Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 17th list of substances for food contact materials


Adopted on 28 - 29 November 2007

SCIENTIFIC PANEL MEMBERS


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 AFC Panel evaluated the following substances:

Ref. No.: 14627  
Name of the substance: 3-chlorophthalic anhydride  
CAS number: 117-21-5  
Classified in list: 3  
Restriction: 0.05 mg/kg food, expressed as 3-chlorophthalic acid

Ref. No.: 14628  
Name of the substance: 4-chlorophthalic anhydride  
CAS number: 118-45-6  
Classified in list: 3  
Restriction: 0.05 mg/kg food, expressed as 4-chlorophthalic acid
Ref. No.: 21498
Name of the substance: [3-(Methacryloxy)propyl]trimethoxysilane
CAS number: 2530-85-0
Classified in list: 3
Restriction: 0.05 mg/kg food
To be used only as a surface treatment agent of inorganic fillers

Ref. No.: 60027
Name of the substance: Hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw: 440-12000)
CAS number: -
Classified in list: 3
Restriction: None

Ref. No.: 80480
Name of the substance: Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-(2,2,6,6-tetramethyl-4-piperidyl)imino) hexa-methylene-(2,2,6,6-tetramethyl-4-piperidyl)imino)
CAS number: 90751-07-8
Classified in list: 3
Restriction: 5 mg/kg food

Ref. No.: 81280
Name of the substance: Polyvinyl alcohol
CAS number: 9002-89-5
Classified in list: 3
Restriction: None

Ref. No.: 92470
Name of the substance: N,N’,N”,N”’-tetrakis(4,6-bis(N-butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)amino)triazin-2-yl)-4,7-diazadecane-1,10-diamine
CAS number: 106990-43-6
Classified in list: 3
Restriction: 0.05 mg/kg food

Ref. No.: 92475
Name of the substance: 3,3’,5,5’-tetrakis(tert-butyl)-2,2’-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid
CAS number: 203255-81-6
Classified in list: 3
Restriction: 0.05 mg/kg food (expressed as the sum of phosphite and phosphate)

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form of the substance)

Ref. No.: 94000
Name of the substance: Triethanolamine
CAS number: 102-71-6
Classified in list: 3
Restriction: 0.05 mg/kg food (including the hydrochloride adduct)

KEYWORDS

Food Contact Materials, Plastics, Monomers, Additives, REF. No 14627, CAS No. 117-21-5, 3-chlorophthalic anhydride, REF. No 14628, CAS No. 118-45-6, 4-chlorophthalic anhydride, REF. No 21498, CAS No. 2530-85-0, [3-(Methacryloxy)propyl] trimethoxysilane, REF. No 60027, Hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw: 440-12000), REF. No 80480, CAS No. 90751-07-8, Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-(2,2,6,6-tetramethyl-4-piperidyl)imino) hexa-methylene-(2,2,6,6-tetramethyl-4-piperidyl)imino), REF. No 81280, CAS No. 9002-89-5, Polyvinyl alcohol, REF. No 92470, CAS No. 106990-43-6, N,N’,N'',N'''-tetrakis(4,6-bis(N-butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)amino)triazin-2-yl)-4,7-diazadecane-1,10-diamine, REF No 92475, CAS No. 203255-81-6, 3,3’,5,5’-tetrakis(tert-butyl)-2,2’-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid, REF. No 94000, CAS No. 102-71-6, triethanolamine.

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 food1.

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.

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ACKNOWLEDGEMENTS

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food wishes to thank Herman Autrup, Mona-Lise Binderup, Laurence Castle, Riccardo Crebelli, Wolfgang Dekant, Roland Franz*, Nathalie Gontard, Eugenia Lampi, Jean-Claude Lhuguenot, François Xavier Malcata, Maria Rosaria Milana, Karla Pfaff, Tjoena Siere, Detlef Wölfle and Esther Zondervan for their contribution to the draft opinion.

* Sandro Grilli, member of the Panel, declared an interest for the substance triethanolamine, REF. No. 94000, because he had advised an Italian distribution company regarding its use in cosmetics. It was not considered as a conflict of interest and he was invited to participate in the discussions.

