EUROPEAN CHEMICALS AGENCY

29 November 2012

Background document for N,N-Dimethylacetamide (DMAC)

Document developed in the context of ECHA's fourth Recommendation for the inclusion of substances in Annex XIV

Information comprising confidential comments submitted during public consultation, or relating to content of Registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

1. Identity of the substance

Chemical name:	N,N-Dimethylacetamide (DMAC)
EC Number:	204-826-4
CAS Number:	127-19-5
IUPAC Name:	N,N-Dimethylacetamide

2. Background information

2.1. Intrinsic properties

N,N-Dimethylacetamide (DMAC) was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as toxic for reproduction 1B, H360D ("May damage the unborn child")[1], and was therefore included in the Candidate List for authorisation on 19 December 2011 following ECHA's decision ED/77/2011.

[1] This corresponds to a classification as toxic for reproduction category 2 (R61: May cause harm to the unborn child) 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) N° 1272/2008

2.2. Imports, exports, manufacture and uses

2.2.1. Volume(s), imports/exports

In 2010 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. 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. 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 per year** (ECHA, 2011).

2.2.2. Manufacture and uses

2.2.2.1. Manufacture and releases from manufacture

DMAC is manufactured by the reaction of dimethylamine (DMA) and acetic acid in closed systems (OECD, 2001 in ECHA, 2011). The reaction takes place at elevated temperature and pressure and the substance is purified by distillation.

According to information provided by registrants during the consultation in the context of the preparation of the A.XV Dossier, DMAC is manufactured within a high integrity contained system where little potential for exposure exists. The end product is transferred into vessels/large containers at dedicated automated facilities. Sampling is undertaken using closed loop systems. The likelihood for worker exposure is higher during maintenance and lab analysis (ECHA, 2011).

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 highest during maintenance operations, in particular in the absence of adequate PPE (ECHA, 2011).

Based on emission factors provided by some of the registrants, it is estimated that approximate 3.5 tonnes of DMAC per year 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 per year (ECHA, 2011).

2.2.2.2. Uses and releases from uses

Uses

According to information provided by the registrants (ECHA, 2011) and further data received during the public consultations (RCOM, 2011; RCOM, 2012), the use in the EU is allocated as follows:

- **Agrochemicals, pharmaceuticals and fine chemicals (65-70% of tonnage)**

  DMAC is a dipolar, aprotic solvent with high solving power for high molecular-weight polymers. The solvent is miscible with - and can be used for - a wide range of organic and inorganic compounds. The polar nature of DMAC enables it to act as a combined solvent and reaction catalyst in many reactions. Furthermore, its boiling point (166ºC) 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.

  DMAC is furthermore reported to be used to some extent as intermediate for synthesis of some substances. DMAC is also used as excipient (carrier ingredient) in human and veterinary pharmaceuticals due to its polar, aprotic characteristics.

  Applications relate to pharmaceuticals (e.g. antibiotics and novel contrast media), agrochemicals (fertilisers, pesticides etc.), and fine chemicals.

  Among the processes reported by industry to be carried out during those uses are: mixing with reactants, (trans)-pouring from containers, separation from products (by filtration or distillation), re-use (after purification by distillation), and equipment cleaning and disposal (ECHA, 2011).

- **Man-made fibres (20-25% of tonnage)**

  DMAC is used in the production of man-made fibres made of polymers such as:

  - acrylic (180kton of fibres produced / 70kton used in the EU; CIRFS – the European Man-made Fibres Association - in RCOM, 2011)
  - polyurethane-polyurea copolymer (elastane; 30kton produced / used) and
  - meta-aramid (6kton produced, <6kton used).

  It acts as the solvent in the polymerization reaction and helps transfer the polymer through the spinning process (see description below) to produce very fine fibres. To some extent, DMAC is also used in mixtures applied to add specific additives or other polymers into the fibre spinning process (RCOM, 2011).

  The main part of the fibres is used for production of clothing. For instance, elastane fibres are used in swimsuits, underwear, socks, absorbent hygiene products such as baby diapers and incontinence products, etc.

