5 March 2020

Draft background document for benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA)

Document developed in the context of ECHA's tenth 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 the 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.

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the consultation on the inclusion of benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA) on the Authorisation List or in the registration dossiers (as of the last day of the consultation, i.e. 5 June 2020) will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Contents

1. Identity of the substance

Identity of the substance as provided in the Candidate List[1]:

Name: Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA)
EC Number: 209-008-0
CAS Number: 552-30-7

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[2]. Results of the prioritisation of all substances included in the Candidate List by July 2019 and not yet recommended or included in Annex XIV of the REACH Regulation are available at https://echa.europa.eu/documents/10162/13640/prior_results_cl_subst_march_2020_en.pdf.

2.1. Intrinsic properties

Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA) 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, category 1, H334 ("May cause allergy or asthma symptoms or breathing difficulties if inhaled"). Taking into account all available information on the intrinsic properties of TMA 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. TMA was identified as a Substance of Very High Concern (SVHC) according to Article 57 (f)[3] and was therefore included in the Candidate List for authorisation on 27 June 2018, following ECHA's decision ED/61/2018.

2.2. Volume used in the scope of authorisation

The amount of TMA manufactured and/or imported into the EU is according to registration data (ECHA, 2019a) in the range of 10,000 - 100,000 t/y.

Based on registration information it appears that the substance is only used for uses falling outside the scope of authorisation (i.e. use as intermediate in manufacture of esters, use as monomer in manufacture of polymers and, to the extent the conditions for the generic exemption for the use in Scientific Research and Development are met, laboratory use).

Therefore, in conclusion, it is estimated that there is no volume in the scope of authorisation.

[1] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[2] Document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf
[3] Commission Implementing Decision (EU) 2018/594 at https://www.echa.europa.eu/documents/10162/a6547852-e697-84ec-512c-5ba264ecf09e

2.3. Wide-dispersiveness of uses

There appears to be no registered uses of TMA falling in the scope of authorisation.

2.4. Further considerations for priority setting

Based on structural similarities benzene-1,2,4-tricarboxylic acid 1,2-anhydride (TMA) might be used as a substitute for the substances cyclohexane-1,2-dicarboxylic anhydride (HHPA)[4] and hexahydromethylphthalic anhydride (MHHPA)[5], which were already recommended for inclusion in Annex XIV. There are indications on the potential for using the substances in the same type of application (hardener for epoxy resins).

More information on the grouping consideration can be found in Annex I.

2.5. Conclusion

Verbal descriptions and scores			Total score	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)	
TMA is classified as respiratory sensitiser (effects to human health) meeting the criteria of Article 57 (f) Score: 1	There is no volume of TMA used in the scope of authorisation. Score: 0	There is no use of TMA in the scope of authorisation. Score: 0	1	Grouping with HHPA and MHHPA already recommended for inclusion in Annex XIV

Conclusion

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

[4] The group entry in the Candidate List covers cyclohexane-1,2-dicarboxylic anhydride, cis-cyclohexane-1,2-dicarboxylic anhydride and trans-cyclohexane-1,2-dicarboxylic anhydride (EC numbers: 201-604-9, 236-086-3 and 238-009-9) and all possible combinations of the cis- and trans-isomers.

[5] The group entry in the Candidate List covers hexahydromethylphthalic anhydride, hexahydro-4-methylphthalic anhydride, hexahydro-1-methylphthalic anhydride and hexahydro-3-methylphthalic anhydride (EC numbers: 247-094-1, 243-072-0, 256-356-4 and 260-566-1), including cis- and trans-stereo isomeric forms and all possible combinations of the isomers.

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 when finalising the recommendation and will use all available relevant information including that received in the consultation. ECHA will apply the Annex XIV entries approach[6] and the criteria described in the implementation document[7]. 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.

The 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 10th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

3.2. Review period for certain uses

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

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.

[6] General approach can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_2020_en.pdf
[7] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_impl_doc_2020_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 TMA 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[8]. 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[9], there is no need to propose an additional specific exemption.

[8] See analysis of most relevant pieces of legislation e.g. in sections C.2.8 – C.2.12 in https://echa.europa.eu/documents/10162/13640/8th_recom_respdoc_methylpyrrolidone_en.pdf, or in section C.2 in https://echa.europa.eu/documents/10162/13640/9th_recom_respdoc_lead_stabilisers_en.pdf including references given therein

[9] Generic exemptions from the authorisation requirement: https://echa.europa.eu/documents/10162/13640/generic_exempt_auth_2020_en.pdf

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 TMA 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 TMA[10].

[10] As of 15 September 2019

4. References

Annex XV SVHC report (2016): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Benzene-1,2,4-tricarboxylic acid 1,2-anhydride. Submitted by the Netherlands, August 2016.

https://echa.europa.eu/documents/10162/9f421f05-f50b-0065-49c5-de373a098770

ECHA (2019a): Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA). ECHA's dissemination website on registered substances. Accessed on 15 September 2019.

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

ECHA (2019b): Background document for cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] (HHPA), October 2019

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

ECHA (2019c): Background for hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] (MHHPA), October 2019

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

OECD (2002): SIDS Initial Assessment Report, trimellitic anhydride and trimellitic acid

https://hpvchemicals.oecd.org/UI/handler.axd?id=be6d8c15-085e-4a6b-8ba0-46585019401d

RCOM (2016): "*Responses to comments*" document. Document compiled by The Netherlands from the commenting period 06/09/2016 – 21/10/2016 on the proposal to identify Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA) as a Substance of Very High Concern.

https://echa.europa.eu/documents/10162/5c4e4ad6-9e8e-cb29-ea46-874e0396145c

Annex I: Further information on uses

1. Basis for grouping considerations

According to the prioritisation approach[2] and the related practical implementation examples[11] substances can be grouped with other substances already recommended for or included in Annex XIV to avoid regrettable substitution. This grouping in the context of the prioritisation is based on structural similarity and the potential interchangeability of substances in some of their uses.

TMA is a cyclic anhydride and structurally similar to HHPA and MHHPA (see Section 2.4), which were recommended for inclusion in Annex XIV as part of ECHA's 9th recommendation. According to registration information as described in the related background documentation (ECHA, 2019 b, c) both substances can be used as hardener for epoxy resins. For TMA the use as epoxy curing agent is reported in literature (OECD, 2002). Furthermore, a comment from an US company submitted in the consultation on SVHC identification refers to the use of TMA as an epoxy potting compound for reinforcing honeycomb structures (RCOM, 2016). This indicates the potential interchangeability of TMA, HHPA and MHHPA in the use as epoxy resin hardener. There is no information available showing that substitution is technically not possible in this use.

2. Structure and complexity of supply chains

According to the general approach for the preparation of draft Annex XIV entries[6] and the related practical implementation document[7] the complexity of supply chain is used as an indicator for the time needed to prepare applications for authorisation.

TMA has no uses in the scope of authorisation. ECHA will do the final LAD assignment considering all substances in the current recommendation and all information received during the consultation.

[11] See https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_impl_examples_2020_en.pdf