

1 October 2019

Background document for trilead bis(carbonate) dihydroxide [basic lead carbonate]

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.

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the public consultation on the inclusion of trilead bis(carbonate) dihydroxide on the Authorisation List or in the registration dossiers¹ as well as the MSC opinion² were taken into consideration when finalising the recommendation and are reflected in the present document.

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¹ As of the last day of the public consultation, i.e. 5 December 2018

² 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 List³:

Name: Trilead bis(carbonate) dihydroxide
EC Number: 215-290-6
CAS Number: 1319-46-6

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 authorisation⁴. 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

Trilead bis(carbonate) dihydroxide was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) as it 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 Toxic for Reproduction, Category 1A, H360D ("May damage the unborn child")⁵, 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 trilead bis(carbonate) dihydroxide manufactured and/or imported into the EU is, according to registration data (ECHA, 2018a), in the range of 10-100 t/y. All tonnage registered is used in the preparation of PTC (positive temperature coefficient) ceramic materials. This use appears to be an intermediate use and therefore not to be in the scope of authorisation. However, information from other sources indicate that there may be some minor uses in the scope of authorisation.

Therefore, in conclusion, the volume in the scope of authorisation is estimated to be <10 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 http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

⁵ The full hazard statement of the Annex VI (CLP) entry for lead compounds with the exception of those specified elsewhere in this Annex (index number 082-001-00-6) is H360Df ("May damage the unborn child. Suspected of damaging fertility.").

2.3. Wide-dispersiveness of uses

There is no registered use of trilead bis(carbonate)dihydroxide appearing to be in the scope of authorisation.

However, information arising from the SVHC public consultation (RCOM, 2012) indicates that the substance may be used as lead stabiliser in PVC and in the manufacture of primary explosives. In addition, further information provided by industry indicates that this substance was used in artists' paints. This use is derogated from the generic restriction on CMR substances used as substances or in mixtures sold to the general public. However, there is a specific entry on lead carbonates where intended for use as paint (entry no. 16 of REACH Annex XVII). Member States may permit on their territory the use of this substance in paints (for use in restoration and maintenance of works of art and historic buildings and their interiors) but given the nature of the restriction it is likely that this would be for professional use only.

ECHA at the request of the Commission submitted a restriction dossier on lead compounds used as stabilisers in PVC in December 2016. RAC adopted its opinion in December 2017 and SEAC adopted its final opinion in March 2018. ECHA sent the combined opinion and supporting documentation to the Commission in April 2018 (ECHA, 2018b).

2.4. Further considerations for priority setting

Lead substances that can be used as stabilisers for PVC are considered as a group. Therefore trilead bis(carbonate) dihydroxide is grouped with dioxobis(stearato)trilead; fatty acids, C16-18, lead salts; trilead dioxide phosphonate; [phthalato(2-)]dioxotrilead; sulfurous acid, lead salt, dibasic and lead oxide sulfate.

Even though the use as stabiliser is not reported in registrations, comments received in the public consultation on SVHC identification acknowledged this use (RCOM, 2012), thereby indicating that trilead bis(carbonate)dihydroxide could potentially replace other lead stabilisers in some of their uses. The substance is also included in the restriction proposal on lead compounds used as stabilisers in PVC that ECHA sent to the Commission in April 2018 (ECHA, 2018b).

2.5. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
<p>Trilead bis(carbonate) dihydroxide is classified as toxic for reproduction 1A meeting the criteria of Article 57(c)</p> <p>Score: 1</p>	<p>The amount of trilead bis(carbonate) dihydroxide used in the scope of authorisation is <10 t/y</p> <p>Score: 3</p>	<p>No use of trilead bis(carbonate)dihydroxide reported in registrations appears to be in the scope of authorisation.</p> <p>Initial score: 0</p> <p>Furthermore, the substance is used by professional workers in volumes <10 t/y in uses that may be in the scope of authorisation.</p> <p>Refined score: 5</p>	9	Grouping with other lead substances used as stabilisers in PVC

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, trilead bis(carbonate) dihydroxide receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, **trilead bis(carbonate) dihydroxide 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 XIV⁶ and as further specified in the practical implementation document⁷. 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.

⁶ General approach can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

⁷ Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf

3.1. Latest application and sunset dates

ECHA recommends the following transitional arrangements for trilead bis(carbonate) dihydroxide:

Latest application date (LAD): Date of inclusion in Annex XIV plus **24 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, i.e. trilead bis(carbonate) dihydroxide is allocated to the same slot as the other lead substances (see Section 2.4).

During the public consultation, comments were received arguing for longer timeframes due to the size and number of recycling companies (more than 100) potentially involved. Other comments supported in general the LAD slots of 18, 21 or 24 months or were favouring the shortest slot (ComRef, 2019 and ComRef documents for other substances in the group).

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

A summary of the information currently 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 trilead bis(carbonate) dihydroxide.