Details on the declarations of interest can be found in the minutes of the Panel meeting at: http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC

Roland Franz, expert of the working group, declared an interest for the substance REF. No. 81280 because his Institute had submitted the petition on behalf of the industry. He left the room during the discussions. He also declared an interest for the substance REF. No. 92470 because his Institute had performed some analytical studies for the petitioner. He stayed in the room only to answer questions.
ASSESSMENT

Within this general task the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) 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)

<table>
<thead>
<tr>
<th>Ref. No.:</th>
<th>14627</th>
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<tbody>
<tr>
<td>Name of the substance:</td>
<td>3-chlorophthalic anhydride</td>
</tr>
<tr>
<td>CAS number:</td>
<td>117-21-5</td>
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</tbody>
</table>

General information: According to the petitioner 3-chlorophthalic anhydride is intended to be used as one of the starting materials to manufacture a polyetherimide resin which is a co-polymer of 1,3-benzenediamine, 3- and 4-chlorophthalic anhydride and bisphenol A. Articles made from the co-polymer are intended to be used in contact with all types of food under all temperature conditions. The specific applications include, but are not limited to, steam trays, utensils, food trays, beverage dispensers, and commercial bakeware.

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

Available data used for this evaluation:

Non-toxicity data:
- Data on identity and physical and chemical properties
- Data on use and authorisation
- Data on migration, additional migration data in olive oil, covering baking conditions;
- Data on overall migration in 95% ethanol and iso-octane

Toxicity data:
- Gene mutation in bacteria
- *In vitro* mammalian cell gene mutation test
- *In vitro* mammalian chromosome aberration test
- *In vivo* micronucleus test
Ref. No.: 14627
Name of the substance: 3-chlorophthalic anhydride

Evaluation: 3-Chlorophthalic anhydride is thermally stable. It is stable in olive oil whilst it hydrolyses in aqueous media to 3-chlorophthalic acid. There was no detectable migration of 3-chlorophthalic anhydride and its hydrolysis product into 3% acetic acid or 10% ethanol after a contact period of 2 hours at 121°C followed by 10 days at 40°C. The detection limit was 0.009 mg/kg expressed as 3-chlorophthalic acid. Similarly there was no detectable migration into olive oil after a contact period of 2 hours at 121°C followed by 10 days at 40°C, 2 hours at 191°C or 4 hours at 191°C. The detection limit in these cases was 0.03 mg/kg.

3-Chlorophthalic anhydride did not show mutagenic potential in bacteria and mammalian cells. It did not induce chromosome aberrations in vitro or micronuclei in bone marrow cells in vivo. 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, expressed as 3-chlorophthalic acid |
| Remark for Commission: | None |
| Needed data or information: | None |


Ref. No.: 14628
Name of the substance: 4-chlorophthalic anhydride

CAS number: 118-45-6

General information: According to the petitioner 4-chlorophthalic anhydride is intended to be used as one of the starting materials to manufacture a polyetherimide resin which is a co-polymer of 1,3-benzenediamine, 3- and 4-chlorophthalic anhydride and bisphenol A. Articles made from the co-polymer are intended for use in contact with all types of food under all temperature conditions. The specific applications include, but are not limited to, steam trays, utensils, food trays, beverage dispensers, and commercial bakeware.
Ref. No.: 14628

Name of the substance: 4-chlorophthalic anhydride

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

Available data used for this evaluation:
- Non-toxicity data: - Data on identity and physical and chemical properties
  - Data on use and authorisation
  - Data on migration, additional migration data in olive oil, covering baking conditions
  - Data on overall migration in 95% ethanol and iso-octane
- Toxicity data: - Gene mutation in bacteria
  - *In vitro* mammalian cell gene mutation test
  - *In vitro* mammalian chromosome aberration test
  - *In vivo* micronucleus test
  - 28 day oral toxicity study in rats
  - A 2-generation reproduction study in rats

Evaluation:
4-Chlorophthalic anhydride is thermally stable. It is stable in olive oil whilst it hydrolyses in aqueous media to 4-chlorophthalic acid. There was no detectable migration of 4-chlorophthalic anhydride and its hydrolysis products into 10% ethanol after a contact period of 2 hours at 121°C followed by 10 days at 40°C. The detection limit was 0.009 mg/kg expressed as 4-chlorophthalic acid. With the same contact conditions applied, migration into 3% acetic acid was 0.0095 mg/kg. There was no detectable migration into olive oil after a contact period of 2 hours at 121°C followed by 10 days at 40°C, 2 hours at 191°C or 4 hours at 191°C. The detection limit in these cases was 0.03 mg/kg.

