SCREENING REPORT

TO ASSESS WHETHER THE USE OF TRIXYLYL PHOSPHATE IN ARTICLES SHOULD BE RESTRICTED IN ACCORDANCE WITH REACH ARTICLE 69(2)

Annex XIV entry	Substance name	Abbreviation	EC	CAS	Latest application date	Sunset date	Intrinsic property
47	Trixylyl phosphate	TXP	246-677-8	25155-23-1	27/11/2021	27/05/2023	Toxic for reproduction (Article 57c)

Source: https://echa.europa.eu/authorisation-list

CONTACT DETAILS:

EUROPEAN CHEMICALS AGENCY
P.O. BOX 400, FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU

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1. Conclusions

Following an assessment of the available evidence, ECHA considers that the use (or presence) of trixylyl phosphate (TXP) in articles poses a risk to human health that is not adequately controlled (see section 2 for more details).

The presence of TXP in articles, such as vehicles, domestic appliances, textiles and leather, and plastic and rubber articles, has the potential to lead to human exposure and consequently inadequately controlled risk.

Therefore, ECHA's view is that the requirements to prepare an Annex XV dossier for restriction (on all or selected) uses of TXP in articles under Article 69(2) are met. The timing of the restriction dossier development will be identified in the Restrictions Roadmap under the Chemicals Strategy for Sustainability[1], considering other priorities.

Given the similar structure and uses, ECHA recommends that such a restriction proposal also considers the risks from other organophosphorus flame retardants as specified in ECHA's regulatory strategy for flame retardants[2]. Therefore, based on a request by the European Commission, the scope of the restriction investigation may be extended to include other flame retardants (not currently on Annex XIV) and other endpoints, such as endocrine disruption (ED) or PBT, in addition to reprotoxicity.

Public call for evidence for TXP took place from 28th June 2023 to 9th August 2023. The information received from stakeholders (four companies) was reviewed and considered in the final version of this report.

2. Summary of findings

2.1. Identified uses

Based on the information gathered during the SVHC listing and recommendation for the inclusion of substances in Annex XIV, uses identified in the REACH registrations and information in the received applications for authorisation, substances in articles notifications (in accordance the Waste Framework Directive (SCIP database)[3]) and external databases, the uses of TXP include:

- vehicles
- plastic articles
- electric and electronic devices
- textiles and leather

Publicly available data suggests that TXP is used for various technical functions. However, concerning its use in articles, flame retardant appears the most prominent technical function. Reported article uses and sectors of use for TXP agree to a large extent with the

[1] Restrictions Roadmap under the Chemicals Strategy for Sustainability: DocsRoom - European Commission (europa.eu)

[2] ECHA' regulatory strategy for flame retardants: All news - ECHA (europa.eu)

[3] In accordance with the Waste Framework Directive (WFD), companies supplying articles containing substances on the Candidate List in a concentration above 0.1% w/w on the EU market have to submit information on these articles to ECHA, from 5 January 2021. The information provided is included in the SCIP database, i.e., Substances of Concern In articles as such or in complex objects (Products): https://echa.europa.eu/scip

general use of flame retardants, with construction (plastics), electronics and transport being the largest sectors. Besides the use as a flame retardant, TXP may be used in articles for other technical functions such as a plasticiser. While there is information on the use of TXP in articles, the tonnage of TXP used in articles is uncertain. Information received in the call for evidence indicates that TXP may be present in plastic articles and complex objects imported to European market.

ECHA has received only one application for authorisation for TXP[4]. This application for authorisation is not related to the production of articles. This information indicates that the uses of these substances in articles have been largely phased out in the EU.

No notifications for substances in articles in accordance with Article 7(2) of REACH[5] were submitted. The submissions of notifications in accordance with the Waste Framework Directive (SCIP database) indicate therefore that TXP is present in imported articles only, and most likely in volumes of less than one tonne of the substances per importer.

Following from its nature as an organic substance, and its use as a flame retardant, TXP is likely present in articles in concentrations between 5% to 25% depending on the material type e.g. polyvinylchloride (PVC) or polyurethane (PUR)[2]. Real concentrations can be lower or higher depending on the technical function, article type and material.

