

10 November 2016

Background document for trixylyl phosphate

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 trixylyl phosphate 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 are reflected in the present document.

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

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1. Identity of the substance

Chemical name: Trixylyl phosphate

EC Number: 246-677-8

CAS Number: 25155-23-1

IUPAC Name: Trixylyl phosphate

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.

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

Trixylyl phosphate 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, H360F ("May damage fertility") and was therefore included in the Candidate List for authorisation on 16 December 2013, following ECHA's decision ED/121/2013.

2.2. Volume used in the scope of authorisation

The amount of trixylyl phosphate (TXP) manufactured and/or imported into the EU is according to registration data above 100 t/y. Taking into account the information on volumes and uses reported in the registrations, it is estimated that the volume used in the scope of authorisation is in the range of 100-1,000 t/y.

2.3. Wide-dispersiveness of uses

Registered uses of trixylyl phosphate in the scope of authorisation include uses at industrial sites (formulation and use in lubricants, lubricant additives, greases, hydraulic fluids and metal working fluids, formulation and use in polymer mixtures and compounds in plastics production) and uses by professional workers (use in lubricants, lubricant additives, greases, hydraulic fluids and metal working fluids)(ECHA, 2016).

Furthermore, the substance is used in articles (plastic articles).

More detailed information on uses is provided in Annex I.

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

Trixylyl phosphate (TXP) and tris(2-chloroethyl) phosphate (TCEP, EC 204-118-5) both belong to the chemical group of organophosphate esters and are reported to be used as additive flame retardants and as plasticisers in polyvinyl chloride and polyurethane in literature (Annex XV report, 2013 and 2009; van der Veen and de Boer, 2012), indicating the possibility for use of TXP as substitute for TCEP in some of its uses. TCEP has already been included in Annex XIV, therefore grouping considerations apply.

2.5. Conclusion

| Verbal descriptions and Scores | | | Total Score (= IP + V + WDU) | Further considerations |
|---|--|---|---------------------------------|---|
| Inherent properties (IP) | Volume (V) | Wide dispersiveness of uses (WDU) | | |
| Trixylyl phosphate is classified as toxic for reproduction 1B meeting the criteria of Article 57(c) Score: 1 | The amount of trixylyl phosphate used in the scope of authorisation is in the range of 100-1,000 t/y Score: 9 | Trixylyl phosphate is used at industrial sites and by professional workers. Initial score: 10 Furthermore, the substance is used in articles in volumes >10 t/y. Refined score: 12 | 22 | Potential grouping with tris(2-chloroethyl) phosphate (TCEP, EC 204-118-5) already in Annex XIV |

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, trixylyl phosphate receives priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, **trixylyl phosphate 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 XIV². 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.

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

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 proposed that the LAD would be the date of inclusion of the substance in Annex XIV plus 21 months and the sunset date 18 months after the LAD. 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. Trixylyl phosphate was assigned to the 2nd LAD slot. The supply chain consists of various layers involving industrial and professional users. The substance is also incorporated into articles (article service life). There are different types of uses. It is assumed however 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.

During the public consultation a request from a company for a later sunset date was received to keep the focus on ongoing initiatives towards substitution instead of application for authorisation.

The current recommendation to include trixylyl phosphate in Annex XIV does not contradict the efforts done by the energy sector to substitute the substance. The efforts already made by the company to find alternatives for TXP will form an important part of any application for authorisation.

The MSC is of the opinion that no information has been provided that would challenge the suggested latest application date and sunset date.

Hence, in the light of the available information, 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 for trixylyl phosphate.

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

ECHA therefore **does not recommend to include in Annex XIV any review periods** for uses of trixylyl phosphate.

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 exemptions for (categories of) uses of trixylyl phosphate 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 any requests for exemptions for the substance.

ECHA therefore **does not recommend exemptions** for uses of trixylyl phosphate 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 trixylyl phosphate for PPORD.

During the public consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substance.

ECHA therefore **does not recommend exempting any use of** trixylyl phosphate **for PPORD** from authorisation.

4. References

- Annex XV report (2013): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Trixylyl phosphate. Submitted by Environment Agency Austria, August 2013.
<http://echa.europa.eu/documents/10162/e887aa86-ff8a-44be-9a31-ade0c8856a92>
- Annex XV report (2009): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Tris (2-chloroethyl) phosphate. Submitted by Environment Agency Austria, August 2009.
<http://echa.europa.eu/documents/10162/47b10d27-024d-47c1-9ad3-c3a6004daaa5>
- 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 trixylyl phosphate 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_trixylyl_phosphate_en.rtf
- ECHA (2016): Trixylyl phosphate. ECHA's dissemination website on registered substances. Accessed on 18 February 2016.
<https://echa.europa.eu/search-for-chemicals>
- van der Veen, I., de Boer, J. (2012): Phosphorus flame retardants: Properties, production, environmental occurrence, toxicity and analysis. Chemosphere, 88, pp. 1119-1153.
<http://dx.doi.org/10.1016/j.chemosphere.2012.03.067>

Annex I: Further information on uses

Trixylyl phosphate is manufactured/imported in the EU in volumes above 100 tonnes per year.

Based on registrations and further information from Annex XV and public consultations, the substance appears to be used in two main types of applications, further detailed below. Information on the volume breakdown per application has not been made available.

- Trixylyl phosphate (TXP) is used as functional fluid (fire resistant fluids, hydraulic fluids, lubricants, lubricant additives, grease products, metal working fluids). The supply chain for these products appears to involve formulators and industrial and professional end-users in a wide-range of sectors.
- TXP is also registered for the use as flame retardant and/or plasticiser in plastic production at industrial sites.

In the Annex XV report (2013) it is reported that TXP might be used in articles made of polyvinyl chloride (PVC), e.g. wire/cable and furniture made of artificial leather (PVC), available to consumers. In addition, use in polyurethane, thermoplastic elastomers, coatings, textiles, cellulosic resin and natural and synthetic rubber as well as for PVC flooring materials are mentioned. TXP seems to be used where high temperature performance is important or long term heat resistance such as in agricultural (greenhouse) film, or in automobile seating. However, these uses could not be confirmed by registration data.