Safety assessment of the substance phosphorous 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, 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 phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], when used as an additive at up to 0.2% w/w in high impact polystyrene. The plastic, in the form of films and articles, is intended for 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. Based on genotoxicity tests with negative results, the Panel considered that there is no evidence of mutagenicity and chromosomal damage of the substance and its phosphate form. From a repeated dose 90-day oral toxicity study in rats, the Panel identified the no-observed-adverse-effect level as 50 mg/kg body weight (bw) per day. No effects of induced delayed neurotoxicity in hens were observed. Migration from high impact polystyrene containing the substance at 0.2%, measured through the phosphorous content of the substance, reached 0.001 mg/kg in 10% ethanol and 0.1 mg/kg in 95% ethanol. Migration into acidic food/simulant is expected to be below 0.001 mg/kg. Regarding the oligomers and other reaction/degradation products detected, the phosphorous-containing substances were adequately represented in the toxicity experiments conducted. Those not containing phosphorous were hydrolysis products either listed in Regulation (EU) 10/2011 and their estimated worst-case migrations were well below their respective specific migration limits (SMLs) or no alerts for genotoxicity were noted. Overall, the CEP Panel concluded that the substance ‘phosphorous acid, triphenyl ester, 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 at up to 0.2% w/w in high impact polystyrene materials and articles and its migration does not exceed 0.05 mg/kg food.

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

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Competing interests: R. Franz declared that Fraunhofer institute at which he is 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 (http://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 1000 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, details of the study reports on genotoxicity testing, composition of low molecular weight (LMW) version of the substance in the phosphate form used in the 90-day study.

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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 1935/20041 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 Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL), 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 requests from EFSA sent on 4 December 2018 (see 'Documentation provided to EFSA').

Data submitted and used for the evaluation are:

**Non-toxicological data and information**
- Chemical identity
- Description of the manufacturing process
- Physical and chemical properties
- Intended use
- Existing authorisation(s)
- Migration of the substance
- Residual content of the substance in the plastic
- 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).

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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-hydroxy[poly(oxy(methyl-1,2-ethanediyl)], C10–16 alkyl esters’ is a polymeric additive to be used as a secondary antioxidant/stabiliser at up to 0.2% w/w in high impact polystyrene (HIPS). The plastic, in the form of films and articles, is intended for 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 maximum 2 h.

3.1. Non-toxicological data

Chemical formula:

\[ A[\{-CH(CH_2) - CH_2 - O\}_{x} - P(OR) - O\}_{y} - B \]

where:

- \( R = \) aliphatic C10–16
- \( A = HO- \) or \((RO)_{2}P-\)
- \( B = R- \) or \( HO-CH_2-CH(CH_3)-\)
- \( x = 2-100 \)
- \( y = 1 \) to at least 500

The substance ‘phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxy[poly(oxy(methyl-1,2-ethanediyl)], C10–16 alkyl esters’ is a polymeric additive, obtained by reaction of \[ \ldots \], with a molecular weight distribution ranging from \[ \ldots \]. The averaged molecular weight (Mw) and number average molecular weight (Mn) values are in the range of \[ \ldots \] and \[ \ldots \], respectively. The fraction below 1,000 Da is \[ \ldots \].

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: \[ \ldots \].

The substance is lipophilic with \( \log P_{ow} \)'s for the individual constituents greater than 9. It is not soluble in water, 10% ethanol or 3% acetic acid, but very soluble in solvents such as hexane or toluene. The additive has no defined melting point and no boiling point.

The maximum processing temperature of HIPS containing the additive is 260°C. By thermogravimetric analysis (TGA), 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 use in HIPS.
In 10% ethanol, the substance hydrolyses slowly into substances already listed in Regulation (EU) 10/2011. Hydrolysis in gastric juice simulant over several hours at 37°C reached [ ]. In performing its role as an antioxidant/stabiliser, oxidation of the substance into the phosphate form takes place during melt processing of the HIPS. The phosphate form is stable against hydrolysis.

Migration tests were carried out from a HIPS sample containing the substance at 0.2% using 10% and 95% ethanol at 100°C for 2 h followed by 30 days at 40°C. The migration was estimated based on the determination of total phosphorous by inductively coupled plasma optical emission spectrometry (ICP-OES). The calculation of the substance concentration from the measured phosphorous migration used a conversion factor derived from the known phosphorous content of the substance of 2. The migration of the substance reached 0.001 mg/kg in 10% ethanol and 0.1 mg/kg in 95% ethanol. The considerably higher migration into 95% ethanol can be explained by strong interaction with the plastic which can give rise to exaggerated migration (FDA, 2007; Genualdi et al., 2014). The Panel noted that the migration into foodstuffs according to the intended use, including fatty foods, will be substantially lower due to weak interactions, if any, between the food and the plastic. No migration tests into 3% acetic acid were performed, but taking into account the low solubility and that in tests with linear low-density polyethylene (LLDPE) the migration was lower than in 10% ethanol, migration into the acidic food simulant is expected to be < 0.001 mg/kg.

