Draft background document for hexahydromethylphthalic anhydride [1], hexahydro-4-methylphthalic anhydride [2], hexahydro-1-methylphthalic anhydride [3], hexahydro-3-methylphthalic anhydride [4] [The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry] (MHHPA)

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

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during public consultation(s), 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.

The following public name is used throughout the document: **MHHPA** (deriving from the name methylhexahydrophthalic anhydride) and covering hexahydromethylphthalic anhydride [1], hexahydro-4-methylphthalic anhydride [2], hexahydro-1-methylphthalic anhydride [3], hexahydro-3-methylphthalic anhydride [4] [The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry].

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the public consultation on the inclusion of MHHPA on the authorisation list or in the registration dossiers (as of the last day of the public consultation i.e. 18 February 2016) will be taken into consideration when finalising the recommendation and will be reflected in an update of the present document.

Contents

1. Identity of the substance

Chemical name: hexahydromethylphthalic anhydride [1], hexahydro-4-methylphthalic anhydride [2], hexahydro-1-methylphthalic anhydride [3], hexahydro-3-methylphthalic anhydride [4] [The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry]

EC Number: 247-094-1
243-072-0
256-356-4
260-566-1

CAS Number: 25550-51-0
19438-60-9
48122-14-1
57110-29-9

IUPAC Name: hexahydromethylphthalic anhydride [1], hexahydro-4-methylphthalic anhydride [2], hexahydro-1-methylphthalic anhydride [3], hexahydro-3-methylphthalic anhydride [4]

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation[1]. Results of the prioritisation of all substances included in the Candidate List by June 2014 and not yet included or recommended in Annex XIV of the REACH Regulation is available at http://echa.europa.eu/documents/10162/13640/prioritisation_results_CL_substances_nov_2015_en.pdf.

2.1. Intrinsic properties

MHHPA 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 a respiratory sensitiser, (amongst other endpoints). Taking into account all available information on the intrinsic properties of MHHPA and their adverse effects, it was concluded that the substance can be regarded as substance for which in accordance with Article 57 (f) of REACH there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57. MHHPA was identified as a Substance of Very High Concern (SVHC) according to Article 57 (f) and was therefore included in the Candidate List for authorisation on 19 December 2012, following ECHA's decision ED/169/2012.

[1] Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

2.2. Volume used in the scope of authorisation

The amount of MHHPA manufactured and/or imported into the EU according to registration data is in the range of 1,000 - <10,000 t/y. Some uses appear not to be in the scope of authorisation, such as use as intermediate including use as a monomer in the manufacture of thermoplastics. However, the volume corresponding to those uses is not available from the registration dossiers.

Therefore, in conclusion, the volume in the scope of authorisation is estimated to be in the range of 1,000 - <10,000 t/y.

2.3. Wide-dispersiveness of uses

Registered uses of MHHPA in the scope of authorisation include uses at industrial sites (formulation of mixtures; hardener for epoxy resins; process regulator for polymer processes).

2.4. Further considerations for priority setting

MHHPA could be grouped with the substance HHPA[2]. HHPA is also listed on the Candidate List and the two substances are structurally very similar - differing only by a single methyl group. The registered uses of MHHPA are almost identical to HHPA (formulation of mixtures; hardener for epoxy resins; process regulator for polymer processes) therefore HHPA could potentially replace MHHPA in some of its uses.

2.5. Conclusions and justification

Verbal descriptions and Scores			Total Score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
MHHPA is a substance with an equivalent level of concern to CMRs having probable serious effects to human health (Article 57 f) Score: 1	The amount of MHHPA used in the scope of authorisation is in the range of 1,000 - <10,000 t/y Score: 12	MHHPA is used at industrial sites. Score: 5	18	Grouping with HHPA (CL)

Conclusion

On the basis of the prioritisation criteria further strengthened by the grouping considerations, MHHPA receives priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise MHHPA for inclusion in Annex XIV.

[2] Deriving from the name "hexahydrophthalic anhydride" and covering cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] [[The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry].

3. Background information for the proposed Annex XIV entry

Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[3]. The draft Annex XIV entries for substances included in this draft recommendation are available at http://echa.europa.eu/documents/10162/13640/7th_recom_draft_axiv_entries_en.pdf.

3.1. Latest application and sunset dates

ECHA proposes to recommend the following transitional arrangements:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **18 months**
Sunset date (SSD):	18 months after LAD

There is a priori no reason to deviate from the three LAD slots of 18, 21 and 24 months after inclusion in Annex XIV that are normally assigned in a recommendation. MHHPA has been considered to be placed in the same slot with HHPA in this draft recommendation. These two substances are assigned to the 1st LAD slot. The supply chain seems to be less complex compared to other substances in this recommendation round (fewer horizontal layers in the supply chain, fewer (different) types of uses) and therefore the preparation of an application for authorisation may require comparatively less time.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for MHHPA.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1. Exemption under Article 58(2)

ECHA proposes not to recommend exemptions for uses of MHHPA on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

3.3.2. Exemption of product and process oriented research and development (PPORD)

ECHA proposes not to include in Annex XIV any exemption from authorisation for the use of MHHPA for PPORD.

4. Further information on uses

Cyclic acid anhydrides are widely used in the chemical industry, especially in the manufacture of polyester and alkyd resins and plasticisers for thermoplastic polymers. The anhydrides are also used as hardeners for epoxy resins and chain cross-linkers for thermoplastic polymers (Annex XV report 2012).

[3] Document can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

Comments received during the SVHC public consultation (RCOM, 2012) indicate the specific application of MHHPA in high voltage electric machines.

The anhydride curing epoxies appear to be widely used for the manufacture of structural composite materials for aerospace, electrical and industrial applications. The material is selected due to a unique combination of processability and chemical/mechanical/thermal and electrical properties.

MHHPA and the related substance HHPA are used in the aerospace and defence industries as a hardener in some epoxy resins[4] and in a Low Density Void Filler (LDVF[5]) that has been recently qualified for use in the aerospace and defence industries (RCOM, 2012).

[4] for spare parts and repairs
[5] Low Density Void Fillers are typically based on epoxy resin technology

5. References

Annex XV report (2012): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. MHHPA. Submitted by the Netherlands, August 2012. http://www.echa.europa.eu/documents/10162/96184c0e-245a-49a2-8a69-691e156dbaf7

ECHA (2015): MHHPA - ECHA's dissemination website on registered substances (accessed 01/06/2015).

RCOM (2012):"*Responses to comments*" document. Document compiled by the Netherlands from the commenting period 03/09/2012-18/10/2012 on the proposal to identify MHHPA as a Substance of Very High Concern: http://echa.europa.eu/candidate-list-table/-/substance-rev/2360/term