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SCIENTIFIC OPINION

Safety assessment of the substance phosphorus acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters, for use in food contact materials

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Abstract

The EFSA Panel on Food Contact Materials (FCM) assessed the safety of phosphorus acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters, intended to be used as additive in acrylonitrile-butadiene-styrene copolymers (ABS) and high impact polystyrene (HIPS). The substance is a polymer with < 10% w/w low molecular weight fraction (< 1000 Da). The safety of its use in HIPS and ABS was already evaluated by the EFSA CEP Panel in 2019 and 2021, respectively. This opinion assesses the safety of the extension of the use to up to 0.25% w/w for ABS and to the contact with alcoholic and fatty food for HIPS. Migration tests were carried out with food simulants and samples containing the substance at the maximum intended levels. For ABS, the specific migration was below the limit of detection (LoD) of 0.005 mg/kg food (3% acetic acid and 10% ethanol) and up to 0.007 mg/kg food (20% and 50% ethanol). For HIPS, the specific migration was up to 0.020 mg/kg food (20% ethanol) and up to 0.039 mg/kg food (50% ethanol). The assessment of toxicological data was reported in the previous opinions and the corresponding conclusions are considered still valid. The FCM Panel concluded that the substance is not of safety concern for the consumer if its migration does not exceed 0.05 mg/kg food and it is used in ABS at up to 0.25% w/w in contact with aqueous, acidic, alcoholic and oil-in-water emulsion foods, and in HIPS at up to 0.2% w/w in contact with all types of food, in both materials for long term storage at room temperature and below, after hot-fill and/or heating up to 100°C for up to 2 h. The use in contact with human milk and infant formula was excluded and hence was not addressed in this assessment.

KEYWORDS

C10-16 alkyl esters, CAS No. 1227937-46-3, FCM substance No. 1076, food contact materials, phosphorus acid, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], safety assessment, triphenyl ester

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1 | INTRODUCTION

1.1 | Background and Terms of Reference as provided by the requestor

Before a substance is authorised to be used in food contact materials (FCM) and is included in a positive list EFSA's opinion on its safety is required. This procedure has been established in Articles 8, 9 and 10 of Regulation (EC) No 1935/2004[1] of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States' competent authorities which transmit the applications to the European Food Safety Authority (EFSA) for their evaluation.

In this case, EFSA received an application from the German competent authority (Federal Office of Consumer Protection and Food Safety), requesting the evaluation of the substance 'phosphorus acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly [oxy(methyl1-1,2-ethanediyl)], C10-16 alkyl esters', with the CAS number 1227937–46-3. The dossier was submitted on behalf of Dover Chemical Corporation, United States of America.

According to Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food, EFSA is asked to carry out an assessment of the risks related to the intended use of the substance and to deliver a scientific opinion.

2 | DATA AND METHODOLOGIES

2.1 | Data

The applicant has submitted a confidential and a non-confidential version of the dossier in support of their application for the authorisation of 'phosphorus acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly [oxy(methyl1-1,2-ethanediyl)], C10-16 alkyl esters' to be used in plastic FCM.

In accordance with Art. 38 of the Commission Regulation (EC) No 178/2002[2] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation and of the Decision of the EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[3] the non-confidential version of the dossier is published on Open.EFSA.[4]

According to Art. 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,[5] EFSA carried out a public consultation on the non-confidential version of the application from 14 October 2025 to 4 November 2025, for which no comments were received.

The applicant submitted data following the EFSA Note for Guidance for the preparation of an application for the safety assessment of a substance to be used in food contact materials (EFSA, 2008). Data submitted and used for the evaluation are:

- Non-toxicological data and information
  - Chemical identity
  - Manufacturing process of substance/FCM
  - Physical and chemical properties
  - Intended use
  - Existing authorisation(s)
  - Migration of the substance
  - Residual content of the substance
  - Oligomers
  - Identification, quantification and migration of reaction products and impurities
- Toxicological data
  - Bacterial gene mutation test
  - In vitro mammalian cell gene mutation test
  - In vitro mammalian chromosome aberration test
  - 90-day oral toxicity study in rats
  - Miscellaneous (delayed neurotoxicity test in hens)

[1]Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

[2]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

[3]Decision available at https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

[4]The non-confidential version of the dossier, following EFSA's assessment of the applicant's confidentiality requests, is published on Open.EFSA and is available at the following link: https://open.efsa.europa.eu/dossier/FCM-2024-27870

[5]Decision available at https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf.