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

ECHA therefore **does not recommend to include in Annex XIV any review periods** for uses of trilead bis(carbonate) dihydroxide.

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 trilead bis(carbonate) dihydroxide 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 for the group of lead stabilisers (see Section 2.4) for the use in the recycling of PVC containing lead and for uses restricted to industrial processing (such as 'formulation for export') (ComRef, 2019 and ComRef documents for other substances in the group). The requests were referring to existing Community legislation but also to the upcoming restriction on lead compounds in PVC articles.

In its opinion MSC concluded that there is currently not a sufficiently clear basis for recommending exemptions for a use or a category of uses for the lead substances, based on existing Community legislation.

ECHA similarly concludes that it is not clear if there is sufficient basis to propose Art. 58(2) exemptions for any uses of the lead compounds and therefore **does not recommend exemptions** for uses of trilead bis(carbonate) dihydroxide on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

However, ECHA considered for its assessment in addition to existing Community legislation also the proposal for restriction on lead compounds in PVC articles (ECHA, 2018b). ECHA concludes that if the Commission were to consider Art. 58(2) exemptions possible, uses of lead compounds in recycling of PVC (which will still be possible after the restriction is in force under the foreseen derogations), may have a stronger case for an Art. 58(2) exemption than other uses, provided that the proposed restriction would be implemented.

ECHA's detailed assessment is provided in the section C.2 of the lead stabilisers response document (RCOM, 2019).

MSC expressed the view that the upcoming restriction for lead stabilisers in PVC, as it is not yet adopted, cannot be taken into account at this stage.

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

In its draft recommendation ECHA had not proposed include in Annex XIV any exemption from authorisation for the use of trilead bis(carbonate) dihydroxide 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 have been submitted for trilead bis(carbonate) dihydroxide by the end of public consultation.

ECHA therefore **does not recommend exempting any use of trilead bis(carbonate) dihydroxide for PPORD** from authorisation.

4. References

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 trilead bis(carbonate) dihydroxide 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_trilead_biscarbonate_dihydroxide_en.rtf

ECHA (2018a): Trilead bis(carbonate) dihydroxide. ECHA's dissemination website on registered substances. Accessed on 5 December 2018.

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

ECHA (2018b): Background document by RAC and SEAC to the opinion on the Annex XV dossier proposing restrictions on lead compounds-PVC⁸. 15 March 2018.

<https://www.echa.europa.eu/documents/10162/79751532-2a8b-aefd-e634-6cc4b4bb21d8>

RCOM (2012): "*Responses to comments*" document. Document compiled by ECHA from the commenting period 03/09/2012- 18/10/2012 on the proposal to identify trilead bis(carbonate) dihydroxide as a Substance of Very High Concern.

<https://www.echa.europa.eu/documents/10162/37a723d0-dd88-40de-9bb5-6e5b0fbd0537>

RCOM (2019): "*Responses to comments*" document. Document compiling the responses to comments from commenting period 05/09/2018 – 05/12/2018 on ECHA's proposal to include lead stabilisers 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_lead_stabilisers_en.pdf

⁸ The background document is based on the restriction report submitted by ECHA (2016) but updated with relevant information received during the opinion forming process.

Annex I: Further information on uses

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 lead stabiliser group is summarised below.

Lead substances that can be used as stabilisers in PVC are manufactured and/or imported by a limited number of registrants. The Lead REACH Consortium commenting during the SVHC public consultation (RCOM, 2012) indicated that in the EU there are less than 10 sites manufacturing lead stabilisers. Up to 20,000 plastic converters are processing PVC (but only a fraction of them may use lead stabilisers). It is assumed that lead stabilisers are used at more than a hundred sites.

The supply chain can be characterised⁹ by the following actors: formulators, producers of articles, professional workers and article assemblers (multi-layer assembling chain) (relevant life cycle stages: F, IS, PW, SL (multi-layer)).

The substances are used in products categorised as polymer preparations and compounds, coatings and paints, thinners, paint removers as well as adhesives and sealants (relevant product categories: PC1, PC9a, PC32).

A number of sectors seem to rely on the substances including manufacturers of plastic products (including compounders and converters), rubber products, machinery, equipment, vehicles, other transport equipment and of bulk, large scale chemicals (including petroleum products), the building and construction as well as the electricity, steam, gas, water supply and sewage treatment sector (relevant sector of use categories: SU8, SU11, SU12, SU17, SU19 and SU23).

The substances end up in a number of article types such as plastic articles, rubber articles, stone, plaster, cement, glass and ceramic articles, metal articles and machinery, mechanical appliances, electrical/electronic articles, electrical batteries and accumulators, paintings and vehicles (relevant article categories: AC1, AC2, AC3, AC4, AC7, AC10, AC13 and AC0: paintings).

Some categories mentioned are not explicitly listed as use descriptors in registrations but could be derived from the information on uses available in the registration dossiers.

⁹ 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