

18 November 2015

Draft background document for lead monoxide

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 lead monoxide 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.

Contents

1. Identity of the substance	2
2. Background information for prioritisation	2
2.1. Intrinsic properties	2
2.2. Volume used in the scope of authorisation.....	2
2.3. Wide-dispersiveness of uses	2
2.4. Further considerations for priority setting.....	3
2.5. Conclusions and justification.....	3
3. Background information for the proposed Annex XIV entry	4
3.1. Latest application and sunset dates	4
3.2. Review period for certain uses	4
3.3. Uses or categories of uses exempted from authorisation requirement	4
4. Further information on uses	5
4.1. Main (sector of) uses and relative share of the total tonnage	5
4.2. Further details on the type of applications and/or functions per use.....	6
4.3. Structure and complexity of supply chains.....	7
5. References	10

1. Identity of the substance

Chemical name: Lead monoxide
EC Number: 215-267-0
CAS Number: 1317-36-8
IUPAC Name: Lead monoxide

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

Lead monoxide 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 lead monoxide manufactured and/or imported into the EU is according to registration data above 100,000 t/y (approx. 540,000 t/y according to information submitted in the public consultation on the 6th draft A.XIV recommendation (ComRef, 2015)).

Part of the volume is for uses that appear not to be in the scope of authorisation, such as uses as intermediate in the manufacture of PVC stabilisers, certain pigments, explosives, technical ceramics, frits and glass (including Lead special glass and Lead crystal glass) as well as some uses as laboratory reagent and in chemical analysis. Based on information provided during the public consultation on 6th draft recommendation, the share of the total tonnage for these uses is estimated at ~6.5%. It is recognised that the intermediate/non-intermediate status of some of these uses is a complex issue (e.g. in the manufacture of glass and frits), 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).

Therefore, in conclusion, the volume in the scope of authorisation is estimated to be in the range of 100,000 - 1,000,000 t/y based on registrations and further information.

2.3. Wide-dispersiveness of uses

Registered uses of lead monoxide which appear to be in the scope of authorisation include uses

¹ Document can be accessed at

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

at industrial sites (e.g. production of batteries and rubber, use in adsorbents and catalysts) (ECHA, 2015).

In addition, according to the information submitted during the public consultation on the 6th draft recommendation, the substance is also used for surface treatment (plating) and in lubricant/corrosion inhibitor products in the aerospace industry (ComRef, 2015).

Professional uses as laboratory reagent and in chemical analysis are registered and the information provided indicates that the conditions for the generic exemption for SRD may not always be met (based on the tonnage for that use). However, based on the information provided in registrations and during the public consultation on the 6th draft recommendation it appears that the use may rather fulfil the description of an industrial use (use limited to industrial facilities and does not seem to be widespread).

Finally, according to registrations the substance is used in articles (e.g. rubber articles).

Some uses are/have been reported 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.

The lead registrant and most of the member registrants have updated their registrations in April - June 2014. They have, inter alia, removed the professional and consumer use in paints and pigments (e.g. artists' paints) from their registrations. There are some members who have not updated their registration and the professional and consumer uses in paints (and professional use of adsorbents) remain in their dossiers. Other members have updated their dossiers and kept these uses. However, all these members refer to the lead registrant's CSR which no longer supports these uses. No own CSRs have been received from these members.

2.4. Further considerations for priority setting

It appears that lead monoxide is used in similar applications (batteries) with orange lead (lead tetroxide), pentalead tetraoxide sulphate and tetralead trioxide sulphate. 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)		
Lead monoxide is classified as toxic for reproduction 1A meeting the criteria of Article 57(c) Score: 1	The amount of lead monoxide used in the scope of authorisation is > 10,000 t/y Score: 15	Lead monoxide is used at industrial sites. Initial score: 5 Furthermore, the substance is used in articles in volumes > 10 t/y (e.g. rubber articles) Refined score: 7	23	Grouping of lead monoxide with other lead substances used in batteries

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, lead monoxide receives priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise lead monoxide 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 inclusion in Annex XIV that are normally assigned in a recommendation. Lead monoxide has been considered to be placed in the same slot with the other lead substances in this draft recommendation. Lead substances (including lead monoxide) 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 lead monoxide.

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 lead monoxide 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 lead monoxide for PPORD.

² 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 lead monoxide manufactured and/or imported into the EU is according to registration data above 100,000 t/y (approx. 540,000 t/y according to information submitted in the public consultation on the 6th draft A.XIV recommendation (ComRef, 2015)).

