

1 September 2014

Draft background document for acetic acid, lead salt, basic

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: Acetic acid, lead salt, basic
EC Number: 257-175-3
CAS Number: 51404-69-4
IUPAC Name: Lead(2+) hydroxide acetate (1:1:1)

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

Acetic acid, lead salt, basic was identified as a Substance of Very High Concern (SVHC) According to article 57 (c) as it is covered by Index number 082-001-00-6 in Regulation (EC) No 1272/2008 and classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) 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 acetic acid, lead salt, basic manufactured and/or imported into the EU is

¹ Document can be accessed at

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

according to registration data >1 t/y. Some uses appear not to be in the scope of authorisation, such as use as intermediate in manufacture of chemicals and use as laboratory chemical in scientific research and development. The use in formulation of laboratory chemicals with the intention to supply them for SRD purposes might potentially also fall outside the scope of authorisation. However, discussions on this issue are ongoing between the Commission and the Member State Competent Authorities.

Taking into account the volume corresponding to those uses, based on information from registrations, the volume in the scope of authorisation is estimated to be in the range of 1 - <10 t/y.

2.3. Wide-dispersiveness of uses

Registered uses of acetic acid, lead salt, basic in the scope of authorisation include uses at industrial sites (formulation and use in coatings, paints, thinners, paint removers, fillers, putties, plasters, modelling clay, ph-regulators, flocculants, precipitants and neutralisation agents). Furthermore, according to information from the SVHC public consultation (RCOM, 2012), the substance is also used in the production of primary explosives and in explosive detonators for defence applications. Therefore, professional use of the substance in explosive detonators could be assumed. Finally, the substance might be used in articles produced during several of the above listed uses, e.g. use of paints, coatings and fillers.

2.4. Further considerations for priority setting

Acetic acid, lead salt, basic is prioritised for inclusion in the draft 6th recommendation together with lead monoxide and lead tetroxide. This is as it appears that they are used in similar applications (e.g. paints). However, it has not been assessed whether the precise 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)		
Acetic acid, lead salt, basic is classified as toxic for reproduction 1A meeting the criteria 57(c) Score: 1	The amount of acetic acid, lead salt, basic used in the scope of authorisation is in the range of 1 - <10 t/y. Score: 3	Acetic acid, lead salt, basic is used at industrial sites. Initial score: 5 Furthermore, the substance may be used in articles and by professional workers in uses that may also be in the scope of authorisation. Refined score: 7	11	Acetic acid, lead salt, basic is prioritised for inclusion in the draft 6th recommendation together with lead monoxide and lead tetroxide due to use in similar applications.

Conclusion

On the basis of further considerations (grouping with lead monoxide and lead tetroxide), it is

proposed to recommend acetic acid, lead salt, basic 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).

Based on registration information, the substance is used at industrial sites in products such as pH-regulators, flocculants, precipitants, neutralisation agents, paints, coatings, thinners, paint removers, fillers, putties and plasters. The sectors of use reported in the registrations include manufacture of chemicals, formulation and packaging of mixtures and production of computer, electronic/optical products and electrical equipment. There is no further information on these applications or other industry sectors where they are used.

According to information communicated by the industry during the SVHC public consultation (RCOM, 2012), acetic acid, lead salt, basic is used in a mixture or solution as an analytical standard in the analysis of sugar according to Horne by industrial and professional users in laboratories. This use is likely to be exempted from the authorisation requirement due to the generic exemption on use in scientific research and development. The use in explosives is not registered but during the SVHC public consultation (RCOM, 2012), industry stated that the substance is used in the production of primary explosives and explosive detonators in aerospace and defence applications. There is no further information available for these uses.

Based on registration information, there is a low number of manufacturers/importers of the substance in the EU. There is no information available on the number or geographical distribution of other actors involved in the supply chain.

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 XIV². 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 acetic acid, lead salt, basic) are assigned to the 2nd LAD slot due

² Document can be accessed at http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf

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 acetic acid, lead salt, basic as a Substance of Very High Concern. <http://echa.europa.eu/documents/10162/4164257b-820a-4254-83b3-d6a6947c6fe2>