14 April 2021

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) in the Authorisation List or in the registration dossiers[1] as well as the MSC opinion[2] were taken into consideration when finalising the recommendation and are reflected in the present document.

Contents

[1] As of the last day of the consultation, i.e. 5 June 2020

[2] Opinion of the Member State Committee on the draft tenth recommendation of the priority substances to be included in Annex XIV, adopted on 10 February 2021

1. Identity of the substance

Identity of the substance as provided in the Candidate List[3]:

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[4]. 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.

The prioritisation results of the substances included in the draft 10th recommendation have been updated as necessary after the consultation. The updated results are available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft10threc_substances_april2021_en.pdf.

As stated above, registration information as available on the last day of consultation (5 June 2020) was considered. Therefore, the impact of the UK withdrawal from the EU (for which the transition period ended 31 December 2020) was not taken into account.

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)[5] 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, 2020) in the range of 10,000 - 100,000 t/y.

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

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.

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)[6] and hexahydromethylphthalic anhydride (MHHPA)[7], which were already recommended for inclusion in Annex XIV. According to registration information, HHPA and MHHPA can be used as hardeners for epoxy resins. Information from literature and a comment from the consultation on the SVHC identification of TMA indicate that the substance can be used in the same type of application.

Comments received during the consultation challenged the grouping of TMA with HHPA and MHHPA used as epoxy resin hardeners arguing that TMA is not a viable alternative for the two substances and that it cannot fully replace them. Another comment supported the grouping (ComRef, 2021).

However, the information provided in the comments does not allow to conclude that it is technically not feasible to use TMA as substitute for HHPA and MHHPA as epoxy resin hardener for some applications (RCOM, 2021). Furthermore, MSC in its opinion expressed the view that the grouping approach is justified.

Therefore, ECHA sees no reason to change the grouping considerations for this substance.

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

[6] 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.
[7] 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.

2.5. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (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 grouping considerations, TMA receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, **TMA is recommended for inclusion in Annex XIV**.

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[8] and as further specified in the practical implementation document[9]. The draft Annex XIV entries for all the substances that underwent consultation are available at https://echa.europa.eu/documents/10162/13640/10th_recom_draft_axiv_entries_en.pdf.

The final draft Annex XIV entries that ECHA recommends are available at https://echa.europa.eu/documents/10162/13640/10th_axiv_recommendation_april2021_en.pdf.

3.1. Latest application and sunset dates

ECHA recommends the following transitional arrangements for TMA:

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

[8] General approach can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_2020_en.pdf
[9] 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

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 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 TMA.

During the consultation ECHA did not receive comments requesting upfront review periods for specific uses.

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

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 uses of TMA on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the consultation ECHA did not receive any requests for exemptions for the substance.

ECHA therefore **does not recommend exemptions** for uses of TMA 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 TMA for PPORD.

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

No PPORD notifications have been submitted by the end of the consultation.

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

4. References

Annex XV SVHC report (2016): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. 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

ComRef (2021): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 05/03/2020 – 05/06/2020 on ECHA's proposal to include benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA) in its 10th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/10th_recom_comref_tma_en.rtf

ECHA (2019a): 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 (2019b): 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

ECHA (2020): Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA). ECHA's dissemination website on registered substances. Accessed on 5 June 2020.

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

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

RCOM (2021): "Responses to comments" document. Document compiling the responses to comments from commenting period 05/03/2020 – 05/06/2020 on ECHA's proposal to include benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride; TMA) in its10th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/10th_recom_respdoc_tma_en.pdf

Annex I: Further information on uses

1. Basis for grouping considerations

According to the prioritisation approach[4] and the related practical implementation examples[10] 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 a, b) 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 of TMA, refers to the use of the substance as an epoxy potting compound for reinforcing honeycomb structures (RCOM, 2016). Similarly, also comments received during the consultation on the draft recommendation confirmed that TMA can be used as epoxy resin hardener (ComRef, 2021). 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[8] and the related practical implementation document[9] 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 did the final LAD assignment considering all substances in the current recommendation and all information received during the consultation.

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