Information from the article categories where the TXP may be incorporated suggest that the articles containing TXP may have industrial, professional and consumer uses. In contrast, some information from registrations indicates that articles are used mainly by workers. Nonetheless, exposure to consumers from articles such as vehicle seating and general plastic articles cannot be excluded.

No information to contradict any of the information or conclusions above was received during the call for evidence.

2.2. Hazards, emissions/releases/exposure and risk

Information on hazards

TXP is included in Annex XIV based on its reprotoxic properties.

It should be noted, that according to ECHA's regulatory strategy for flame retardants and assessment of regulatory needs[6], TXP has been considered as a likely endocrine disruptor (ED) as well as a likely persistent, bioaccumulative and toxic (PBT) properties. Consequently, the potential ED and PBT properties of TXP should be clarified as they would affect the regulatory needs of the substance considering their non-threshold nature.

[4] Information on adopted opinions and submitted applications for authorisation can be found here: https://echa.europa.eu/applications-for-authorisation-previous-consultations. Information on submitted applications for authorisation currently under public consultation can be found here: https://echa.europa.eu/applications-for-authorisation-consultation

[5] Producers and importers have to notify ECHA the substances listed on the Candidate list which are present in their articles, if both the following conditions are met: i) the substance is present in their relevant articles above a concentration of 0.1% w/w; ii) the substance is present in these relevant articles in quantities totalling over 1 tonne per year. Companies have to notify no later than six months after the inclusion of the substance in the Candidate List. For further details see: https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles

[6] GMT 253 Triphenyl phosphates derivatives: https://echa.europa.eu/documents/10162/901a4f73-f000-8550-98ac-61e51bf5daaa

Nonetheless, these endpoints are not considered further in this screening report but they may further influence ECHA's future conclusion about TXP in articles and the scope of a future restriction.

Information on emissions/release/exposure

According to the information reviewed for this report, such as information gathered during the SVHC listing and recommendation for the inclusion of substances in Annex XIV, SCIP notifications ECHA's regulatory strategy for flame retardants and scientific literature[7,8,9], significant levels of dermal exposure of consumers and workers to TXP may result from uses of articles containing it, particularly in furniture, seating and plastic articles. In addition, there may be other uses and exposure routes, such as inhalation via particulates released into the air which could potentially lead to inadequately controlled risk and should be investigated more.

TXP is likely additively included into a material matrix at higher than trace concentrations (>1%) to fulfil the function of flame retardant. Additively included flame retardants have potential for releases as they are chemically unbound. Moreover, the low molecular weight of TXP (410.45) suggests it could be released resulting in potential dermal exposure. In contrast, while some data suggests inhalation exposure is possible, TXP has a low vapour pressure (8.5×10^{-5} Pa at 20 °C) and thus is unlikely to evaporate. Consequently, inhalation exposure may mostly result from the release of inhalable particles rather than via evaporation. Concerning releases to the environment, the low water solubility suggests the substance would rather stay in carbon matrix or transfer to other environmental compartments than water. Nonetheless, while minimisation of releases of chemicals to the environment is desirable this would become more significant in case environmental hazards are confirmed.

Uncertainties considering exposure arise from the lack of quantitative data on releases from the different matrixes (materials) as well as the over-conservative nature and estimated input parameters in quantitative model used in exposure estimation.

These conclusions were not challenged during the call for evidence.

Characterisation of risk

TXP was included to Annex XIV due to its reproductive toxicity which is a threshold property. Thus, a quantitative risk characterisation approach was applied, and conservative risk characterisation ratios (RCR) calculated for relevant uses to demonstrate the level of risk control. All calculations were carried out using the ECETOC TRA[10] tool for inhalation and dermal routes which were considered the most relevant.

