5 September 2018

Draft background document for cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3][1] (HHPA)

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: **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. 5 December 2018) will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Contents

[1] The individual cis-HHPA [2] and trans-HHPA [3] isomer substances and all possible combinations of the cis- and trans-isomers of HHPA [1] are covered by this entry

1. Identity of the substance

Identity of the substance as provided in the Candidate List[2]:

Name:	cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3]
EC Number:	201-604-9 [1], 236-086-3 [2], 238-009-9 [3]
CAS Number:	85-42-7 [1], 13149-00-3 [2], 14166-21-3 [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[3]. 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 is available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_cl_substances_sept_2018_en.pdf.

2.1. Intrinsic properties

Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] (**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 respiratory sensitiser. 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.

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, 2018) 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 (ECHA, 2018) and from public consultation (ComRef, 2016), 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] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[3] Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

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).

More detailed information on uses is provided in Annex I.

2.4. Further considerations for priority setting

HHPA can be grouped with the substance MHHPA[4]. MHHPA 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 MHHPA (formulation of mixtures; hardener for epoxy resins; process regulator for polymer processes), therefore MHHPA could potentially replace HHPA 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)		
HHPA is classified as respiratory sensitiser (effects to human health) meeting the criteria of 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

Conclusion

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

[4] 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].

3. Background information for the proposed Annex XIV entry

3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **18, 21 or 24 months**
Sunset date:	18 months after LAD

ECHA will make the final LAD allocation only when finalising the recommendation and will use all available relevant information including that received in the public consultation. ECHA will apply the Annex XIV entries approach[5] and the criteria described in the implementation document[6]. According to these documents, substances for which the available information indicates a relatively high number of uses and/or complex supply chain(s) are allocated to the "later" LAD slots.

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

Time needed to prepare an authorisation application of sufficient quality has been estimated to require 18 months in standard cases. When setting the LADs ECHA has also to take into account the anticipated workload of ECHA's Committees and Secretariat to process authorisation applications. This is done by allocating the substances proposed to be included in the final recommendation in slots, normally 3, and setting the application dates with 3 months intervals in between these slots (standard LAD slots: 18, 21 and 24 months).

For substances to be included in the 9th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

ECHA will allocate to the same slot substances considered as a group (see Section 2.4), i.e. HHPA will be allocated to the same slot as MHHPA.

3.2. Review period for certain uses

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

In general, ECHA does not propose any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. Setting review periods in Annex XIV for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. Such information is generally not available to ECHA at the recommendation step. It is to be stressed that, in the next step of the authorisation process, i.e. during the decision on whether authorisation is granted based on specific applications by manufacturers, importers or downstream users of the substance, all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation.

[5] General approach can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[6] Practical implementation document can be accessed at https://www.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)

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

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'.

ECHA considers the following elements in deciding whether to recommend an exemption of a use of a substance:

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted;

- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;

- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

Where interested parties are considering making a request for exemption from authorisation under Art. 58(2) for a particular use, it is strongly recommended that they take into account ECHA's previous responses to Art. 58(2) exemption requests[7]. It is noted that any Art. 58(2) request is assessed case-by-case.

Furthermore, it should be noted that if a use falls under the generic exemptions from authorisation[8], there is no need to propose an additional specific exemption.

[7] See analysis of most relevant pieces of legislation e.g. in sections C.2.8 – C.2.12 in https://echa.europa.eu/documents/10162/b80fccc0-c055-7cd7-4743-8d3c26956b15, or in section C.2 in https://echa.europa.eu/documents/10162/b1820209-b7f4-4f87-998a-a996729c7375

[8] Generic exemptions from the authorisation requirement: https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc

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

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

So far, ECHA has not considered it appropriate to recommend specific exemptions for PPORD for any substance. ECHA notes that an operator may use a substance included in Annex XIV for a PPORD activity if that operator has obtained authorisation for that use of the substance in accordance with Articles 60 to 64 of the REACH Regulation.

No PPORD notifications have been submitted for HHPA[9].

[9] As of 1 February 2018.

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. HHPA. Submitted by the Netherlands, August 2012.

https://echa.europa.eu/documents/10162/6a9bf645-3e36-4540-b9b8-48da3afb8245

ComRef (2016): Comments on ECHA's Draft 7th Recommendation for HHPA (EC number: 201-604-9, 236-086-3, 238-009-9) 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 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/10162/2f9aea0f-b3bf-4c7a-beff-680ba2d13b90

ECHA (2018): HHPA. ECHA's dissemination website on registered substances. Accessed on 1 February 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 HHPA as a Substance of Very High Concern.

https://echa.europa.eu/documents/10162/e1af509e-7b16-43bd-b0f3-d066120d55ad

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

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 reacts completely and subsequent service life is not relevant (ECHA, 2018). Therefore, article service life is not considered.

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 (Annex XV SVHC report, 2012).

In the RCOM (2012), the dossier submitter provides a breakdown of the registered uses: 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). From these registered uses, only the use as hardener for epoxy resins is considered to be in the scope of authorisation and will be further described below.

The anhydride curing epoxy resins are materials selected due to a unique combination of processability and chemical, mechanical, thermal and electrical properties. According to ComRef (2016) 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 adhesives
- in resin systems used in Low Density Void Filler (LDVF[10]) or composite part repair
- for the production of isolation material for ignition coils in gasoline engines
- for encapsulations in lighting technology (LEDs) and IT equipment (fibre optics)
- for explosion protection
- for photovoltaic cells

Sectors of uses of epoxy resins hardened with HHPA include Aerospace and Defence industries, automotive manufacturers, shipbuilding, electronical component and electromechanical industry, energy generation and distribution, including solar energy, as well as mining industry (ComRef, 2016 and RCOM, 2012).

2. Structure and complexity of supply chains

The following assumptions are made based on currently available information and will be used, together with any relevant information from public consultation, to allocate HHPA and MHHPA to a specific LAD slot in the final recommendation:

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

The substance is 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 substances is currently used.

The supply chain can be characterised[11] by the following actors: formulators and use at industrial sites (relevant life cycle stages: F, IS).

MHHPA is used in the following product categories (PC):

- Polymer preparations and compounds (PC 32)
- Adhesives, sealants (PC 1)
- Coatings and paints (PC 9a)
- Semiconductors (PC 33)

Sectors of use (SU) relying on the substance are:

- Manufacture of bulk, large scale chemicals (SU 8)
- Mining (SU 2a)
- Manufacture of plastic products (SU 12),
- Manufacture of computer, electronic and optical products, electrical equipment (SU 16),
- General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment (SU 17),
- Electricity, steam, gas, water supply and sewage treatment (SU 23)

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 draft Annex XIV Recommendation (ComRef, 2016).

[11] 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