

## SCIENTIFIC OPINION

### 25<sup>th</sup> list of substances for food contact materials<sup>1</sup>

#### Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF)

#### Question N°

EFSA-Q-2008-202, EFSA-Q-2006-144, EFSA-Q-2007-031, EFSA-Q-2007-025,  
EFSA-Q-2007-030, EFSA-Q-2007-029, EFSA-Q-2007-028

Adopted on 21 July 2009

#### PANEL MEMBERS\*

Arturo Anadón, David Bell, Mona-Lise Binderup, Wilfried Bursch, Laurence Castle, Riccardo Crebelli, Karl-Heinz Engel, Roland Franz, Nathalie Gontard, Thomas Haertlé, Trine Husøy, Klaus-Dieter Jany, Catherine Leclercq, Jean-Claude Lhuguenot, Wim Mennes, Maria Rosaria Milana, Karla Pfaff, Kettel Svensson, Fidel Toldrá, Rosemary Waring, Detlef Wölfle.

#### 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 evaluated the following substances:

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<sup>1</sup> For citation purposes: Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF) on 25<sup>th</sup> list of substances for food contact materials. *The EFSA Journal* (2009). *The EFSA Journal* (2009) **1196-1202**, 1-20.

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\* M.-L. Binderup declared an interest for the substance REF. No. 25872 as she had prepared the evaluation report of the substance under contract with EFSA. This was considered as a conflict of interest because she could not act at the same time as a representative of the contractor and a member of the Panel with voting rights. She was allowed to stay in the room to answer questions specifically addressed to her but did not participate in the discussion of the opinion. Another Panel member presented the draft opinion.

EFSA Question Number: EFSA-Q-2008-202  
Ref. No.: 25187  
Name of the substance: 2,2,4,4-Tetramethylcyclobutane-1,3-diol  
CAS number: 3010-96-6  
SCF\_List: 3  
Restriction: 5 mg/kg food  
Only for repeated use articles for long term storage at room temperature or below and hotfill  
Remark for Commission: Good manufacturing practices would keep migration in all cases well below 0.05 mg/kg food

EFSA Question Number: EFSA-Q-2006-144  
Ref. No.: 25872  
Name of the substance: 2,3,6-Trimethylphenol  
CAS number: 2416-94-6  
SCF\_List: 3  
Restriction: 0.05 mg/kg food  
Remark for Commission: None

EFSA Question Number: EFSA-Q-2007-031  
Ref. No. : 40619  
Name of the substance: (Butyl acrylate, methyl methacrylate, butyl methacrylate) copolymer  
CAS number: 25322-99-0  
SCF\_List: 3  
Restriction: Only to be used in rigid PVC at a maximum level of 1%  
Remark for Commission: None

EFSA Question Number: EFSA-Q-2007-025  
Ref. No. : 40620  
Name of the substance: (Butyl acrylate, methyl methacrylate) copolymer, cross-linked with allyl methacrylate  
CAS number: -  
SCF\_List: 3  
Restriction: Only to be used in rigid PVC at a maximum level of 7%  
Remark for Commission: None

EFSA Question Number: EFSA-Q-2007-030  
Ref. No. : 40815  
Name of the substance: (Butyl methacrylate, ethyl acrylate, methyl methacrylate) copolymer  
CAS number: 40471-03-2  
SCF\_List: 3  
Restriction: Only to be used in rigid PVC at a maximum level of 2%  
Remark for Commission: None

EFSA Question Number: EFSA-Q-2007-029  
Ref. No. : 53245  
Name of the substance: (Ethyl acrylate, methyl methacrylate) copolymer  
CAS number: 9010-88-2  
SCF\_List: 3  
Restriction: Only to be used in rigid PVC at a maximum level of 2%  
Remark for Commission: None

