

## SCIENTIFIC OPINION

### Scientific Opinion on the safety evaluation of the substance, 1,3,5-tris(2,2-dimethylpropanamido)benzene, CAS No. 745070-61-5, for use in food contact materials<sup>1</sup>

#### EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)<sup>2,3</sup>

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#### ABSTRACT

This scientific opinion of EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids deals with the safety evaluation of the additive 1,3,5-tris(2,2-dimethylpropanamido)benzene with the CAS No. 745070-61-5, the Ref. No 95420, the FCM Substance No 784, for use as a nucleating agent/clarifier at a maximum use level of 250 mg/kg in polypropylene (PP). Final articles are intended to be used in contact with all type of foods for short term contact (1 hour) at temperatures up to 100 °C and/or for long term storage at ambient temperature or below. Specific migration of the substance into 3 % acetic acid, 10 % ethanol and olive oil, was measured to be up to 48 µg/kg, 79 µg/kg and 94 µg/kg, respectively. *In vitro* and *in vivo* genotoxicity tests showed no evidence for a genotoxic potential of the substance. A 90-day dietary toxicity study in Wistar rats showed no effects at any dose and the NOAEL was considered to be 961 mg/kg bw/day in males and 1104 mg/kg bw/day in females or higher. Therefore, the CEF Panel concluded that the substance 1,3,5-tris(2,2-dimethylpropanamido)benzene does not raise a safety concern for the consumer if it is used in polyolefins and the migration does not exceed 5 mg/kg food.

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#### KEY WORDS

1,3,5-Tris(2,2-dimethylpropanamido)benzene; CAS No. 745070-61-5; Ref. No 95420; FCM Substance No 784; Food Contact Materials; Polyolefins; Safety evaluation.

<sup>1</sup> On request from the Food Standards Agency, UK, Question No EFSA-Q-2012-00695, adopted on 4 July 2013.

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<sup>3</sup> Acknowledgement: The Panel wishes to thank the members of the Working Group on Food Contact Materials: Mona-Lise Binderup, Laurence Castle, Riccardo Crebelli, Roland Franz, Nathalie Gontard, Ragna Bogen Hetland, Eugenia Lampi, Maria Rosaria Milana, Maria de Fátima Tavares Poças, Philippe Saillard, Kjetil Svendsen and Detlef Wölfle for the preparatory work on this scientific opinion.

Suggested citation: EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2013. Scientific Opinion on the safety evaluation of the substance, 1,3,5-tris(2,2-dimethylpropanamido)benzene, CAS No. 745070-61-5, for use in food contact materials. EFSA Journal 2013;11(7):3306, 8 pp. doi:10.2903/j.efsa.2013.3306

Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

## SUMMARY

Within the general task of evaluating substances intended for use in materials in contact with food according to the 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 foodstuffs, the CEF Panel received a request from Food Standards Agency, UK, for the safety evaluation of the substance 1,3,5-tris(2,2-dimethylpropanamido)benzene, following an application from BASF Schweiz AG, Switzerland.

The safety evaluation of 1,3,5-tris(2,2-dimethylpropanamido)benzene with the CAS No 745070-61-5, the Ref. No 95420 and the FCM Substance No 784, was requested for use as a nucleating agent/clarifier at a maximum use level of 250 mg/kg in polypropylene (PP). Final articles are intended to be used in contact with all type of foods, for short term contact (1 hour) at temperatures up to 100 °C and/or for long term storage at ambient temperature or below.

The substance has already been evaluated by the EFSA AFC Panel in 2006 for the same use with the conclusion that the substance does not raise a safety concern if the migration does not exceed 0.05 mg/kg food (EFSA, 2006). This application represents therefore an extension in the migration limit of the previous evaluation up to 5 mg/kg food.

Specific migration from PP plaques containing the substance at its maximum intended use level was measured into 3 % acetic acid, 10 % ethanol and olive oil, for 1 hour at 121 °C and for 1 hour at 121 °C followed by 10 days at 40 °C. Migration was up to 48 µg/kg, 79 µg/kg and 94 µg/k, respectively.

