

18 November 2015

Draft background document for sodium perborate; perboric acid, sodium salt

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 sodium perborate; perboric acid, sodium salt 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	3
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
3.3.1. Exemption under Article 58(2)	4
3.3.2. Exemption of product and process oriented research and development (PPORD)	4
4. Further information on uses	4
5. References	6

1. Identity of the substance

Chemical name: Sodium perborate; perboric acid, sodium salt
EC Number: 239-172-9, 234-390-0
CAS Number: -
IUPAC Name: Sodium perborate

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

Sodium perborate; perboric acid, sodium salt 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 1B, (H360Df: "May damage the unborn child. Suspected of damaging fertility"), and was therefore included in the Candidate List for authorisation on 16 June 2014, following ECHA's decision ED/49/2014.

2.2. Volume used in the scope of authorisation

The amount of sodium perborate; perboric acid, sodium salt manufactured and/or imported into the EU is according to registration data in the range of 10,000 - 100,000 t/y. Based on information from industry received during the preparation of the Annex XV report (2014) and as documented therein, the volume has decreased over the past years and was estimated to be < 40,000 t/y in 2013.

Some uses appear to be outside the scope of authorisation, such as use as laboratory chemical in scientific research and development (SRD), use in detergents and bleaching products below the specific concentration limit (SCL) as well as use in cosmetic products.

Based on information from registration and from industry submitted during the SVHC public consultation (RCOM, 2014), almost the complete volume used in the EU corresponds to uses appearing to fall in the scope of authorisation. Therefore, it is estimated that the volume in the scope of authorisation is > 10,000 t/y.

2.3. Wide-dispersiveness of uses

Registered uses of sodium perborate; perboric acid, sodium salt (ECHA, 2015) in the scope of authorisation include uses at industrial sites (formulation of mixtures) and uses by professional workers (use in detergents and bleaching products above SCL).

¹ Document can be accessed at

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

2.4. Further considerations for priority setting

Based on structural similarities it appears that sodium perborate; perboric acid, sodium salt could potentially replace other boron compounds already recommended for inclusion in Annex XIV. Although currently not registered, there is another borate substance on the Candidate List (sodium peroxometaborate) that might have the potential to be used in similar applications.

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)		
Sodium perborate; perboric acid, sodium salt is classified as toxic for reproduction 1B meeting the criteria of Article 57(c) Score: 1	The amount of sodium perborate; perboric acid, sodium salt used in the scope of authorisation is > 10,000 t/y Score: 15	Sodium perborate; perboric acid, sodium salt is used at industrial sites and by professional workers. Score: 10	26	Grouping with sodium peroxometaborate (CL) and with other boron substances included in the 6th A.XIV Recommendation.

Conclusion

On the basis of the prioritisation criteria further strengthened by the grouping considerations, sodium perborate; perboric acid, sodium salt receives priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise sodium perborate; perboric acid, sodium salt 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.

² Document can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.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 **21 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. Sodium perborate; perboric acid, sodium salt has been considered to be placed in the same slot with sodium peroxometaborate in this draft recommendation. These two boron substances are assigned to the 2nd LAD slot. As the number of different uses seems limited, it is assumed that preparation of an application for authorisation may require less time when compared with the lead compounds (proposed to be placed in the 3rd slot) due to their higher (overall) supply chain complexity.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for sodium perborate; perboric acid, sodium salt.

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 sodium perborate; perboric acid, sodium salt 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 sodium perborate; perboric acid, sodium salt for PPORD.

4. Further information on uses

According to the Annex XV report (2014), perboric acid, sodium salt (PBS)³ is used in chemical mixtures for bleaching and cleaning agents. According to AISE (International Association for Soaps, Detergents and Maintenance Products), 96% of the PBS used in detergent products in 1999 was used in heavy duty bleach-containing powders or tablets, and 3% in machine dishwashing detergents (powders or tablets). Further uses mentioned are denture cleansers

³ Part II of the Annex XV report (2014) refers to "perboric acid, sodium salt (PBS)" which covers the following EC numbers: 239-172-9, 234-390-0, 231-556-4.

and stain removers. According to the Annex XV report (2014) the concentrations of PBS in the detergents products and in bleaching agents are between 4 – 25 % and 5 – 50 %, respectively.

The consumer use of bleaching products and detergents is registered but the derogation for detergents from the restriction on the supply of CMRs to the general public expired in June 2013. Therefore, consumer uses of the substance in these products above the specific concentration limit are not allowed anymore.

The supply chain consists of formulators and end-users. The uses seem to be limited to washing and cleaning products. A high number of diverse professional users is expected to be involved.

Over the last years the volume of PBS has to a large extent decreased (i.e. European production in 2010 reduced to about 90 % of that from 1997) due to replacement by sodium percarbonate. Further information can be found in the Annex XV report (2014).

5. References

Annex XV report (2014): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Sodium perborate; perboric acid, sodium salt. Submitted by Denmark, March 2014.

<http://echa.europa.eu/documents/10162/ffdb7fc4-0e71-4292-988a-3f6f46200c38>

ECHA (2015): Sodium perborate; perboric acid, sodium salt. ECHA's dissemination website on registered substances as of 1 June 2015.

<http://echa.europa.eu/search-chemicals>

RCOM (2014): "*Responses to comments*" document. Document compiled by Denmark from the commenting period 03/03/2014 - 17/04/2014 on the proposal to identify sodium perborate; perboric acid, sodium salt as a Substance of Very High Concern.

http://echa.europa.eu/candidate-list-table/-/substance-rev/2383/del/200/col/staticField_-105/type/desc/pre/1/view