  DMAC is mainly used for the manufacturing of continuous filament fibres[2] and to a less extent for staple, discontinuous lengths of fibre[3]. The fibres are to some extent used in combination with other fibres (e.g. elastane mixed with cotton or polyester fibres; meta-aramid fibres in combination with fibre glass, for instance for protective clothing and gloves).

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[2] Continuous filament fibres are used for weaving, knitting or carpet production

[3] Non-continuous fibres can be spun into yarn or incorporated in unspun uses such as fillings or nonwovens

A part of fibres are used as technical textiles for other applications, for example:

- Fibreglass/meta-aramid nonwoven (felt) fabrics used for aerospace composites
- Surface tissue made of polyacrylonitril used in fibre reinforced plastics (FRP-applications, e.g. for truck cabins).
- 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.
- Paper made from synthetic meta-aramid polymer in two physical forms: short fibres (floc) and microscopic fibrous binder particles (fibrids). 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.

Spinning refers to the process where fluid polymer filaments emerge from the holes in a spinneret, and gradually solidify; when DMAC is used, solidification is achieved either by precipitation in a chemical bath where the spinneret is submerged – so called wet spinning - or by evaporating the solvent in a stream of air or inert gas, named dry spinning.

The solvent is recovered and recycled several times in the process. The consumption of DMAC (0.5-1% per cycle) is due to: the solvent losses caused by the acid hydrolysis during recovery, environmental releases, residuals of solvent remaining in the fibres and DMAC disposed of as waste from the process. Recovery is reported to be achieved by installations comprising a distillation unit, a squeezing column unit and a DMAC stripping unit.

The fibres are further processed (transfer and filling operations, rewinding and beaming, spinning of yearn, and knitting/weaving in order to produce the fabric, which will consequently be dyed and/or washed), with DMAC typically being present as a residue at significant concentration only in the first steps of the fibre processing (raw fibres may contain up to 3% of residual DMAC, but typical DMAC[4] content is between 0.1and 0.5%; the greige fabric,- i.e. the fabric before it's bleached / dyed- normally contains DMAC levels below 0.1%[5], which will further be reduced during dying/washing.; No detectable or very low level of residual DMAC are reported to be present in final textiles (e.g. in baby diapers, residues are reportedly at ppb levels).

- **Industrial coatings (3-5% of tonnage)**

Approximately 3-5% of the DMAC in the EU is used as solvent in coatings for industrial use. The only use which has been described in detail (during consultations with industry) is the use of the substance in the production of

4 For acrylic fibres residues are reported by CIRFS European Man-made Fibres Association to be lower than 0.3%, for elastane around 0.3% and for m-aramid residues are reported to be higher with an average of 0.6% (RCOM, 2011). In the most recent public consultation (RCOM, 2012), the average DMAC residues reported herein for raw fibres (0.1 – 0.5%) were basically confirmed. It was also confirmed that higher residue values (up to 1 - 1.2%) may occur in some cases, but it was also stated that upper reported levels of 3% are historical.

5 So-called spun dyed fibres, where the fibre is dyed during the fibre production, thereby avoiding consumption of substantial volumes of water and chemicals in comparison with the conventional dying process, may contain somewhat higher DMAC residues.

polyamide-imide (PAI) enamels (varnishes) used for electrical wire insulation (2% of the use of DMAC in EU – EUROPACABLE in RCOM, 2012), but manufacturers of DMAC have indicated that the substances is used for other coatings as well. Some coatings may be applied in industrial setting by spraying, roller application/brushing or dipping, as indicated in some registration dossier(s). DMAC in the PAI enamels (on average at a concentration of 10%) is anticipated to be decomposed at the elevated temperatures at which the application of the enamels in industrial settings takes place.

- **Films (<2% of tonnage)**

DMAC is considered a good solvent for polyimide resins used in film production. It is also reported as the "ideal" solvent for the production of dialyser membranes, based on polysulfones (Taminco, 2011 in ECHA, 2011).

