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Safety assessment of the substance phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10–16 alkyl esters (FCM No 1076), for use in food contact materials

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Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP Panel) assessed the safety of the substance 'phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10–16 alkyl esters' obtained by reaction of [REDACTED]. This food contact material (FCM) substance No 1076 was evaluated by the CEP Panel in 2019 for its use in high impact polystyrene. This opinion deals with the safety assessment of the substance when used as an additive at up to 0.025% w/w in acrylonitrile-butadiene-styrene (ABS) copolymers. The plastic is intended for repeated use in contact with aqueous, acidic, alcoholic and oil-in-water emulsion foods, for long-term storage at room temperature and below. Migration from ABS formulated with the substance at 0.02% w/w was up to 0.002 mg/kg in 10% ethanol, 0.005 mg/kg in 3% acetic acid and 0.027 mg/kg in 50% ethanol. Migration levels into 50% ethanol declined under repeated-use test conditions and this decline was considered to also cover repeated contacts with 10% ethanol and 3% acetic acid simulants. The toxicological data are the same as those submitted by the same applicant in a previous dossier (EFSA-Q-2018-00411). They were reported in the scientific opinion of the CEP Panel in 2019 and the conclusions on toxicity are still valid. Overall, the CEP Panel concluded that the substance phosphorous acid, triphenyl esters, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10–16 alkyl esters, does not raise a safety concern for the consumer if it is used as an additive at up to 0.025% w/w in ABS materials and articles for single and repeated use in contact with aqueous, acidic, alcoholic and oil-in-water emulsion foods, for long-term storage at room temperature and below, and if its migration does not exceed 0.05 mg/kg food.

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

Requestor: Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

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Competing interests: R. Franz declared that Fraunhofer institute at which he was employed provides advisory services to private business operators active in the sector on food contact materials. In line with EFSA's Policy on Independence (http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf) and the Decision of the Executive Director on Competing Interest Management (https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf), a waiver was granted to R. Franz regarding his participation to the EFSA's Working Group on Food Contact Materials (FCM WG) in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, the involvement of R. Franz is authorised as member in the FCM WG, allowing him to take part in the discussions and in the drafting phase of the scientific output, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the working group.

Note: The full opinion will be published in accordance with Article 10(6) of Regulation (EC) No 1935/2004 once the decision on confidentiality, in line with Article 20(3) of the Regulation, will be received from the European Commission. The following information has been provided under confidentiality and it is redacted awaiting the decision of the Commission: The number average and molecular weight of the substance, molecular mass range and fraction below 1,000 Da, starting substances, impurities, products of thermal degradation, hydrolysis percentage, phosphorous content of the substance, identity of the analytical standards/migrating compounds in the qualitative migration study.

Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at <https://ess.efsa.europa.eu/doi/doiweb/doisearch>.

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Table of contents

Abstract.....	1
1. Introduction.....	4
1.1. Background and Terms of Reference as provided by the requestor.....	4
2. Data and methodologies.....	4
2.1. Data.....	4
2.2. Methodologies.....	4
3. Assessment.....	5
3.1. Non-toxicological data.....	6
3.1.1. Identity of the substance.....	6
3.1.2. Physical and chemical properties.....	6
3.1.3. Specific migration.....	6
3.1.4. Screening of migrating reaction products related to the substance.....	6
3.2. Toxicological data.....	7
4. Conclusions.....	7
Documentation provided to EFSA.....	7
References.....	7
Abbreviations.....	8

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 1935/2004¹ 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 Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, requesting the evaluation of the substance phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10–16 alkyl esters, with the CAS number 1227937-46-3 and the FCM substance No 1076. The dossier was submitted on behalf of Dover Chemical Corporation.

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 dossier in support of their application for the authorisation of phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10–16 alkyl esters to be used in plastic food contact materials.

Additional information was provided by the applicant during the assessment process in response to a request from EFSA sent on 11 June 2020 (see 'Documentation provided to EFSA').

Data submitted and used for the evaluation are:

Non-toxicological data and information

- Chemical identity
- Description of 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 (immune, delayed neurotoxicity study)

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).

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.

