1 October 2019

Background document for hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4][1]
(MHHPA)

Document developed in the context of ECHA's ninth 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, 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 covers hexahydromethylphthalic anhydride [1], hexahydro-4-methylphthalic anhydride [2], hexahydro-1-methylphthalic anhydride [3], hexahydro-3-methylphthalic anhydride [4] and all possible combinations of the isomers [1] (including their cis- and trans stereo isomeric forms).

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[2], as well as the MSC opinion[3] were taken into consideration when finalising the recommendation and are reflected in the present document.

Contents

[1] 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
[2] As of the last day of the public consultation, i.e. 5 December 2018
[3] Opinion of the Member State Committee on the draft ninth recommendation of the priority substances to be included in Annex XIV, adopted on 26 June 2019

1. Identity of the substance

Identity of the substance as provided in the Candidate List[4]:

Name:	hexahydromethylphthalic anhydride [1], hexahydro-4-methylphthalic anhydride [2], hexahydro-1-methylphthalic anhydride [3], hexahydro-3-methylphthalic anhydride [4][1]
EC Number:	247-094-1 [1], 243-072-0 [2], 256-356-4 [3], 260-566-1 [4]
CAS Number:	25550-51-0 [1], 19438-60-9 [2], 48122-14-1 [3], 57110-29-9 [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[5]. Results of the prioritisation of all substances included in the Candidate List by January 2018 and not yet included or recommended in Annex XIV of the REACH Regulation are available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_cl_substances_sept_2018_en.pdf.

The prioritisation results of the substances included in the draft 9th 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_draft9threc_substances_October2019_en.pdf.

2.1. Intrinsic properties

Hexahydromethylphthalic anhydride [1], hexahydro-4-methylphthalic anhydride [2], hexahydro-1-methylphthalic anhydride [3], hexahydro-3-methylphthalic anhydride [4], (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 respiratory sensitiser. 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.

2.2. Volume used in the scope of authorisation

The amount of MHHPA manufactured and/or imported into the EU according to registration data (ECHA, 2018) 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. Based on information from registrations, this volume corresponds to around 30 % of the total volume whereas that volume is claimed to be around 65 % according to information provided during public consultation

[4] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[5] Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

(ComRef, 2019).

In any case, the total volume of MHHPA 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 (e.g. formulation of mixtures; hardener for epoxy resins; process regulator for polymer processes; production of switchgears; production of high voltage rotating machines).

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[6]. 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. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
MHHPA is classified as respiratory sensitiser (effects to human health) meeting the criteria of 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

Conclusion

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

[6] 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[7] and as further specified in the practical implementation document[8]. The draft Annex XIV entries for all the substances that underwent public consultation are available at https://www.echa.europa.eu/documents/10162/13640/9th_recom_draft_axiv_entries_en.pdf.

The final draft Annex XIV entries that ECHA recommends are available at https://echa.europa.eu/documents/10162/13640/9th_axiv_recommendation_October2019_en.pdf.

3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements for MHHPA:

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

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV).

Allocation of (groups of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD. ECHA proposes to allocate those substances to the “later” LAD slots (21 months or more) for which the available information indicates a relatively higher complexity of supply chain. Groups of substances are considered together.

ECHA made the final LAD allocation using all available relevant information including that received in the public consultation.

A summary of the information available is provided in Annex I.

3.2. Review period for certain uses

In its draft recommendation ECHA had seen no ground to include in Annex XIV any review period for MHHPA.

During the public consultation ECHA did not receive comments requesting upfront review period for certain uses.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of MHHPA.

[7] General approach can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[8] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

In its draft recommendation ECHA had not proposed any exemptions for (categories of) uses of MHHPA on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation ECHA received requests for exemptions which were however not referring to any existing Community legislation.

In its opinion MSC expresses the view that there is currently not a sufficiently clear basis for recommending exemptions for a use or a category of uses for this substance.

ECHA has carefully assessed all the requests made (see detailed assessment in Section C of the response document (RCOM, 2019)) and concluded that there is no ground to recommend an exemption from the authorisation requirement under Article 58(2) for a use or a category of uses of MHHPA.

ECHA therefore does not 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)

In its draft recommendation ECHA had not proposed to include in Annex XIV any exemption from authorisation for the use of MHHPA for PPORD.

During the public consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substance.

No PPORD notifications had been submitted by the end of public consultation.

ECHA therefore does not recommend exempting any use of MHHPA for PPORD from authorisation.