2.2 | Methodologies

The assessment was conducted in line with the principles laid down in Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. This Regulation underlines that applicants may consult the Guidelines of the Scientific Committee on Food (SCF) for the presentation of an application for safety assessment of a substance to be used in FCM prior to its authorisation (European Commission, 2001), including the corresponding data requirements. The dossier that the applicant submitted for evaluation was in line with the SCF guidelines (European Commission, 2001).

The methodology is based on the characterisation of the substance that is the subject of the request for safety assessment prior to authorisation, its impurities and reaction and degradation products, the evaluation of the exposure to those substances through migration and the definition of minimum sets of toxicity data required for safety assessment.

To establish the safety from ingestion of migrating substances, the toxicological data indicating the potential hazard and the likely human exposure data need to be combined. Exposure is estimated from studies on migration into food or food simulants and considering that a person may consume daily up to 1 kg of food in contact with the relevant FCM.

As a general rule, the greater the exposure through migration, the more toxicological data is required for the safety assessment of a substance. Currently there are three tiers with different thresholds triggering the need for more toxicological information as follows:

a. In case of high migration (i.e. 5–60 mg/kg food), an extensive data set is needed.
b. In case of migration between 0.05 and 5 mg/kg food, a reduced data set may suffice.
c. In case of low migration (i.e. < 0.05 mg/kg food), only a limited data set is needed.

More detailed information on the required data is available in the SCF guidelines (European Commission, 2001).

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and considering the relevant guidance from the EFSA Scientific Committee.

3 | ASSESSMENT

According to the applicant, the substance 'phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10–16 alkyl esters' is a polymeric additive to be used as a secondary antioxidant/stabiliser in acrylonitrile-butadiene-styrene copolymers (ABS) and in high impact polystyrene (HIPS). According to the applicant, typical examples for articles made from HIPS are trays, containers (e.g. cups, beakers, plates, bowls) and blister packs. Typical examples for articles made from ABS are housings of kitchen machines, bowls, containers for preparing and holding food, and interior housing of refrigerators and freezers.

The safety of the substance was already evaluated by the EFSA CEP Panel in 2019 and 2021 for its use in HIPS and ABS, respectively (EFSA CEP Panel, 2019, 2021). The CEP Panel concluded that the intended use of the substance (i.e. contact with aqueous, acidic, low-alcohol and fatty foods for long term storage at room temperature and below, after hot-fill and/or heating up to 100°C for up to 2 h) did not raise a safety concern, if the substance is used at up to 0.2% w/w in HIPS materials and articles and its migration does not exceed 0.05 mg/kg food. Regarding ABS, the CEP Panel concluded that the intended use of the substance (repeated use in contact with aqueous, acidic, alcoholic and oil-in-water emulsion foods, for long term storage at room temperature and below) did not raise a concern if the substance is used at up to 0.025% w/w in ABS materials and articles and its migration does not exceed 0.05 mg/kg food.

For this evaluation, the applicant provided new data on the migration of the substance to support the safety of its use in ABS at up to 0.25% and in HIPS in contact with food for which simulants C and D1 are assigned in Annex III of Regulation (EU) 10/2011. Additionally, the applicant re-submitted unchanged information that was already provided in support to the previous evaluations (i.e. identity of the substance, physical and chemical properties and toxicological data).

The contact with human milk and infant formula was not reported as an intended application of the substance.

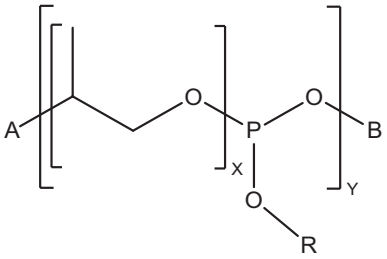
3.1 | Non-toxicological data

3.1.1 | Identity of the substance[6]

Chemical formula: A[[-CH(CH_3)-CH_2-O]$_x$-P(OR)-O]$_y$-B.