4-Chlorophthalic anhydride did not show mutagenic potential in bacteria and mammalian cells. The result from the *in vitro* chromosome aberration test was equivocal. An adequately performed *in vivo* micronucleus assay in bone marrow was negative. Based on these results the substance is considered as non-genotoxic *in vivo*.

4-Chlorophthalic anhydride was tested in a 28-day oral gavage toxicity study in rats. The NOAEL derived from this study was 10 mg/kg bw/day based on evidence of general toxicity and histological alterations in the higher dose group (100 mg/kg bw). In a 2-generation reproduction study in rats the NOAEL is 50 mg/kg bw/day, based on an increase in pup deaths observed in the highest
Ref. No.: 14628
Name of the substance: 4-chlorophthalic anhydride
dose group (250 mg/kg bw) associated with failure of the pups to be nursed.

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

SCF_List: 3
Restriction: 0.05 mg/kg food, expressed as 4-chlorophthalic acid
Remark for Commission: None
Needed data or information: None

References:

Ref. No.: 21498
Name of the substance: [3-(Methacryloxy)propyl]trimethoxysilane
CAS number: 2530-85-0

General information:
According to the petitioner [3-(methacryloxy)propyl]trimethoxysilane is intended to be used as a coupling agent on inorganic materials (fillers) which are blended into polymers, acting as an adhesion promoter and/or surface modifier. These filled polymers are intended for contact with all types of foods.

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

Available data used for this evaluation:
Non-toxicity data: - data on the identity and physical and chemical properties,
- data on the intended use and authorisation,
- determination of residual content in the filler
- worst case calculation of specific migration

Toxicity data: - gene mutation in bacteria
- in vitro chromosomal aberrations and sister chromatid exchange in cultured mammalian cells
Ref. No.: 21498
Name of the substance: [3-(Methacryloxy)propyl]trimethoxysilane

- *in vitro* gene mutation in cultured mammalian cells
- *in vivo* erythrocyte micronucleus test in mice

**Evaluation:**

The substance is used to bond to the surface of the substrate and promote adhesion and mutual compatibility between the inorganic filler and the organic polymer. The residual content has been determined by solvent extraction of a mat of glass fibres surface-treated using the substance at the highest application rate intended, and without any protective polymer binder used. No residual test substance was detected using a method with a detection limit of 0.8 mg/kg glass fibres. Assuming the density of a filled polymer is 2, that 90% of filler is used, that migration is restricted to a layer of 0.25 mm, and for the conventional ratio of 6 dm² to 1 kg of food, the worst case migration was calculated to be 22 µg/kg food.

[3-(Methacryloxy)propyl]trimethoxysilane did not induce mutation in bacteria and in mammalian cells *in vitro*. *In vitro* assay for chromosomal aberrations gave inconsistent results. In a sister chromatid exchange (SCE) assay *in vitro*, the substance did not cause concentration-dependent increase in SCEs in the presence and absence of S9. In a second chromosome aberration study, the substance was weakly clastogenic in the absence of S9, and produced concentration-dependent clastogenic effects in the presence of S9. In an *in vivo* erythrocyte micronucleus assay, the substance did not induce effects. The Panel noted that the test substance is not stable in aqueous solutions. Thus it may be questioned if the genotoxicity of the substance can be assessed in *in vitro* or *in vivo* systems. However, such tests would provide adequate information on the genotoxicity of the degradation products, methanol and a polymeric gel. Methanol is an authorised substance for food contact materials listed in the Commission Directive 2002/72/EC (Commission, 2002). The polymeric gel may be expected not to be absorbed by cells, thus excluding its possibility to cause DNA damage. Therefore, the Panel concluded that for the parent substance, genotoxicity is not relevant with respect to its occurrence in foods. The degradation products may be considered as being of no concern with respect to genotoxicity.

**Conclusion:**

| SCF_List | 3 |
| Restriction | 0.05 mg/kg of food |

To be used only as a surface treatment agent of inorganic fillers

Remark for Commission: Only a method of analysis for the determination of the residual
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<td>Name of the substance:</td>
<td>[3-(Methacycloxy)propyl]trimethoxysilane</td>
</tr>
<tr>
<td>Needed data or information:</td>
<td>monomer in the treated filler is provided</td>
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<tr>
<td>Needed data or information:</td>
<td>None</td>
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</table>

References: - Unpublished data from the petitioner in July 2006

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<th>Ref. No.:</th>
<th>60027</th>
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<tbody>
<tr>
<td>Name of the substance:</td>
<td>Hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw: 440-12000)</td>
</tr>
<tr>
<td>CAS number:</td>
<td>-</td>
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</table>

General information: According to the petitioner hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene, commonly called polyalphaolefins (PAOs), are added to polypropylene to improve the polymer’s properties, such as softness and flexibility, especially at low temperature. Finished articles are intended to come into contact with dry, aqueous, acidic and low alcoholic foods but not with fatty foods. Weight average molecular weight (Mw) of PAOs ranges from 440-12000 Da depending on the type of PAOs. The maximum amount of PAOs used in polypropylene is 10% w/w.

Previous evaluations (by SCF or AFC): The application represents an extension of the range of monomers used in the manufacture of hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene, Ref. No. 60025, which was evaluated by EFSA in 2006 (EFSA, 2006).

Available data used for this evaluation:

Non-toxicity data: - Data on identity
- Data on physical and chemical properties
- Data on use and authorisation
- Data on migration
- Data on residual content of the substance

Toxicity data: - Gene mutation in bacteria
- *In vitro* chromosomal aberrations in cultured mammalian cells
- *In vivo* mouse bone marrow micronucleus studies
Ref. No.: 60027

Name of the substance: Hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw: 440-12000)

- 90-day oral toxicity studies in rats

Evaluation:
The migration of PAOs with low viscosity from a polypropylene sample containing the maximum foreseeable amount of PAO has been determined into 10% ethanol as the worst case simulant and using the contact conditions of 2 hours at 66°C followed by 10 days at 40°C. The migration was not detectable at the level of 0.2 mg/kg. The calculated worst case migration of the residual monomers was < 0.014 mg/kg food for each of the monomers 1-hexene, 1-octene, 1-decene, 1-dodecene, 1-tetradecene. Long chain organic chlorides may be formed as minor impurities. Their worst case migration was calculated to be less than 0.00085 mg/kg food.

A number of compounds representative for the compounds covered by the application did not induce mutagenicity in bacteria and did not induce chromosome aberrations in mammalian cells. Moreover, representative compounds for the group did not induce micronucleus formation in the bone marrow of mice treated with high doses (up to 5000 mg/kg bw) according to OECD-guidelines. Therefore, the compounds covered by the application are considered as non-genotoxic. In adequate 90-day oral feeding studies in rats the NOAEL was 20000 mg/kg food (circa 1200 mg/kg bw/day). This value is in agreement with NOELs observed in four 28-day studies with different representatives of hydrogenated homopolymers. Considering the poor gastrointestinal absorption of structurally related compounds, including hydrogenated poly-1-decene which is an authorised food additive (Commission, 2003) evaluated by the SCF in 2001 (SCF, 2001), accumulation in man is considered unlikely.

Based on the toxicological data provided the proposed uses do not raise safety concerns. Therefore and in view of the low migration of the substance, the Panel considers that there is no need for a specific migration limit.

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

- SCF List: 3
- Restriction: None
- Remark for Commission: Not intended for fatty food contact

Specifications:
- Minimum viscosity (at 100°C) = 3.8 cSt
- Weight average molecular weight >440 Da
Ref. No.: 60027
Name of the substance: Hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw: 440-12000)

Needed data or information: None

References:
- Unpublished data submitted by the petitioner in March 2007
- 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 13th list of substances for food contact materials – Adopted on 29 November 2006;
  [http://europa.eu.int/comm/food/fs/sc/scf/out95_en.pdf](http://europa.eu.int/comm/food/fs/sc/scf/out95_en.pdf)

Ref. No.: 80480
Name of the substance: Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino]

CAS number: 90751-07-8

General information: According to the petitioner, the polymeric additive poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino] is used as a UV light stabiliser in polyolefins. The maximum use level is 0.3% w/w and the plastics are intended for contact with all types of food under conditions of hot fill and long-term ambient temperature storage.

