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Background document for 2,2'-dichloro-4,4'-methylenedianiline (MOCA)

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:	2,2'-dichloro-4,4'-methylenedianiline
EC Number:	202-918-9
CAS Number:	101-14-4
IUPAC Name:	4,4'-methylenebis(2-chloroaniline)

2. Background information

2.1. Intrinsic properties

2,2'-dichloro-4,4'-methylenedianiline (MOCA) was identified as a Substance of Very High Concern (SVHC) in accordance with Article 57 (a) 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 carcinogen, Carc. 1B[1] (H350: "May cause cancer"), 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 carcinogen cat. 2 (R45: "May cause cancer") 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

According to the Annex XV report (ECHA, 2011), MOCA is not manufactured in Europe. The import is between 1,000 – 10,000 t/y (aggregated registration information). Less than 100 t/y are exported (ECHA, 2011).

The main use of MOCA is as a curing agent in the manufacture of polyurethane. This use is within the scope of authorisation (ECHA, 2011). MOCA is here not used to manufacture a substance, polyurethane for instance, but to provide specific properties, such as high abrasion resistance, heat, fuel and solvent resistance, high load-bearing and good mechanical and dynamic properties to the already existing substance (ECHA, 2011). Polyurethane is manufactured from isocyanate and polyols. Polyamines, such as MOCA, are used as curing agents, cross-linker or chain extender to provide certain properties to the final articles (e.g. industrial rollers, wheels and mining equipment; see ECHA, 2011 and RCOM, 2011) containing the polymer.

Moreover, transformation of MOCA takes usually place during the so called "in mould" phase where (a part of) an article is produced (ECHA, 2011; RCOM, 2011). Such uses are defined in the Guidance on intermediates (ECHA, 2010) as end uses, as the outcome of the process is not a new substance, but (a part of) an article.

A further minor use of the substance is as a monomer in the manufacture of a pre-polymer. This might be considered as a use of MOCA as an intermediate, as the outcome are pre-polymer flakes without defined shape and further additives determine the properties of the final polymer.

Nevertheless, it can be concluded that a high volume of MOCA (1,000 – 10,000 t/y) is used in the scope of authorisation.

2.2.2. Manufacture and uses

2.2.2.1. Manufacture and releases from manufacture

MOCA is manufactured by reaction of formaldehyde and 2-chloroaniline. No manufacturing sites have been identified within the EU. No information on specific manufacturing conditions have been provided in the Annex XV report (ECHA, 2011) and the registration (ECHA, 2012).

2.2.2.2. Uses and releases from uses

The registration information (ECHA, 2012) indicates several activities and process steps, in particular in the context of uses of the substance as a curing agent in the manufacture of polyurethane, where significant exposure to the substance is likely (e.g. mixing or blending, or use in batch and other processes where opportunity of exposure arises).

The major exposure route for MOCA is the dermal route. Therefore, MOCA residues at workplace surfaces and urinary samples of workers are more adequate to indicate and assess exposure than concentrations in air only. Some

monitoring studies focussing on residues at the workplace and in worker's urine have been carried out in the polyurethane sector, in which the substance is mainly used (ECHA, 2011). Those studies have shown a potential for significant occupational exposure. Monitoring information provided during public consultation (RCOM, 2012) shows that proper handling of MOCA and effective implementation of risk management measures is essential to reduce releases and occupational exposure.

At industrial sites, usually technical means (e.g. stoichiometric relation between curing agent and monomers) are in place that ensure that content of unreacted MOCA is minimised (<< 0.1 %, ECHA, 2011; RCOM, 2011). However, where such measures are not taken, the content of unreacted MOCA increases quickly (RCOM, 2012) and free MOCA might be present in final articles above amounts of 0.1 % by weight (levels of up to 4 % reported, in general for curing agents, in literature cited in ECHA, 2011), which could lead to human exposure.

Professional uses have not been reported in the registration dossiers, however it can not be excluded that the substance is used by professionals in bi-component resins (resins + hardener) that are known to have been used earlier in construction and arts (ECHA, 2011). The Annex XV report does not provide information on releases from these applications; however potential for significant exposure to MOCA during preparation of the final component mix by professional workers cannot be excluded. Nevertheless, because of the uncertainty that this use still takes place it has not been taken into account for prioritisation of the substance.

In conclusion, significant releases of MOCA with high potential for worker exposure from a range of processes and applications cannot be excluded.