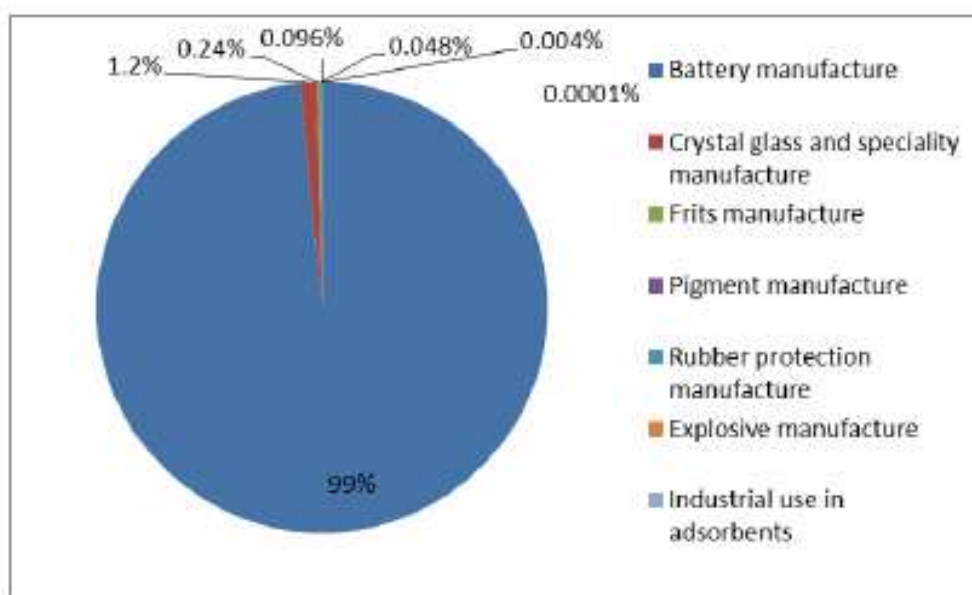
Lead monoxide has several uses in a range of EU industries. Based on information from registration dossiers and information provided by the Lead (Pb) Reach Consortium³ during the public consultation on the draft 6th recommendation (ComRef, 2015), the uses can be summarised as follow:

- the production of automotive and industrial lead acid batteries represents the main use of lead monoxide since it represents ~94% of its total use;
- the (intermediate) uses of lead monoxide in manufacture of lead based PVC stabilisers comprises most of the rest of the relative share (~5%) (though the use of these stabilisers is being phased out due to an industry voluntary commitment);
- other (intermediate) uses include glass manufacture (1.1%), frits manufacture (0.23%), ceramics and explosive manufacture (0.003%).
- the use in the rubber production which account for <200 t/y according to the Lead (Pb) Reach consortium, up to ~600 t/y based on other information provided during the 6th recommendation public consultation;
- the use in adsorbents (<50 t/y) and catalysts;
- use as laboratory reagents and in chemical analysis (low tonnage).

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

The figure below presents the end-use pattern of lead monoxide, as defined by the lead registrant in a recent update of its registration dossier (March 2015). It is noted that the (intermediate) use in the manufacture of PVC stabilisers is not reported anymore (suggesting that the volume for that use has significantly decreased).

³ representing 5 of the lead monoxide registrants, ~80 companies and 12 industry associations representing the predominant uses of lead monoxide



4.2. Further details on the type of applications and/or functions per use⁴

4.2.1. Battery production

In lead acid battery production, lead monoxide is used in the production of battery pastes. (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 approximately one third of the tonnage of lead monoxide used in batteries is used in industrial batteries and the remaining two thirds in automotive 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

Several uses of lead monoxide in the rubber industry have been reported which include: use as antioxidant especially for use in contact with acids and/or steam (e.g. in rubber rollers, valves and accessories); use as vulcanizing agent (in hoses); use as adhesion promoter and corrosion inhibitor (e.g. in steel cable conveyor belts); use to reduce water absorption in membranes (RCOM, 2012). Lead monoxide is also used in specific applications such as cable insulation and sheathing where specifications for electrical performance in wet conditions need to be fulfilled (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

⁴ The section is limited to uses likely to be in the scope of authorisation

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. Adsorbent / catalyst

The use of lead monoxide in adsorbent is reported in registrations. One company commenting during the public consultation on the draft 6th recommendation reported use of a low quantity (<50t/y) in the removal of arsine and sulphur compounds from hydrocarbon streams (e.g. cracked gases) (ComRef, 2015). The Lead (Pb) Reach consortium commenting on this use confirmed the low tonnage (ComRef, 2015).

The comments received on the use in catalysts relate to the special use of lead acetate where lead monoxide could be formed in the catalyst (e.g. Lindlar catalyst) (ComRef, 2015).

