

20 June 2012

# Draft 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")<sup>1</sup>, and was therefore included in the Candidate List for authorisation on 19 December 2011 following ECHA's decision ED/77/2011.

<sup>&</sup>lt;sup>1</sup> 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 <u>manufactured</u> volume was in the range of 15,000-20,000 tonnes. The total <u>import</u> of DMAC into the EU as a substance on its own was in the range of 1,000-2,000 tonnes and the total <u>export</u> 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 <u>consumption</u> 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. Worker exposure may take place during automated filling, 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 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 (ECHA, 2011).

#### 2.2.2.2. Uses and releases from uses

#### Uses

According to information provided by the registrants, the use in the EU is allocated as follows (ECHA, 2011):

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 (166°C) 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 also reported to be used to some extent as intermediate for synthesis of some substances. Finally, DMAC is to some extent 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.

Processes reported by industry to be involved in those uses include spraying, mixing with reactants, (trans)-pouring from containers, separation from products (by filtration or distillation), re-use (after purification by distillation), and equipment clean-downs and disposal.

#### Man-made fibres (20-25%)

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 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<sup>2</sup> and to a less extent for staple, discontinuous lengths of fibre<sup>3</sup>. 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).

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).

<sup>3</sup> Non-continuous fibres can be spun into yarn or incorporated in unspun uses such as fillings or nonwovens

<sup>&</sup>lt;sup>2</sup> Continuous filament fibres are used for weaving, knitting or carpet production

- 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; solidification, in the case of use of DMAC, is achieved either by precipitation in a chemical bath where the spinneret is submerged - wet spinning - or by evaporating the solvent in a stream of air or inert gas - dry spinning).

The solvent is recovered and recycled several times in the process. The consumption of DMAC (0.5-1% per cycle) 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. 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 have up to 3%, but typically 0.1-0.5% DMAC<sup>4</sup>; 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 residues are reported to be present in final textiles, e.g. in baby diapers residues are reportedly at ppb levels).

#### • Industrial coatings (3-5%)

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 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. Some coatings may be applied in industrial setting by spraying, roller application/brushing or dipping. DMAC in the PAI enamels (on average at a concentration of 10%) is anticipated to be destroyed during the application of the enamels at elevated temperatures, in industrial settings.

#### • Films (<2%)

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

There is no concrete evidence that polyimide and polysulphone films are produced within the EU, although these materials are imported into the EU.

<sup>&</sup>lt;sup>4</sup> 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).

<sup>&</sup>lt;sup>5</sup> An exception applies for some so-called spun dyed fibres, where the fibre is dyed during the fibre production, which avoids the use of substantial volumes of water and chemicals needed during the conventional dying process, although results in somehow higher DMAC residues

Similarly with the textile fibres, residual DMAC from the production of the films is present in the films (from below 0.1% up to 1% depending on film thickness; DuPont (U.K.) in RCOM, 2011) and membranes used by downstream users.

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

#### Paint strippers (<1%)</li>

DMAC is formulated into 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<sup>6</sup>) in conjunction with other solvents (mainly dichloromethane) for dissolvation and removal of paint/varnish. The paint stripers are applied (depending on the type) either by dipping or by hand with a brush or bristle on the item (the paint is afterwards removed with a scraper) (Singoli, 2011 in ECHA, 2011).

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

#### Other applications (probably <1.5%)</li>

Those include (ECHA, 2011; AIA in RCOM, 2011) petrochemical applications, laboratory use (0.3-0.6%), sealants, putty, paints, adhesives, plastic / anti-set off agents in polymer moulding/casting, lubricants in metal working fluids, ink removers (< 0.01t in eraser pens, to be ceased by mid 2012), and potentially in the production of cellulose fibres such as cellophane.

#### **Releases from uses**

#### • 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<sup>7</sup> and are likely to be a small fraction of the IOELV where processes are contained and effective ventilation is employed (ECHA, 2011).

<sup>&</sup>lt;sup>6</sup> 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.

<sup>&</sup>lt;sup>7</sup> 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

According to the pharmaceuticals industry (RCOM, 2011), the manufacture of Active Pharmaceutical Ingredients and associated intermediates are performed in enclosed reactor trains in accordance with Good Manufacturing Practices. Transfer systems are designed to minimise environmental release, by trained personnel using appropriate protective equipment, and are thus contained within the process stream. In practice virtually all DMAC used will end/be handled in the waste streams.

#### Man-made fibres

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 to form textiles, 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.

Although the reported inhalation exposures were within the IOELV, the estimated intakes by dermal exposure (assuming no dermal protection) in the SID Dossier were 2-10 times higher (650 – 3,900 mg/day) than the intake that would be associated with the inhalation IOELV (360 mg/day). It is also noted that, even at low workplace concentrations of DMAC, dermal absorption via gas phase can be considerable, as DMAC can stick to the skin (especially if it is wet) and continuously absorbed by the skin both during and after work, unless a shower and change of clothing at the end of the shift take place (urinary analysis study for DMAC and its metabolite by Perbellini et al., 2003 – see reference in ECHA, 2011).