Genotoxicity potential of 1,3,5-tris(2,2-dimethylpropanamido)benzene was already evaluated by the AFC Panel in 2006. The AFC Panel concluded that there was no evidence for a genotoxic potential of the substance. A new OECD compliant 90-day dietary toxicity study in Wistar rats showed no effects at any dose. Therefore the NOAEL was considered to be 961 mg/kg bw/day in males and 1104 mg/kg bw/day in females or higher. In addition, the Panel concluded that the substance does not raise concern for accumulation in man.

Therefore, the CEF Panel concluded that the substance 1,3,5-tris(2,2-dimethylpropanamido)benzene does not raise a safety concern for the consumer if it is used in polyolefins and the migration does not exceed 5 mg/kg food.

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## **BACKGROUND AS PROVIDED BY THE LEGISLATION**

Before a substance is authorised to be used in food contact materials and is included in a positive list EFSA's opinion on its safety is required. This procedure has been established in Articles 8 and 9 of the 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<sup>4</sup>.

According to this procedure the industry submits applications to the Member States competent Authorities which in their turn transmit the applications to the EFSA for their evaluation. The application is supported by a technical dossier submitted by the industry following the SCF guidelines for the "presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation" (EC, 2001).

In this case, EFSA received an application from the Food Standards Agency, UK, requesting the evaluation of the additive 1,3,5-tris(2,2-dimethylpropanamido)benzene with the CAS Number 745070-61-5, the EEC packaging material reference number Ref. No 95420 and the FCM Substance No 784.

## **TERMS OF REFERENCE AS PROVIDED BY THE LEGISLATION**

The EFSA is required to carry out assessment on the risks originating from the migration into food of the additive 1,3,5-tris(2,2-dimethylpropanamido)benzene, intended to be used as a nucleating agent/clarifier to manufacture polypropylene articles, and to deliver a scientific opinion 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.

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<sup>4</sup> 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.

## ASSESSMENT

### 1. Introduction

The European Food Safety Authority was asked by the Food Standards Agency, UK, to evaluate the safety of 1,3,5-tris(2,2-dimethylpropanamido)benzene, with the CAS No 745070-61-5, the Ref. No 95420 and the FCM Substance No 784. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2012-00695. The dossier was submitted by BASF Schweiz AG, Switzerland.

### 2. General information

According to the applicant, the substance 1,3,5-tris(2,2-dimethylpropanamido)benzene, CAS 745070-61-5, is intended to be used as a nucleating agent/clarifier at a maximum level of 250 mg/kg in polypropylene (PP). Final articles are intended to be used in contact with all types of foodstuffs for short term contact (1 hour) at temperatures up to 100 °C and/or for long term storage at ambient temperature or below.

The substance has already been evaluated by the EFSA AFC Panel in 2006 for the same use. Based on migration tests and *in vitro* and *in vivo* genotoxicity tests, it was concluded that the substance does not raise a safety concern if the migration does not exceed 0.05 mg/kg food (EFSA, 2006).

This application represents therefore, an extension in the migration limit of the previous evaluation up to 5 mg/kg food.

### 3. Data available in the dossier used for this evaluation

The studies submitted for evaluation followed the SCF guidelines for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation (EC, 2001).

#### Non-toxicity data:

- Data on identity
- Data on physical and chemical properties
- Data on the purity of the substance
- Data on intended use and authorisation
- Data on migration

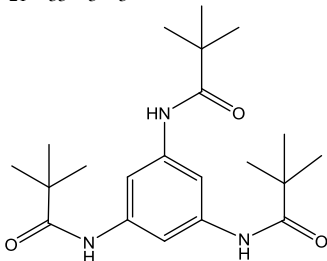
#### Toxicity data:

- 90-day oral toxicity study in rats

## 4. Evaluation

### 4.1. Non-toxicological data

Chemical formulae:  $C_{21}H_{33}N_3O_3$



Chemical structure:

The substance 1,3,5-tris(2,2-dimethylpropanamido)benzene has a molecular weight of 375.5 Da and a purity of 99.5 %. It has a log Po/w of 2.45 and it is soluble in miglyol (synthetic triglycerides mixture) (ca 43 mg/L after 10 days at 40 °C) and in 10 % ethanol (ca. 0.35 mg/L after 10 days at 40 °C).

