

**10 November 2016**

## **Background document for 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] (HHPA)**

### **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: **HHPA** (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] and all possible combinations of the cis- and trans-isomers [1].

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the public consultation on the inclusion of HHPA 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.

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## 1. Identity of the substance

Chemical name: 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]

EC Number(s): 201-604-9  
236-086-3  
238-009-9

CAS Number(s): 85-42-7  
13149-00-3  
14166-21-3

IUPAC Names: Hexahydro-2-benzofuran-1,3-dione [1], (3aR,7aS)-Hexahydro-2-benzofuran-1,3-dione [2], (3aR\*,7aR\*)-Hexahydro-2-benzofuran-1,3-dione [3]

## 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<sup>1</sup>. 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](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 7<sup>th</sup> 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](https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft7threc_substances_feb2016_en.pdf).*

### 2.1. Intrinsic properties

HHPA 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 HHPA 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. HHPA 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.

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<sup>1</sup> Document can be accessed at [http://echa.europa.eu/documents/10162/13640/gen\\_approach\\_svhc\\_prior\\_in\\_recommendations\\_en.pdf](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 HHPA manufactured and/or imported into the EU according to registration data (ECHA, 2016) is >10,000 t/y. Some uses appear not to be in the scope of authorisation, such as use as an intermediate including use as a monomer in the manufacture of thermoplastics. Based on information on the volume corresponding to those uses from registrations (CSR), 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 HHPA in the scope of authorisation include uses at industrial sites (formulation of mixtures; hardener for epoxy resins; process regulator for polymer processes).

Information from the SVHC public consultation (RCOM, 2012), indicated that the substance was used by professional workers (use of paints) in volumes < 10t/y.

During the public consultation on the draft recommendation, comments on the wide-dispersiveness of the uses were received (ComRef, 2016). The lead registrant and consortium members indicated that they only support industrial use of the anhydrides due to the inherent properties of the substances and the related worker hygiene conditions. This was also reflected in updates of registrations.

Therefore, it is assumed that the substance is only used at industrial sites. The assessment of the wide-dispersiveness of the uses (and the respective score) was revised accordingly.

More detailed information on uses is provided in Annex I.

## 2.4. Further considerations for priority setting

HHPA can be grouped with the substance MHPA<sup>2</sup>. MHPA 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 HHPA are almost identical to MHPA (formulation of mixtures; hardener for epoxy resins; process regulator for polymer processes), therefore MHPA could potentially replace HHPA in some of its uses.

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<sup>2</sup> 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].

## 2.5. Conclusion

Verbal descriptions and Scores			Total Score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
HHPA 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 HHPA used in the scope of authorisation is in the range of 1,000 - <10,000 t/y  Score: 12	HHPA is used at industrial sites.  Score: 5	18	Grouping with MHHPA (CL)

After re-assessment of the wide-dispersiveness of uses, HHPA has a similar priority to other substances that were not considered for this recommendation. It would therefore be appropriate to assess the priority to include HHPA in Annex XIV together with those substances. 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 leave out HHPA and MHHPA (grouped together) from this recommendation.

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

ECHA has carefully assessed the MSC opinion. However, considering the lower priority together with ECHA's wish to shorten the recommendation for the reasons stated above, leaving out these two substances from this recommendation is justified. They will be considered in future recommendation rounds.

### Conclusion

**HHPA is not recommended for inclusion in Annex XIV in this recommendation.**

<sup>3</sup> MSC opinion on ECHA's 7<sup>th</sup> draft recommendation

<sup>4</sup> 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 7<sup>th</sup> recommendation mainly based on the substances' lower priority.

### 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<sup>5</sup>. The draft Annex XIV entries that underwent public consultation are available at:*

*[http://echa.europa.eu/documents/10162/13640/7th\\_recom\\_draft\\_axiv\\_entries\\_en.pdf](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 7<sup>th</sup> recommendation.]*

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<sup>5</sup> Document can be accessed at

[http://echa.europa.eu/documents/10162/13640/recom\\_general\\_approach\\_draft\\_axiv\\_entries.pdf](http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf)

## 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. HHPA. Submitted by the Netherlands, August 2012.

<http://www.echa.europa.eu/documents/10162/6a9bf645-3e36-4540-b9b8-48da3afb8245>

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 HHPA 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\\_hhpa\\_en.rtf](https://echa.europa.eu/documents/10162/13640/7th_recom_comref_hhpa_en.rtf)

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

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

Keskinen, H. (2004): The Nordic Expert Group for Criteria Documentation of Health Risk from Chemicals and the Dutch Expert Committee on Occupational Standards. 136. Cyclic acid anhydrides, *Arbete och Hälsa*. 15: 1-74.

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 HHPA as a Substance of Very High Concern.

<https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dcd60>

## 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).

For HHPA specifically, the following uses are identified in the literature: manufacture of alkyd resins, plasticisers, insect repellents, rust inhibitors and as hardener in epoxy resins (Keskinen, 2004).

The following uses are identified in the registration dossiers: industrial use as hardener for epoxy resins (23% of total production), industrial use as intermediate in chemical synthesis (3-8% of total production) and industrial use as monomer in the manufacture of resins (74% of total production).

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<sup>6</sup>) 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.

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<sup>6</sup> Low Density Void Fillers are typically based on epoxy resin technology