EFSA Question Number: EFSA-Q-2007-028  
Ref. No.: 66763  
Name of the substance: (Butyl acrylate, methyl methacrylate, styrene) copolymer  
CAS number: 27136-15-8  
SCF\_List: 3  
Restriction: Only to be used in rigid PVC at a maximum level of 3%  
Remark for Commission: None

## KEYWORDS

Food Contact Materials ; Plastics, Additives ; Ref. No. 25187, CAS number 3010-96-6, 2,2,4,4-Tetramethylcyclobutane-1,3-diol ; Ref. No. 25872, CAS number 2416-94-6, 2,3,6-Trimethylphenol ; Ref. No. 40619, CAS number 25322-99-0, (Butyl acrylate, methyl methacrylate, butyl methacrylate) copolymer ; Ref. No. 40620, (Butyl acrylate, methyl methacrylate) copolymer, cross-linked with allyl methacrylate ; Ref. No. 40815, CAS number 40471-03-2, (Butyl methacrylate, ethyl acrylate, methyl methacrylate) copolymer ; Ref. No. 53245, CAS number 9010-88-2, (Ethyl acrylate, methyl methacrylate) copolymer ; Ref. No. 66763, CAS number 27136-15-8, (Butyl acrylate, methyl methacrylate, styrene) copolymer.

## BACKGROUND

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>2</sup>.

## TERMS OF REFERENCE

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.

## ACKNOWLEDGEMENTS\*

The European Food Safety Authority wishes to thank Mona-Lise Binderup, Laurence Castle, Riccardo Crebelli, Roland Franz, Nathalie Gontard, Sander Koster, Eugenia Lampi, Jean-Claude Lhuguenot, Maria Rosaria Milana, Karla Pfaff, Tjoena Siere, Kettel Svensson, Detlef Wölfle and Esther Zondervan for their contribution to the draft opinions.

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\* M.-L. Binderup declared an interest for the substance REF. No. 25872, as she had prepared the evaluation report of the substance under contract with EFSA. She presented the evaluation results and another member of the wg was appointed as rapporteur to present it to the Panel.

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<sup>2</sup> This Regulation replaces Directive 89/109/EEC of 21 December 1988, OJ L 40, 11.2.1989, P.38

## ASSESSMENT

Within this general task the Scientific Panel on food contact materials, enzymes, flavourings and processing aids (CEF) evaluated the following substances used in food contact materials.

The substances examined are listed in ascending order of their Reference Number (REF No.), with their chemical name, Chemical Abstract Number (CAS No.) and classification according to the “SCF list”. 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.

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

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2008-202</b>
<b>Ref. No.:</b>	<b>25187</b>
<b>Name of the substance:</b>	<b>2,2,4,4-Tetramethylcyclobutane-1,3-diol</b>

CAS number: 3010-96-6

Document reference: SDS EFSA/CEF/FCM/1232-Rev.IB/25187 of July 2009

**General information:** According to the petitioner, the substance “2,2,4,4-tetramethylcyclobutane-1,3-diol” (TMCD) is used as a co-monomer in amounts up to 33 % mole in the production of polyesters for food contact articles. Intended uses are for repeated use applications such as reusable food containers including baby bottles and food processing equipment. Typical contact conditions include room temperature or below and brief contact with hot foods and hotfills.

**Previous evaluations (by SCF, AFC or CEF):** None (new substance)

### Available data used for this evaluation:

Non-toxicity data: - Data on identity  
 - Data on physical and chemical properties  
 - Data on intended uses and authorisation of the substance  
 - Data on migration of the substance and overall migration  
 - Data on the nature of oligomers and their possible migration  
 - Data on residual content and calculated worst case migration

Toxicity data: - Gene mutation in bacteria test

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2008-202</b>
<b>Ref. No.:</b>	<b>25187</b>
<b>Name of the substance:</b>	<b>2,2,4,4-Tetramethylcyclobutane-1,3-diol</b>

- *In vitro* mammalian chromosomal aberrations test
- *In vitro* mammalian cell gene mutations test
- 90-day oral toxicity study in rats
- Reproductive toxicity study in rats

**Evaluation:**

Chemically, the substance is a mixture of two isomers with cis and trans position of the OH groups (where cis-TMCD : trans-TMCD = 47:53). The log Po/w was calculated to be 1.3.

Specific migration of the substance from a typical polyester sample was tested for repeated use applications (3 times in series) under test conditions of both 10 days at 40°C and 2 hours at 100°C at a ratio of 10 dm<sup>2</sup> per 1 kg food using as food simulants 3% acetic acid, 10% ethanol and olive oil. As a result, no migration of the substance was detected at a detection limit of 13 µg/kg for aqueous food simulants and 1 µg/kg for olive oil.

Five volatile compounds were identified in the final material and were shown to be linked to the manufacturing process of the substance itself and the polymer. Two of these substances were detected only in the aqueous migrates under conditions simulating hotfill, at levels below 20 µg/kg. In successive migration tests simulating repeated use, these substances were not detectable anymore.

No toxicity data were provided for these volatile substances which, however, are closely related to flavouring substances recently evaluated by the EFSA as non-genotoxic. Thus, based on read-across, it is concluded that at the level of migration detected these volatile substances do not raise a toxicological concern.

TMCD did not induce mutagenicity in bacteria or gene mutations and chromosomal aberrations in mammalian cells. Therefore the substance is considered as non-genotoxic.

A NOAEL of 25 mg/kg bw/twice a day was established in an oral subchronic toxicity study in the rat based on the hypertrophy/hyperplasia of adrenal glands observed at higher doses. In a rat developmental toxicity study, the NOAELs for maternal toxicity and prenatal developmental toxicity were 75 and 150 mg/kg bw/twice a day, respectively.

In view of the low log Po/w value, TMCD does not raise concerns for accumulation in man.

**Conclusion:**

Based on the above-mentioned data the substance is classified:

**SCF\_List: 3**

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2008-202</b>
<b>Ref. No.:</b>	<b>25187</b>
<b>Name of the substance:</b>	<b>2,2,4,4-Tetramethylcyclobutane-1,3-diol</b>

**Restriction:** 5 mg/kg food

**Only for repeated use articles for long term storage at room temperature or below and hotfill**

**Remark for Commission:** Good manufacturing practices would keep migration in all cases well below 0.05 mg/kg food

**Needed data or information:** None

**References:** Unpublished data from petitioner, February 2008.

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2006-144</b>
<b>Ref. No.:</b>	<b>25872</b>
<b>Name of the substance:</b>	<b>2,3,6-Trimethylphenol</b>

CAS number: 2416-94-6

Document reference: SDS EFSA/CEF/FCM/1141-Rev.IB/25872 of July 2009

**General information:** According to the petitioner, the substance “2,3,6-trimethylphenol” is intended to be used as a comonomer in the production of high heat poly(phenylene oxide) (HH PPO) resin. HH PPO blends with other polymers are intended to come into contact with all types of foods at temperatures up to 121°C.

**Previous evaluations (by SCF, AFC or CEF):** None (new substance)

**Available data used for this evaluation:**

- Non-toxicity data:
- Data on identity
  - Data on physical and chemical properties
  - Data on intended uses and authorisation
  - Data on migration

- Toxicity data:
- Gene mutation in bacteria test
  - *In vitro* mammalian chromosomal aberrations test
  - *In vitro* mammalian cell gene mutations test



<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2006-144</b>
<b>Ref. No.:</b>	<b>25872</b>
<b>Name of the substance:</b>	<b>2,3,6-Trimethylphenol</b>

**Evaluation:** 2,3,6-Trimethylphenol is thermally stable at the maximum process temperature of 300°C. The log Po/w is 2.7.  
The specific migration of the substance from a HH PPO/polystyrene blend (70:30) into 3% acetic acid, 10% ethanol and olive oil after a contact period of 0.5 hour at 100 °C followed by 10 days at 40 °C was below the detection limit of 10 µg/kg simulant.

