

1 October 2019

Background document for fatty acids, C16-18, lead salts

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 fatty acids, C16-18, lead salts on the Authorisation List or in the registration dossiers¹ as well as the MSC opinion² were taken into consideration when finalising the recommendation and is 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:

Chemical name: Fatty acids, C16-18, lead salts

EC Number: 292-966-7

CAS Number: 91031-62-8

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 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

Fatty acids, C16-18, lead salts 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 Fatty acids, C16-18, lead salts 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 of 1,000 - 10,000 t/y.

The total tonnage of Fatty acids, C16-18, lead salts 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 restriction⁶. However, this use is still reported, also in recently updated dossiers and despite the assumed phase-out by industry⁶. ECHA cannot exclude that the tonnage reported relates to the use that is not covered by the voluntary commitment and/or the upcoming restriction (i.e. formulation of lead stabilisers for export). This use falls under the scope of authorisation.

Therefore, in conclusion the tonnage for use 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 fatty acids, C16-18, lead salts in the scope of authorisation include uses at industrial sites (formulation of lead stabilisers).

Further registered uses of fatty acids, C16-18, lead salts 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 restriction⁶ 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 for the use in lead stabilised articles was assigned.

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.

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. Fatty acids, C16-18, lead salts is grouped with dioxobis(stearato)trilead; lead oxide sulfate; trilead dioxide phosphonate; [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.

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

Furthermore ECHA at the request of the Commission submitted a restriction dossier on lead compounds used as stabilisers in PVC in December 2016⁷. 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 (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
Fatty acids, C16-18, lead salts is classified as toxic for reproduction Category 1A meeting the criteria of Article 57(c) Score: 1	The amount of fatty acids, C16-18, lead salts used in the scope of authorisation is estimated to be in the range of 1,000-10,000 t/y Score: 12	Fatty acids, C16-18, lead salts is used at industrial sites (formulation) Score: 5	18	Grouping with other lead substances used as stabilisers in PVC

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, fatty acids, C16-18, lead salts receives priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, fatty acids, C16-18, lead salts 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 XIV⁸ and as further specified in the practical implementation document⁹. The draft Annex XIV entries for all the substances that underwent public consultation are available at

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

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

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 fatty acids, C16-18, lead salts:

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. fatty acids, C16-18, lead salts 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).

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 fatty acids, C16-18, lead salts.

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 fatty acids, C16-18, lead salts.

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 fatty acids, C16-18, lead salts 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 fatty acids, C16-18, lead salts 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 fatty acids, C16-18, lead salts for PPORD.

No PPORD notifications have been submitted for fatty acids, C16-18, lead salts by the end of the public consultation¹⁰.

ECHA therefore does not recommend exempting any use of fatty acids, C16-18, lead salts 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 fatty acids, C16-18, lead salts 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_fatty_acids_c16-18_lead_salts_en.rtf

ECHA (2018): Fatty acids, C16-18, lead salts. 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 Fatty acids, C16-18, lead salts as a Substance of Very High Concern.

<https://echa.europa.eu/documents/10162/c93cbfc7-5881-4080-a61c-5a0b5aabffe0>

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 total tonnage of fatty acids, C16-18, lead salts manufactured/imported in the EU is for formulation and 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 (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). Article 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 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 characterised¹¹ 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).

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

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.