1 October 2019

Background document for trilead dioxide phosphonate

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 dioxide phosphonate on 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 is reflected in the present document.

Contents

[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 List[3]:

Chemical name: trilead dioxide phosphonate
EC Number: 235-252-2
CAS Number: 12141-20-7

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 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.

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 dioxide phosphonate 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 19/12/2012, following ECHA's decision ED/169/2012.

2.2. Volume used in the scope of authorisation

The amount of trilead dioxide phophonate manufactured and/or imported into the EU is according to registration data in the range of 1,000 - 10,000 t/y. Part of the tonnage manufactured is directly exported outside EU. The volume for use in the EU is estimated to be in the range 1,000 - 10,000 t/y.

The total tonnage of trilead dioxide phosphonate manufactured and/or imported appears to have significantly decreased over the last years. However, recent registration updates (from 2018) confirm manufacture/import over 1,000 t/y.

Based on registration information, it cannot be excluded that part of the tonnage reported relates

[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.").

to the use as stabiliser in PVC that will be covered by the upcoming restriction[6]. However, this use is still reported, also in recently updated dossiers, and despite the assumed phase-out by industry[6]. ECHA cannot exclude that the tonnage reported relates to the uses that are not covered by the voluntary commitment and/or the upcoming restriction (i.e formulation of lead stabilisers for export; use in rubber; use in mirror coating). These uses fall under the scope of authorisation. It is noted that no information has been provided in registrations on the tonnage for the different uses.

Therefore, in conclusion the tonnage for uses in the scope of authorisation is estimated to be in the range of 1,000- 10,000 t/y.

Further information on uses is provided in Annex I.

2.3. Wide-dispersiveness of uses

Registered uses of trilead dioxide phosponate in the scope of authorisation include uses at industrial sites (formulation, use in rubber production, use in the production of coatings and application of coatings for mirror backing) (ECHA, 2018). In addition, comments received during the SVHC and the Annex XIV public consultations (RCOM, 2012; ComRef, 2019) indicate a use in greases (anti-friction coating), assumed to be limited to industrial use.

Furthermore, based on registration data, the substance appears to be used in articles (e.g. rubber articles, coatings).

Further registered uses of trilead dioxide phosphonate include industrial use of stabilisers; PVC processing; uses of lead-stabilised plastic articles. These uses are not considered for priority setting as they should not happen anymore when the foreseen restriction[6] will apply. This approach deviates from the opinion expressed by the MSC that the impact of the proposed restriction should not be taken into account at this stage, considering that the restriction process is not yet finalised.

However, ECHA considers that the restriction process is sufficiently advanced and clear in scope to allow to take into account the impact it will have on uses taking place within the EU. Therefore, registered uses that will fall under the upcoming restriction were not considered for the priority assessment. Consequently, no articles service life score was assigned on the basis of the use in lead stabilised articles. The service life score assigned was triggered by the uses in rubber articles and coatings.

The difference in priority score triggered by considering or not the uses covered by the upcoming restriction does not impact the overall priority of the lead stabiliser group. Notwithstanding its opinion, MSC notes that fact.

More detailed information on uses is provided in Annex I.

[6] See section 2.4 for further information on the upcoming restriction and on the voluntary phase-out by industry.

2.4. Further considerations for priority setting

Grouping

Lead substances on the Candidate List that can be used as stabilisers in PVCs are considered as a group for the purpose of their inclusion in Annex XIV. Trilead dioxide phosphonate is grouped with dioxobis(stearato)trilead; fatty acids, C16-18, lead salts; lead oxide sulfate; [phthalato(2-)]dioxotrilead; sulfurous acid, lead salt, dibasic and trilead bis(carbonate) dihydroxide.

Other further consideration

The stabiliser sector had a voluntary commitment to replace lead-based stabilisers in all their formulations sold in the EU market by the end of 2015. According to Vinylplus progress reports 2016 and 2017, ESPA members (European Stabilisers Producers Association representing most of the registrants of lead compounds used as stabilisers) completed the replacement. The use as stabiliser is however still reported in (recently updated) registration dossiers.

Furthermore ECHA at the request of the Commission submitted a restriction dossier on lead compounds used as stabilisers in PVC in December 2016[7]. The restriction proposal was presented for first discussion at REACH Committee in February 2019 and is expected to be adopted in the course of 2019. The scope of the restriction is specific in that it will cover the use of lead compounds for the production of PVC articles and the placing on the market of PVC articles stabilised with lead compounds.

The uses in the scope of the restriction are not considered for priority assessment as they should not happen anymore when the restriction will come into force.

The restriction and the voluntary commitment do however not cover the formulation of lead stabilisers for export. This use was therefore considered for priority assessment.

2.5. Conclusion

Verbal descriptions and scores			Total score	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)	
Trilead dioxide phosphonate is classified as toxic for reproduction Category 1A meeting the criteria of Article 57(c) Score: 1	The amount of trilead dioxide phosphonate used in the scope of authorisation is estimated to be in the range of 1,000-10,000 t/y Score: 12	Trilead dioxide phosphonate is used at industrial sites Initial score: 5 Furthermore, the substance is used in articles in volumes >10 t/y Refined score: 7	20	Grouping with other lead substances used as stabilisers in PVC

Conclusion

[7] See https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions/-/dislist/details/0b0236e180a40af7

On the basis of the prioritisation criteria further strengthened by grouping considerations, trilead dioxide phosphonate receives priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, trilead dioxide phosphonate 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 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 .