2,3,6-Trimethylphenol was not mutagenic in bacteria. Equivocal results were received from an *in vitro* mammalian cell gene mutation assay which were however ruled out by a second confirmatory assay. Furthermore, the substance did not induce chromosomal aberrations in mammalian cells *in vitro*. Therefore, the substance is considered as non-genotoxic.

**Conclusion:** Based on the above-mentioned data the substance is classified:

**SCF\_List:** 3

**Restriction:** 0.05 mg/kg food

Remark for Commission: None

Needed data or information: None

**References:** Unpublished data from the petitioner in September 2006, May 2007, May 2008 and January 2009.

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2007-031</b>
<b>Ref. No.:</b>	<b>40619</b>
<b>Name of the substance:</b>	<b>(Butyl acrylate, methyl methacrylate, butyl methacrylate) copolymer</b>

CAS number: 25322-99-0

Document reference: SDS EFSA/CEF/FCM/1038-Rev.IIB/40619 of July 2009

**General information:** According to the petitioner, the substance “(butyl acrylate, methyl methacrylate, butyl methacrylate) copolymer” is a polymeric additive used in rigid poly(vinyl chloride) (PVC). Finished articles may contain up to 1% of the substance and are intended for contact with all types of food at room temperature and below.

**Previous evaluations (by SCF, AFC or CEF):** None (new substance)

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2007-031</b>
<b>Ref. No.:</b>	<b>40619</b>
<b>Name of the substance:</b>	<b>(Butyl acrylate, methyl methacrylate, butyl methacrylate) copolymer</b>

**Available data**

**used for this evaluation:**

- Non-toxicity data:
- Data on identity
  - Data on physical and chemical properties
  - Data on intended uses and authorisation
  - Data on residual monomers and impurities
  - Identification of the fraction with MW below 1000 Da
  - Migration data (modelled) for the fraction with MW below 1000 Da

Toxicity data: None

**Evaluation:**

The substance is a polymeric additive composed from the monomers butyl acrylate, butyl methacrylate and methyl methacrylate, authorised, each with a group restriction of 6 mg/kg food (EC, 2002). The polymeric additive is stable under foreseeable conditions of processing and use. The substance has a weight average molecular weight Mw = 2,642,000 Da and a number average molecular weight Mn = 10,000 Da.

The fraction with molecular weight below 1000 Da was estimated to be up to 8.3%. This fraction contains predominantly the authorised surfactant and lubricant used in the manufacturing process of the substance along with a small amount of oligomers, but the precise composition was not determined. Taking the conservative assumption that this fraction consists exclusively of oligomers, their migration was estimated by modelling to be 20 µg/kg food.

Based on the very low migration and the fact that oligomers are derived from authorised substances, the oligomeric fraction is not of safety concern.

**Conclusion:**

Based on the above-mentioned data the substance is classified:

**SCF\_List: 3**

**Restriction: Only to be used in rigid PVC at a maximum level of 1%**

Remark for Commission: None

Needed data or information: None

**References:**

- Unpublished information provided by the petitioner in January and July 2007 and April and August 2008 and February 2009.
- EC (European Commission), 2002. Commission Directive 2002/72/EC and its amendments, relating to plastic materials and articles intended

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2007-031</b>
<b>Ref. No.:</b>	<b>40619</b>
<b>Name of the substance:</b>	<b>(Butyl acrylate, methyl methacrylate, butyl methacrylate) copolymer</b>

to come into contact with foodstuffs;  
[http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72\\_en.pdf](http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72_en.pdf).