4.2.4. Anti-corrosion and lubricant products

Lead monoxide is part of formulations used in aerospace and defence industry to provide lubrication and corrosion protection on critical aerospace products where the technical requirements are significantly demanding. Dry film lubricants utilise lead monoxide due to its thermal stability and low coefficient of friction in temperatures up to 650°C. Specialty uses include rings, seals and bearing races (ComRef, 2015).

4.2.5. Surface treatment

Use of lead monoxide for surface treatment (plating) is reported in comments received during the public consultation on the draft 6th recommendation (ComRef, 2015) for localized and selective applications (e.g. in the manufacture of bearings for equipment such as larger engines and compressors). The treatment can be required at production stage or at maintenance stage for repair purposes. The Printing, Oil & Gas, Marine, Aerospace and Automotive industries are reported to rely on this surface treatment activity (ComRef, 2015).

4.3. Structure and complexity of supply chains

Detailed information on the structure and complexity of supply chains involved in the use of lead monoxide 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 consultations⁵:

- 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
- AEA (European Association of Airlines)
- ACEA (European Automobile Manufacturers' Association)

Comments were also received from glass, frits, ceramics, crystal, lead stabilisers and explosives associations⁶ which uses of lead monoxide were claimed as intermediate. Based on

⁵ Comments submitted do not necessarily relate to supply chain description

⁶ 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, European semi-conductor industry association, FEEM (Federation of European Explosives Manufacturers)

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 58 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 oxides produced in EU, out of the battery industry which produces lead oxide for internal consumption in battery manufacturing process.

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

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 represents 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 equipment to battery manufacturers, and Battery Systems Integrator Members.

According to information provided by EUROBAT during the SVHC public consultation (RCOM, 2012) ~93% of the lead monoxide used in the battery industry is produced by the battery industry itself. The rest is purchased directly from lead oxide manufacturers operating in the EU.

Based on registration information complemented by information provided during public consultations (ComRef, 2015; RCOM, 2012), it appears that the manufacture of lead monoxide, the production of battery paste and the production steps leading to the final batteries often take place at the same plant. Therefore, it is assumed that the supply chain is in most cases very short and does not involve formulators.

Europe counts many battery production sites (> 50 sites). The production process is likely to be similar in the different plants.

Key countries for lead-based battery manufacture in Europe include the Czech Republic, France, Germany, Italy, Spain, Poland and the United Kingdom.

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 monoxide is used as additive in rubber materials and further used for specific article applications. These articles are used by a number of sectors including: chemical industry; gas

pipe installations; mining industry; automotive industry; cement industry; power plants; ports and inflatable structures manufacturers.

ETRMA (the European Tyre & Rubber Manufacturers' Association) indicates that lead monoxide is 'used in rubber' at 17 European sites located in Germany, the Czech Republic, Slovakia and Greece (ComRef, 2015).

ETRMA further indicates that 80% of rubber companies using lead oxides are represented by SMEs (RCOM, 2012). In the automotive industry there may be between 101-1,000 downstream automobile component manufacturers using the associated rubber products.

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

The supply chain does not seem to include recyclers.

4.3.4. Adsorbent / catalyst

The uses of lead monoxide in applications such as adsorbents or catalysts seem to be limited to specific industrial applications. The supply chain is likely to be short and not to involve many actors.

4.3.5. Anti-corrosion and lubricant products

According to comments received during the public consultation on the 6th draft recommendation, lead compounds are widely used within the aerospace industry for maintenance of existing fleets (even though the tonnage for those uses is expected to be low).

It can be reasonably assumed that the supply chain of mixtures containing lead oxide 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 (involving e.g. the airlines companies but also independent MRO (maintenance, repair and overhaul) services in Europe).

4.3.6. Surface treatment

Use of lead monoxide for surface treatment (plating) is reported for localized and selective applications (e.g. in the manufacture of bearings for equipment such as larger engines and compressors). However, many sectors are reported to rely on this surface treatment activity (Printing, Oil & Gas, Marine, Aerospace and Automotive industries) (ComRef, 2015). Moreover, it is mentioned that treatment can be required at production stage or at maintenance stage for repair purposes. Therefore, it can reasonably be assumed that many small actors may be involved in this activity.

5. References

- ComRef (2015): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 01/09/2014 – 01/12/2014 on ECHA's proposal to include lead monoxide 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_lead_monoxide_en.pdf
- ECHA (2015): Lead monoxide. 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 lead monoxide as a Substance of Very High Concern.
<http://echa.europa.eu/candidate-list-table/-/substance/2427/search/215-267-0/term>