[7] OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 3 EMISSION SCENARIO DOCUMENT ON PLASTIC ADDITIVES available at http://www.oecd.org/officialdocuments/displaydocument/?cote=env/jm/mono(2004)8/rev1&doclanguage=en

[8] ARCADIS (2011) Identification and evaluation of data on flame retardants in consumer products FINAL REPORT

[9] Papazoglou (2004) Papazoglou, E.S. (2004). FLAME RETARDANTS FOR PLASTICS. In Harper, C.A. (Ed.), Handbook of Building Materials for Fire Protection. USA: The McGraw-Hill Companies.

[10] https://www.ecetoc.org/tools/tra-main/

The reference DNELs as set by RAC[11] were used in the calculations, as well as a hypothetical concentration of 25% which represents a worst-case concentration based on the information reviewed. Table 1 shows the results of the calculations. It should be noted that the calculations cover the uses suggested by the data examined for this report where uncontrolled risk was considered probable due to potential prolonged dermal exposure and subsequent risk to consumers and workers. It is likely that TXP may be incorporated in quite many different types of articles, all of which are not covered in Table 1.

Table 1: Calculated risk characterisation ratios (RCR) for relevant uses

Exposure scenario	**Route of exposure**	**Exposure estimate**	**DNEL (RAC)**	**RCR**
Service life of furniture - airborne particulates	Inhalation	0.0525 mg/m^3	0.014 mg/m^3	3.75
Service life of Clothing, towels (AC5 - clothing ((all kind of materials), towel)	Dermal	596.46 mg/kg/d	0.04 mg/kg/d	14 911.46
Service life of car seat, chairs, flooring (AC5 - Car seat, chair, flooring)	Dermal	364.58 mg/kg/d	0.04 mg/kg/d	9 114.58
Service life of toys (AC5 – Toys (cuddly toy))	Dermal	139.20 mg/kg/d	0.04 mg/kg/d	3 480.00
Service life of bedding, mattress (AC5 - (Bedding, mattress)	Dermal	59.65 mg/kg/d	0.04 mg/kg/d	1 491.15
Service life of furniture (AC6 - Furniture (sofa)	Dermal	36.46 mg/kg/d	0.04 mg/kg/d	911.46
Service life of plastic chair, PVC-flooring, lawn mower, PC (AC13 - plastic chair, PVC-flooring, lawn mower, PC)	Dermal	36.46 mg/kg/d	0.04 mg/kg/d	911.46
Service life of Toys (doll, car, animals, teething rings (AC13: - Toys (doll, car, animals, teething rings))	Dermal	13.92 mg/kg/d	0.04 mg/kg/d	348.00
Service life of Footwear (AC6 - Footwear (shoes, boots))	Dermal	8.68 mg/kg/d	0.04 mg/kg/d	216.93
Service life of Flooring (AC10 - Flooring	Dermal	8.68 mg/kg/d	0.04 mg/kg/d	216.93
Service life of Footwear (AC10 - Footwear (shoes, boots)	Dermal	8.68 mg/kg/d	0.04 mg/kg/d	216.93

11 https://echa.europa.eu/documents/10162/17229/afa_rac_final_note_txp_dnel_en.pdf/dd296722-e10c-244a-37e2-f0ceddf761fb?t=1614100469763

Exposure scenario	Route of exposure	Exposure estimate	DNEL (RAC)	RCR
Service life of Rubber toys (AC10 - Rubber toys	Dermal	3.18 mg/kg/d	0.04 mg/kg/d	79.50
Service life of Purse, wallet, covering steering wheel (car) (AC6 - Purse, wallet, covering steering wheel (car)	Dermal	1.79 mg/kg/d	0.04 mg/kg/d	44.66
Service life of Rubber handles, tyres (AC10 - Rubber handles, tyres)	Dermal	1.79 mg/kg/d	0.04 mg/kg/d	44.66
Service life of Plastic, small articles (ball pen, mobile phone) (AC13 - Plastic, small articles (ball pen, mobile phone)	Dermal	0.15 mg/kg/d	0.04 mg/kg/d	3.72

Uncertainties in the calculated Risk Characterisation Ratios (RCR) originate from the uncertainties in the input values and include, among others, concentration of substance in the material and concentration available for migration. Nonetheless, the RCR values for all the calculated article uses suggest inadequately controlled risk via dermal route (RCR>1) with uses in fabrics, textiles and apparel, leather articles and plastic articles having the highest risk. In addition, inadequately controlled risk via inhalation cannot be excluded with an RCR higher than one. While there are uncertainties in calculations and they are considered conservative estimations, the RCRs are orders of magnitude higher than the level indicating safe use thus it is impossible to exclude inadequately controlled risk.