DMAC is used in the EU by the medical device industry as a solvent for production of filters and membranes, which then are used in dialysis treatment (used for renal replacement therapy) and other lifesaving extracorporeal therapies (comments # 4, 17 in RCOM, 2012). The substance serves as solvent in the spinning solution consisting of polysulfone (PSU) and poly-N-vinylpyrrolidone (PVP), in a continuous wet spinning process, as it is the state of art for hollow fibre production.

Polyimide films imported in the EU are used in a range of industries including consumer electronics, solar, photovoltaic. and wind energy, aerospace, automotive and industrial applications (ECHA, 2011). 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.

Similar to the textile fibres, residual DMAC is present in the films (from below 0.1% up to 1% in polyimide films, depending on film thickness; RCOM, 2011) and membranes (below 0.01% in membranes for medical devices; comment #4 in RCOM, 2012) used by downstream users.

- **Paint strippers (<1% of tonnage)**

DMAC is used in the formulation of paint stripper products by producers of cleaning products for the industrial sector.

Paint strippers or paint removers are used (by metal industry, but also professional users) in conjunction with other solvents (mainly dichloromethane[6]) for removal of paints/varnishes. The paint strippers are applied (depending on the type) on the item by dipping or manually with a brush or bristle. The paint is afterwards removed with a scraper. (Singoli, 2011 in ECHA, 2011).

According to information from SDSs, DMAC in commercial products is in the range of 0.1-5% (i.e. appearing to rather be below the SCL of 5%).

[6] According to Commission Regulation No 276/2010, 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 the use on their territories and for certain activities, by specifically trained professionals.

According to comments received during consultation, some registrants seem to consider to advise against this use in their registration dossiers (RCOM, 2012).

- **Other applications (probably <2.5% of tonnage)**

  Those include (ECHA, 2011; AIA in RCOM, 2011; e.g. comments #4, 17 in RCOM, 2012) use of DMAC in: **petrochemical applications**, **laboratory use** (0.3-0.6%) **filling / packaging for scientific research and development, adhesives**, **plastic / anti-set off agents in polymer moulding/casting**, and potentially in **sealants**, **putty**, **paints**, **lubricants in metal working fluids**, and the **production of cellulose fibres** such as cellophane. A minor use in **ink removers,** < 0.01t in eraser pens, has been reported to be ceased from mid 2012 on.

Releases from uses

In the following paragraphs for each use a short discussion on the potential for release is included, after which reflections by industry stakeholders (some of the registrants and individual companies using the substance, as well as some associations), as submitted during consultations, on the exposure situation and RMM applied to mitigate the risks are also summarized.

- **Agrochemicals, pharmaceuticals and fine chemicals**

  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.

  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[7] (ECHA, 2011).

  Industry stakeholders stated during public consultations (RCOM, 2011; RCOM, 2012) that use of DMAC in synthesis is mostly in closed industrial installations. Automated filling and workers wearing gloves (butyl) and goggles could be regarded as common industry standard for large scale industrial installations. For maintenance operations, standard protection would according to the comments provided include gloves (butyl), face protection, chemical protection suit and respirator if there is a possibility of occupational exposure of the worker to the substance.

  According to stakeholders of the pharmaceuticals industry, the manufacture of active pharmaceutical ingredients (API) and associated intermediates is performed in enclosed reactor trains in accordance with Good Manufacturing Practice. Batch synthesis is run in multipurpose plants where workers'

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[7] The EU has derived Indicative Occupational Exposure Limit (OEL) Values (IOELVs) of 10 ppm (36 mg/m3) as an 8 hour Time Weighted Average (TWA) and 20 ppm (72 mg/m3) as a short term (15 minute) average. According to the SIDS document the IOELV for DMAC have been based on the most sensitive toxicity endpoints of respiratory tract irritation and hepatoxicity, as for inhalation exposures adverse effects on the respiratory tract and liver in mothers are manifested at dose levels much lower than the levels that would trigger developmental effects (RCOM, 2011). The IOELV 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. **Note:** Comparisons of available exposure data / estimations with the IOELV (used as a reference point) in the current background document 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.

exposure would be reduced by the presence of local exhaust ventilation (LEV). Transfer systems are designed to minimise releases, while critical processes such as loading of the solvent, maintenance and cleaning are performed by trained personnel using appropriate protective equipment. In practice virtually all DMAC used in the pharmaceuticals industry would end/be handled in the waste streams.