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

Based on information from industry (ECHA, 2011), the supply chain consists of importers, distributors and industrial users with a total of more than 200 use sites within the EU. Furthermore, it can not be excluded that MOCA may also be used by professional workers outside industrial settings (ECHA, 2011).

In any case, it can be concluded that MOCA is used at a high number of sites within the EU.

2.3. Availability of information on alternatives[2]

Industry acknowledges the availability of alternative curing products but also claims that the final products produced with the alternatives will not have as good properties as the MOCA based ones. This lack of performance is considered the main factor limiting the use of the alternative curing agents. However, costs may as well be a limiting factor as such alternative curing agents are more expensive than MOCA.

The Annex XV report (ECHA, 2011) lists several of these substances or substance groups, such as other aromatic amines, aliphatic amines or isobutylesters that

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

can be used as alternative curing agents although their suitability would need to be assessed for each specific application.

Two such substances, namely MDA (4,4'-Diaminodiphenylmethane, EC 202-974-4, CAS 101-77-9) and technical MDA (formaldehyde, oligomeric reaction products with aniline, EC 500-036-1, CAS 25214-70-4) are already included in Annex XIV (MDA) or placed on the Candidate List (technical MDA). It can be expected that MOCA could replace MDA or technical MDA in many of their applications, for example as curing agent. However, due to different reactivity and other properties MOCA might not be a suitable alternative in all applications of (technical) MDA (ECHA, 2011).

2.4. Existing specific Community legislation relevant for possible exemption

There seems to be no specific Community legislation in force that would allow to consider exemption 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)

Not available.

3. Conclusions and justification

3.1. Prioritisation

The substance is used in high volumes in the scope of authorisation. The use of the substance takes place at a high number of sites, with significant potential for worker exposure.

Verbal-argumentative approach

On the basis of the prioritisation criteria, 2,2'-dichloro-4,4'-methylenedianiline (MOCA) gets high priority for inclusion in Annex XIV.

Scoring approach

Score			Total Score
Inherent properties (IP)	Volume (V)	Uses - wide dispersiveness (WDU)	(= IP + V + WDU)
1 Art. 57 (a); Carc 1B	7 High volume (1,000 – 10,000 t/y) used in the scope of authorisation	Overall score: 3 * 3 = 9 Site-#: 3 Use of the substance takes place at a high number (>200) of sites Release: 3 Releases to be expected from a number of uses and processes with potential for significant exposure of workers	17

Conclusion, taking regulatory effectiveness considerations into account

On the basis of the prioritisation criteria, 2,2'-dichloro-4,4'-methylenedianiline (MOCA) gets high priority for inclusion in annex XIV.

In addition, regulatory effectiveness considerations support the recommendation of MOCA for inclusion in Annex XIV since the substance could be used as an alternative to MDA and technical MDA (and vice versa) in uses as curing agent. The substance MDA is already included in Annex XIV whereas technical MDA is on the Candidate List and, like MOCA, has been included in ECHA's fourth recommendation of substances for inclusion in Annex XIV.

Therefore, it is proposed to prioritise 2,2'-dichloro-4,4'-methylenedianiline (MOCA) for inclusion in Annex XIV.

4. References

ECHA (2010): Guidance on intermediates. Version: 2.
http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf

ECHA (2011): 2,2'-dichloro-4,4'-methylenedianiline. Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Submitted by ECHA, August 2011.
http://echa.europa.eu/documents/10162/e3f2c73b-1fcd-4106-85f0-698a6204063d

ECHA (2012): 4,4'-methylenebis[2-chloroaniline]. ECHA's dissemination website on registered substances. http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d935cd5-ed84-0f57-e044-00144f67d249/DISS-9d935cd5-ed84-0f57-e044-00144f67d249_DISS-9d935cd5-ed84-0f57-e044-00144f67d249.html

RCOM (2011): "Responses to comments" document. Document compiled by ECHA from commenting period 29/08/2011 – 13/10/2011 on the identification of 2,2'-dichloro-4,4'-methylenedianiline as Substance of Very High Concern.
http://echa.europa.eu/documents/10162/908f0f73-86f1-4412-a6c5-6797d7ab827d

RCOM (2012): Responses to comments document (RCOM) on ECHA's draft 4th for 2,2'-dichloro-4,4'-methylenedianiline (EC number: 202-918-9). Document compiled by ECHA from the commenting period 20/06/2012 – 19/09/2012.

http://echa.europa.eu/documents/10162/13640/axiv_4th_recommendation_moca_rcom_en.pdf