

**1 July 2015**

## **Background document for acetic acid, lead salt, basic**

### **Document developed in the context of ECHA's 6<sup>th</sup> 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 authorisation<sup>1</sup>. 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](http://echa.europa.eu/documents/10162/13640/prioritisation_results_6th_rec_en.pdf).

*The prioritisation results of the substances included in the draft 6<sup>th</sup> recommendation have been updated as necessary after the public consultation. The updated results are available at*  
[http://echa.europa.eu/documents/10162/13640/updated\\_prioritisation\\_results\\_6th\\_axiv\\_rec\\_en.pdf](http://echa.europa.eu/documents/10162/13640/updated_prioritisation_results_6th_axiv_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.

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<sup>1</sup> Document can be accessed at  
[http://echa.europa.eu/documents/10162/13640/gen\\_approach\\_svhc\\_prior\\_in\\_recommendations\\_en.pdf](http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)

## 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 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.

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

In the priority setting for the draft 6<sup>th</sup> recommendation, acetic acid, lead salt, basic was grouped with orange lead as it appeared that they are used in similar applications (e.g. paints). However, it was not 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.

Based on the information submitted in the public consultation on the different water solubilities and different functions of these substances in paints (ComRef, 2015), the inter-substitution of acetic acid, lead salt, basic and orange lead seems unlikely. Therefore, there may not be sufficiently strong reasons to group these substances.

## 2.5. Conclusions and justification

Verbal descriptions and Scores			Total Score (= IP + V + WDU)
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

### Conclusion

Other Candidate List substances assessed in the sixth recommendation round receive higher priority than acetic acid, lead salt, basic based on the Art. 58(3) prioritisation criteria (see link to the prioritisation results above). Furthermore, based on the information submitted in the public consultation, there do not appear to be sufficiently strong reasons to group the substance with other higher priority lead substances. Consequently, acetic acid, lead salt, basic is not included in ECHA's final 6<sup>th</sup> recommendation for inclusion of substances in Annex XIV. The substance will be reassessed for priority in future recommendation rounds.

## 3. Further information on uses

In addition to the registration information, further details on uses can be found in comments provided during the public consultations on the draft 6<sup>th</sup> A.XIV recommendation (ComRef, 2015) and on the SVHC identification (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.

In the public consultations on SVHC identification and on the draft 6<sup>th</sup> A.XIV recommendation, further information on some uses of the substance in the scope of authorisation was submitted. Industry commented that the substance is used in a purification process during the manufacture of an active pharmaceutical ingredient (ComRef, 2015). This use seems to be in the scope of authorisation. It was also commented that the substance can be used as a mordant or drying agent in paints and a fixing agent in dyes (ComRef, 2015). Furthermore, 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 this use.

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 XIV<sup>2</sup>. The draft Annex XIV entries for substances included in the 6<sup>th</sup> recommendation are available at [http://echa.europa.eu/documents/10162/13640/6th\\_axiv\\_recommendation\\_july2015\\_en.pdf](http://echa.europa.eu/documents/10162/13640/6th_axiv_recommendation_july2015_en.pdf).*

*[This section is not relevant as the substance is not included in the final 6<sup>th</sup> recommendation.]*

## 5. References

ComRef (2015): "Comments and references to responses" document for acetic acid, lead salt, basic. 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\\_acetic\\_acid\\_lead\\_salt\\_en.pdf](http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_acetic_acid_lead_salt_en.pdf)

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>

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<sup>2</sup> Document can be accessed at  
[http://echa.europa.eu/documents/10162/13640/draft\\_axiv\\_entries\\_gen\\_approach\\_6th\\_en.pdf](http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf)