

1 September 2014

Draft background document for silicic acid, lead salt

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: Silicic acid, lead salt
EC Number: 234-363-3
CAS Number: 11120-22-2
IUPAC Name: Lead(2+) silicate

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

Silicic acid, lead salt 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 silicic acid, lead salt manufactured and/or imported into the EU is according to registration data in the range of 100 - <1,000 t/y. There is no available information indicating

¹ Document can be accessed at

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

that the use of the substance in glass production would be intermediate use. Therefore, all tonnage appears to be in the scope of authorisation.

2.3. Wide-dispersiveness of uses

Registered uses of silicic acid, lead salt in the scope of authorisation appear to include use at industrial sites in the production of lead crystalware. Registration information is submitted in accordance with Art. 10 of REACH and there is no information indicating that the use is an intermediate use.

Furthermore, according to registrations the substance is used in articles (lead crystalware). However, it appears that the release of the substance from these articles might be negligible as the substance is bound into a matrix.

2.4. Further considerations for priority setting

Silicic acid, lead salt 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 (production of glass). 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)		
Silicic acid, lead salt is classified as toxic for reproduction 1A meeting the criteria 57(c) Score: 1	The amount of silicic acid, lead salt used in the scope of authorisation is in the range of 100 - <1,000 t/y. Score: 9	Silicic acid, lead salt is used at industrial sites. Score: 5	15	Silicic acid, lead salt is prioritised for inclusion in the draft 6th recommendation together with lead monoxide and lead tetroxide due to use in a similar application.

Conclusion

On the basis of further considerations (grouping with lead monoxide and lead tetroxide), it is proposed to recommend silicic acid, lead salt for inclusion in Annex XIV.

3. Further information on uses

Based on registration information, there is a low number of manufacturers/importers of silicic

acid, lead salt in the EU, and it appears that the substance might be used in a small or medium number of sites.

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 silicic acid, lead salt) are assigned to the 2nd LAD slot due to the potentially high number of uses and overall complexity of supply chain.

² Document can be accessed at

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