- **Man-made fibres**

Occupational exposure to DMAC may occur during its use as a solvent during fibre production (among critical processes for potential exposure according to the SIDS report; OECD, 2001 in ECHA, 2011) or during the further processing of fibres, both due to inhalation or dermal contact (DMAC is known to be absorbed dermally).

Published measured data and estimations relating to inhalation exposure to DMAC during fibre production indicate (median) exposures not higher than 2 ppm (Perbellini, 2003, Speis, 1995, OECD, 2001; in ECHA, 2011). 90th percentile of about 20 ppm with a maximum measured concentration of 28 ppm has been reported in a study by Tanaka (in ECHA, 2011). The SIDS dossier (OECD, 2001 in ECHA, 2011) indicates that North American workers involved in spinning acrylic fibre were exposed to concentrations of DMAC of less than 5 ppm. In the SIDS dossier it is stated that preparation, drawing and drying of the tows take place in closed or semi-closed units fitted with air extraction equipment.

The estimated intakes by dermal exposure (assuming no dermal protection) in the SID Dossier were in the range of 650 – 3,900 mg/day. One company though commented (RCOM, 2012) that this estimated dose had relied on an unlikely scenario (not reasonable to assume no dermal protection) and extremely conservative estimate (contact with saturated aqueous solution for 8 hours[8]). It is also noted that dermal absorption of DMAC via gas phase is known to contribute to the overall exposure, as DMAC can stick to the skin (especially if it is wet) and, having a high boiling point, continues being absorbed by the skin both during and after work, unless a shower and change of clothing at the end of the shift take place (e.g. see urinary analysis study for DMAC and its metabolite by Perbellini et al., 2003 – see reference in ECHA, 2011).

Similar levels of occupational exposures (inhalation, dermal) are reported for the formulation of mixtures used in fibre production (in the OECD report; OECD, 2001 in ECHA, 2011).

Industry provided information on the current exposure situation during the preparation of the A.XV Dossier and in the public consultations on the proposed SVHC identification of DMAC and the recommendation to include it in Annex XIV. During the most recent consultation (recommendation to include DMAC in Annex XIV; RCOM, 2012) information was provided by an industry association, while more site-specific descriptions were submitted individually by involved companies. It was stated that the process is well controlled, with most of the modules involved in the process being closed,

[8] Contact, as such, with DMAC solutions is a relevant scenario, in particular for the start/stop of spinning lines during fibre production. At the site studied by Perbellini et al., 2003 (in ECHA, 2011), some workers involved in such operations, which took about 30 minutes, had to immerse their hands (protected by gloves) in a water/DMAC solution (50%) at a temperature of 50°C. The equipment used at least in some of today's active sites in EU may though reduce the extent of contact required.

and others, such as spinning, practically enclosed / equipped with LEV. Only some process steps would bear risk of exposure, such as start/stop of the spinning line, maintenance operations, or cleaning. However, according to the comments provided during such steps all necessary RMM would be taken and strict protocols followed in order to minimise exposure of workers to DMAC. Workers would be 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. Further, biological monitoring programs would ensure that a worker's total exposure is controlled (RCOM, 2011; RCOM, 2012).

As regards fibre processing, inhalation exposures of equal magnitude of those relating to fibre production cannot be excluded. Industry stakeholders have commented (RCOM, 2012) that DMAC is bound to the polymer, and that extensive heat is required to release DMAC; and that after the first steps of processing the residues would be negligible.

According to CIRFS (RCOM, 2011), the DMAC used for fibre production ends as release to the air (about 650t/y), emission to water treatment (350 t/y), waste such as out-of-spec material and old filter media / waste during maintenance or cleaning (950 t/y; which is for example incinerated, land-filled, or disposed as dangerous waste), and residues in fibres (450t/y). A further part is hydrolyzed in the process (500t/y).