[6]Technical report, section 'Identity of the Substance'.

Chemical structure:



where:
R = aliphatic C10–16.
A = HO– or $(RO)_2P$–.
B = R– or HO–CH2–CH(CH3)–.
[redacted]

The substance 'phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10–16 alkyl esters' is a polymeric additive, obtained by reaction of [redacted]. Phenol is released during the reaction and is removed [redacted]. [redacted], the substance has a molecular weight distribution ranging from ~500 Da to [redacted] Da. The weight average molecular weight (Mw) and number average molecular weight (Mn) values are in the range of [redacted] Da and [redacted] Da, respectively, with typical values reported to be [redacted] and [redacted] Da respectively. The low molecular weight fraction (LMWF), that is the fraction below 1000 Da, is reported as a specification to be < 10% w/w.

The specifications for the levels of impurities in the substance were reported by the applicant as follows: phenol: < 1% w/w; C10–16 alcohols: < 5% w/w; triphenyl phosphite: < 0.05% w/w; alkyl phenyl ethers: < 1% w/w. The level of impurities was determined by gas chromatography–mass spectrometry (GC–MS) or gas chromatography–flame ionisation detection (GC–FID). Residual polypropylene glycol was not determined, assuming that it completely reacts during the manufacturing process. Based on the typical levels of impurities, the purity of the substance was reported to be 96%.

3.1.2 | Physical and chemical properties[7]

The substance is highly lipophilic with log Po/w values greater than 9 for the individual low molecular weight (LMW) constituents. It is virtually insoluble in water and in the aqueous food simulants 10% ethanol and 3% acetic acid, but it is soluble in solvents such as hexane and toluene (solubility > 1 g/10 mL at room temperature). It is a liquid at room temperature and has no defined melting and boiling points because of decomposition starting at 310°C, as shown by thermogravimetric analysis (TGA).

The onset of thermal decomposition shown by TGA was around 310°C, with a minor loss in mass starting at 220°C. Taking into account evaporation of volatiles and the short heat treatment applied during processing, the Panel concluded that the additive is thermally stable for the proposed uses in ABS and HIPS with reported typical processing temperatures of 220–260°C.

The substance is used as an antioxidant/stabiliser and is oxidised from phosphite to phosphate during melt processing of the polymers.

Phosphites are known to slowly hydrolyse in the presence of moisture. The stability of the substance was studied in 10% ethanol and in gastric juice simulant. The substance slowly hydrolyses in substances that are listed in Regulation (EU) No 10/2011. The extent of hydrolysis in gastric juice simulant after 4 h at 37°C was about 85%. The phosphate, generated by the oxidation during melt processing of ABS and HIPS, was demonstrated to be stable against hydrolysis.

3.1.3 | Specific migration[8]

The migration of the additive was investigated by determining the total phosphorous (P) in the simulants using inductively coupled plasma–optical emission spectroscopy (ICP–OES), which was calibrated using a certified P standard. The analytical method was, therefore, able to detect all species containing P, that is the additive, its oxidation products (phosphates), LMW oligomers and all impurities containing P.

The specific migration was calculated by the applicant using a P content of 4.7%, i.e. the P content in its chemical formula of the additive (Section 3.1.1). The Panel noted that the applicant should have used the P content of the LMWF, i.e. the fraction with potential to migrate into food simulants, which is expected to consist of monomers, dimers and trimers having a higher P content than the additive. However, the P content of the LMWF could not be determined, as the applicant did not comprehensively address its composition. The Panel noted that the use of the correct P content would result in

[7]Technical report, section 'Physical and Chemical Properties of Substance'.
[8]Technical report, section 'Data on Migration of Substance'.

lower calculated specific migrations, hence the use of the P content of the additive (4.7%) is conservative and for this reason considered acceptable.

To support that the method was appropriate in measuring all substance-related migrating species, the applicant submitted a study on the identification of potentially migrating LMW species from linear low-density polyethylene (LLDPE, selected as a worst-case high-diffusivity plastic) specimens by high performance liquid chromatography–evaporative light scattering detection (HPLC–ELSD). The study was already submitted as part of the previous dossier on ABS (EFSA CEP Panel, 2021) and considered appropriate by the Panel.

3.1.3.1 | *Specific migration from ABS*

Migration tests on ABS were carried out in total immersion mode with a 508 μm-thick sample. The sample was formulated with the substance at 0.23% w/w (i.e. slightly lower than the intended use level of 0.25% w/w).

Tests for repeated use were conducted with the food simulants 3% acetic acid, 10% ethanol, 20% ethanol, 50% ethanol and for three consecutive tests at 40°C for 10 days. The specific migration of the P-containing substances in 3% acetic acid, 10% ethanol and 20% ethanol was below the limit of detection (LoD) of 0.005 mg/kg food in all consecutive tests, while it was 0.007, < 0.005, < 0.005 mg/kg food in 50% ethanol. The Panel noted that, according to the intended uses, test conditions of 10 days at 60°C would normally be required. However, it is known that contact with 50% ethanol at 60°C can cause severe swelling of ABS (e.g. Guazzotti et al., 2021). Taking this into consideration along with the comonomer composition of the sample used that is sufficiently representative of the ABS types of plastics, the Panel considered the applied test conditions appropriate. The available migration data would also support single use applications.

Migration tests for single use were conducted with 3% acetic acid, 10% ethanol and 20% ethanol at 100°C for 2 h. The specific migration was below the LoD of 0.005 mg/kg food in 3% acetic acid and 10% ethanol, but up to 0.007 mg/kg food in 20% ethanol.

Migration into solid foods was not tested, but considering the measured migration in aqueous simulants (i.e. up to 0.007 mg/kg food) and the low volatility of the migrating species, the Panel considered that the potential migration into solid foods will be far below 0.050 mg/kg food.

The total mass transfer (TMT) of impurities was calculated by the Panel considering a ABS specimen with a theoretical thickness of 250 μm containing the substance at the maximum requested level of 0.25% w/w. The impurities not containing phosphorous listed in Regulation (EU) No 10/2011 are either without any restriction (for C10–16 alcohols, polypropylene glycol) or their TMT was up to 0.4 mg/kg food for phenol, well below the SML of 3 mg/kg food. The TMT for triphenyl phosphite and alkyl phenyl ethers was up to 0.02 and 0.4 mg/kg food, respectively. However, the Panel estimated that, based on generally recognised migration modelling (Hoekstra et al., 2005), the actual migration of triphenyl phosphite/phosphate and alkyl phenyl ethers from ABS would be at least one order of magnitude lower than the calculated TMT. Therefore, the actual migration of alkyl phenyl ethers from ABS would be lower than 0.05 mg/kg food.

3.1.3.2 | *Specific migration from HIPS*

Migration tests on HIPS were carried out in total immersion mode with a 508-μm-thick sample. The sample was formulated with the substance at 0.23% w/w (i.e. slightly above the intended use level of 0.2% w/w). Tests were conducted with the food simulants 20% and 50% ethanol for 2 h at 100°C, followed by 30 days at 40°C. The chosen conditions did not match the testing conditions required by Regulation (EU) 10/2011 (i.e. 60°C for 10 days), but were considered acceptable by the Panel based on the same considerations made for ABS in Section 3.1.3.1.

The specific migration of the P-containing substances was up to 0.020 mg/kg food in 20% ethanol and up to 0.039 mg/kg food in 50% ethanol.

Migration into solid foods was not tested. However, taking into account the measured migration into aqueous simulants (i.e. up to 0.020 mg/kg food) and the low volatility of migrating species, the Panel considered that the potential migration into solid foods would be far below 0.050 mg/kg food.

