

1 September 2014

Draft background document for 1-bromopropane

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: 1-bromopropane; n-propyl bromide
EC Number: 203-445-0
CAS Number: 106-94-5
IUPAC Name: 1-bromopropane; n-propyl bromide

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

1-bromopropane 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, H360Fd ("May damage fertility. Suspected of damaging the unborn child.")², 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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http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

² There is a mistake in the entry for the substance in the CLP Regulation (EC) No 1272/2008, Annex VI, part 3, Table 3.1, indicating its classification as 'Repr. 1B, H360FD'. However, the correct hazard statement code is Repr. 1B, H360Fd.

2.2. Volume used in the scope of authorisation

The amount of 1-bromopropane (n-propyl bromide) manufactured and/or imported into the EU is according to registration data above 1,000 t/y.

The registered use as an intermediate in manufacture of chemicals appears not to be in the scope of authorisation. Furthermore, according to information from the industry (RCOM, 2012), the substance may also be used in some laboratory analyses but this use seems to fall outside the scope of authorisation due to the generic exemption on scientific development and research. Taking into account the volume corresponding to these uses – up to 69 % of the total EU volume based on information from the industry (RCOM, 2012) - the volume in the scope of authorisation is estimated to be in the range of 1,000 - <10,000 t/y.

2.3. Wide-dispersiveness of uses

Registered uses of 1-bromopropane (n-propyl bromide) in the scope of authorisation include uses at industrial sites (formulation and use as a solvent in mixtures for vapour degreasing and surface cleaning) and by professional workers (use as a solvent in mixtures for vapour degreasing and surface cleaning).

2.4. Further considerations for priority setting

Based on information from the industry received during the SVHC public consultation (RCOM, 2012), 1-bromopropane may be used to substitute trichloroethylene (already on Annex XIV) in vapour degreasing.

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)		
1-bromopropane is classified as toxic for reproduction 1B meeting the criteria 57(c) Score: 1	The amount of 1-bromopropane used in the scope of authorisation is in the range of 1,000 - <10,000. Score: 12	1-bromopropane is used at industrial sites and by professional workers. Score: 10	23	1-bromopropane may be used to substitute trichloroethylene (Annex XIV) in some of its uses.

Conclusion

On the basis of the prioritisation criteria and grouping considerations, 1-bromopropane received high priority among the substances in the Candidate List (refer to link to the prioritisation results above). Therefore, it is proposed to recommend 1-bromopropane for inclusion in Annex XIV.

3. Further information on uses

According to the registration information and information received during the public consultation on SVHC identification (RCOM, 2012), the substance is used as a solvent in surface cleaning and vapour degreasing of e.g. metal parts and printed circuit boards. Examples of sectors of use include the aerospace and defence industries (RCOM, 2012). Given the technical function of the substance there is no indication that the substance would be present in the final articles.

Based on registration information, there is a low number of manufacturers/ importers of 1-bromopropane in the EU. There is no information available on the number of sites where the substance is used but taking into account the total EU tonnage of the substance used in surface cleaning and degreasing and the maximum tonnage used per site according to the registration information, it can be assumed that the substance is used at a high number of sites (>100) in the EU.

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 XIV³. 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). 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. All substances can therefore not be set at the same LAD, however, the time differences between the LADs set out in a recommendation (i.e. 3-6 months) can be considered as minor compared to the total time reserved for the potential applicants to prepare their applications.

The time required for the preparation of application(s) for authorisation for 1-bromopropane may be relatively shorter than for other (groups of) substances prioritised for this recommendation, considering e.g. the number of uses and complexity of the supply chain.

Therefore the substance is assigned in the 1st slot.

³ Document can be accessed at:

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

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 1-bromopropane as a Substance of Very High Concern. <http://echa.europa.eu/documents/10162/b4bf4c88-a60e-4aec-a9db-e338f39b46ed>