After it is released, DMAC is likely to be transported in water and soil. As DMAC is reported to be readily biodegradable and digestible by activated sludge[9] in biological wastewater treatment plants (RCOM, 2011), the risk for exposure of man via the environment from production and processing of man-made fibres is likely to be low.

- **Industrial coatings**

This use covers both formulation and use of industrial coatings. Exposure may occur during formulation of DMAC (in batch formulation processes workers may have multiple and/or significant contact with DMAC), transfers of DMAC or of mixtures containing DMAC to and from large containers using either dedicated or non-dedicated facilities, or application of DMAC-containing coatings by spraying, roller application/brushing or dipping.

According to comments by an industry association (EUROPACABLE) and one of the companies using DMAC in coatings, at all 4 sites involved in the formulation of enamel mixtures the process is carried out in closed systems (sealed circuits). Limited and short time exposure could occur during maintenance / filter sockets change and sampling operations; but during these operations PPEs (inhalation and skin) and adequate ventilation would be employed as standard practice. Control by local authorities would take place and typical measurements of exposure would be 10 times under the OELs (RCOM, 2012).

In the submitted comments it was explained that the enamel application for copper wires for the electronics sector is a specific process where enamels are directly applied on the running wire in the ovens, in a closed system. All

[9] The fate of DMAC in the wastewater treatment plants is estimated to be 32.5% to surface water, with 67.4% degraded and negligible amounts to air and sludge (ECHA, 2011)

(40) plants in Europe were mentioned to be fitted with recycling ovens and catalyst systems, where DMAC is evaporated and mineralised (ECHA, 2011; RCOM, 2012).

Also other coating applications were mentioned to be automated; therefore no worker exposure would be associated with the respective registered processes such as industrial spraying / roller / brushing and pouring (RCOM, 2012).

- **Films**

During the public consultations (RCOM, 2011; RCOM, 2012), a company stated that residual DMAC is removed during processing from some of the films by downstream users, which takes place at temperatures between 90 and 180°C; with the released DMAC removed from the waste stream typically by incineration. While, according to the same comment, in other films DMAC remains contained through the life cycle even if the films are processed at temperatures up to 400°C (DMAC has strong affinity to polymer, therefore even at extreme temperatures only an insignificant amount could be released); with any theoretical leaching during the waste stage claimed to be not an issue, as the waste will be handled properly, and DMAC is biodegradable and does not bioaccumulate.

The same company reported that engineering controls such as local exhaust ventilation (LEV) are widely used and that PPE are used only as a last resort by the industrial downstream users of the imported films. Direct contact of consumers with the final product is not anticipated because the films are enclosed in the end product and the residual DMAC is considered negligible (RCOM, 2011).

- **Paint strippers**

Exposure may occur during formulation (in batch formulation processes workers may have significant contact with DMAC) or use (industrial or professional) of paint stripper mixtures (those mixtures appear though to rather have DMAC levels below the SCL of 5%). Paint strippers that contain DMAC are largely used in industrial settings and can be applied by dipping or brushing. Such mixtures may however also be applied by professionals (mainly by brushing).

Estimates of inhalation exposure to fumes arising from paint strippers (containing 5% DMAC) derived using ART indicate that exposure levels are likely to be low (less than 0.05 ppm) in relation to the IOELV (10 ppm) On the other hand, dermal contact with paint stripper is likely depending on the viscosity of the stripper and on whether protective clothing and gloves are used. In the absence of protective clothing or gloves and assuming exposure to 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 (therefore exceeding the equivalent intake to the inhalation IOELV up to 6 times). The dermal exposure associated with application by brushing is likely to be even more severe, i.e. of the order of 150-430 mg/kg/day. The use of suitable protective clothing and gloves would be needed to reduce exposure levels by at least a factor of ten (ECHA, 2011).

