SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 26 January 2022

doi: 10.2903/j.efsa.2022.7172

Safety assessment of diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl] phosphonate for use in a food contact material

EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP), Claude Lambré, José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob, Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis, Holger Zorn, Laurence Castle, Emma Di Consiglio, Roland Franz, Nicole Hellwig, Maria Rosaria Milana, Stefan Merkel, Eric Barthélémy, Daniele Comandella and Gilles Rivière

Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) assessed the safety of the substance diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl] phosphonate, FCM substance No. 1007, which is intended to be used in the polymerisation reaction to make poly(ethylene 2,5-furandicarboxylate) (PEF) plastic. The substance is intended to become a component of the backbone of the polymer and has an antioxidant function that provides thermal stability to the polyester during heat processing. The resulting plastic is intended to be used in contact with all types of food under any condition of time and temperature. A PEF sample made using 0.1% w/w of the substance (which is the maximum intended use) was used in a comprehensive set of migration tests with food simulants. The migration of the substance was below the quantification limits estimated around 10 μg/kg. Solvent extraction tests showed no presence of impurities or breakdown products of the substance. The toxicological data provided are the same as those submitted by the same applicant and previously evaluated. The resulting assessment and conclusions are considered still valid by the CEP Panel. Therefore, the CEP Panel concluded that the substance diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate does not raise a safety concern for the consumer if used at up to 0.1% w/w (based on the weight of the polymer) in the polymerisation to make PEF intended for contact with all types of foods under any contact conditions.

Keywords: diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl] phosphonate, CAS No. 976-56-7, FCM substance No. 1007, food contact materials, safety assessment

Requestor: Competent Authority of The Netherlands (Ministry of Health, Welfare and Sport)

Question number: EFSA-Q-2020-00615

Correspondence: ral@efsa.europa.eu

Panel members: José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob, Claude Lambré, Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Vittorio Silano (until 21 December 2020†), Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis and Holger Zorn.

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.

Acknowledgments: The Panel wishes to acknowledge all European competent institutions, Member State bodies and other organisations that provided data for this scientific output.

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 (https://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.

Suggested citation: EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids), Lambré C, Barat Baviera JM, Bolognesi C, Chesson A, Cocconcelli PS, Crebelli R, Gott DM, Grob K, Lampi E, Mengelers M, Mortensen A, Steffensen I-L, Tlustos C, Van Loveren H, Vernis L, Zorn H, Castle L, Di Consiglio E, Franz R, Hellwig N, Milana MR, Merkel S, Barthélémy E, Comandella D and Rivière G, 2022. Scientific Opinion on the safety assessment of diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl] phosphonate for use in a food contact material. EFSA Journal 2022;20(3):7172, 6 pp. https://doi.org/10.2903/j.efsa.2022.7172

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

† Deceased.

Table of contents

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 Competent Authority of The Netherlands (Ministry of Health, Welfare and Sport), requesting the evaluation of the substance diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate, with the CAS number 976-56-7 and the FCM substance No. 1007. The dossier was submitted on behalf of Avantium Renewable Polymers BV.

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 diethyl [[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate to be used in plastic FCM.

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
- Identification, quantification and migration of reaction products and impurities

Toxicological data

- Bacterial gene mutation test
- *In vitro* mammalian cell micronucleus test
- Review on the neurotoxicity potential of a structurally similar substance

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/are 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.

[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.

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

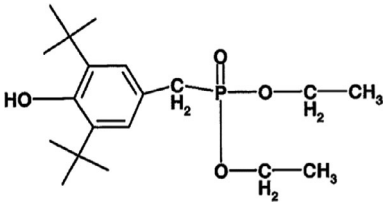
According to the applicant, the substance diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl] methyl]phosphonate is intended to be used at up to 0.1% w/w in the polymerisation reaction to produce poly(ethylene 2,5-furandicarboxylate) (PEF) plastic. During polymerisation, the substance is incorporated as a component of the backbone of the polymer. Its function is to act as an antioxidant providing thermal stability to PEF during processing and moulding of end-use articles, such as bottles and films. The resulting PEF is intended for contact with all types of food under any conditions of time and temperature.

