpag.htm.

Aramid. 2011. Aramet® Paper meta-aramid paper. Aramid Ltd. Accessed August 2011 at: http://www.aramid.com/index.php?option=com_content&task=view&id=40&Itemid=105

Arkema. 2011. DMSO. Dimethyl sulphoxide. Product info. http://www.arkema.com/sites/group/en/products/detailed_sheets/thiochemicals/dmso/product_info/technical_info.page. Toxic profile accessed June 2011 at: http://www.arkema.com/pdf/EN/products/thiochemicals/dmso/dmso_tox.pdf

BGF. 2011. Aramid Fabrics. Accessed August 2011 at: http://www.bgf.com/prodAeroKevlar.asp.

CIRFS. 2011. Acrylic in Europe. European Man-Made Fibres Association, Brussels. Accessed August 2011 at: http://www.cirfs.org/KeyStatistics/AcrylicinEurope.aspx

Creely KS, Cowie H, Van Tongeren M, Kromhout H, Tickner J, Cherrie JW. 2007. Trends in inhalation exposure - a review of the data in the published scientific literature. *Ann Occup Hyg.* 51(8):665-678.

Dupont. 2010. Dimethylacetamide. http://www2.dupont.com/Products/en_RU/Dimethylacetamide_en.html

Dupont, 2011a. Kapton® polyimide film. Accessed at: http://www2.dupont.com/Kapton/en_US/

Dupont. 2011b. DuPont™ Nomex®. Accessed August 2011 at: http://www2.dupont.com/Products/en_RU/Nomex_en.html

EFPIA. 2011. Personal communication with Isabelle Clamou, European Federation of Pharmaceutical Industries and Associations (EFPIA), July 2011.

ECHA. 2011a. 1-methyl-2-pyrrolidone. Comments on an Annex XV dossier for identification of a substance as SVHC and responses to these comments. Accessed June 2011 at: http://echa.europa.eu/doc/about/organisation/msc/agreement_svhc_2011/rcom_methylpyrrolidone_20110510.rtf

ECHA. 2011b. Annex XV dossier for 1-methyl-2-pyrrolidone. February 2011.

EMC. 2011. Busilvex 6 mg/ml concentrate for solution for infusion. The electronic Medicines Compendium (eMC). Accessed June 2011 at: http://www.medicines.org.uk/emc/medicine/12967/SPC/

Environment Canada. 2009. Screening Assessment for the Challenge Acetamide, N,N-dimethyl-Chemical Abstracts Service Registry Number 127-19-5. Environment Canada, Health Canada.

France. 2011. Proposal for harmonised classification and labelling of a chemical substance. N-ethyl-2-pyrrolidone (NEP). March 2011. http://echa.europa.eu/doc/consultations/cl/CLH_AXVREP_FR_NEP.pdf

JRC. 2004. Safety Data Sheet Tetramethylurea. http://www.irmm.jrc.be/html/reference_materials_catalogue/catalogue/attachements/STA-003_msds.pdf

Honnert, B. and Grzebyk, M. 2010. Utilation den amides en France. Hygiène et sécurité du travail, 2e trimestre 2010, 219: 49-49.

Accessed June 2011 at: http://www.hst.fr/inrs-pub/inrs01.nsf/IntranetObject-accesParReference/ND%202329/$File/ND2329.pdf

Lantor. 2011. Lantor Finishmat® D7760. Accessed August 2011 at: http://www.lantor.nl/index.php/id_pagina/27736/lantor_finishmat_d7760.html

Leyco (2011). Liquid product used as a dip for the removal of paint and varnish. Leyco Chemische Leyde GmbH, Cologne. Accessed June 2011 at: http://www.zetolan.com/England/Technical%20data%20sheet/LEYCO-STRIP2%20englisch.pdf

MFC. 2011. Dimethylacetamide (DMAC) recovery plant. MFC Progretti s.r.l., Vedano al Lambro. Accessed May 2011 at: http://www.mfcprogetti.com/eng/15-technologies_plant/11-Dimethylacetamide_(DMAC)_RECOVERY_PLANT.html

Mitsui. 2011. DMI 1,3 Dimethyl-2-Imidazolidinone. Technical sheets at: http://www.mitsuichemicals.com/dmi.htm

Nita-Vertrieb.2011. ABF flüssig. Nita Vertrieb, Bergisch Gladbach. Accessed June 2011 at: http://www.nita-vertrieb.de/images/produkte/abbeizer/abv_fluessig.pdf

OECD. 2001. N,N-dimethylacetamide (DMAC) CAS N°:127-19-5. SIDS Initial Assessment Report for 13th SIAM, Bern, Switzerland, 6-9 November 2001.

RPA. 2007. Impact assessment of potential restrictions on the marketing and use of dichloromethane in paint strippers. RPA for the European Commission.

Scientific Committee on Occupational Exposure Limits. 1994. Recommendation of the Scientific Expert Group on Occupational Exposure Limits for N,N-Dimethylacetamide SEG/SUM/37 1994 Accessed August 2011 at: ec.europa.eu/social/BlobServlet?docId=3803&langId=en

Sinco. 2011. Since stripper. Singoli Chemie Schweiz AG. Accessed May 2011 at: http://www.singoli.de/downloads/sincostripper.pdf.

Taminco. 2010. Dimethylacetamide. Technical data sheet. Taminco N.V., Belgium.: Accessed May 2011 at: http://www.taminco.com/index.php?option=com_docman&task=doc_download&gid=375

TCI. 2010a. Safety Data Sheet. Tetramethylurea. Revision date: 11/26/2010. TCI Europe NV. Accessed May 2011 at: http://www.tcieurope.eu/en/catalog/T0158.html

TCI. 2010b. Safety Data Sheet. 1,3-Dimethyl-2-imidazolidinone. Accessed May 2011 at: http://www.tcieurope.eu/en/catalog/D1477.html

Solway. (2011). Torlon® PAI Powders for Coatings and Adhesives. Solvay Advanced Polymers. Accessed June 2011 at: http://www.ides.com/info/datasheet/E135275/Torlon-4000T

ANNEX 1: INFORMATION FROM MEMBER STATES

As part of the stakeholder consultation the following information on DMAC has been obtained from Member States and Norway. In addition, some Member States have indicated that no information was available.

Finland

1. No manufacture of DMAC (Year 2010).

2. Import of DMAC was between 1-10 tonnes. (Year 2010).

3. Products containing N,N-dimethylacetamide are categorized as: laboratory reagent, solvent, varnish remover or sealant.

Sweden

Swedish Chemical Register includes information on the following applications (in decreasing order): Laboratory chemical, hardener (construction industry), professional cleaning agent, paint (maybe also in paint available to consumers), solvent, putty. Import: About 0.5 tonnes in 27 mixtures 2009 (articles not included).

Lithuania

Lacquer 1823/30 MB used for production of enamel coated wire. Percentage of DMAC by mass is 2.5-10 %. Most recent information: 2008 one company in the wire industry used has registered consumption of 9.66 tonnes.

Norway

According to the information in the Norwegian Product Register the quantity imported to Norway from the EU in 2009 was about 75 tonnes.

SPIN database: According to the online database of the Nordic product registers, SPIN, in 2010 a total of 0.2 tonnes DMAC was registered in 10 mixtures in the category “adhesives, binding agents” in Finland. No quantitative data are available in SPIN for any other uses in the four Nordic countries.

ANNEX 2: CONFIDENTIAL INFORMATION ON MANUFACTURE, IMPORT AND SALES

Non-disclosure of confidential information

ANNEX 3: CONFIDENTIAL INFORMATION ON IMPURITIES

Non-disclosure of confidential information