

18 November 2015

Draft background document for orange lead (lead tetroxide)

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 orange lead (lead tetroxide) 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: Orange lead (lead tetroxide)
EC Number: 215-235-6
CAS Number: 1314-41-6
IUPAC Name: Lead tetroxide

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_20_15_en.pdf.

2.1. Intrinsic properties

Orange lead (lead tetroxide) 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 December 2012, following ECHA's decision ED/169/2012.

2.2. Volume used in the scope of authorisation

The amount of orange lead (lead tetroxide) manufactured and/or imported into the EU is according to registration data in the range of 10,000 - <100,000 t/y (min. 45,000 t/y according to information submitted in the public consultation on the 6th draft recommendation (ComRef, 2015)).

Part of the volume is for uses that appear not to be in the scope of authorisation, such as use as intermediate in manufacture of certain pigments, technical ceramic materials (PZT, PTC, PLZT), frits and glass (including crystal and special glass). It is recognized that the intermediate/non-intermediate status of some of these uses (e.g. in glass and frits) is a complex issue, and it is stressed that this prioritisation exercise is not taking a formal position whether certain uses of the substance are regarded as uses as intermediates in accordance with the definition in Article 3(15).

The volume in the scope of authorisation is estimated to be in the range of 10,000 - <100,000 t/y based on registrations and further information (ComRef, 2015).

2.3. Wide-dispersiveness of uses

Registered uses of orange lead (lead tetroxide) in the scope of authorisation include uses at industrial sites (e.g. use in the production of batteries, rubber and explosives, use in adsorbents) and uses by professional workers (use in paints) (ECHA, 2015). In addition, according to the information from industry (ComRef, 2015) the substance can be used in

¹ Document can be accessed at

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

lubrication and corrosion protection products in the aerospace industry.

Finally, based on registration information the substance is used in articles (e.g. rubber articles and painted articles).

Some uses have been mentioned in the past in registrations, which however may not take place anymore:

During the public consultation on the SVHC identification (RCOM, 2012) non-registered, potentially professional-, uses in graphite containing dispersion pastes, machining, scraping compounds and friction breaks were mentioned by industry. However the lead registrant in a recent update of its registration dossier specified that these uses did not happen/do not happen anymore and provided further information on why these uses were mentioned before.

Consumer use of artists' paints² containing orange lead were mentioned in the past in the lead and members registration dossiers. The lead registrant and most of the member registrants have updated their registrations in April-June 2014 and they have removed this use from their dossiers and CSR. There are some members who have not updated their registrations, and the use remains in their dossiers. However, these members refer to the lead registrant's CSR which no longer supports the use. No own CSRs have been received from these members.

2.4. Further considerations for priority setting

Orange lead (lead tetroxide) is used in similar applications (batteries) with lead monoxide, pentalead tetraoxide sulphate and tetralead trioxide 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. Conclusions and justification

Verbal descriptions and Scores			Total Score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
Orange lead (lead tetroxide) is classified as toxic for reproduction 1B meeting the criteria of Article 57(c) Score: 1	The amount of orange lead (lead tetroxide) used in the scope of authorisation is $\geq 10,000$. Score: 15	Orange lead (lead tetroxide) is used at industrial sites and by professional workers. Initial score: 10 Furthermore, the substance is used in articles Refined score: 12	28	Grouping of orange lead (lead tetroxide) with other lead substances used in batteries

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, orange lead (lead tetroxide) receives priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise orange lead (lead

² This use is derogated from the restriction to supply CMR substances on their own or in mixtures to the general public.

tetroxide) 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 XIV³. 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 inclusion in Annex XIV that are normally assigned in a recommendation. Orange lead (lead tetroxide) has been considered to be placed in the same slot with the other lead substances in this draft recommendation. Lead substances (including orange lead (lead tetroxide)) 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 orange lead (lead tetroxide).

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 orange lead (lead tetroxide) 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 orange lead (lead tetroxide) for PPORD.