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 at up to 0.025% w/w in acrylonitrile-butadiene-styrene copolymers (ABS). The plastic, in the form of materials and articles, is intended for contact with aqueous, acidic, alcoholic foods (> 20%) and oil-in-water emulsion foods for repeated use and for long-term storage at room temperature and below.

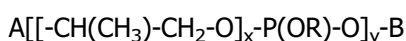
The safety of the substance for its use in high impact polystyrene (HIPS) was evaluated by the EFSA CEP Panel (2019) which concluded that it is not of safety concern for the consumer if used as an additive up to 0.2% w/w in HIPS materials and articles in contact with aqueous, acidic, low-alcohol and fatty 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, and if its migration does not exceed 0.05 mg/kg food.²

In the context of the current dossier, submitted by the same applicant, new data were provided on migration of the substance from ABS whereas the other information (e.g. identity of the substance, physical and chemical properties and toxicological data) were already provided in support of the previous evaluation and were re-submitted unchanged.

3.1. Non-toxicological data

3.1.1. Identity of the substance³

Chemical formula:



where:

R = aliphatic C10–16

A = HO– or (RO)₂P–

B = R– or HO–CH₂–CH(CH₃)–

x = 2–100

y = 1 to greater than 500

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], with a molecular mass distribution

² The substance has afterwards been listed as FCM 1076 in Annex I to Regulation (EC) 10/2011 in accordance with amendment 2020/1245 of 02.09.2020 to Regulation (EC) 10/2011.

³ Technical dossier/section 1; Appendix B-Technical dossier/Annexes 1–4.

ranging from [REDACTED]. The averaged molecular mass and number average molecular mass values are in the range of [REDACTED] and [REDACTED], respectively. The fraction below 1,000 Da is [REDACTED].

The purity of the substance is about 96%, which is derived from the determination of the known impurities and subtraction of them from 100%. Impurity levels in the substance are: [REDACTED].

3.1.2. Physical and chemical properties⁴

The substance is lipophilic with log $P_{o/w}$ values of greater than 9 for the individual constituents. It is practically insoluble in water, 10% ethanol or 3% acetic acid, but very soluble in solvents such as hexane or toluene. The substance has no defined melting point and no boiling point.

The maximum processing temperature of ABS containing the substance as an additive is 260°C. By thermogravimetric analysis (TGA) of the substance, the onset of thermal decomposition was around 310°C, although some loss in mass started at 220°C. Taking into account evaporation of volatiles and the short heat treatment in processing, the Panel concluded that the additive has sufficient thermal stability for the proposed use in ABS.

In 10% ethanol, the substance hydrolyses slowly into substances already listed in Regulation (EU) No 10/2011. Hydrolysis in gastric juice simulant over several hours at 37°C reached [REDACTED]. No hydrolysis study using 3% acetic acid was submitted. In performing its role as an antioxidant/stabiliser, oxidation of the substance into the phosphate form takes place during melt processing of the ABS. The phosphate form is stable against hydrolysis.

3.1.3. Specific migration⁵

Migration tests were carried out from an ABS sample formulated with the substance at 0.02% w/w, using the food simulants 10% ethanol and 3% acetic acid, each at 100°C for 2 h followed by 10 days at 40°C, and using 50% ethanol with 3 successive exposures to simulant for 10 days at 40°C. The formulation level of 0.02% used for these tests is considered to be sufficiently close to the maximum use level proposed (0.025%) and the migration results obtained are adequately representative of the intended uses and use levels of the additive in ABS plastics. The migration of the additive was estimated based on the determination of total phosphorous in the simulant by inductively coupled plasma optical emission spectrometry (ICP-OES). The analysis was calibrated using the substance itself and so this corrects automatically for the phosphorous content of the substance of [REDACTED].⁶ The analytical method measuring total phosphorous has an added advantage that it encompasses the additive as phosphite along with any oxidised phosphate units plus any LMW components or impurities that contain phosphorous. The migration of the substance was up to 0.002 mg/kg in 10% ethanol and 0.005 mg/kg in 3% acetic acid. For 50% ethanol, the migration level declined on repeated contacts, with migration from the first, second and third contacts being 0.027, 0.013 and < 0.005 mg/kg, respectively. According to the intended uses, test conditions of 10 days at 60°C would normally be required. However, it was noted that 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 sufficient to mimic migration expected into food. Based on the observed falling trend seen with 50% ethanol and on the respective migration levels on first contact, the normal requirement for information on repeated-use testing with 10% ethanol and 3% acetic acid was waived. The migration data available would also support single use applications.

