Substance name: 4,4'-Diaminodiphenylmethane (MDA)
EC number: 201-622-7
CAS number: 85-68-7

JUSTIFICATION FOR THE DRAFT RECOMMENDATION OF INCLUSION IN ANNEX XIV

14 January 2009

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1. Identity of the substance

Substance name:	4,4'-Diaminodiphenylmethane (**MDA**)
IUPAC name:	Bis (4-aminophenyl)methane
Chemical name:	4,4'-Diaminodiphenylmethane
EC number:	202-974-4
CAS number:	101-77-9

2. Intrinsic properties of the substance

MDA was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) as it is classified as Carcinogenic, Category 2 and it was included in the candidate list for authorisation by the ECHA's decision ED/67/2008 on 28 October 2008, after agreement of the Member State Committee.

Possible route for authorisation:
The substance meets the criteria in Article 57(a) and according to available information, it is not possible to determine a toxicological threshold in accordance with section 6.4 of Annex I. Therefore, an authorisation may only be granted in accordance with Article 60(4) ('socio-economic route').

3. Proposed transitional arrangements

Proposal:

- *Latest application date*:
  24 months after the entry into force of the Decision to include the substance in Annex XIV

- *Sunset date*:
  42 months after the entry into force of the Decision to include the substance in Annex XIV

Justification:

Complexity of the supply chain:

MDA is mainly used as an on-site intermediate, in a rather limited number of sites throughout the EU.

According to the available information, the only non-intermediate uses of MDA are as hardener in epoxy resins and adhesives. According to available information the involved supply-chains appear to be rather short. The use of MDA as a hardener in epoxy resins and adhesives may potentially involve a high number of professional and industrial actors, however, within a limited number of relatively similar industrial sectors and professional user groups.

In conclusion, based on the available information, it is anticipated that the preparation of applications for authorisation would be facilitated by the nature of actors and the number of levels in the supply chains, which justifies an early application date.

Availability of alternatives:

There appears to be information available on alternatives to MDA for its non-intermediate uses. Furthermore the available information indicates substitution of MDA is already ongoing for these non-intermediate uses, and in particular for its use as hardener in adhesives. There appears also to be information on the limitation of the applicability of the alternatives for certain uses as hardener in epoxy resins Therefore, the available information on potential alternatives facilitates preparing an analysis of alternatives for uses for which actors wish to apply for.

Consequently, the available information suggests that potential applicants would be well prepared to develop an application, in particular the analysis of alternatives.
Hence, the available information justifies an early application date.

Conclusion:

The available information on the complexity of the supply chains provides reasons to propose an early application date.

4. Proposed review periods for certain uses

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5. Proposed exempted (categories of) uses

Proposal:

To exempt from the authorisation requirement the placing on the market of MDA in preparation for the supply to general public for the use as artists' paints when these are covered by Directive 1999/45/EC.

Justification:

MDA is substance which use is restricted by Directive 76/769/EEC. This restriction can be found in entry 30 of that Directive as well as in entry of Annex XVII of the REACH Regulation. Annex I of Directive 76/769/EEC permits use of MDA under the conditions set out below.

First, pursuant to entry 30 of Annex I of Directive 76/769/EEC substances (e.g., MDA) which appear in Annex I to Directive 67/548/EEC classified as toxic to reproduction category 1 or 2, shall not be placed on the market for supply to the general public as a substance on its own or in preparations when equal to or greater than either the relevant concentration specified in Annex I to Directive 67/548/EEC, or the relevant concentration specified in Directive 1999/45/EC (i.e., is equal to or greater than 0.5%). Thus, use of MDA in concentrations lower than 0.5% is permitted.

Article 56(6)(b) of REACH provides that the authorisation requirement does not apply to the use of substances in preparations below the lowest of the concentration limits specified in Directive 1999/45/EC or in Annex I to Directive 67/548/EEC.

Accordingly, the concentration limits specified for MDA in Directive 76/769/EEC (and in Annex XVII of REACH) are in fact the same as the concentration limits referred to in Article 56(6)(b). Therefore, the use of MDA below the concentration limits set out in Directive 76/769/EEC (and Annex XVII of REACH) does not need to be subject to an exemption from authorisation.

Second, pursuant to entry 30 the concentration limits described above do not apply to medicinal or veterinary products, cosmetic products, motor fuels, mineral oil products intended for use as fuel, fuels sold in closed systems, and artists' paints.

Pursuant to Articles 2(5)(a), 56(4) (c) and (d) and 56(5)(a) the provisions on authorisation under REACH do not in any event apply to medicinal or veterinary products, cosmetic products[1], motor fuels, mineral oil products intended for use as fuel and fuels sold in closed systems. Use of MDA in these products therefore does not need to be exempted from authorisation under Article 58(2) of the REACH Regulation.

The use of MDA in artists' paints covered by Directive 1999/45/EC is not automatically exempted from authorisation under the REACH Regulation. In light of the fact that such use was already permitted under Directive 76/769/EEC which is legislation imposing minimum requirements relating to the protection of human health, the use of artists' paints can be exempted from authorisation pursuant to Article 58(2) of the REACH Regulation.

However, it should be noted that there is no available information indicating that MDA would currently (or could technically) be used in artists' paints.

[1] In the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health.