Regarding the products of thermal degradation under processing conditions, qualitative migration tests were performed using containing the substance at and a primary antioxidant at . The samples were extruded at up to , i.e. at higher temperatures than applied in HIPS processing. Migration was tested with isooctane for 1.5 h at 60°C followed by 48 h at 40°C. 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 as 100% migration from a HIPS specimen of 250 μm thickness. For the components not containing phosphorous, that are listed in Regulation (EU) 10/2011, are either without any restriction ( ), or the worst-case migration has been estimated to be well below the respective SML value ( ). The complete migration of the phosphorous-containing impurity ( ) from HIPS would amount to food, but the Panel estimated that, based on generally recognised migration modelling (Hoekstra et al., 2005), the amount actually migrating would be at least one order of magnitude lower and part of it is oxidised to during manufacturing. Complete migration of the would amount to . Similarly, real migration of from HIPS would be at least one order of magnitude lower.

3.2. Toxicological data

3.2.1. Genotoxicity

The substance was tested in three in vitro genotoxicity tests with and without metabolic activation

A bacterial reverse mutation assay (Ames test) was made according to OECD TG 471. Four strains of Salmonella Typhimurium (TA1535, TA1537, TA98 and TA100) and Escherichia coli WP2 uvrA were used in the presence or absence of S9 mix. Two experiments were performed in which eight concentrations (3, 10, 33, 100, 333, 1,000, 2,500 and 5,000 μg/plate) were tested in triplicate employing the plate incorporation and the pre-incubation method, respectively. No cytotoxicity, evident as reduction in number of revertants, was observed at any concentration of the test substance. No increase in revertant colony number of any of the tester strains was observed following treatment with the substance.

The substance was tested in gene mutation studies at the thymidine-kinase (TK) locus using mouse lymphoma assay following the OECD TG 476. Two separate experiments were performed in which six concentrations were tested (namely, 5,000 and 5,000 μg/ml for 4 h and 24 h treatment, respectively with and without S9).

2 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 . 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.
No increase of the mutation frequency was noted in both experiments with and without metabolic activation.

An in vitro mammalian chromosomal aberration test in Chinese Hamster V79 cells was carried out according to OECD TG 473. Cell cultures were exposed for 4-14h recovery to the substance at 5,000 \( \mu g/ml \) without S9, and at 5,000 \( \mu g/ml \) with S9 and for 18h continuous treatment at without S9. Cytotoxicity as reduction in mitotic index was observed at the highest concentrations tested (without S9). The frequency of structural and numerical chromosomal aberrations in treated cultures was comparable to the values detected in negative controls.

The phosphate form of the substance was also tested in three in vitro genotoxicity tests with and without metabolic activation

A bacterial reverse mutation assay (Ames test) was made according to OECD TG 471. The phosphate form of the substance was tested using the \( S. \) Typhimurium strains TA1535, TA1537, TA98, TA100, and the \( E. \) coli strain WP2 uvrA. The assay was performed in triplicate in two independent experiments both with and without S9 at the following concentrations in both experiments: 3, 10, 33, 100, 333, 1,000, 2,500 and 5,000 \( \mu g/plate \). No cytotoxicity, evident as reduction in number of revertants, was observed at any concentration of the test substance in both experiments. No increase in revertant colony number of any of the tester strains was observed following treatment with the substance.

The substance was tested for gene mutation at the TK locus using mouse lymphoma assay following the OECD TG 476. Six concentrations of the substance were tested (namely, 4 h treatment without S9 and \( 4,852.8 \mu g/ml \) for 4 h treatment with S9 and 24 h treatment with and without S9). No increase of the mutation frequency was noted in both experiments with and without metabolic activation.

According to the Note for Guidance (EFSA, 2008), genotoxicity tests with polymeric additives are not generally considered necessary when starting substances are not genotoxic. In case of this polymeric additive, starting substances are either listed in Regulation (EU) 10/2011 or evaluated as non-genotoxic. Furthermore, the Panel noted that no additional functional groups raising concerns for genotoxicity are generated during the manufacturing process.