The substance is thermally stable up to 380 °C and is not chemically transformed or decomposed under the manufacturing process conditions at temperatures up to 280 °C.

Specific migration tests were performed on PP plaques, containing 250 mg/kg (maximum intended use level) of 1,3,5-tris (2,2-dimethylpropanamido)benzene, having 1 mm thickness,  $d\ 0.9\ g/cm^3$ ) and a surface to mass ratio of 6 dm<sup>2</sup>/kg. Migration into 3 % acetic acid, 10 % ethanol and olive oil, for 1 hour at 121 °C and also for 1 hour at 121 °C followed by 10 days at 40 °C, was up to 48 µg/kg, 79 µg/kg and 94 µg/kg respectively.

In order to verify that no pH dependent hydrolysis of 1,3,5-tris(dimethylpropanamido)benzene occurred under physiological conditions, hydrolysis tests in saliva simulant (pH 8.7, 0.5h at 37°C) and in gastric juice simulant (pH 1.14, 4 h at 37 °C) were performed for the evaluation in 2006. No primary aromatic amines were detected (EFSA, 2006).

### 4.2. Toxicological data

Genotoxicity potential of 1,3,5-tris(2,2-dimethylpropanamido)benzene was evaluated by the AFC Panel in 2006. It did not show mutagenic potential in bacteria and in mammalian cells *in vitro*. It did not induce chromosome aberrations *in vitro* or micronuclei in bone marrow cells *in vivo*. Therefore it was concluded that there is no evidence for a genotoxic potential (EFSA, 2006).

In order to support the extension of the specific migration limit (SML) up to 5 mg/kg food (Regulation (EU) No 10/2011<sup>5</sup>), 1,3,5-tris(2,2-dimethylpropanamido)benzene was tested in an OECD compliant 90-day dietary toxicity study in Wistar rats. Rats were exposed by gavage at concentrations of 1500 ppm (corresponding to 91mg/kg bw/day in males and 115 mg/kg bw/day in females), 5000 ppm (corresponding to 306 mg/kg bw/day in males and 361mg/kg bw/day in females) and 15 000 ppm (corresponding to 961 mg/kg bw/day in males and 1104 mg/kg bw/day in females). In conclusion, there were no effects at any dose. Therefore the NOAEL was considered to be 961 mg/kg bw/day in males and 1104 mg/kg bw/day in females or higher.

<sup>5</sup> Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food Text with EEA relevance. OJ L 12, 15.1.2011, p. 1–89.

The substance has a log Po/w value of 2.45 and can be expected to be metabolised to more hydrophilic derivative through aromatic and aliphatic hydroxylation and N-oxydation (ToxTree 2.5). Therefore the Panel concluded that substance does not raise concern for accumulation in man.

## CONCLUSIONS

After having considered the above mentioned data, the CEF Panel concluded that the substance 1,3,5-tris(2,2-dimethylpropanamido)benzene does not raise a safety concern for the consumer if it is used in polyolefins and the migration does not exceed 5 mg/kg food.

## DOCUMENTATION PROVIDED TO EFSA

Dossier Dated: 12 June 2012. Submitted by BASF Schweiz AG.

## REFERENCES

EC (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 its authorisation; [http://ec.europa.eu/food/fs/sc/scf/out82\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out82_en.pdf).

EFSA (European food Safety Authority), 2006. Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 12<sup>th</sup> list of substances for food contact materials; <http://www.efsa.europa.eu/en/efsajournal/doc/395.pdf>.

## ABBREVIATIONS

CAS	Chemical Abstracts Service
CEF	Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FCM	Food Contact Materials
SCF	Scientific Committee on Food
SML	Specific Migration Limit
OECD	Organization of Economic Co-operation and Development
NOAEL	No Observed Adverse Effect Level
Po/w	Octanol/water partition coefficient
PP	Polypropylene