

1 September 2014

Draft background document for Tetralead Trioxide Sulphate

Document developed in the context of ECHA's sixth 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.

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 authorisation¹. Results of the prioritisation of all substances included in the Candidate List by June 2013 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_6th_rec_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 in the range of 1,000,000 - 10,000,000 t/y.

¹ Document can be accessed at

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

Part of the registered tonnage is claimed as being used as an intermediate. However, based on available information it appears that the uses described are likely not to be intermediate uses².

2.3. Wide-dispersiveness of uses

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

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

2.4. Further considerations for priority setting

It appears that tetralead trioxide sulphate is used in some similar applications (batteries) with lead monoxide, lead tetroxide and pentalead tetraoxide sulphate (the latter substances were prioritised for inclusion in Annex XIV). 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)		
Tetralead trioxide sulphate is classified as toxic for reproduction 1A meeting the criteria 57c 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	Prioritisation of tetralead trioxide sulphate together with other high priority lead substances used in batteries

Conclusion

On the basis of the prioritisation criteria and grouping considerations, tetralead trioxide sulphate received high priority among the substances in the Candidate List (refer to link to the prioritisation results above). Therefore, it is proposed to recommend tetralead trioxide sulphate for inclusion in Annex XIV.

² It is stressed that the prioritisation exercise is not taking a formal position whether certain uses of substances are regarded as uses as intermediates in accordance with the definition in article 3(15).

3. Further information on uses

In addition to the registration information, further details on uses can be found in comments provided during the SVHC public consultation (RCOM, 2012).

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 stabilisers production and PVC processing and the use in lead battery production. The uses in the production of coatings and inks and 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.

Information on the main (sector of) uses, tonnage and current trends are provided below.

Use as stabiliser

A significant use of tetralead trioxide sulphate is as a stabiliser in PVC production (RCOM, 2012). No up-to-date information on the tonnage allocated to that use is available. The stabiliser sector has a voluntary commitment to replace lead stabilisers completely by the end of 2015 across the EU-27. According to industry (RCOM, 2012) in many cases lead-based stabilisers are replaced by calcium-based stabilisers and during the period 2001-2011, the lead stabiliser consumption decreased by approximately 82%. However, the total tonnage of Pb-stabilisers used in the EU seems to remain above 10,000 t/y.

According to information from industry (RCOM, 2012) there are less than 10 sites manufacturing lead stabilisers in the EU-27 (totalling probably between 100 and 500 employees directly involved with lead stabilisers) while up to 20,000 plastic converters are processing PVC and a fraction of them may use lead stabilisers to produce articles such as discharge water pipes and window profiles, roofing, flooring and many others.

Use in the production of batteries

Tetralead trioxide sulphate is used in the process to produce automotive and industrial lead-acid batteries. The battery production process begins with initial chemical reactions for lead oxide and lead tetroxide, leading into 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).

During the production process tetralead trioxide sulphate is converted into another substance and only some residual concentrations remain in the final article (RCOM, 2012).

From aggregated survey data of its member companies, EUROBAT (The Association of European Automotive and Industrial Battery Manufacturers) estimates that 369,000 tonnes of tetralead trioxide sulphate and 39,000 tonnes of pentalead tetraoxide sulphate are produced during the battery production process by the European battery industry per annum (RCOM, 2012):

- 173,000 tonnes of tetralead trioxide sulphate and 18,000 tonnes of pentalead tetraoxide sulphate being used for the production of **automotive** batteries;
- 196,000 tonnes of tetralead trioxide sulphate and 21,000 tonnes of pentalead tetraoxide sulphate being used for the production of **industrial** batteries.

Lead-based batteries are widely used in automotive vehicles (e.g. SLI 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).

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. 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 XIV³. The draft Annex XIV entries for substances included in this draft recommendation are available at http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_summarytable_6th_en.pdf. The section below provides background for allocation of the substance to the Latest Application Date slots.

The LAD slots are set in 3 months intervals (i.e. 18, 21 and 24 months after inclusion in Annex XIV).

Lead substances have been considered to be placed in the same slot as they may fulfil the definition of a group according to section 1.5 of Annex XI of REACH (provision allowing submitting common applications for authorisation).

The allocation of (group of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. The differences between the total time for preparing the application (i.e. 18, 21 and 24 months) can be regarded minor. However, substances for which the preparation of the application may require longer time are assigned to the later LAD slots (2nd and 3d).

Lead substances (including tetralead trioxide sulphate) are assigned to the 2nd LAD slot due to the potentially high number of uses and overall complexity of supply chain.

5. References

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.

<http://echa.europa.eu/documents/10162/0a7b3187-f051-46d5-b3cb-39a4485b36d2>

³ Document can be accessed at

http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf