10 November 2016

Background document for tetralead trioxide sulphate

Document developed in the context of ECHA's seventh 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(s), 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 tetralead trioxide sulphate on the authorisation list or in the registration dossiers (as of the last day of the public consultation, i.e. 18 February 2016) was taken into consideration when finalising the recommendation and is reflected in the present document.

The background document also describes how ECHA has taken into account the MSC opinion.

Contents

1. Identity of the substance

Chemical name: Tetralead trioxide sulphate
EC Number: 235-380-9
CAS Number: 12202-17-4
IUPAC Name: Tetralead trioxide sulphate

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[1]. Results of the prioritisation of all substances included in the Candidate List by June 2014 and not yet included or recommended in Annex XIV of the REACH Regulation is available at http://echa.europa.eu/documents/10162/13640/prioritisation_results_CL_substances_nov_2015_en.pdf.

The prioritisation results of the substances included in the draft 7th 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_draft7threc_substances_feb2016_en.pdf.

2.1. Intrinsic properties

Tetralead trioxide sulphate 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"), 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 tetralead trioxide sulphate manufactured and/or imported in the EU is according to registration data > 1,000,000 t/y.

Part of the registered tonnage is claimed as being used as an intermediate (tonnage for use in lead-based battery production). However, based on available information it appears that the use described is likely not to be an intermediate use.

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

More detailed information on the main uses and the relative share of the total tonnage is provided in Annex I.

[1] Document can be accessed at:
http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

2.3. Wide-dispersiveness of uses

Registered uses of tetralead trioxide sulphate in the scope of authorisation include uses at industrial sites (use as stabiliser, PVC processing, lead battery production, production and application of coatings and inks for mirror backing, use as an industrial reactant) (ECHA, 2015).

Furthermore, according to the registration data the substance is used in articles (such as plastic articles).

More detailed information on uses is provided in Annex I.

2.4. Further considerations for priority setting

It appears that tetralead trioxide sulphate is used in similar applications (batteries) with orange lead (lead tetroxide), lead monoxide and pentalead tetraoxide sulphate also included in the Candidate List. However, it has not been assessed whether the function of these substances in these applications is the same and whether or under which conditions substitution could happen in practice.

2.5. Conclusion

Verbal descriptions and Scores			Total Score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
Tetralead trioxide sulphate is classified as toxic for reproduction 1A meeting the criteria of Article 57(c) Score: 1	The amount of tetralead trioxide sulphate used in the scope of authorisation is in the range of 1,000,000 - 10,000,000 t/y Score: 15	Tetralead trioxide sulphate 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 of tetralead trioxide sulphate with other lead substances used in batteries

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations tetralead trioxide sulphate receives priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, **tetralead trioxide sulphate 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[2]. The draft Annex XIV entries that underwent public consultation are available at: *http://echa.europa.eu/documents/10162/13640/7th_recom_draft_axiv_entries_en.pdf* .

The final draft Annex XIV entries that ECHA recommends are available at: *https://echa.europa.eu/documents/10162/13640/7th_axiv_recommendation_november2016_en.pdf.*

3.1. Latest application and sunset dates

The LAD slots are set in 3-month intervals (normally 18, 21 and 24 months after inclusion in Annex XIV but more slots can be considered on a case-by-case basis). In its draft recommendation, ECHA had proposed that the LAD would be the date of inclusion of the substance in Annex XIV plus 24 months and the sunset date 18 months after the LAD. ECHA had seen no reason to deviate from the three LAD slots of 18, 21 and 24 months after inclusion in Annex XIV that are normally assigned in a recommendation. Tetralead trioxide sulphate had been considered to be placed in the same slot with the other lead substances in this draft recommendation. Lead substances (including tetralead trioxide sulphate) were assigned to the 3rd LAD slot due to the potentially high number of uses and overall complexity of supply chain.

During the public consultation on the draft 7th recommendation the International Lead Association (ILA) supported the LAD of 24 months as most of the volume is used for battery production and supply chains are not regarded complex. Two industry associations requested longer transition periods especially for plastic converters and recyclers (ComRef, 2016).

Placing the substance in the 3rd LAD slot takes already into account the time needed to prepare application for authorisation, which may be comparatively longer for tetralead trioxide sulphate than for other substances in this recommendation round.

The MSC is of the opinion[3] that no information has been provided during the public consultation that would challenge the suggested latest application date and sunset date.

ECHA recommends therefore the following transitional arrangements:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **24 months**
Sunset date (SSD):	18 months after LAD

It is recognised that tetralead trioxide sulphate and pentalead tetraoxide sulphate are used in similar applications as lead monoxide and orange lead for which finally a LAD of 27 months is recommended. The recommended LADs do not impede joint applications for authorisation for those uses that are similar for the four substances. Applicants can always submit an application for authorisation before the latest application date.

More information on the structure and complexity of the supply chain of tetralead trioxide sulphate is provided in Annex I (section 3).

[2] Document can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[3] MSC opinion on ECHA's 7th draft recommendation

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 tetralead trioxide sulphate.

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

ECHA therefore **does not recommend to include in Annex XIV any review periods** for uses of tetralead trioxide sulphate.

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 exemption for (categories of) uses of tetralead trioxide sulphate on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultations on the draft 6th Recommendation and on the draft 7th Recommendation[4], ECHA received a number of requests for exemptions, for specific uses or broader spectrum of uses (e.g. covered by certain legislation) (ComRef, 2015; ComRef, 2016). The list of uses for which an Article 58(2) exemption request has been received is presented in the table below for the 4 lead substances included in the draft recommendation. Many of these requests refer to the extensive body of legislation relevant to lead and its compounds.

Table 1. Uses of lead compounds for which an Article 58(2) exemption request has been received.

Substance	**Use**
Lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate	Batteries
Lead monoxide and lead tetroxide	Manufacture of pyrochlore antimony lead yellow
Lead monoxide and lead tetroxide	Technical / Piezo-ceramics
Lead monoxide and lead tetroxide	Frits
Lead monoxide and lead tetroxide	Glass (including special glass and crystal glass)
Lead monoxide	Glass frits (semiconductor industry)
Lead monoxide and lead tetroxide	Rubber
Lead monoxide	Electroplating
Lead monoxide and lead tetroxide	Airlines e.g. lead oxide is used in dry film lubricant products (and in batteries)

[4] All exemption request submitted during the public consultation on the 6th and on the 7th draft recommendation are assessed in the 7th recommendation round, this is as the substance was not included in the 6th recommendation.

Lead monoxide	Laboratory reagent / processing aid for analysis of precious metal content of secondary and complex materials
Lead monoxide	Propellants in rocket motors
Lead monoxide	Catalysts and adsorbents
Lead monoxide and lead tetroxide	Explosives and detonators
Pentalead tetraoxide sulphate and tetralead trioxide sulphate	PVC stabiliser (virgin and recycled PVC)
Lead monoxide	Manufacture of PVC stabilisers
Tetralead trioxide sulphate	Production of microporous plastic separators for lead-based batteries

After assessing the information provided in the public consultations, the MSC in its opinion concludes that there could possibly be grounds for exemptions from authorisation for the uses of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate that are regulated under the RoHS[5] and ELV[6] legislation. However, the MSC notes that these pieces of legislation do not regulate the whole lifecycle and may therefore not offer the same level of protection for the environment or human health as could be achieved under the authorisation scheme.

For other uses of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate MSC is of the opinion that no information was submitted during the public consultation that would form the basis for inclusion of a specific exemption under Article 58(2) in Annex XIV.

ECHA has carefully assessed the requests made in the comments submitted during the public consultations as well as the MSC opinion.

ECHA's detailed assessment of the requests taking into account the relevant EU legislation is provided in the section 'C.2.1. Response to requests for exemptions under Art. 58(2)' of the Response document to the comments submitted during the public consultation (RCOM, 2016).

ECHA concludes that it is not clear if there is sufficient basis to propose Art 58(2) exemptions for any uses of lead compounds. ECHA has therefore **not suggested exemptions for uses** of tetralead trioxide sulphate on the basis of Article 58(1) (e) in combination with **Article 58(2)** of the REACH Regulation in its recommendation.

If the Commission were to consider Art 58(2) exemptions possible, uses of lead compounds exempted and subject to regular review under RoHS and ELV legislation may have a stronger case for Art 58(2) exemption than other uses.

[5] Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0065&from=en

[6] Directive 2000/53/EC on end-of life vehicles: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02000L0053-20130611&qid=1405610569066&from=EN

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 tetralead trioxide sulphate for PPORD.

During the public consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substance.

ECHA therefore **does not recommend exempting any use** of tetralead trioxide sulphate **for PPORD** from authorisation.

4. References

ComRef (2016): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 18/11/2015 – 18/02/2016 on ECHA's proposal to include tetralead trioxide sulphate in its 7th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/7th_recom_comref_tetralead_trioxide_sulphate_en.rtf

ComRef (2015):"Comments and references to responses". Document compiling comments and references to respective answers from commenting period 01/09/2014-01/12/2014 on ECHA's proposal to include tetralead trioxide sulphate in its 6th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_tetralead_trioxide_sulphate_en.pdf

ECHA (2015): Tetralead trioxide sulphate. ECHA's dissemination website on registered substances. Accessed on 18 February 2016.

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

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 tetralead trioxide sulphate as a Substance of Very High Concern.
https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807ddbbf

RCOM (2016): "Responses to comments" document. Document compiling the responses to comments from commenting period 18/11/2015 – 18/02/2016 on ECHA's proposal to include lead monoxide, orange lead, pentalead tetraoxide sulphate and tetralead trioxide sulphate in its 7th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/7th_recom_respdoc_leads_en.pdf

Annex I: Further information on uses

1. Main (sector of) uses and relative share of the total tonnage

Based on registration data and on the comments received during the SVHC public consultation the main uses of tetralead trioxide sulphate appear to be the use in lead battery production and the use in stabilisers production and PVC processing. The uses in the production of coatings and inks, the application of coatings and inks for mirror backing and the use as an industrial reactant appear to be less significant in terms of tonnages. No detailed information is available on these uses.

