5 September 2018

Draft background document for dioxobis(stearato)trilead

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 dioxobis(stearato)trilead 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.

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1. Identity of the substance

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

Chemical name: dioxobis(stearato)trilead
EC Number: 235-702-8
CAS Number: 12578-12-0

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 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

Dioxobis(stearato)trilead 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")[3] 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 dioxobis(stearato)trilead manufactured and/or imported into the EU is according to registration data in the range 10,000 – 100,000 t/y (ECHA, 2018). Part of that tonnage is directly exported after manufacture. All tonnage for use in the EU appears to be in the scope of authorisation.

Therefore, in conclusion, the volume of dioxobis(stearato)trilead in the scope of authorisation is estimated to be > 10,000 t/y.

2.3. Wide-dispersiveness of uses

Registered uses of dioxobis(stearato)trilead in the scope of authorisation include uses at industrial sites (use as stabiliser, PVC processing) (ECHA, 2018).

Furthermore, according to registration data the substance is used in plastic articles in volumes > 10t/y.

[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 http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf
[3] 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.").

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 uses as stabiliser are however still reported in 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. 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 during April 2018[4]. The scope of the restriction is specific in that it will cover the placing on the market and use of PVC articles stabilised with lead compounds.

The restriction and the voluntary commitment do not cover however the uses for export. Based on the information currently available it is unclear whether such uses for export currently take place and/or will continue in future.

More detailed information on uses is provided in Annex I.

2.4. Further considerations for priority setting

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. Dioxobis(stearato)trilead is grouped with fatty acids, C16-18, lead salts; lead oxide sulfate; trilead dioxide phosphonate; [phthalato(2-)]dioxotrilead; sulfurous acid, lead salt, dibasic and trilead bis(carbonate) dihydroxide.

2.5. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
Dioxobis(stearato)trilead is classified as toxic for reproduction Category 1A meeting the criteria of Article 57(c) Score: 1	The amount of Dioxobis(stearato)trilead used in the scope of authorisation is >10,000 t/y Score: 15	Dioxobis(stearato)trilead is used at industrial sites Initial score: 5 Furthermore, the substance is used in articles in volumes >10 t/y Refined score: 7	23	Grouping with other lead substances used as stabilisers in PVC

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, dioxobis(stearato)trilead receives priority among the substances in the Candidate List (see link

[4] See https://www.echa.europa.eu/web/guest/previous-consultations-on-restriction-proposals/-/substance-rev/16119/term.

to the prioritisation results above). Therefore, it is proposed to prioritise dioxobis(stearato)trilead for inclusion in Annex XIV.

The final outcome of the restriction process (see section 2.3) and its possible impact on the priority of the substance will be considered by ECHA when finalising its recommendation for inclusion of the substance in Annex XIV, together with any new information on tonnage and uses that will be made available via registrations updates or via the public consultation.

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 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.

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 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. Dioxobis(stearato)trilead will be allocated to the same slot as the other lead substances.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for dioxobis(stearato)trilead.

[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

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.

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 dioxobis(stearato)trilead 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.

[7] See analysis of most relevant pieces of legislation e.g. in sections C.2.8 – C.2.12 in

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.

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 dioxobis(stearato)trilead for PPORD.

No PPORD notifications have been submitted to ECHA for the substance[9].

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.

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

[9] As of 1 February 2018.

4. References

ECHA (2018): Dioxobis(stearato)trilead. 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 ECHA from the commenting period 3/09/2012 – 18/10/2012 on the proposal to identify Dioxobis(stearato)trilead] as a Substance of Very High Concern.

https://echa.europa.eu/documents/10162/61748739-b9eb-4f51-81c8-721c8f24602d

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

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 total tonnage manufactured/imported in the EU is for use as stabilisers in PVC production.

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[10].

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). Articles types mentioned by the Lead REACH Consortium commenting during the SVHC public consultation (RCOM, 2012) include water pipes and window profiles.

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 the substance group to a specific LAD slot in the final recommendation.

Dioxobis(stearato)trilead is 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 and up to 20,000 plastic converters processing PVC (but only a fraction of them using lead stabilisers). 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, producers of articles and article assemblers (multi-layer assembling chain) (relevant life cycle stages: F, IS, SLs).

The substances seems to be formulated in the following type of products: polymer preparations and compounds (relevant Product Categories: PC32).

A number of sectors is relying on the substance in some of their uses including the plastic manufacturer sector, the building and construction sector as well as the electricity, steam, gas, water supply and sewage treatment sector (relevant Sectors of Use: SU12, SU19, SU23).

The substance ends up in a number of article types such as plastic articles, metal articles, vehicles, machinery, mechanical appliances, electrical/electronic articles (relevant Articles Categories: AC1, AC2, AC7, AC13).

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

[10] As of 1 February 2018

[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