Previous evaluations (by AFC): The AFC Panel evaluated this polymeric additive in 2005 along with the residual content of the monomer N,N’-bis[(2,2,6,6-tetramethyl)-4-piperidinyl]-1,6-hexanedianine (BPIP), the reaction
Ref. No.: 80480

Name of the substance: Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino]

intermediate 2,4-dichloro-6-morpholino-1,3,5-triazine (DCMT) and the precursor substance morpholine. The hypothetical formation of genotoxic and carcinogenic N-nitroso derivatives from residual BBIP, DCMT and morpholine reacting with nitrite in stored foods or in the gastrointestinal tract, was raised by the petitioner. Consequently, the Panel classified the additive in List 7 with the requirement that the petitioner provide evidence for the absence of formation of N-nitroso derivatives from migrated BPIP, DCMT and morpholine (EFSA, 2005).

Available data used for this evaluation:

Non-toxicity data:
- Data on identity, physical and chemical properties, use, authorisation;
- Migration data into food simulants;
- Data on the residual content;
- Data on log Po/w;
- Analytical method for the determination of the specific migration into food simulants, suitable for enforcement purposes;
- Analytical results on nitrosated substances using in vitro nitrosation conditions.

Toxicity data:
- In vitro mutagenicity assays on the polymeric additive;
- In vitro mutagenicity assays on the monomer BPIP;
- 90-day oral toxicity study for the additive in rats;
- 90-day oral toxicity study for the additive in dogs.

Evaluation:

The polymeric additive is a mixture of oligomers with a molecular weight (MW) range of 286 – 16100 Da and with a 19 – 21% fraction with MW < 1000 Da. Morpholine is a chemical precursor and the residual level of morpholine in the additive is < 30 mg/kg. 2,4-Dichloro-6-morpholino-1,3,5-triazine (DCMT) is a reaction intermediate in the synthesis of the polymeric additive and the residual level of DCMT is <20 mg/kg. A third chemical used in the synthesis is the monomer N,N’-bis(2,2,6,6-tetramethylpiperidin-4-yl)hexane-1,6-diamine (BPIP) and the residual level of BPIP is quite high with a specification of <15000 mg/kg in the polymeric additive.

Specific migration tests were performed using three different
poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino] polyolefin plastics containing the additive up to 0.3% w/w. The tests were performed for 10 d at 40°C and 2 hr at 70°C/2 hr at 100°C. Migration of the polymeric additive into a fatty food simulant was up to 6.8 mg/kg. Migration of the polymeric additive into aqueous simulants was up to 2.9 mg/kg. Assuming simple proportionality, with a migration level of 2.9 mg/kg of the polymeric additive the BPIP present at a 15000 mg/kg level in the additive itself would give migration of 0.044 mg/kg food.

The migrate solutions were subjected to nitrosation conditions as described in European Norm EN 12868 and with more severe conditions as described below. Four separate experiments were conducted to model packaged foods containing nitrite before and after ingestion. The conditions included:

- **incubation for 24 hours at 40°C at pH 8.7 with 175 mg/L sodium nitrite added;**
- **same conditions as above (a) then followed by acidification to pH 1.4 and incubation for 30 minutes at room temperature;**
- **incubation for 24 hours at 40°C at pH 8.7 with 30 mg/L sodium nitrite added;**
- **same conditions as above (c) then followed by acidification to pH 1.4 and incubation for 4 hours at 37°C.**

The incubated solutions were extracted with solvent and the extracts were analysed using gas chromatography coupled to high resolution mass spectrometry (GC-MS). The GC-MS method was validated using authentic N-nitrosomorpholine. For the other substances tested for, the accurate mass of the molecular ion was monitored and in the absence of analytical standards a response factor of 1 was assumed. There was no N-nitrosomorpholine, N-nitroso BPIP or N-nitroso DCMT detectable in the samples with detection limits estimated to be about 0.1µg/kg.