³ Document can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

4. Further information on uses

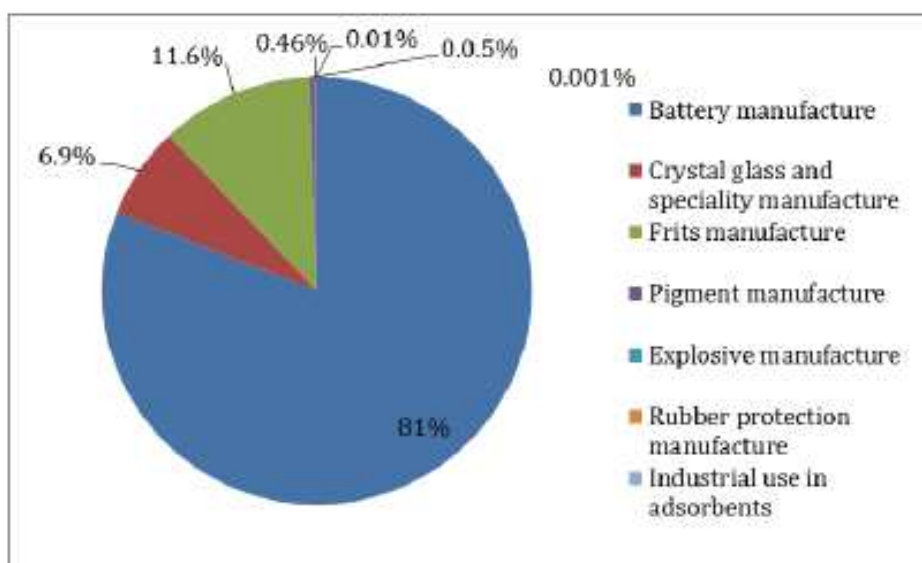
4.1. Main (sector of) uses and relative share of the total tonnage

The amount of orange lead manufactured and/or imported into the EU is according to registration data in the range of 10,000 - <100,000 t/y (~ 45,000 t/y according to information submitted in the public consultation on the 6th draft recommendation (ComRef, 2015)).

The substance has several uses in a range of EU industries. Based on information provided by the Lead (Pb) Reach Consortium⁴ during the public consultation on the draft 6th recommendation (ComRef, 2015) the uses can be summarised as follow:

- the production of lead-acid batteries represents the main use of orange lead since it represents over 80% of its total use;
- the (intermediate) uses of orange lead in crystal, special glass and frits comprise most of the rest of the relative share (approx. 19 %)⁵;
- and all the other uses represent less than 1% of the total volume (ComRef, 2015). However, as the total EU tonnage is high (10,000 - <100,000 t/y), the tonnage corresponding to some of the uses representing a low relative share may still be in the range of tens or hundreds of tons per year.

The figure below presents the end-use pattern of lead tetroxide as defined by the Lead (Pb) Reach Consortium.



Estimated volumes for uses in the scope of authorisation (based on information from the registrations and from industry provided in the public consultation on the 6th draft recommendation (ComRef, 2015)) are given below:

- use in production of a battery paste for certain types of positive battery plates which are used in the production of industrial and automotive lead-acid batteries: 36,000 t/y;
- use in rubber compounds used for specific article applications, e.g. hoses and damping elements in the automotive sector, insulation and lining of cables: > 20 t/y

⁴ representing 5 of the orange lead registrants, ~80 companies and 12 industry associations representing the predominant uses of orange lead

⁵ Based on current interpretation, these uses may fulfil the intermediate definition and is therefore of less relevance in the context of recommendation for inclusion in Annex XIV

- use in delay elements of detonators in explosives used in civil works and mining: 30-90 t/y;
- use as pigment in anti-corrosive paints: 100 t/y
- use in adsorbents: unknown tonnage

In addition, during the public consultation on the draft 6th Recommendation (ComRef, 2015) industry stated that the substance can be used for surface treatment (plating) and in mixtures that provide lubrication and corrosion protection on critical aerospace products.

Further information on some of the above listed uses is given below.

4.2. Further details on the type of applications and/or functions per use⁶

4.2.1. Battery production

According to information from the industry (ComRef, 2015), orange lead is used together with lead monoxide in the production of battery pastes in lead acid battery production (further details on battery production available in ILA and EUROBAT comments - RCOM, 2012; ComRef, 2015).

Lead-based batteries are widely used in automotive vehicles and 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).

It is reported that over 95 % of the tonnage of orange lead used in batteries is used in industrial batteries (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. Rubber production

Orange lead is currently used in the rubber industry as an accelerator/cross linker for rubber compounds used for specific article applications such as hoses and damping elements in the automotive sector (RCOM, 2012). It is also used as an additive in rubber compounds for insulation, lining and sheathing of materials exposed to sea water and of cables which have to meet electrical performance specifications for safety reasons (ComRef, 2015). All the above applications are industrial.

Depending on the specific application, lead oxides might be used to fulfil one or more functions ranging from corrosion protection/antioxidants, water swelling resistance, rubber metal adhesion promoters, functional fillers (as gas diffusion barriers), bonding agent in materials exposed to sea and water neutralizers forming insoluble and stable salts to co-agents in rubber crosslinking. In some compounds all these functions need to be fulfilled.

4.2.3. Explosives

The use of orange lead in explosives is registered. According to information from industry (ComRef, 2015), the substance is used in delay elements of detonators. The explosives are mainly used in civil works and mining, but also uses in other applications including safety

⁶ The section is limited to uses likely to be in the scope of authorisation

systems, aerospace items, seismic studies, special effects and amusement parks are mentioned (RCOM, 2012; ComRef 2015).

4.2.4. Paints

Professional use of orange lead in paints is registered, and during the public consultation industry confirmed that the substance is used as a pigment in anti-corrosive paints applied to iron and steel (mainly ships) (ComRef, 2015).

4.2.5. Other uses

No further information is available on the other uses reported in registrations (adsorbent) or during the 6th recommendation public consultation (use in corrosion inhibitor products in the aerospace industry).

4.3. Structure and complexity of supply chains

Detailed information on the structure and complexity of supply chains involved in the use of orange lead is not readily available. Indicative information on the sectors concerned can be retrieved from the identity of the comments submitters during public consultations. The following European sector-specific associations have commented during the SVHC and draft 6th recommendation public consultations⁷:

- ELOA (European Lead Oxide Association, representative of lead oxide manufacturers)
- EUROBAT (Association of European Automotive and Industrial Battery Manufacturers)
- ETRMA (European Tyre & Rubber Manufacturers' Association)
- Europacable
- FEEM (Federation of European Explosives Manufacturers)
- AEA (European Association of Airlines)
- ACEA (European Automobile Manufacturers' Association)

Comments were also received from glass, frits, ceramics and crystal associations⁸, which uses of lead tetroxide were claimed as intermediate. Based on information available it was concluded that these uses may indeed fulfil the intermediate definition.

4.3.1. Suppliers

According to ECHA's dissemination website there are 10 active registrants in the EU (ECHA, 2015).

According to one comment submitted by ELOA (European Lead Oxide Association) during the SVHC public consultation (RCOM, 2012), its 6 members companies are producing 95% of the lead oxide produced in EU, out of the battery industry which produces lead oxide for internal consumption in battery manufacturing process.

⁷ Comments submitted do not necessarily relate to supply chain description

⁸ Cerame-Unie (the European Ceramics Industry Association), ESGA (European Special Glass Association), EDG (European Domestic Glass Association), Frit Consortium, LightingEurope, ICF (International Crystal Federation), Inorganic Pigments Consortium

ELOA's membership has manufacturing facilities in Germany, Spain, Italy or Poland.

The lead metal used for the manufacture of lead oxides by the ELOA members seems to come prevalently from recycling (RCOM, 2012).

