1 September 2014

Draft background document for orange lead (lead tetroxide)

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: 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 authorisation[1]. 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

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. Some uses appear not to be in the scope of authorisation, such as use as intermediate in manufacture of certain

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

pigments and PTC / piezoelectric ceramics. The volume used in glass and frits is taken into account when allocating the volume score. It is recognized that the intermediate/non-intermediate status of these uses is a complex issue, and stressed that this 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). It is further noted that whether or not the use in glass and frits is taken into account does not ultimately change the volume score.

Taking into account the volume corresponding to uses appearing to fall outside the scope of authorisation based on registrations and further information sources, the volume in the scope of authorisation is estimated to be in the range of 10,000 - <100,000 t/y.

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). There might potentially also be professional use in explosives as according to the information from industry (RCOM, 2012) the explosives are used in civil works. In addition, according to the information from the industry (RCOM, 2012) the substance can be used in graphite containing dispersion pastes, machining, scraping compounds, friction breaks. There is no further information on these uses and therefore it is not possible to conclude whether the uses take place at industrial sites or whether some of them could be carried out by professional workers.

The lead registrant and most of the member registrants have recently updated their registrations and they have removed the consumer use of artists' paints[2] containing lead tetroxide from their dossiers and CSR. Furthermore, the International Lead Association has informed that the use in artists' paints is an obsolete use and the lead registrant has asked the member registrants to update their dossiers. There are some members who have not yet 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.

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

2.4. Conclusions and justification

Verbal descriptions and Scores			Total Score
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)
Orange lead (lead tetroxide) is classified as toxic for reproduction 1A meeting the criteria 57(c). Score: 1	The amount of orange lead (lead tetroxide) used in the scope of authorisation is in the range of 10,000 - <100,000 t/y. 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[3]. Refined score: 12	28

[2] This use is derogated from the restriction to supply CMR substances on their own or in mixtures to the general public.
[3] There is still some uncertainty on whether the substance might still be used by consumers (see section 2.3 for more information). However, that uncertainty does not seem to justify a higher score than resulting from the other refinements.

Conclusion

On the basis of the prioritisation criteria, orange lead (lead tetroxide) received high priority among the substances in the Candidate List (refer to link to the prioritisation results above). Therefore, it is proposed to recommend orange lead (lead tetroxide) for inclusion in Annex XIV.

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).

Lead tetroxide has several different uses in a range of EU industries. The production of lead-acid batteries represents the main use of lead tetroxide since it represents over 80% of its total use based on information from the industry (RCOM, 2012). The use of lead tetroxide in crystal, specialty glass and frits comprises most of the rest of the relative share, and all the other uses represent less than 1% of the total volume (RCOM, 2012). However, as the total EU tonnage is high (10,000 - <100,000 t/y), the tonnage corresponding to some of the uses representing low relative share may still be in the range of tens or hundreds of tons per year.

The estimated volumes corresponding to different uses of lead tetroxide in the scope of authorisation based on the information from the registrations and from the industry during the SVHC public consultation (RCOM, 2012) are given below:

- in lead acid battery production: it is used to make a battery paste for certain types of positive battery plates used in the production of automotive and industrial batteries (above 30,000 t/y);
- as an accelerator/cross linker for rubber compounds used for specific article applications such as hoses and damping elements in the automotive sector (< 20 t/y)
- in delay elements of detonators in explosives used in civil works and mining (5-10 t/y);
- as pigment in anti-corrosive paints
- in adsorbents (unknown tonnage)

Furthermore, uses which may be in the scope of authorisation include[4]:

- in production of domestic glass (which includes crystal glass), and Special Glass (e.g. radiation shielding glass) (less than 3,000 t/y);
- in manufacture of frits (less than 5,000 t/y);

In addition, during the SVHC public consultation industry stated that < 500 t/y of lead tetroxide can be used in graphite containing dispersion pastes, machining, scraping compounds and friction brakes (RCOM, 2012).

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

Use in the production of batteries

According to information from the industry (RCOM, 2012,), in lead acid battery production lead tetroxide is used together with lead monoxide in the production of battery pastes and they are transformed in the course of the battery production process into pentalead tetraoxide sulphate and tetralead trioxide sulphate, and then ultimately into lead metal (Pb) and lead dioxide (PbO_2). The latter two substances are the lead-based active substances present in the battery. Chemical reactions for lead tetroxide occur throughout the battery production process and when the battery is charged the substance has fully reacted and only some residual

concentrations remain in the final article (further details on battery production available in ILA and EUROBAT comments - RCOM, 2012).

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 lead tetroxide used in batteries is used in industrial batteries (RCOM, 2012). Key countries for lead-based battery manufacture in Europe include France, Germany, Italy, Spain, Poland, the Czech Republic, Portugal and the UK.

Use in the manufacture of rubber

Lead tetroxide 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. Industry indicates that lead tetroxide is used in the production of rubber at 17 European sites located in Germany, the Czech Republic, Slovakia and Greece. (RCOM, 2012).

Use in explosives

The use of lead tetroxide in explosives is registered. According to information from the industry (RCOM, 2012), the substance is used in delay elements of detonators. The explosives are mainly used in civil works and mining, but also use in other applications including safety systems and aerospace sector is mentioned (RCOM, 2012).

Use in adsorbents and paints

Use of lead tetroxide in paints is registered, and during the SVHC public consultation (RCOM, 2012) industry stated that it is used as a pigment in anti-corrosive paints. Based on the registrations lead tetroxide is also used in adsorbents however there is little further information available on this use.

Use in the production of glass

Lead tetroxide is used in the production of domestic and special glass. The EU glass industry represents ca. 1,200 companies (including SMEs to multinationals). Special glass represents roughly 2% of the total EU glass production. In the manufacture of special glass lead tetroxide is used for a wide variety of glasses, e.g. lead protection glass, lead ophthalmic glass, optical glasses, lead flint glass, nuclear shielding protection windows/blocs. According to information from the industry (RCOM, 2012) lead tetroxide is the source of lead, and is used to achieve protection against gamma radiation. Lead tetroxide is required for producing glass that allows safe use of modern medicine (x-ray application) and safe use of nuclear power supply. Key countries for glass manufacture are Austria, Belgium, Czech Republic, France, Germany, Italy, Poland, and Spain (RCOM, 2012).

Use in the manufacture of frits

Lead tetroxide is used in the manufacture of frits which are then used for preparation of ceramic glazes. During the process lead tetroxide is incorporated into a complex matrix, and the substance as such is not present in the frits. During the SVHC public consultation (RCOM, 2012), industry stated that lead is used to give some specific properties to the frits, e.g. to ensure a smooth surface by healing the pin-holes in the glaze during the firing stage, to allow the glazes to be fired at lower temperatures and to enhance the colours used for decoration. According to information from the industry (RCOM, 2012), frits are not manufactures at the same sites as the ceramic articles. It is estimated that there are around 60 installations in the EU, mostly in Spain and Italy, manufacturing frits for glazes and enamels, though this figure could include those manufacturing frits from other substances than lead tetroxide (RCOM,

2012). The lead-containing frits are widely used in the ceramics sector for the production of roof tiles, wall and floor tiles, sanitary ware, and table and ornamental ware.

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 XIV[5]*. 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 orange lead (lead tetroxide)) 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 orange lead (lead tetroxide) as a Substance of Very High Concern.
http://echa.europa.eu/documents/10162/f1279a45-27c1-4071-b37e-c502d0796ef3

[5] Document can be accessed at
http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf