1 October 2019

Background document for lead oxide sulfate

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 lead oxide sulfate 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 are 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]:

Name: Lead oxide sulfate
EC Number: 234-853-7
CAS Number: 12036-76-9

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 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

Lead oxide sulfate 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

Lead oxide sulfate is according to registration data currently not manufactured and/or imported into the EU (ECHA, 2018a). However, the registration status of the substance is still active, and uses in the scope of authorisation are still in the registration dossier. During the public consultation industry commented that the registered uses are taking place in small volumes (ComRef, 2019).

In conclusion, the volume in the scope of authorisation is estimated to be in the range of 0 - <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

Uses of the substance at industrial sites in the scope of authorisation (in the production of coatings and inks and application of coatings and inks for mirror backing) are still registered. Industry stated that these uses are taking place (ComRef, 2019).

Furthermore, according to registration data the substance is used in articles (mirror coatings). However, it appears that the release of the substance from these articles might be negligible.

2.4. Further considerations for priority setting

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

Although the use as stabiliser is no longer reported in registration dossiers of lead oxide sulfate that use was reported in previous dossier versions, thereby indicating that the substance 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).

Comments received during the public consultation challenged the grouping of lead oxide sulfate with other lead substances used as stabilisers arguing that this use of the substance is no longer reported in registration dossiers and that the substance has not been used as stabiliser although the use was included in earlier registration dossiers (ComRef, 2019). However, the information provided in the comments does not allow to conclude that it is technically not feasible to use lead oxide sulfate as substitute for other lead substances used as stabiliser. Therefore, ECHA did not change the grouping considerations for this substances (RCOM, 2019).

2.5. Conclusion

Verbal descriptions and scores			Total score	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)	
Lead oxide sulfate is classified as toxic for reproduction 1A meeting the criteria of Article 57(c) Score: 1	The amount of lead oxide sulfate used in the scope of authorisation is in the range of 0 - <10 t/y Score: 0-3	Lead oxide sulfate is potentially used at industrial sites. Score: 0-5	1-9 (middle value 5)	Grouping with other lead substances used as stabilisers in PVC

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, lead oxide sulfate receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, **lead oxide sulfate 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[6] and as further specified in the practical implementation document[7]. 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 lead oxide sulfate:

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. lead oxide sulfate 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 lead oxide sulfate.

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

[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

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

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 lead oxide sulfate 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 lead oxide sulfate 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 to include in Annex XIV any exemption from authorisation for the use of lead oxide sulfate for PPORD.
During the public consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substance.

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 lead oxide sulfate by the end of the public consultation.

ECHA therefore **does not recommend exempting any use of lead oxide sulfate 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 lead oxide sulfate 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_lead_oxide_sulfate_en.rtf

ECHA (2018a): Lead oxide sulfate. 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-PVC[8]. 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 lead oxide sulfate as a Substance of Very High Concern.

https://www.echa.europa.eu/documents/10162/08869a9e-cd0e-4f83-9fed-4eed067bb1cb

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

1. Further details on use and tonnage

According to active registration dossiers lead oxide sulfate is currently not manufactured or imported into the EU. However, uses in coatings for mirror backing are still reported in registration dossiers (ECHA, 2018a). During the public consultation industry commented that the substance is used in small volumes in the application of mirror backing, i.e. the coating of glass with a reflective surface (ComRef, 2019).

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 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 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[9] 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