- **Other uses**

  No substantial information is available with respect to process descriptions / operational conditions or potential for exposure for the further confirmed or potential uses of DMAC (i.e. petrochemical applications, adhesives, plastic / anti-set off agents in polymer moulding/casting, and potentially in sealants, putty, paints, lubricants in metal working fluids, and production of cellulose fibres), apart from some information on use for laboratory applications (see ECHA, 2011).

- **Summary and conclusion**

  The above described uses and processes entail as such a potential for significant exposure to the substance. The operational conditions and risk management measures referred to by stakeholders from industry in the public consultations may be applied in specific applications or at specific sites, but evidence is lacking that such operational conditions and risk management measures are consistently applied across all uses and at all sites at which DMAC is used. Therefore, no evidence is available allowing to conclude that either exposure to the substance is unlikely to occur or that exposure generally can be considered as controlled.

2.2.2.3. Geographical distribution and conclusions in terms of (organisation and communication in) supply chain

The number of sites in the EU involved in the uses listed above appear to be in the following orders of magnitude (ECHA, 2011; RCOM, 2012):

- Synthesis of other substances: *no conclusive data, only part of the suppliers provided some info; at least 10s of sites can be concluded*
- Man-made fibres: production *6*, processing (non-negligible DMAC residues in raw fibres) *100-1000*, textiles production (DMAC typically very low): *>1,000*
- PAI enamels: formulation *4*, application on electrical wire: *40*
- Films: production of polysulphone films (e.g. dialyzer membranes) *up to 10 sites*; use of imported polyimide films (non-negligible DMAC residues) *potentially 100s*
- Further formulation (including paint strippers and other, not specified mixtures): *confirmed, but unknown number of sites*
- Other coating applications: *had been indicated by manufacturers; based also on CSR information and the latest consultation they cannot be excluded*
- Further end uses, including at least in the sectors of petrochemicals, adhesives, plastics, and paint strippers (the latter appears to be below the SCL)*: unknown total number of sites*

The spatial distribution of the sites is rather even across the EU.

Based on the available information, it appears that, in particular for uses in the scope of authorisation, the supply chains contain a medium number of EU manufacturers and importers, and a high number of downstream users.

2.3. Availability of information on alternatives[10]

For some of its uses DMAC could potentially be substituted by other solvents (information from industry consultation and literature; see more details in ECHA, 2011; RCOM, 2011; and RCOM, 2012). Many of them have though similar or potentially similar inherent properties, such as:

- NMP (1-methyl-2-pyrrolidone; Repr. 1B; this substance is also in the Candidate List)
- DMF (N,N-dimethylformamide; Repr.1B)
- Formamide (Repr. 1B; this substance is be included in the Candidate List in June 2012)
- N-methylformamide (Repr. 1B)
- N-methylacetamide (Repr. 1B)
- NEP (1-ethylpyrrolidin-2-one; France submitted in 2011 a proposal for classification as Repr.)
- TMU (tetramethylurea; SDSs state that is also Repr., e.g. "R63 - Possible risk of harm to the unborn child")
- DMI (1,3-dimethylimidazolidin-2-one; industry considered it reasonable to assume that it is also reprotoxic based on the chemical similarity with NMP and the other solvents in this group; also low biodegradability)
- DCM (dichloromethane; Carc.2)
- DMPU (tetrahydro-1,3-dimethyl-1H-pyrimidin-2-one; Repr.2)

The first two (NMP, DMF) are in fact reported to have been considered as potential alternatives (though not safer ones) for several of the application areas of DMAC, i.e. fibres, pharmaceuticals, polyimide films, and, in the case of NMP, also in the areas of enamels and polysulphone films (membranes). The other substances have been considered as potential alternatives for the use of DMAC in the pharmaceuticals (e.g. TMU, DMI, DCM, DMPU, formamide, N-methylformamide, N-methylacetamide) and/or fibres (e.g. NEP, DMI) areas.