4. References

Annex XV SVHC 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.

https://echa.europa.eu/documents/10162/96184c0e-245a-49a2-8a69-691e156dbaf7

ComRef (2016): Comments on ECHA's Draft 7th Recommendation for MHHPA (EC number: 247-094-1, 243-072-0, 256-356-4, 260-566-1) and references to responses. 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/d059be7e-8020-4c5d-8a84-32d6aadb5a1a

ComRef (2019): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 05/09/2018 – 05/12/2018 on ECHA's proposal to include MHHPA in its 9th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/9th_recom_comref_mhhpa_en.rtf

ECHA (2018): MHHPA. ECHA's dissemination website on registered substances. Accessed on 5 December 2018.

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/documents/10162/529bafce-9751-409d-84c5-607943a71bc0

RCOM (2016): "Response document". Document compiling the responses to comments from commenting period 18/11/2015 – 18/02/2016 on ECHA's proposal to include HHPA and 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/f17720a0-07a9-4300-bdff-8de4273b2fb8

RCOM (2019): "Responses to comments" document. Document compiling the responses to comments by ECHA from the commenting period 05/09/2018 – 05/12/2018 on ECHA's proposal to include cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] (HHPA) and hexahydromethylphthalic anhydride [1], hexahydro-4-methylphthalic anhydride [2], hexahydro-1-methylphthalic anhydride [3], hexahydro-3-methylphthalic anhydride [4] (MHHPA) in its 9th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/9th_recom_respdoc_hhpa_mhhpa_en.pdf

Annex I: Further information on uses

1. Main (sector of) uses and relative share of the total tonnage

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 SVHC report, 2012). During the use of the substance as hardener in epoxy resins, the substance seems to react and releases are considered unlikely (ECHA, 2018). Therefore, article service life is not considered for prioritisation.

According to registration information (ECHA, 2018), the uses taken into account for prioritisation, correspond to 70 % of the total volume, including the uses as hardener for epoxy resins, regulator for polymer processes, the production of high voltage rotating machines and the production of switch gears.

In the comments received during public consultation (ComRef, 2019) the Anhydrites Joint Industry Taskforce (AJIT) provided information on combined tonnages of the two substances HHPA and MHHPA per uses, i.e. it is not possible to conclude on tonnage per use for MHHPA only. AJIT represents the lead registrants, some members and a number of downstream users of both substances. The information provided suggests that the tonnage of uses considered for authorisation would be lower (~ 35 %). In any case, the total volume of MHHPA in the scope of authorisation would still be in the range of 1,000 - <10,000 t/y.

Epoxy resins cured with HHPA/MHHPA are materials selected due to a unique combination of processability and chemical, mechanical, thermal and electrical properties. According to ComRef (2016 and 2019) and RCOM (2012), these uses as hardeners in epoxy resins are specifically:

- for filament winding wire
- for the manufacture of structural composite materials
- for high voltage electric applications
- in semiconductors
- in insulators
- in high voltage switchgears
- in generators, motors and transformers
- in super conducting magnets
- in adhesives and coatings
- in resin systems used in Low Density Void Filler (LDVF[9]) or composite part repair
- for the production of isolation material for ignition coils in gasoline engines

Sectors of uses of epoxy resins hardened with MHHPA include Aerospace and Defence industries, automotive manufacturers, shipbuilding, electronical component and electromechanical industry, energy generation and distribution (RCOM, 2012, ComRef, 2016 and 2019).

2. Structure and complexity of supply chains

The following assumptions were made to allocate the substance to a specific LAD slot. For the purpose of LAD assignment groups of substances are considered together. The information for the group is summarised below.

HHPA/MHHPA are manufactured/imported into the EU by a limited number of registrants. No precise and up-to-date information is available on the number of industrial sites where the

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

substances is currently used.

The supply chain can be characterised[10] by the following actors: formulators and use at industrial sites, articles assemblers (multi-layer assembling chain), relevant life cycle stages: F, IS, SL (multi-layer).

HHPA/MHHPA are used in the following Polymer preparations and compounds (PC 32)

Sectors of use (SU) relying on the substances are manufacture of bulk, large scale chemicals, manufacture of fine chemicals and manufacture of plastic products (SU8, SU9, SU12)

The majority of categories mentioned are not explicitly listed as use descriptors in registrations but could be derived from use descriptions in registration dossiers and information provided in the Annex XV SVHC report (2012) and the public consultations for SVHC identification (RCOM, 2012) as well as on ECHA's 7th and 9th draft Annex XIV Recommendation (ComRef, 2016 and 2019).

[10] Categories listed here after (life cycle stage, SU, PC and AC) make reference to the use descriptor system described in ECHA's guidance on use description: https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf