10 November 2016

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) was taken into consideration when finalising the recommendation and is reflected in the present document.

The background document also describes how ECHA has taken into account the MSC opinion.

Contents

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 authorisation[1]. 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*.

The prioritisation results of the substances included in the draft 7th recommendation have been updated as necessary after the public consultation. The updated results are available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft7threc_substances_feb2016_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. Comments submitted during the public consultation on the 7th draft recommendation also claim a constant decrease over the last years in the EU (ComRef, 2016).

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 public consultations on the SVHC identification and on the draft Annex XIV recommendation (RCOM, 2014; ComRef, 2016), 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.

[1] Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

More detailed information on the main uses and the relative share of the total tonnage is provided in Annex I.

2.3. Wide-dispersiveness of uses

Registered uses of sodium perborate; perboric acid, sodium salt (ECHA, 2016) 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).

More detailed information on uses is provided in Annex I.

2.4. Further considerations for priority setting

Based on structural similarities it appears that sodium perborate; perboric acid, sodium salt could potentially replace sodium peroxometaborate, another perborate compound in the Candidate List. Although sodium peroxometaborate is currently not registered, there is the potential that both substances could be used in similar applications.

2.5. Conclusion

Verbal descriptions and Scores			Total Score	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + 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

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, sodium perborate; perboric acid, sodium salt is recommended 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 XIV[2]. The draft Annex XIV entries that underwent public consultation are available at: *http://echa.europa.eu/documents/10162/13640/7th_recom_draft_axiv_entries_en.pdf* .

The final draft Annex XIV entries that ECHA recommends are available at: *https://echa.europa.eu/documents/10162/13640/7th_axiv_recommendation_november2016_en.pdf.*

3.1. Latest application and sunset dates

The LAD slots are set in 3-month intervals (normally 18, 21 and 24 months after inclusion in Annex XIV but more slots can be considered on a case-by-case basis). In its draft recommendation ECHA had seen 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 had been considered to be placed in the same slot with sodium peroxometaborate in the draft recommendation. These two perborate compounds were assigned to the 2nd LAD slot. As the number of different uses seems limited, it was assumed that the preparation of an application for authorisation may require less time when compared with the lead compounds (that were proposed to be placed in the 3rd slot) due to their higher (overall) supply chain complexity.

During the public consultation no comments were received that challenged the proposed transitional arrangements.

ECHA recommends the following transitional arrangements:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **21 months**
Sunset date (SSD):	18 months after LAD

3.2. Review period for certain uses

In its draft recommendation ECHA had seen no ground to include in Annex XIV any review period.

During the public consultation ECHA did not receive comments requesting upfront review period for certain uses.

ECHA therefore **does not propose to include in Annex XIV any review period** for sodium perborate; perboric acid, sodium salt.

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

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1. Exemption under Article 58(2)

In its draft recommendation, ECHA had not proposed any exemption for (categories of) 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.

During the public consultation ECHA did not receive requests for exemptions under Article 58(2).

ECHA therefore **does not 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)

In its draft recommendation ECHA had not proposed to include in Annex XIV any exemption from authorisation for the use of sodium perborate; perboric acid, sodium salt for PPORD.

During the public consultation ECHA did not receive requests for such type of exemption.

ECHA therefore **does not recommend exempting any use** of sodium perborate; perboric acid, sodium salt for **PPORD** from authorisation.

4. 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

ComRef (2016): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 18/11/2015 – 18/02/2016 on ECHA's proposal to include sodium perborate; perboric acid, sodium salt in its 7th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/7th_recom_comref_sodium_perborate_en.rtf

ECHA (2016): Sodium perborate; perboric acid, sodium salt. ECHA's dissemination website on registered substances. Accessed on 18 February 2016.

https://echa.europa.eu/search-for-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.

https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807df1ae

ANNEX I: 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 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. Comments received during the public consultation on the 7th draft recommendation referred to PBS and PCS[4] as the only sources of so-called solid hydrogen peroxide (ComRef, 2016).

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).

[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.
[4] Assumingly this refers to a substance with trade name "sodium percarbonate" (EC 239-707-6).