10 November 2016

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 substance 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) was taken into consideration when finalising the recommendation and is reflected in the present document.

The background document also describes how ECHA has taken into account the MSC opinion.

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: Reaction mass of 5-methylhexahydro-2-benzofuran-1,3-dione and 4-methylhexahydro-2-benzofuran-1,3-dione

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*.

The prioritisation results of the substances included in the draft 7th recommendation have been updated as necessary after the public consultation. The updated results are available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft7threc_substances_feb2016_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.

More detailed information on the main uses and the relative share of the total tonnage is provided in Annex I.

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).

During the public consultation on the draft recommendation, comments on the wide dispersiveness of the uses were received. These comments confirmed the absence of consumer or professional uses for MHHPA (ComRef, 2016).

More detailed information on uses is provided in Annex I.

2.4. Further considerations for priority setting

MHHPA can 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] 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].

2.5. Conclusion

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)

MHHPA was considered for being recommended based on grouping consideration with HHPA (see Section 2.4).

The wide-dispersiveness of uses for both substances was reassessed after the public consultation resulting in a lower priority for HHPA (BD HHPA, 2016). HHPA has now a similar priority as other substances that were not considered for this recommendation. It would therefore be appropriate to assess the priority to include HHPA and MHHPA in Annex XIV together with those substances.

In its opinion[3] MSC expresses the view that the relatively small change in priority would not warrant leaving the substances out from the 7th recommendation as it could be expected that the substances will be re-prioritised in the 8th recommendation[4].

ECHA has carefully assessed the MSC opinion. However, recognising also that there is still a substantial number of substances recommended by ECHA that have not yet been included in Annex XIV by the Commission and taking account of the capacity to manage authorisation applications, ECHA considers that it is justified to recommend less substances this time. Reflecting on the overall functioning and predictability of the authorisation process, ECHA decided to postpone the recommendation of HHPA and MHHPA (grouped together). The substances will be re-considered in the next recommendation round.

Conclusion

MHHPA is not recommended for inclusion in Annex XIV in this recommendation.

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. The draft Annex XIV

[3] MSC opinion on ECHA's 7th draft recommendation

[4] Two member states (UK, IT) made a statement to the minutes of MSC-49 expressing support for ECHA for intending not to include HHPA/MHHPA in the 7th recommendation mainly based on the substances' lower priority.

entries that underwent public consultation are available at:

http://echa.europa.eu/documents/10162/13640/7th_recom_draft_axiv_entries_en.pdf.

[This section does not contain additional information as the substance is not included in the final 7th recommendation.]

4. 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

BD HHPA (2016): Background document for HHPA developed in the context of ECHA's 7th recommendation for inclusion of substances in Annex XIV (10 November 2016)

https://echa.europa.eu/documents/10162/13640/7th_recom_final_backgdoc_hhpa_en.pdf

ComRef (2016): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 18/11/2015 – 18/02/2016 on ECHA's proposal to include MHHPA in its 7th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/7th_recom_comref_mhhpa_en.rtf

ECHA (2015): MHHPA. ECHA's dissemination website on registered substances. Accessed on 18 February 2016.

https://echa.europa.eu/search-for-chemicals

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.

https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807de9d4

ANNEX I: 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).

The anhydride curing epoxies appear to be widely used in aerospace, electrical and industrial applications. The material is selected due to a unique combination of processability and chemical, mechanical, thermal and electrical properties. Specifically these uses are as hardeners in epoxy resins:

- for filament winding wire
- for the manufacture of structural composite materials
- for high voltage electric applications
- in resin systems used in Low Density Void Filler (LDVF[5]) or composite part repair (ComRef, 2016).

The Anhydrides Joint Industry Taskforce also indicated that the substance is used in the following processes (ComRef, 2016):

- Vacuum casting
- Automatic Pressure Gelation
- Vacuum Pressure Impregnation
- Atmospheric casting
- Pultrusion.

[5] Low Density Void Fillers are typically based on epoxy resin technology