3.1.4. Screening of migrating reaction products related to the substance⁷

Regarding the products of thermal degradation under processing conditions, migration tests were performed using [REDACTED] formulated with the substance at [REDACTED] and with a primary antioxidant at [REDACTED]. These tests were conducted to help identify and quantify

⁴ Technical dossier/section 2; Appendix B-Technical dossier/Annexes 5–10&25.

⁵ Technical dossier/section 5.1; Appendix B-Technical dossier/Annexes 13A&B.

⁶ No specific method of analysis in food was provided, but a method based on the determination of the total phosphorous content in food simulants multiplying it by a factor of [REDACTED]. Migration modelling can be used in order to estimate the migration of the substance based on the content of the low molecular part of the substance in the polymer measured as such.

⁷ Technical dossier/sections 5.3&6; Appendix B-Technical dossier/Annexes 13C,14&28.

possible migrating reaction products using a worse-case plastic sample. The samples were extruded at up to [REDACTED], i.e. at higher temperatures than applied in ABS processing, and [REDACTED] has higher diffusion/migration properties compared to ABS. Migration was tested with isooctane for 1.5 h at 60°C followed by 48 h at 40°C. [REDACTED]

[REDACTED] were detected and identified. No comprehensive compositional analysis of the low molecular mass fraction of the substance and the degradation products was provided, but all phosphorous-containing substances were included in the migration measurements.

Theoretical maximum possible migration of reaction and breakdown products as well as non-reacted starting substances was calculated by assuming a 100% migration from an ABS specimen of 250 µm thickness formulated with the substance at the maximum requested level of 0.025% w/w. For the components not containing phosphorous, that are listed in Regulation (EU) No 10/2011, they are either without any restriction ([REDACTED]) or the worst-case migration has been estimated to be well below the respective specific migration limit (SML) value ([REDACTED]). The complete migration of the phosphorous-containing impurity ([REDACTED]) from ABS would amount to [REDACTED] food, but the Panel estimated that, based on generally recognised migration modelling (Hoekstra et al., 2005), the amount actually migrating would be even lower and part of it is oxidised to [REDACTED] during manufacturing. Complete migration of the [REDACTED] would amount to [REDACTED] food. Similarly, actual migration of [REDACTED] from ABS would be lower than this worst-case estimate.

3.2. Toxicological data

The toxicological data are the same as those submitted by the same applicant in a previous dossier (EFSA-Q-2018-00411). They were reported in the scientific opinion (EFSA CEP Panel, 2019) and the conclusions are still valid. Considering the lack of genotoxicity and the tiered approach, the CEP Panel concluded on the same migration restriction of 0.05 mg/kg food.

4. Conclusions

The CEP Panel concluded that the substance phosphorous acid, triphenyl esters, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10–16 alkyl esters, does not raise a safety concern for the consumer if it is used as an additive at up to 0.025% w/w in ABS materials and articles for single and repeated use in contact with aqueous, acidic, alcoholic and oil-in-water emulsion foods, for long-term storage at room temperature and below, and if its migration does not exceed 0.05 mg/kg food.

Documentation provided to EFSA

- 1) Phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl esters. January 2020. Submitted by WTConsulting GmbH on behalf of Dover Chemical Corporation.
- 2) Additional data. March 2021. Submitted by WTConsulting GmbH on behalf of Dover Chemical Corporation.

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Abbreviations

ABS	acrylonitrile-butadiene-styrene
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
CAS	Chemical Abstracts Service
CEP	EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
FCM	food contact materials
HIPS	high impact polystyrene
ICP-OES	inductively coupled plasma optical emission spectrometry
LMW	low molecular weight
$P_{o/w}$	octanol/water partition coefficient
SCF	Scientific Committee on Food
SML	specific migration limit
TGA	thermogravimetric analysis
w/w	weight by weight