The substance was already evaluated in a previous EFSA scientific opinion (EFSA CEF Panel, 2016) corresponding to the dossier EFSA-Q-2012-00908. In that case, it was concluded that the substance was not a safety concern for the consumer if used at up to 0.2% w/w for its use in the polymerisation reaction to produce poly(ethylene terephthalate) (PET).

3.1. Non-toxicological data

Chemical formula: $C_{19}H_{33}O_4P$.

Chemical structure:



3.1.1. Physical and chemical properties[2]

The molecular weight of the substance is 356 Da. The log $P_{o/w}$ of the substance is estimated to be 4.9. The substance has high chemical purity and the impurities identified were typical for such an antioxidant considering the information on the production process that was provided by the applicant as confidential. It is virtually insoluble in water and soluble in organic solvents, such as methanol, acetone, chloroform, benzene and *n*-hexane. According to differential scanning calorimetry, the substance decomposes above 350°C, which is well above the maximum intended polymer processing temperature (approx. 230°C) of PEF. Therefore, no thermal degradation products of the substance are to be expected.

[2] Technical dossier/3subm131021_valid/Appendix B/sections 1 and 2 & Annexes 1.1.9, 1.1.10, 2.1.3, 2.1.4, 2.1.5.

3.1.2. Specific migration[3]

Tests were conducted with a sample of PEF prepared with the maximum intended level of the substance (0.1% w/w). The food simulants used were 10% ethanol, 3% acetic acid and olive oil for 10 days at 60°C. The potential migration of the substance was determined with liquid chromatography coupled with mass spectrometry (LC–MS). No migration of the substance was found, with quantification limits estimated by the Panel to be around 10 μg/kg, depending on the simulant used. One reason for this low migration could be that the substance is chemically incorporated ('bound') into the polyester chain during the polymerisation process. This was supported by the finding that the substance was not detected after dissolution of a PEF sample.

The presence of potential degradation products of the substance was checked during the same migration tests (food simulants: 10% ethanol, 3% acetic acid and olive oil for 10 days at 60°C). Analysis by LC–MS showed no migration of degradation products with a detection limit estimated to be up to 5 μg/kg.

3.2. Toxicological data[4]

The toxicological data provided are the same as those submitted by the same applicant for a previous dossier and evaluated in the scientific opinion (EFSA CEF Panel, 2016). The resulting assessment and conclusions are considered still valid by the CEP Panel.

4. Conclusions

The CEP Panel concluded that the substance diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl] methyl]phosphonate is not of safety concern for the consumer if it is used up to 0.1% w/w (based on the polymer weight) during the polymerisation process to make PEF intended for contact with all types of food under any conditions of time and temperature.

5. Documentation as provided to EFSA

Dossier diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate'. September 2020. Submitted by Intertek France S.A.S. on behalf of Avantium Renewable Polymers BV.

References

EFSA (European Food Safety Authority), 2009. Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessments carried out by EFSA. Part 2: general principles. EFSA Journal 2009;7 (5):1051, 22 pp. https://doi.org/10.2903/j.efsa.2009.1051

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2016. Safety assessment of the substance diethyl [[3, 5-bis (1, 1-dimethylethyl)-4-hydroxyphenyl] methyl] phosphonate, for use in food contact materials. EFSA Journal 2016;14(7):e04536, 7 pp. https://doi.org/10.2903/j.efsa.2016.4536

European Commission, 2001. Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation. Available online: https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out82_en.pdf

Abbreviations

CAS	Chemical Abstracts Service
CEF Panel	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
FCM	food contact materials
LC–MS	liquid chromatography–mass spectrometry
$P_{o/w}$	octanol/water partition coefficient
PEF	poly(ethylene 2,5-furandicarboxylate)
PET	poly(ethylene terephthalate)
SCF	Scientific Committee on Food
TTC	threshold of toxicological concern

[3] Technical dossier/3subm131021_valid/Appendix B/sections 5 and 6 & Annexes 5.1, 6.1.
[4] Technical dossier/3subm131021_valid/Appendix B/section 8 & Annexes 8.1.1, 8.1.2, 8.4.2.