4.3.2. Batteries

During the SVHC and 6th recommendation public consultations, the battery sector has been represented by EUROBAT. EUROBAT is composed of ~ 40 members who according to EUROBAT represent over 90% of the automotive and industrial battery industry in Europe. EUROBAT membership comprises companies who manufacture and sell batteries, companies that are contractors or suppliers of raw materials, systems or of equipment to battery manufacturers, and Battery Systems Integrator Members.

With the exception of one company, EUROBAT's membership does not produce lead tetroxide. Instead, lead tetroxide is purchased from other EU suppliers (RCOM, 2012).

Based on registration information complemented by information provided during public consultations (ComRef, 2015; RCOM, 2012), it is assumed that the battery supply chain is composed of a relatively low number of lead tetroxide manufacturers, supplying the substance to the battery producers. According to registration information, lead tetroxide used in the production of batteries, is supplied 'as such' for that use. Therefore, it is assumed that the supply chain does not involve formulators. It needs to be clarified however whether the registrants directly provide lead tetroxide to the battery producers or whether some 'intermediate steps' may occur.

Europe counts many battery production sites (> 50 sites). Based on the process description provided during the public consultation it is assumed that the paste and battery production processes usually take place at the same production plant. The production process is likely to be similar in the different plants.

Key countries for lead-based battery production in Europe include France, Germany, Italy, Spain, Poland, the Czech Republic, Portugal and the UK.

Recycling of lead-based batteries appears to be done partly by the battery industry itself, partly by other smelters with the secondary lead being reused in the manufacture of Lead Oxide and Tetroxide and new batteries (RCOM, 2012). The batteries returned at e.g. vehicle workshops, vehicle dealerships, accessory shops or DIY stores are picked up at collection points by specialised companies who transport and deliver the batteries to secondary smelting plants.

4.3.3. Rubber

Lead tetroxide is used as additives in rubber materials, further used for specific article applications.

ETRMA (the European Tyre & Rubber Manufacturers' Association) indicates that lead tetroxide is 'used in rubber' at 17 European sites located in Germany, the Czech Republic, Slovakia and Greece, and that there may be between 101-1,000 downstream automobile component manufacturers using the associated rubber products. Moreover, it indicates that 80% of rubber companies using lead oxides are represented by SMEs (RCOM, 2012).

Based on the above mentioned information, it is assumed that the supply chain is composed of few manufacturers (less than 10) supplying relatively few formulators (~17 sites), supplying a high number of articles producers (101-1,000), being mainly SMEs.

The supply chain does not seem to include recyclers.

4.3.4. Explosive

According to information submitted in the SVHC public consultation (RCOM, 2012), there are 9 factories in the EU that produce some millions of detonators each year.

Based on comments submitted during the 6th recommendation public consultation it seems that in some cases lead tetroxide is supplied as such for the production of the explosive items (mixing with other components takes place at the production site) while in other cases, formulators may be involved (ComRef, 2015).

4.3.5. Paints and other anti-corrosion products⁹

No detailed information is available on the supply chain for paints and anti-corrosion products, however, it can be reasonably assumed that it consists of formulators and end-users. Considering the low tonnage involved and the specificity of the applications, the number of formulators is likely to be limited.

The number of end-users is likely to be high and can involve small actors (e.g. professional workers in the case of paint). Airlines companies but also independent MRO (maintenance, repair and overhaul) services are involved in the case of anti-corrosion products.

⁹ E.g. as used in the aerospace industry

5. References

ComRef (2015): "Comments and references to responses" document for orange lead (lead tetroxide). Document compiling comments and references to respective answers from commenting period 01/09/2014 –01/12/2014 on ECHA's 6th draft 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_lead_tetroxide_en.pdf

ECHA (2015): Orange lead (lead tetroxide). ECHA's dissemination website on registered substances. Accessed on 1 June 2015.

<http://echa.europa.eu/search-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 orange lead (lead tetroxide) as a Substance of Very High Concern.

<http://echa.europa.eu/documents/10162/f1279a45-27c1-4071-b37e-c502d0796ef3>