The exact breakdown of the volume between these uses remains uncertain, the data available not being fully consistent. The lead (Pb) Reach Consortium commenting during the 6th draft recommendation public consultation (ComRef, 2015) indicates that the use in the production of batteries represents <95% of the total tonnage, the use as a stabiliser in PVC production being the other significant use with approximatively 4.5% of the market.

However, from aggregated survey data carried out in 2012 by EUROBAT in its member companies, it appears that approximatively 369,000 tonnes of tetralead trioxide sulphate are produced during the battery production process by the European battery industry per annum (RCOM, 2012). Comparing this 369,000 t/y with the total tonnage registered (see confidential annex), it appears that it represents far less than the 95% indicated by the lead (Pb) Reach Consortium.

The stabiliser sector had a voluntary commitment to replace lead stabilisers completely by end of 2015 across the EU-27. According to comments received the European PVC industry has completed its phase out commitment by the end of 2015 (ComRef, 2016). This needs yet to be confirmed in registration dossiers.

2. Further details on the type of applications, functions and market trend per use

2.1 Batteries

Tetralead trioxide sulphate is used in the process to produce automotive and industrial lead-acid batteries. From aggregated survey data of its member companies, EUROBAT estimates that ~47 % of the volume is for use in the production of automotive batteries, and 53% for the production of industrial batteries (RCOM, 2012).

Lead-based batteries are widely used in automotive vehicles (e.g. SLI[7] batteries, start-stop systems in micro-hybrid vehicles, batteries used in mild, full and plug-in hybrid vehicles) and in industrial motive and standby applications, e.g. in forklift trucks and electric wheelchairs, as Uninterruptible Power Supply (UPS) for hospitals, IT applications and telecommunication systems including both landline and mobile telephone base station applications (RCOM, 2012).

The battery production process begins with initial chemical reactions of lead oxide and lead tetroxide, leading to the transformation of both substances into a mix of tetralead trioxide sulphate and pentalead tetraoxide sulphate, and further into lead metal and lead dioxide. Detailed information on the production process of lead-acid batteries, including a description on how the above-mentioned substances are interlinked in the production process, can be found in the comments received during the SVHC public consultation (EUROBAT and ILA comments - RCOM, 2012; ComRef, 2015). During the production process tetralead trioxide sulphate is

[7] Starting, Lighting, Ignition

converted into another substance and only some residual concentrations remain in the final article (RCOM, 2012).

According to the industry, the collection and recycling rate of automotive batteries in Europe is ~99%. No precise data for the recycling of industrial lead-based batteries was provided.

2.2 Stabiliser in Polyvinyl Chloride (PVC)

One application of tetralead trioxide sulphate is as a stabiliser in PVC production. Lead-containing stabilisers are used in plastic formulations with a variety of applications that include insulating coatings for electrical wiring, water pipes, and structural elements of buildings (e.g. window profiles). Lead-containing stabilisers are incorporated into the matrix of plastics such as PVC to impart stability against degradation due to thermal or photological stress.

The stabiliser sector has a voluntary commitment to replace lead stabilisers completely by end of 2015 across the EU-27. According to comments received the European PVC industry has completed its phase out commitment by the end of 2015 (ComRef, 2016). This needs yet to be confirmed in registration dossiers.

In many cases lead stabilisers are replaced by calcium based stabilisers. In the 2007-2013 period, use of lead stabilisers decreased by ~81% in the EU-27.

2.3 Other uses

No detailed information is available on the uses in the production of coatings and inks, the application of coatings and inks for mirror backing or on the use as an industrial reactant.

3. Structure and complexity of supply chains

Substance suppliers

According to ECHA's dissemination website there are 44 registrants/suppliers active in the EU (ECHA, 2015).

Batteries

Tetralead trioxide sulphate seems to be manufactured and used at the battery production plants.

Europe counts many battery production sites (> 50 sites). Key countries for lead-based battery production in Europe include the Czech Republic, France, Germany, Italy, Spain, Poland and the United Kingdom (RCOM, 2012).

Stabiliser in PVC

According to information from industry (RCOM, 2012) there is less than 10 sites manufacturing lead stabilisers in the EU-27.

Many plastic converters are processing PVC (up to 20,000) and a fraction of them may use lead stabilisers to produce articles such as discharge water pipes and window profiles.

The sector also counts a very high number of PVC recyclers (mainly SMEs) handling post-consumer waste. Lead is expected to remain in recycled PVC for many years even after the phase out due to the long life time of most PVC products (ComRef, 2015).

Other uses

No detailed information is available on the uses in the production of coatings and inks, the application of coatings and inks for mirror backing and on the use as an industrial reactant.