Both the polymeric additive itself and the monomer BPIP gave negative results in three in vitro mutagenicity assays (reversion in bacteria, forward mutation and chromosomal aberrations in cultured mammalian cells). No genotoxicity data are available on the reaction intermediate DCMT. In two 90-day subchronic dietary toxicity studies, in rats and dogs, a NOAEL of 100 mg/kg bw/day was derived for the polymeric additive. The logPo/w value of the oligomeric fraction with MW < 1000 Da was measured to be 2.51 and so no potential for accumulation in man is expected.
Ref. No.: 80480
Name of the substance: Poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino]

Conclusion:

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

SCF_List: 3
Restriction: 5 mg/kg food
Remark for Commission: Migration from LDPE containing 0.3% w/w of the substance into fatty foods may exceed the migration restriction.
Specifications: Weight average molecular weight \( \geq 2400 \) Da.
Residual content of morpholine \( \leq 30 \) mg/kg, of N,N'-bis(2,2,6,6-tetramethylpiperidin-4-yl)hexane-1,6-diamine \( \leq 15000 \) mg/kg, and of 2,4-dichloro-6-morpholino-1,3,5-triazine \( \leq 20 \) mg/kg in the UV stabiliser

Needed data or information: None

References:

Ref. No.: 81280
Name of the substance: Polyvinyl alcohol

General information:

According to the petitioner, polyvinyl alcohol (PVA) used as a polymeric additive is prepared by the complete hydrolysis of polyvinylacetate. The PVA is intended to be used as an additive in fibrillated polyolefin fibres called synthetic wood pulp. A number of olefin homopolymers, copolymers and modified polymers are used with PVA added at up to 2.2%. These plastic fibres are then used to make 2-layer papers with natural pulp at up to a 1:3 plastic: natural fibres ratio. The 2-layer paper is intended for hot and cold filter applications with all types of liquid food and beverages.

Previous evaluations:
The AFC Panel has evaluated PVA as a food additive used as film additive in plastic fibres. The petitioner of this evaluation submitted unpublished data to the EFSA, which was used to update the previous evaluation.
Ref. No.: 81280
Name of the substance: Polyvinyl alcohol (by AFC)

coating agent for food supplements (EFSA, 2005). The PVA evaluated by the Panel was a partially hydrolysed polymer, with a weight average molecular weight (Mw) in the range of 26,000 to 30,000 Da.

There was no evidence of toxicity in either the 90-day or 2-generation studies at the highest dose levels tested of 5000mg/kg bw/day. PVA is neither mutagenic nor genotoxic. There was no evidence to indicate that PVA has carcinogenic activity.

Potential human exposures to PVA under the intended conditions of use were expected to be low. The highest assumed intake according to the most conservative scenario was in the range of 4.8 mg/kg bw/day. This is approximately 1,040-fold below the established NOAEL. Therefore, the Panel concluded that the consumption of the PVA as specified by the petitioner, through use as a coating agent for food supplement tablets and/or capsules at its intended use level is not of safety concern.

Available data used for this evaluation:

Non-toxicity data: - Data on identity, physical and chemical properties including molecular weight distribution and viscosity in solution
- Details of the manufacturing process
- Data on use and authorization
- Data on specific and overall migration for the requested use

Toxicity data: - This aspect was previously evaluated by the EFSA in 2005

Evaluation: The PVA additive has a Mw of 32,500 Da and the weight fraction below 1,000 Da is 0.45%. Two samples of 2-layer filter papers made using the highest intended level of PVA were tested under worst-foreseeable conditions of use into different food simulants and solvents. There was no detectable migration of PVA using a method with a detection limit equivalent to 18 µg/kg food and the overall migration was low (less than 1 mg/dm²) in all cases.

Based on the method of manufacture, the weight average molecular weight and the viscosity in solution, the PVA which was evaluated in 2005 by the AFC Panel (EFSA, 2005) is considered to be representative of the PVA which is the subject of the present evaluation.