The TMT of impurities was calculated by the Panel for a HIPS specimen with a theoretical thickness of 250 μm containing the substance at the maximum requested level of 0.2% w/w. The impurities not containing phosphorous listed in Regulation (EU) No 10/2011 are either without any restriction (C10–16 alcohols, polypropylene glycol) or their TMT was up to 0.32 mg/kg food for phenol, well below the SML of 3 mg/kg food. The TMT of triphenyl phosphite and alkyl phenyl ethers was up to 0.016 and 0.32 mg/kg food, respectively. Similarly to the migration from ABS (Section 3.1.3.1), the Panel noted that the actual migration of triphenyl phosphite and alkyl phenyl ethers from HIPS would be at least one order of magnitude lower than the TMT. Therefore, the actual migration of alkyl phenyl ethers from HIPS would be lower than 0.05 mg/kg food.

3.2 | Toxicological data[9]

The toxicological data were the same as those already submitted by the same applicant for the previous dossiers (EFSA-Q-2018-00411 and EFSA-Q-2020-00014) and were reported in the related scientific opinions (EFSA CEP Panel, 2019, 2021). The

[9]Technical report, section 'Toxicological data'.

corresponding conclusions on the toxicology assessment are still valid. Considering the lack of genotoxicity and the tiered approach, the CEP Panel concluded on the migration restriction of 0.05 mg/kg food.

3.3 | Discussion

The Panel noted that the reported migration levels of the substance and the estimated migration of degradation/reaction products and impurities are all below 0.05 mg/kg food. Therefore, the proposed extension of use of the substance does not raise safety concerns.

The use in HIPS and ABS articles in contact with infant formula and human milk was not specified as an intended application of the substance. The Panel noted that even though bottled water was not reported as intended use, the substance could be used in HIPS and ABS articles that may contact water (e.g. cups). This water could be used, in principle, to reconstitute infant formula. Considering that the specific migration into 10% ethanol was below the LoD of 0.005 mg/kg food from ABS and up to 0.001 mg/kg food from HIPS (EFSA CEP Panel, 2019), and that it was measured under conservative conditions, a potential exposure of infants to the substance from water used to reconstitute infant formula, if any, is of no concern.

4 | CONCLUSIONS

Based on the above-mentioned data, the FCM Panel concluded that the substance 'phosphorus acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters' is not of safety concern for the consumer if its migration does not exceed 0.05 mg/kg food and it is used in:

- ABS at up to 0.25% w/w in contact with aqueous, acidic, alcoholic and oil-in-water emulsion foods for long term storage at room temperature and below, including hot-fill and/or heating up to 100°C for up to 2 h;
- HIPS at up to 0.2% w/w in contact with all types of food for long term storage at room temperature and below, including hot-fill and/or heating up to 100°C for up to 2 h.

As ABS and HIPS materials and articles containing the substance are not intended to be used in contact with human milk and infant formula, such uses were not addressed in this assessment.

5 | DOCUMENTATION AS PROVIDED TO EFSA

Dossier for the extension of use of the substance phosphorus acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly [oxy(methyl1-1,2-ethanediyl)], C10-16 alkyl esters. February 2025. Submitted on behalf of Dover Chemical Corporation.

ABBREVIATIONS

ABS	acrylonitrile-butadiene-styrene
CAS	Chemical Abstracts Service
CEP Panel	EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
Da	Dalton
FCM	food contact materials
FCM Panel	EFSA Panel on Food Contact Materials
GC–FID	gas chromatography–flame ionisation detector
GC–MS	gas chromatography–mass spectrometry
HIPS	high impact polystyrene
HPLC–ELSD	high performance liquid chromatography–evaporative light scattering detection
ICP-OES	inductively coupled plasma–optical emission spectroscopy
LLDPE	linear low-density polyethylene
LMW	low molecular weight
LMWF	low molecular weight fraction
LoD	limit of detection
Mw	weight average molecular weight
Mn	number average molecular weight
Po/w	octanol/water partition coefficient
SCF	Scientific Committee on Food
SML	specific migration limit
TGA	thermogravimetric analysis
TMT	total mass transfer

REQUESTOR

German Competent Authority (Federal Office of Consumer Protection and Food Safety).

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