There may be uses, such as printed circuit boards (PCB), where the risk in using plastic articles may be considered lower than what is calculated in Table 1 for articles which are mostly used within confined environment, e.g. inside containers, resulting in likely lower exposure even though significant releases could occur.

In the case where other hazards such as endocrine disruption (ED) or PBT are confirmed for the substance, the inadequately controlled risk becomes more evident due to the non-threshold nature of these hazards.

The conclusions from the risk characterisation were not contradicted during the call for evidence.

2.3. Justification that action is required on an EU-wide basis

The main justifications for an EU-wide measure include to address the risk posed by exposure/releases of TXP in articles and to maintain the good functioning of the internal market.

While the production of articles containing TXP in the EU is phased out, there is a concern from potentially wide and dispersive use of imported articles throughout the EU.

In addition, TXP was proposed for future restriction measures in recent ARN work[6] and ECHA flame retardant strategy which clearly indicates the identified need for EU wide measure.

No information was provided in the call for evidence to contradict the justification for action on EU-wide basis.

2.4. Justification that the proposed restriction is the most appropriate EU-wide measure

While the purpose of this screening report is not to evaluate the appropriateness of different risk management options, including options for restriction, a brief assessment of existing EU-wide legal requirements shows that no other EU-wide measure, other than a restriction, appears suitable to address the identified risk.

Considering effectiveness, practicality and monitorability, restriction would be capable of reducing the risks to an acceptable level within a reasonable period of time and proportional to the risk.

No information was received in the call for evidence to contradict the justification of restriction as the most appropriate EU-wide regulatory measure for TXP.

Background and scope of Article 69(2) screening

This screening report is prepared according to Article 69(2) of REACH Regulation (EC) No. 1907/2006. The article requires that ECHA, after the sunset date has passed for a substance included on the Authorisation List (Annex XIV), considers if risks from the use of the substance in articles are adequately controlled and, if this is not the case, prepares an Annex XV restriction dossier.

Thus, this screening report is targeted at the potential release or exposure to the Annex XIV substance(s) from an article throughout its lifecycle (including the waste stage) and whether such use(s) should be restricted. The report is focused on the human health and/or environmental hazards due to which the substance is placed on the Annex XIV. Other hazards are not required to be taken into account for the purpose of the screening. Similarly, in the event ECHA proposes that an Annex XV dossier for restrictions is prepared, the scope of the work will be restricted to the risks arising from the Annex XIV intrinsic properties only unless the scope is expanded on request by the European Commission to include other endpoints. It is to be noted that REACH restrictions do not apply in certain cases. These include manufacture and placing on the market or use of a substance in scientific research and development, risks to human health of the use of the substance in cosmetic products, and when a substance is used as an on-site isolated intermediate.

In most cases, risks stemming from the incorporation of the substance into an article are not in the scope of this screening report. Incorporation of a substance in articles has to be authorised, unless this use is exempted in accordance with Article 56(1) of REACH[12]. The incorporation process carried out in third countries is outside the scope of EU legislation (and REACH Authorisation). However, it should be noted that articles, if imported to the EU, are within the scope of this investigation. The incorporation is regarded to cover two types of uses[13]:

a) The substance is incorporated into an article during its production, or

b) The substance, alone or in a mixture, is incorporated into/onto an existing article (isolated or incorporated in a complex object) at a later stage (e.g. coatings, primers, adhesives, sealants) and become an integral part of the article (or of the complex object).

[12] Q&A ID: 0564: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0564
Note that ECHA will investigate for this report whether applications for authorisation/authorisation decisions cover the incorporation of the substance into an article and possible cumulative effects of the substance due to authorisations.

[13] https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c