

SCIENTIFIC OPINION

Scientific Opinion on the safety evaluation of the substance, cyclic oligomers of (butylene terephthalate), CAS No. 263244-54-8, for use in food contact materials¹

**EFSA Panel on food contact materials, enzymes,
flavourings and processing aids (CEF)^{2,3}**

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ABSTRACT

This scientific opinion of EFSA deals with the risk assessment of the substance cyclic oligomers of (butylene terephthalate), CAS No. 263244-54-8, REF. No. 45676 for which the CEF Panel concluded that there is no safety concern for the consumer if the substance is only used in PET, PBT, PC, PS and rigid PVC plastics up to 1% w/w, in contact with aqueous, acidic and alcoholic foods, for long term storage at room temperature.

KEY WORDS

Cyclic oligomers of (butylene terephthalate); CAS number 263244-54-8; Ref. No. 45676; Food contact materials; Safety assessment; Evaluation.

1 On request from the Food Standards Agency, United Kingdom, Question No EFSA-Q-2007-096 adopted on 26 November 2009.

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3 Acknowledgement: The Panel wishes to thank the members of the Working Group on Food Contact Materials for the preparation of this opinion: Mona-Lise Binderup, Laurence Castle, Riccardo Crebelli, Roland Franz, Nathalie Gontard, Eugenia Lampi, Jean-Claude Lhuguenot, Maria Rosaria Milana, Karla Pfaff, Kjetil Svensson and Detlef Wölfle for the support provided to this EFSA scientific output.

For citation purposes: EFSA Panel on food contact materials, enzymes; flavourings and processing aids (CEF), Scientific Opinion on the safety evaluation of the substance cyclic oligomers of (butylene terephthalate), CAS No. 263244-54-8, for use in food contact materials. EFSA Journal 2009; 7(12):1399. [11 pp.]. doi:10.2903/j.efsa.2009.1399. Available online: www.efsa.europa.eu

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 a competent Member State Authority for safety evaluation of a substance following a corresponding application from the industry.

The request received and the outcome of the safety evaluation is summarised below:

The Food Standards Agency, United Kingdom, requested the evaluation of the additive cyclic oligomers of (butylene terephthalate) with CAS number 263244-54-8 and European Commission reference number (REF. No.) 45676, to be used up to 1% (w/w) in poly(ethylene terephthalate) (PET), poly(butylene terephthalate) (PBT), polycarbonate (PC), polystyrene (PS) and poly(vinyl chloride) (PVC) intended to be used for contact with aqueous, acidic and alcoholic foodstuffs, for long term storage at room temperature. The dossier was submitted by the applicant, Cyclics Corporation.

The CEF Panel concluded that there is no safety concern for the consumer if the substance is used only in PET, PBT, PC, PS and rigid PVC plastics up to 1% w/w, in contact with aqueous, acidic and alcoholic foods, for long term storage at room temperature.

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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 food⁴.

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, the EFSA received an application from the Food Standards Agency, United Kingdom, requesting the evaluation of the substance cyclic oligomers of (butylene terephthalate) with the CAS number 263244-54-8 and the European Commission reference number (REF. No.) 45676.

TERMS OF REFERENCE AS PROVIDED BY THE LEGISLATION

The EFSA is required by Article 10 of Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food to carry out risk assessments on the risks originating from the migration of substances from food contact materials into food and deliver a scientific opinion on:

1. new substances intended to be used in food contact materials before their authorisation and inclusion in a positive list;
2. substances which are already authorised in the framework of Regulation (EC) No. 1935/2004 but need to be re-evaluated.

⁴ This Regulation replaces Directive 89/109/EEC of 21 December 1988, OJ L 40, 11.2.1989, P.38.

ASSESSMENT

1. Introduction

The European Food Safety Authority was asked by the Food Standards Agency, United Kingdom, to evaluate the safety of the substance cyclic oligomers of (butylene terephthalate) with a CAS number 263244-54-8 and a REF. No. 45676. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2007-096. The dossier was submitted by the applicant, Cyclics Corporation.

Since in the past the evaluation of substances used in food contact materials was undertaken by the Scientific Committee on Food (SCF), the same system of classification into a "SCF list" is retained for uniformity purposes. The definitions of the various SCF lists and the abbreviations used are given in the Appendix A.

2. General information

According to the applicant, the substance cyclic oligomers of (butylene terephthalate) is a mixture consisting mainly of the dimer, the trimer, the tetramer and the pentamer. It is intended to be used up to 1% w/w in poly(ethylene terephthalate) (PET), poly(butylene terephthalate) (PBT), polycarbonate (PC), polystyrene (PS) and poly(vinyl chloride) (PVC). Its technological functions are (i) to lower the viscosity of melted polymers to facilitate their processing and (ii) to facilitate the dispersion of colorants into polymeric matrixes. Plastics are intended to be used for contact with aqueous, acidic and alcoholic foodstuffs, for long term storage at room temperature.

The substance has not been evaluated by the SCF or EFSA in the past.

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 intended use and authorisation
- Data on specific migration
- Data on residual content of the substance

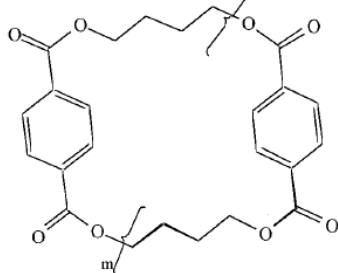
Toxicity data: None

4. Evaluation

4.1. Non-toxicological data

The substance cyclic oligomers of (butylene terephthalate) is a mixture mainly composed of the dimer (Mw=440 Da, 33 %), the trimer (Mw=660 Da, 39%), the tetramer (Mw=880 Da, 12%) and the pentamer (Mw=1100 Da, 13%). 85% of the mixture has a molecular weight below 1000 Da.

The structural formula of the substance is shown below:



m may vary from 1 to 5

The purity was described as being higher than 99%. The substance has a lipophilic character with a Log Po/w of 3.5.

PET containing the substance at the highest use level of 1% was tested for specific migration of the substance. The food simulants used were 10% ethanol and 3% acetic acid and the test conditions used for each simulant were 10 and 30 days at 40°C. The highest migration result was 8 µg/kg.

Analysis of PET formulated with 1% of the substance revealed that only 50% of the initial additive could be extracted. The remaining 50% that was non-extractable will also be non-migratable. It can be expected to be polymer-bound due to transesterification reactions during the high-temperature processing of PET. This loss would not be expected for non polyester materials. However, due to the low diffusivity of the polymers in which it is intended to be used, the migration is expected to be below 50 µg/kg food.

4.2. Toxicological data

The substance is a mixture of oligomers made from the monomers terephthalic acid (Ref No 24940) and 1,4-butanediol (Ref No 40580) that are authorised with restrictions of 7.5 mg/kg food and 5 mg/kg food respectively (EC, 2002). Starting monomers are devoid of functional groups associated with genotoxicity and so are the oligomeric esters resulting from their reaction. In conclusion no genotoxic properties are expected for the substance. Due to the low migration, no further toxicity data on the substance are required according to the SCF Guidelines on Food Contact Materials (EC, 2001).

CONCLUSIONS

The CEF Panel after having considered the above-mentioned data proposes that the substance cyclic oligomers of (butylene terephthalate) be classified in the SCF_List 3 with the restriction only to be used in PET, PBT, PC, PS and rigid PVC plastics up to 1% w/w, in contact with aqueous, acidic and alcoholic foods, for long term storage at room temperature.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier referenced: EFSA/AFC/FCM/1047; Dated: May 2007. Submitted by Cyclics Corporation.
2. Dossier referenced: EFSA/AFC/FCM/1472; Dated: July 2009. Submitted by Cyclics Corporation.

REFERENCES

- EC (European Commission), 2002. Commission Directive 2002/72/EC, relating to plastic materials and articles intended to come into contact with foodstuffs; http://ec.europa.eu/food/food/chemicalsafety/foodcontact/2002-72_en.pdf.
- 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.

APPENDICES

1. APPENDIX A

DEFINITION OF THE SCF LISTS

The classification into a SCF_List is a tool used for tackling authorisation dossiers and do not prejudice the management decisions that will be taken on the basis of the scientific opinions of the CEF Panel and in the framework of the applicable legislation

List 0 Substances, e.g. foods, which may be used in the production of plastic materials and articles, e.g. food ingredients and certain substances known from the intermediate metabolism in man and for which an ADI need not be established for this purpose.

List 1 Substances, e.g. food additives, for which an ADI (=Acceptable Daily Intake), a t-ADI (=temporary ADI), a MTDI (=Maximum Tolerable Daily Intake), a PMTDI (=Provisional Maximum Tolerable Daily Intake), a PTWI (=Provisional Tolerable Weekly Intake) or the classification "acceptable" has been established by this Committee or by JECFA.

List 2 Substances for which this Committee has established a TDI or a t-TDI.

List 3 Substances for which an ADI or a TDI could not be established, but where the present use could be accepted.

Some of these substances are self-limiting because of their organoleptic properties or are volatile and therefore unlikely to be present in the finished product. For other substances with very low migration, a TDI has not been set but the maximum level to be used in any packaging material or a specific limit of migration is stated. This is because the available toxicological data would give a TDI, which allows that a specific limit of migration or a composition limit could be fixed at levels very much higher than the maximum likely intakes arising from present uses of the additive.

Depending on the available toxicological studies a restriction of migration into food of 0.05 mg/kg of food (3 mutagenicity studies only) or 5 mg/kg of food (3 mutagenicity studies plus 90-day oral toxicity study and data to demonstrate the absence of potential for bio-accumulation in man) may be allocated.

List 4 (for monomers)

4A Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method.

4B Substances for which an ADI or TDI could not be established, but which could be used if the levels of monomer residues in materials and articles intended to come into contact with foodstuffs are reduced as much as possible.

- List 4 (for additives)**
- Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method.
- List 5** Substances that should not be used.
- List 6** Substances for which there exist suspicions about their toxicity and for which data are lacking or are insufficient.
- The allocation of substances to this list is mainly based upon similarity of structure with that of chemical substances already evaluated or known to have functional groups that indicate carcinogenic or other severe toxic properties.
- 6A** Substances suspected to have carcinogenic properties. These substances should not be detectable in foods or in food simulants by an appropriate sensitive method for each substance.
- 6B** Substances suspected to have toxic properties (other than carcinogenic). Restrictions may be indicated.
- List 7** Substances for which some toxicological data exist, but for which an ADI or a TDI could not be established. The required additional information should be furnished.
- List 8** Substances for which no or only scanty and inadequate data were available.
- List 9** Substances and groups of substances which could not be evaluated due to lack of specifications (substances) or to lack of adequate description (groups of substances).
- Groups of substances should be replaced, where possible, by individual substances actually in use. Polymers for which the data on identity specified in "SCF Guidelines" are not available.
- List W** "Waiting list". Substances not yet included in the Community lists, as they should be considered "new" substances, i.e. substances never approved at national level. These substances cannot be included in the Community lists, lacking the data requested by the Committee.

2. APPENDIX B

TERMS USED RELEVANT TO MIGRATION:

Overall migration: The sum of the amounts of volatile and non volatile substances, except water, released from a food contact material or article into food or food simulant

Specific migration: The amount of a specific substance released from a food contact material or article into food or food simulant

ABBREVIATIONS

AFC	Scientific Panel on additives, flavourings, processing aids and materials in contact with food
CAS	Chemical abstracts service
CEF	Scientific Panel on food contact materials, enzymes, flavourings and processing aids
Da	Dalton
EC	European Commission
EFSA	European food safety authority
FCM	Food Contact Material(s)
Mw	Weight average molecular weight
PBT	Poly(butylene terephthalate)
PC	Polycarbonate
PET	Poly(ethylene terephthalate)
Po/w	Octanol/water partition coefficient
PVC	Poly(vinyl chloride)
PS	Polystyrene
REF No	Reference Number
SCF	Scientific Committee on food
w/w	Weight by weight