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

Current exposures are expected in several sites to be lower than in the early 1990s. According to the industry consulted during the preparation of the A.XV Dossier, 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

sensitive toxicity endpoints of respiratory tract irritation and hepatoxicity and, 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 (ROCM, 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 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 (ECHA, 2011). Dupont (UK) highlighted that the OELs developed by regulatory organisations include a skin notation for DMAC to indicate that skin contact should be avoided. Therefore PPEs such as gloves and coveralls are also required to limit skin contact during steps where contact with DMAC may occur, while biological monitoring programs ensure that a worker's total exposure is considered (RCOM, 2011).

As regards fibre processing, inhalation exposures of equal magnitude of those relating to fibre production cannot be excluded. 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; while the inhalation exposure associated with spinning elastane containing DMAC was estimated using EASE as 1-3 ppm (OECD, 2001 in ECHA, 2011). As concerns dermal exposure, for sweaty skin, the maximum potential dermal exposure from hand contact with acrylic fibres containing DMAC was estimated as approximately 0.7 mg/day; while 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 (OECD, 2001 in ECHA, 2011).

According to CIRFS (RCOM, 2011), the DMAC used for fibre production ends as releases to the air (about 650t/y), emissions 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), hydrolyzed in the process (500t/y), and residues in fibres (450t/y).

After such releases DMAC is likely to be transported in water and soil. As DMAC is reported to be readily biodegradable and digestible by activated sludge<sup>8</sup> in biological wastewater treatment plants (RCOM, 2011), the risk for exposure of man via the environment may 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 some respondent(s) during industry's consultation, LEV is used wherever releases of DMAC are possible. It was stated that all operators wear solvent-resistant gloves and protective clothing, while respiratory protection is used for the filter sockets change operation. During the application of coatings, DMAC was reported to evaporate by the heating; with the evaporated DMAC to be burned and transformed to CO<sub>2</sub> and NO<sub>2</sub> (ECHA, 2011).

 $<sup>^8</sup>$  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)

#### Films

Given that the DMAC content of imported films is small, the exposure to DMAC could be anticipated to be low during the industrial use of these films.

During the public consultation (RCOM, 2011), Dupont (UK) stated that for some of the films residual DMAC is removed during processing by downstream users, which occurs at temperatures between 90 and 180°C; with the released DMAC to be removed from the waste stream typically by incineration. While, according to the same comment, for other films DMAC remains contained through the waste cycle even if the films are processed at temperatures up to 400°C; 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 referred to the use of engineering controls such as local exhaust ventilation (LEV) and, only as a last resort, of PPEs, to be typically used at all industrial downstream users of the imported films. Direct contact by consumers of the final product was not anticipated because the films are enclosed in the end product and the residual DMAC is negligible (RCOM, 2011).

#### Paint strippers

Exposure may occur during formulation (in batch formulation processes workers may have multiple and/or 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 an industrial setting and can be applied by dipping or brushing. Such mixtures may also be applied by brushing during professional use.

Estimates of inhalation exposure to fumes arising from paint stripper (containing 5% DMAC) derived using ART indicate that exposure levels are likely to be very low in relation to the IOELV (less than 0.05 ppm). On the other hand, dermal contact with paint stripper could be extensive 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 (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 expected to reduce exposure levels by at least a factor of ten (ECHA, 2011).

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

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

- > Synthesis of other substances: 100-1000 (estimation)
- ➤ Fibres: production 1-10, processing 100-1000, textiles production (DMAC typically very low): >1,000
- > PAI enamels: formulation 1-10, application on electrical wire: 10-100

- Films: production *not confirmed*, use in production of electr. components: 100-1000 (estimation)
- ▶ Paint strippers: formulation 1-100, application 10-100 (industrial) plus professional users

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 very high number of downstream users.

### 2.3. Availability of information on alternatives<sup>9</sup>

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 and RCOM, 2011). 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)
- 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 area of enamels. 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; although 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)

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<sup>&</sup>lt;sup>9</sup> Please note that this information was not used for prioritisation.

- Sulfolane (tetrahydrothiophene 1,1-dioxide; pharmaceuticals; although it has a high melting point range ~20-26°C 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 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 such as intermediate in synthesis or uses in medicinal products (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 at least some uses have a high likelihood for releases and exposure. Worker exposure (dermal and by inhalation) during the main industrial 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. The highest levels of exposure are likely to occur during mixing and blending of DMAC in batch formulation processes where workers may have multiple and/or significant contact with DMAC; or during not enclosed or partially enclosed operations during uses such as fibre spinning or applying coatings by spraying / roller / brushing / pouring / dipping. Industrial and in some cases

professional workers might also be exposed to lower amounts of DMAC found as residues in fibres (up to 3%, mostly removed during further processing), or in polyimide films (<1%) or in coatings.

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

#### Scoring approach

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

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

RCOM (2011): "Responses to comments" document compiled by ECHA from the commenting period 29/08/2011 - 13/10/2011 on the identification of N,N-Dimethylacetamide (DMAC) as SVHC.

http://echa.europa.eu/documents/10162/29be1528-3e46-4550-9268-3882b0b22292