Further potential alternatives (not classified as CMR, although some of them are classified for other hazards) that have been considered include:

- DMSO (dimethyl sulfoxide; considered for the areas of pharmaceuticals, polyimide films, paint strippers, and solvent cleansers; however this solvent is reported to have higher permeability e.g. through gloves, as well as thermal instability, decomposition products with unpleasant odour, and less solvating power for polymers)
- Sulfolane (tetrahydrothiophene 1,1-dioxide; pharmaceuticals; however it has a high melting point - range ~20-26ºC - and consequently may often prove operationally impracticable)
- Acetone, acetonitrile (pharmaceuticals; less solvating power and lower boiling point, thus less potential to facilitate higher temperature reactions; also flammable)

The above solvents are currently not suggested as solvents for producing 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.

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

[10] Please note that this information was not used for prioritisation.

DMAC are marketed. In fact, paint strippers based on dichloromethane are due to be restricted from being used by consumers or professionals.

2.4. Existing specific Community legislation relevant for possible exemption

There seems to be no specific Community legislation in force that would allow consideration of an exemption(s) of (categories of) uses from the authorisation requirement on the basis of Article 58(2) of the REACH Regulation.

2.5. Any other relevant information (e.g. for priority setting)

No information available.

3. Conclusions and justification

3.1. Prioritisation

Verbal-argumentative approach

Most of the amount in the EU seems to be used in applications in the scope of authorisation, except from uses in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004 and Directives 2001/82/EC and 2001/83/EC of the European Parliament and of the Council (exempted according to Art. 2(5a) of REACH). The substance is therefore used in very high quantities within the scope of authorisation.

DMAC has widespread uses and some uses, respectively processes involved in these uses, have a high potential for releases. The potential for worker exposure (dermal and by inhalation) during the main industrial uses of DMAC is highly variable and thereby reflecting the diversity of the processes employed and the degree of enclosure and of other risk management measures applied. The highest levels of exposure are likely to occur during mixing and blending of DMAC in batch formulation processes where significant contact of workers with DMAC cannot be excluded; or during not enclosed or partially enclosed operations during uses such as fibre spinning, applying coatings by spraying / roller / brushing / pouring / dipping, or maintenance and cleaning (as well as transfer) activities associated with various uses. Industrial and in some cases professional workers might also be exposed to residual amounts of DMAC in fibres [11] or in polyimide films.

The above described uses and processes entail as such a potential for significant exposure to the substance. The operational conditions and risk management measures referred to by stakeholders from industry in the public consultations may be applied in specific applications or at specific sites, but evidence is lacking that such OCs and RMMs are consistently applied across all uses and at all sites at which DMAC is used. Therefore, no evidence is available allowing to conclude that

[11] Processing of raw fibres seems to concern many sites, and which would not necessarily be expected to implement the same level of risk management as e.g. the sites producing the fibres. The overall potential for dermal or inhalation exposure can therefore not a priori be neglected.

either exposure to the substance is unlikely to occur or that exposure generally can be considered as controlled.

On the basis of the criteria, DMAC is of high priority.

Scoring approach

Score			Total Score (= IP + V + WDU)
Inherent properties (IP)	Volume (V)	Uses - wide dispersiveness (WDU)	
Score: 0 Toxic for reproduction 1B.	Score: 9 Very high volume in the scope of authorisation.	Overall score: 9 Site-#: 3 Uses in industrial settings at a high number of sites. Release: 3 Potential for significant occupational exposure during formulation or non-enclosed / partially enclosed operations	18

Conclusion, taking regulatory effectiveness considerations into account

On the basis of the prioritisation criteria, DMAC gets high priority for inclusion in annex XIV.

Therefore, it is proposed to recommend DMAC for inclusion in Annex XIV.

4. References

ECHA (2011): Annex XV dossier for the proposal for identification of N,N-Dimethylacetamide (DMAC) as a category 1A or 1B CMR, PBT, vPvB or a substance of an equivalent level of concern. Submitted by ECHA at the request of the European Commission, August 2011.

http://echa.europa.eu/documents/10162/11fc0850-0f0a-4dbe-9caa-5f7c01dd4dfe

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