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2007-025</b>
<b>Ref. No.:</b>	<b>40620</b>
<b>Name of the substance:</b>	<b>(Butyl acrylate, methyl methacrylate) copolymer, cross-linked with allyl methacrylate</b>

CAS number:

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Document reference:

SDS EFSA/CEF/FCM/1040-Rev.IIB/40620 of July 2009

**General information:**

According to the petitioner, the substance “(butyl acrylate, methyl methacrylate copolymer) cross-linked with allyl methacrylate”, is a polymeric additive used in rigid poly(vinyl chloride) (PVC). Finished articles may contain up to 7% of the substance and are intended for contact with all types of food at room temperature and below.

**Previous evaluations (by SCF, AFC or CEF):**

None (new substance)

**Available data**

**used for this evaluation:**

- Non-toxicity data:
- Data on identity
  - Data on physical and chemical properties
  - Data on intended uses and authorisation
  - Data on residual monomers and impurities
  - Migration data (modelled) for the fraction with MW below 1000 Da

Toxicity data: None

**Evaluation:**

The substance is a polymeric additive composed from the monomers butyl acrylate (BA) and methyl methacrylate (MMA) and then further crosslinked with allyl methacrylate (ALMA) where BA and MMA are authorised substances, each with a group restriction of 6 mg/kg food and ALMA is authorised with a restriction of 0.05 mg/kg food (EC, 2002). The polymeric additive is stable under foreseeable conditions of processing and use. The molecular weight distribution could not be

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2007-025</b>
<b>Ref. No.:</b>	<b>40620</b>
<b>Name of the substance:</b>	<b>(Butyl acrylate, methyl methacrylate) copolymer, cross-linked with allyl methacrylate</b>

determined because of insolubility of the substance.

The fraction with molecular weight below 1000 Da was estimated to be up to 0.65%. This fraction contains predominantly the authorised surfactant and lubricant used in the manufacturing process of the substance along with a small amount of oligomers, but the precise composition was not determined. Taking the conservative assumption that this fraction consists exclusively of oligomers, their migration was estimated by modelling to be 16 µg/kg food.

Based on the very low migration and the fact that oligomers are derived from authorised substances, the oligomeric fraction is not of safety concern.

**Conclusion:** Based on the above-mentioned data the substance is classified:

**SCF\_List:** 3

**Restriction:** Only to be used in rigid PVC at a maximum level of 7%

Remark for Commission: None

Needed data or information: None

**References:**

- Unpublished data submitted by the petitioner in January and July 2007 and April and August 2008 and February 2009.
- EC (European Commission), 2002. Commission Directive 2002/72/EC and its amendments, relating to plastic materials and articles intended to come into contact with foodstuffs; [http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72\\_en.pdf](http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72_en.pdf).

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2007-030</b>
<b>Ref. No.:</b>	<b>40815</b>
<b>Name of the substance:</b>	<b>(Butyl methacrylate, ethyl acrylate, methyl methacrylate) copolymer</b>

CAS number: 40471-03-2

Document reference: SDS EFSA/CEF/FCM/1097-Rev.IIB/40815 of July 2009

**General information:** According to the petitioner, the substance “(butyl methacrylate, ethyl acrylate, methyl methacrylate) copolymer” is a polymeric additive used

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2007-030</b>
<b>Ref. No.:</b>	<b>40815</b>
<b>Name of the substance:</b>	<b>(Butyl methacrylate, ethyl acrylate, methyl methacrylate) copolymer</b>

in rigid poly(vinyl chloride) (PVC). Finished articles may contain up to 2% of the substance and are intended for contact with all types of food at room temperature and below.

**Previous evaluations (by SCF, AFC or CEF):** None (new substance)

**Available data used for this evaluation:**

- Non-toxicity data:
- Data on identity
  - Data on physical and chemical properties
  - Data on intended uses and authorisation
  - Data on residual monomers and impurities
  - Identification of the fraction with MW below 1000 Da
  - Migration data (modelled) for the fraction with MW below 1000 Da

Toxicity data: None

**Evaluation:** The substance is a polymeric additive made from the monomers butyl methacrylate, ethyl acrylate and methyl methacrylate, authorised, each with a group restriction of 6 mg/kg food (EC, 2002). The polymeric additive is stable under foreseeable conditions of processing and use. The substance has a weight average molecular weight  $M_w = 1,922,000$  Da and a number average molecular weight  $M_n = 14,000$  Da.

The fraction with molecular weight below 1000 Da was estimated to be up to 3.7%. This fraction contains predominantly the authorised surfactant and lubricant used in the manufacturing process of the substance along with a small amount of oligomers, but the precise composition was not determined. Taking the conservative assumption that this fraction consists exclusively of oligomers, their migration was estimated by modelling to be 18 µg/kg food.

Based on the very low migration and the fact that oligomers are derived from authorised substances, the oligomeric fraction is not of safety concern.

**Conclusion:** Based on the above-mentioned data the substance is classified:

**SCF\_List:** 3

**Restriction:** Only to be used in rigid PVC at a maximum level of 2%

Remark for Commission: None

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2007-030</b>
<b>Ref. No.:</b>	<b>40815</b>
<b>Name of the substance:</b>	<b>(Butyl methacrylate, ethyl acrylate, methyl methacrylate) copolymer</b>

Needed data or information: None

**References:**

- Unpublished data submitted by the petitioner in January 2007, April and August 2008 and February 2009.
- EC (European Commission), 2002. Commission Directive 2002/72/EC and its amendments, relating to plastic materials and articles intended to come into contact with foodstuffs; [http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72\\_en.pdf](http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72_en.pdf).

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2007-029</b>
<b>Ref. No.:</b>	<b>53245</b>
<b>Name of the substance:</b>	<b>(Ethyl acrylate, methyl methacrylate) copolymer</b>

CAS number: 9010-88-2  
 Document reference: SDS EFSA/CEF/FCM/1098-Rev.IIB/53245 of July 2009

**General information:**

According to the petitioner, the substance “(ethyl acrylate, methyl methacrylate) copolymer” is a polymeric additive used in rigid poly(vinyl chloride) (PVC). Finished articles may contain up to 2% of the substance and are intended for contact with all types of food at room temperature and below.

**Previous evaluations (by SCF, AFC or CEF):**

None (new substance)

**Available data used for this evaluation:**

- Non-toxicity data:
- Data on identity
  - Data on physical and chemical properties
  - Data on intended uses and authorisation
  - Data on residual monomers and impurities
  - Identification of the fraction with MW below 1000 Da
  - Migration data (modelled) for the fraction with MW below 1000 Da

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2007-029</b>
<b>Ref. No.:</b>	<b>53245</b>
<b>Name of the substance:</b>	<b>(Ethyl acrylate, methyl methacrylate) copolymer</b>

Toxicity data: None

**Evaluation:**

The substance is a polymeric additive made from the monomers ethyl acrylate and methyl methacrylate, authorised with a group restriction of 6 mg/kg food for each monomer (EC, 2002). The polymeric additive is stable under foreseeable conditions of processing and use. The substance has a weight average molecular weight  $M_w = 998,000$  Da and a number average molecular weight  $M_n = 11,000$  Da.

The fraction with molecular weight below 1000 Da was estimated to be up to 2.7%. This fraction contains predominantly the authorised surfactant and lubricant used in the manufacturing process of the substance along with a small amount of oligomers, but the precise composition was not determined. Taking the conservative assumption that this fraction consists exclusively of oligomers, their migration was estimated by modelling to be 19 µg/kg food.

Based on the very low migration and the fact that oligomers are derived from authorised substances, the oligomeric fraction is not of safety concern.

**Conclusion:**

Based on the above-mentioned data the substance is classified:

**SCF\_List:** 3

**Restriction:** Only to be used in rigid PVC at a maximum level of 2%

Remark for Commission: None

Needed data or

information: None

**References:**

- Unpublished data submitted by the petitioner January 2007, April and August 2008 and February 2009.
- EC (European Commission), 2002. Commission Directive 2002/72/EC and its amendments, relating to plastic materials and articles intended to come into contact with foodstuffs; [http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72\\_en.pdf](http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72_en.pdf).