3.2.2. Subchronic toxicity

A LMW version of the substance in the phosphate form was synthesised, for the subchronic toxicity testing. Based on the information provided on the method used for synthesis and the analytical data on the synthetic mix, the Panel concluded that this mixture was sufficiently representative of the LMW fraction of the substance. The LMW fraction was used to allow better absorption by the gastrointestinal tract. The synthetic mixture was tested in a 90-day...
dietary toxicity study in Wistar rats at the target dose levels of 15, 50, 150 and 500 mg/kg body weight (bw) per day including a recovery group (4 weeks). No deaths or clinical signs (daily or weekly) of toxicological relevance and no changes in body weight, daily food consumption, ophthalmological findings and no macroscopical changes at necropsy were observed. Results from the Functional Observational Battery (FOB) did not indicate any effects of neurotoxicological relevance (including mean fore- or hind-limb grip strength, body temperature, landing foot splay and locomotor activity including rearing). Increases in relative liver weights along with microscopic changes (increased incidence of single cell necrosis) were found in males and females at 150 and 500 mg/kg bw per day. At 500 mg/kg bw per day, fine periportal vacuolisation and an increased severity of inflammatory cell foci were observed in the livers of males and females at terminal and recovery sacrifice. It was also noted that the test item (itself or as derivatives) might accumulate in macrophages (liver, spleen and mesenteric lymph node) and in Kupffer cells (liver) at and above 50 mg/kg bw per day, without reversibility after four weeks. The latter finding per se was not considered adverse by the Panel. In an additional part of the study, no effects of immunological relevance were noted in the primary immune response of female or male rats, nor did the leukocyte distribution show any effects.

The no observed adverse effect level (NOAEL) is considered to be 50 mg/kg bw per day based on the liver effects in males and females at 150 and 500 mg/kg bw per day.

3.2.3. Neurotoxicity

In a delayed neurotoxicity study (OECD TG No 418) with a LMW fraction of the phosphate form of the substance, a limit dose of 2,000 mg/kg bw in corn oil was applied to hens (n = 15) by oral gavage. The test item neither inhibited neuropathy target esterase (NTE) activity (at 24 and 48 h) nor induced gross lesions or histopathological changes in different brain areas compared to vehicle controls. To develop positive control data, hens were treated with tri-ortho-cresyl phosphate (TOCP). The TOCP-treated hens (n = 15; oral gavage, single dose of 750 mg/kg bw) exhibited an approximately threefold lower NTE activity in the brain and lumbar spinal cord (at 24 and 48 h) as well as typical locomotor ataxia and histopathological changes indicative of organophosphate induced delayed neurotoxicity. In conclusion, the data do not provide any evidence of induction of delayed neurotoxicity by the LMW fraction of the phosphate form of the substance.

3.2.4. Concluding remarks on toxicity

The Panel noted that the accumulation potential was not fully addressed by the applicant. Therefore, notwithstanding the availability of the 90-day subchronic toxicity study and the evidence for lack of neurotoxicity, it was considered prudent to conclude on the safety based on the lack of genotoxicity, which according to the tiered approach gives rise to a migration restriction of 0.05 mg/kg food.

The Panel concluded that the phosphorous-containing oligomers and other reaction/degradation products are adequately represented by the toxicity studies provided. The components not containing phosphorous are listed in Regulation (EU) 10/2011. The , which is expected to migrate at less than 0.001 mg/kg, is reported to be not mutagenic in the Ames test (NTP, 2018). The Panel noted that there are no alerts for genotoxicity in

4. Conclusions

The CEP Panel, after having considered the above-mentioned data, concluded that the substance phosphorous acid, triphenyl ester, 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 in HIPS materials and articles intended for 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.

Documentation provided to EFSA

1) Initial dossier. May 2018. Submitted on behalf of Dover Chemical Corporation.
2) Additional data. February 2019. Submitted on behalf of Dover Chemical Corporation.
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Abbreviations

bw body weight
BVL Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
CAS Chemical Abstracts Service
CEP Panel EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
FCM food contact materials
FOB Functional Observational Battery
HIPS high impact polystyrene
ICP-OES inductively coupled plasma optical emission spectrometry
LLDPE linear low-density polyethylene
LMW low molecular weight
Mn number average molecular weight
Mw molecular weight
NOAEL no observed adverse effect level
NTE neuropathy target esterase
OECD Organisation for Economic Co-operation and Development
P<sub>oct/w</sub> octanol/water partition coefficient
SCF Scientific Committee on Food
SML specific migration limit
TGA thermogravimetric analysis
TK thymidine-kinase
TOCP tri-ortho-cresyl phosphate
w/w weight by weight