3.1. Latest application and sunset dates

ECHA recommends the following transitional arrangements for trilead dioxide phosphonate:

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 dioxide phosphonate is allocated to the same slot as the other lead substances that can be used as stabilisers in PVC (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.

Based on the available information ECHA had seen no reason to deviate from the three standard LAD slots mentioned above (RCOM, 2019).

[8] General approach can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[9] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf

A summary of the information available on the structure and complexity of the supply chain 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 dioxide phosphonate.

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 dioxide phosphonate.

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 dioxide phosphonate 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 dioxide phosphonate 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[Error! Bookmark not defined.] . 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 to include in Annex XIV any exemption from authorisation for the use of trilead dioxide phosphonate for PPORD.

No PPORD notifications have been submitted for trilead dioxide phosphonate by the end of the public consultation[10].

ECHA therefore does not recommend exempting any use of trilead dioxide phosphonate for PPORD from authorisation.

[10] As of 5 December 2018

4. References

ComRef (2019): “Comments and references to responses” document. Document compiling comments and references to respective answers from commenting period 05/09/2019 – 05/12/2019 on ECHA’s proposal to include Trilead dioxide phosphonate 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_dioxide_phosphonate_en.rtf

ECHA (2018): Trilead dioxide phosphonate. ECHA’s dissemination website on registered substances. Accessed on 5 December 2018.

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

RCOM (2012): “*Responses to comments*” document. Document compiled by ECHA from the commenting period 3/09/2012 – 18/10/2012 on the proposal to identify Trilead dioxide phosphonate as a Substance of Very High Concern.

https://echa.europa.eu/documents/10162/551628e8-85c8-4637-bfd0-b59e03511a93

Vinylplus (2016): Vinylplus Progress report 2016 (Reporting on 2015 activities)

https://vinylplus.eu/uploads/160826_VINYPLUS_2016_WEB_PS_Singlepage_version.pdf

Vinylplus (2017): Vinylplus Progress report 2017 (Reporting on 2016 activities)

https://vinylplus.eu/uploads/downloads/VinylPlus_Progress_Report_2017.pdf

RCOM (2019): “*Responses to comments*” document. Document compiling the responses to comments from commenting period 05/09/2019 – 05/12/2019 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

Annex I: Further information on uses

1. Further details on main (sector of) uses, market trend per use and type of applications

Based on registrations (ECHA, 2018), it seems that the substance is used in 3 main types of applications:

- use as stabiliser in PVC (pure PVC and recycled PVC),
- use in rubber production,
- use in the manufacture of coatings and application of coatings for mirror backing.

In addition, during the SVHC and Annex XIV public consultations (RCOM, 2012; ComRef, 2019) companies and associations from the aerospace and defense industries[11] indicated a use of the substance in greases (anti-friction coating). According to the comments submitted trilead dioxide phosphonate is used in anti-friction coating mixtures both inside and outside of the EU for critical aerospace and military applications such as the coating and lubrication of torque tubes in brake systems, wheel faces/flanges and key slots for aircraft and to prevent thread seizure in other applications.

No precise information has been made available on the tonnage still used in the EU for the different uses. The available information on the different uses is summarised below.

In the last two decades lead stabiliser consumption has decreased significantly. According to Vinylplus (2016, 2017) ESPA members (European Stabilisers Producers Association representing most of the registrants of lead compounds used as stabilisers) completed the replacement of lead stabilisers for use in the EU by the end of 2015. However, the uses are still reported in registrations (ECHA, 2018). During public consultation, one company claimed that “having the uses reported in existing registrations do not necessarily mean that the substances are still in production. A registration is required to enable recycling of the substance (according to (EC) No 1907/2006, Article 2 Paragraph 7 Letter d)”. The commenting company concluded that a registrant can keep his registration active to enable recycling, even if he does not produce the lead compound any more (ComRef, 2019). ECHA notes that no information has been provided in registration dossiers indicating that the tonnage manufactured/imported or the uses reported would refer to recycling material.

According to registrations, the substance is used in plastic articles used by professional workers and consumers (external plastics, plastic materials used as an internal structural component of buildings) (ECHA, 2018). Plastic articles types mentioned by the Lead REACH Consortium commenting during the SVHC public consultation (RCOM, 2012) include water pipes and window profiles.

The Lead REACH consortium (ILA) commenting during the Annex XIV public consultation (ComRef, 2019) indicated that the use in rubber production and the use in mirror coating are specialist industrial uses only representing small volumes. However no specific volume range was provided. The Lead REACH consortium (ILA) futher reported that during the Consortium's 2009-2012 blood lead survey, the rubber sector indicated that some companies had ceased using lead compounds entirely by virtue of substitution. Therefore, this niche use of trilead dioxide phosphonate should be noted as in decline (ComRef, 2019).

[11] GIFAS (Groupement des industries françaises aeronautiques et spatiales); ASD (AeroSpace and Defence Industries Association of Europe; ADS Group Limited; Meggitt plc)

2. 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 (see section 2.4) 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). Some of the lead stabiliser substances are also used at other industrial sites such as rubber production sites, mirror coatings sites and in the aviation industry. It is assumed that lead stabilisers are used at more than a hundred sites.

The supply chain can be characterised[12] 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.

[12] 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