

18 November 2015

Draft background document for pentalead tetraoxide 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 pentalead tetraoxide sulphate on the authorisation list or in the registration dossiers (as of the last day of the public consultation, i.e. 18 February 2016) will be taken into consideration when finalising the recommendation and will be reflected in an update of the present document.

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1. Identity of the substance

Chemical name:	Pentalead Tetraoxide Sulphate
EC Number:	235-067-7
CAS Number:	12065-90-6
IUPAC Name:	Pentalead Tetraoxide 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 authorisation¹. 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.

2.1. Intrinsic properties

Pentalead tetraoxide 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 pentalead tetraoxide sulphate manufactured and/or imported into the EU is according to registration data and other information sources (public consultation on the draft 6th recommendation) in the range of 100,000 -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.

2.3. Wide-dispersiveness of uses

Registered uses of pentalead tetraoxide sulphate in the scope of authorisation include uses at industrial sites (use as stabiliser, PVC processing, use in lead battery production).

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

2.4. Further considerations for priority setting

It appears that pentalead tetraoxide sulphate is used in similar applications (batteries) with orange lead (lead tetroxide), lead monoxide and tetralead trioxide sulphate also included in the

¹ Document can be accessed at

http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

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. Conclusions and justification

Verbal descriptions and Scores			Total Score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
Pentalead tetraoxide sulphate is classified as toxic for reproduction 1A meeting the criteria of Article 57(c) Score: 1	The amount of pentalead tetraoxide sulphate used in the scope of authorisation is estimated to be > 10,000 t/y. Score: 15	Pentalead tetraoxide sulphate is used at industrial sites. Initial score: 5 Furthermore, the substance is used in articles in volumes >10t/y. Refined score: 7	23	Grouping of pentalead tetraoxide sulphate together with other lead substances used in batteries

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations pentalead tetraoxide sulphate receives priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise pentalead tetraoxide sulphate 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 XIV². The draft Annex XIV entries for substances included in this draft recommendation are available at http://echa.europa.eu/documents/10162/13640/7th_recom_draft_axiv_entries_en.pdf.

3.1. Latest application and sunset dates

ECHA proposes to recommend the following transitional arrangements:

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

Sunset date (SSD): 18 months after LAD

There is a priori no reason to deviate from the three LAD slots of 18, 21 and 24 months after

² Document can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

inclusion in Annex XIV that are normally assigned in a recommendation. Pentalead tetraoxide sulphate has been considered to be placed in the same slot with the other lead substances in this draft recommendation. Lead substances (including pentalead tetraoxide sulphate) are assigned to the 3rd LAD slot due to the potentially high number of uses and overall complexity of supply chain.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for pentalead tetraoxide sulphate.

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 pentalead tetraoxide sulphate on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

3.3.2. Exemption of product and process oriented research and development (PPORD)

ECHA proposes not to include in Annex XIV any exemption from authorisation for the use of pentalead tetraoxide sulphate for PPORD.

4. Further information on uses

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

The uses of pentalead tetraoxide sulphate can be summarised as follow:

- use in stabilisers and in PVC processing;
- use in lead battery production.

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 an aggregated survey data carried out in 2012 by EUROBAT in its member companies, it appears that approximatively 39,000 tonnes of pentalead tetraoxide sulphate are produced during the battery production process by the European battery industry per annum (RCOM, 2012). Comparing this 39,000 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.

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

4.2.1. Batteries

Pentalead tetraoxide sulphate is used in the process to produce automotive and industrial lead acid batteries. From an aggregated survey data of its member companies, EUROBAT estimates that ~46 % of the volume is for use in the production of automotive batteries, and 54% for the production of industrial batteries (RCOM, 2012).

Lead-based batteries are widely used in automotive vehicles (e.g. SLI³ 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 pentalead tetraoxide sulphate and tetralead trioxide 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 pentalead tetraoxide sulphate is 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.

4.2.2. Stabiliser in Polyvinyl Chloride (PVC)

A significant use of pentalead tetraoxide 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 is on track to fulfil its phase out commitment. In many cases lead stabilisers are replaced by calcium based stabilisers. In the 2007-2013 period, use of lead stabilisers decreased by ~81.4% in the EU-27.

4.3. Structure and complexity of supply chains

4.3.1. Substance suppliers

According to ECHA's dissemination website there are 34 registrants/suppliers active in the EU (ECHA, 2015).

³ Starting, Lighting, Ignition

4.3.2. Batteries

Pentalead tetraoxide 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).

4.3.3. 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).

5. References

ComRef (2015): "Comments and references to responses" document for pentalead tetraoxide sulphate. Document compiling comments and references to respective answers from commenting period [01/09/2014-01/12/2014] on ECHA's proposal to include pentalead tetraoxide 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_pentalead_tetraoxide_sulphate_en.pdf

ECHA (2015): Pentalead tetraoxide sulphate. ECHA's dissemination website on registered substances. Accessed on 1 June 2015

<http://echa.europa.eu>

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 pentalead tetraoxide sulphate as a Substance of Very High Concern.

<http://echa.europa.eu/documents/10162/6c2affb2-73d9-4a06-b774-857603a6282a>