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2007-028</b>
<b>Ref. No.:</b>	<b>66763</b>
<b>Name of the substance:</b>	<b>(Butyl acrylate, methyl methacrylate, styrene) copolymer</b>
CAS number:	27136-15-8

<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2007-028</b>
<b>Ref. No.:</b>	<b>66763</b>
<b>Name of the substance:</b>	<b>(Butyl acrylate, methyl methacrylate, styrene) copolymer</b>

Document reference: SDS EFSA/CEF/FCM/1096-Rev.IIB/66763 of July 2009

**General information:** According to the petitioner, the substance “(butyl acrylate, methyl methacrylate, styrene) copolymer” is a polymeric additive used in rigid poly(vinyl chloride) (PVC). Finished articles may contain up to 3 % of the substance and are intended for contact with all types of food at room temperature and below.

**Previous evaluations (by SCF, AFC or CEF):** None (new substance)

**Available data used for this evaluation:**

- Non-toxicity data:
- Data on identity
  - Data on physical and chemical properties
  - Data on intended uses and authorisation
  - Data on residual monomers and impurities
  - Migration data (modelled) for the fraction with MW below 1000 Da

Toxicity data: None

**Evaluation:** The substance is a polymeric additive made from the monomers butyl acrylate, methyl methacrylate and styrene. Butyl acrylate and methyl methacrylate are authorised, each with a group restriction of 6 mg/kg food and styrene is authorised without restriction (EC, 2002). The polymeric additive is stable under foreseeable conditions of processing and use. The substance displays a dual distribution curve where each peak has a weight average molecular weight  $M_w = 1,372,000$  Da respective  $M_w = 57,000$  Da and a number average molecular weight  $M_n = 850,000$  Da respective 8,000 Da.

The fraction with molecular weight below 1000 Da was estimated to be up to 2.8%. This fraction contains predominantly the authorised surfactant and lubricant used in the manufacturing process of the substance along with a small amount of oligomers, but the precise composition was not determined. Taking the conservative assumption that this fraction consists exclusively of oligomers, their migration was estimated by modelling to be 30 µg/kg food.

Based on the very low migration and the fact that oligomers are derived from authorised substances, the oligomeric fraction is not of safety concern.



<b>EFSA-Q-Nr.:</b>	<b>EFSA-Q-2007-028</b>
<b>Ref. No.:</b>	<b>66763</b>
<b>Name of the substance:</b>	<b>(Butyl acrylate, methyl methacrylate, styrene) copolymer</b>

**Conclusion:** Based on the above-mentioned data the substance is classified:

**SCF\_List:** 3

**Restriction:** Only to be used in rigid PVC at a maximum level of 3%

Remark for Commission: None

Needed data or information: None

**References:**

- Unpublished data submitted by the petitioner January 2007, April and August 2008 and February 2009.
- EC (European Commission), 2002. Commission Directive 2002/72/EC and its amendments, relating to plastic materials and articles intended to come into contact with foodstuffs; [http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72\\_en.pdf](http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72_en.pdf).

## APPENDIX

### 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.

**Term 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 stimulant

**List of abbreviations:**

AFC	Scientific Panel on “additives, flavourings, processing aids and materials in contact with food”
ALMA	Allyl methacrylate
BA	Butyl acrylate
bw	Body weight
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)
HH PPO	High heat poly(phenylene oxide)
MW	Molecular weight
MMA	Methyl methacrylate
Mn	Number average molecular weight
Mw	Weight average molecular weight
NOAEL	No observed adverse effect level
Po/w	Octanol/water partition coefficient
PVC	Poly(vinyl chloride)
REF No	Reference Number
SCF	Scientific Committee on Food
TMCD	Tetramethylcyclobutane-1,3-diol