Accordingly, the toxicological database evaluated in 2005 leading to a NOAEL of 5,000 mg/kg bw/day, can be used for the evaluation of
Ref. No.: 81280
Name of the substance: Polyvinyl alcohol

This PVA used as a polymeric additive. Migration up at the 18 µg/kg would give rise to an estimated exposure of around 0.3 µg/kg bw/day resulting in a margin of exposure 16,500,000-fold lower than the NOAEL for PVA. Consequently, the proposed use of PVA in food contact materials is not of safety concern.

Conclusion:

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

SCF_List: 3
Restriction: None
Remark for Commission: Weight average molecular weight should not be less than 25000 Da
Needed data or information: None

References:

- Unpublished data provided by the petitioner in January 2007

Ref. No.: 92470
Name of the substance: N,N’,N”’,N”’-tetrakis(4,6-bis(N-butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)amino)triazin-2-yl)-4,7-diazadecane-1,10-diamine

CAS number: 106990-43-6

General information:

According to the petitioner the substance is intended to be used as an additive (light stabiliser) for many common polymers, in contact with all types of foods, under refrigerated conditions, prolonged storage at room temperature and up to 2 hours at 100°C, except for acidic foods in contact with Linear Low Density Polyethylene (LLDPE) and Low Density Polyethylene (LDPE). The concentrations used range from 0.1 to 0.4 % w/w depending on the type of polymer.

Previous evaluations (by SCF or AFC): None (new substance)
Ref. No.: 92470
Name of the substance: N,N”,N”’N’’-tetrakis(4,6-bis(N-butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)amino)triazin-2-yI)-4,7-diazadecane-1,10-diamine

Available data used for this evaluation:
Non-toxicity data: - Data on identity and impurities
- Data on physical and chemical properties
- Data on intended use and authorisations
- Data on specific migration of the additive in food simulants
- Data on residual content in food contact polymers

Toxicity data: - Gene mutation test in bacteria
- *In vitro* mammalian cell gene mutation test
- *In vivo* micronucleus assay in Chinese Hamster

Evaluation:
The substance has a molecular weight of 2286 Da.
No degradation products were found in stability tests.
A high performance liquid chromatography analytical method was developed and validated.
Specific migration tests in food simulants have been performed.
A range of plastics were tested for migration, comprising polyethylene (high density, low density and linear-low density grades), polypropylene and acrylonitrile-butadiene-styrene. The simulants used were 3% acetic acid, 10%, 15%, 50% and 100% ethanol. 100% ethanol was used as alternative test medium for fat simulation because olive oil was demonstrated to be technically unsuitable. Test conditions were 10 days at 40°C and 2 hours at 100°C or at reflux temperature. The highest migration observed was 48 µg/kg.

The substance did not show mutagenic potential in bacteria and mammalian cells. An adequately performed *in vivo* micronucleus assay in bone marrow was negative. Based on these results the substance is considered to be non-genotoxic.

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

| SCF_List: 3 |
| Restrictions: 0.05 mg/kg food |
| Remark for Commission: None |
| Needed data or information: None |
Ref. No.: 92470
Name of the substance: N,N’,N”,N”’-tetrakis(4,6-bis(N-butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)amino)triazin-2-yl)-4,7-diazadecane-1,10-diamine

References: - Unpublished data submitted by the petitioner in December 2006

Ref. No.: 92475
Name of the substance: 3,3’,5,5’-tetrakis(tert-butyl)-2,2'-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid

CAS number: 203255-81-6

General information: According to the petitioner, 3,3’,5,5’-tetrakis(tert-butyl)-2,2'-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid is intended to be used as an antioxidant in the manufacture of polyolefins for contact with aqueous, acidic and alcoholic foodstuffs. Maximum use level is 0.01% w/w.

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

Available data used for this evaluation:

Non-toxicity data: - Data on identity, physical and chemical properties
- Data on use and authorisation
- Data on migration of subject substance, its oxidation product and hydrolysis products
- Data on residual content of subject substance, its oxidation product and hydrolysis products

Toxicity data: For the compound covered by the application, its oxidation and its hydrolysis products:
- Gene mutation in bacteria
- *In vitro* chromosomal aberrations in cultured mammalian cells
- *In vitro* gene mutation in cultured mammalian cells

Evaluation: Analysis of a low density polyethylene (LDPE) sample demonstrated that the antioxidant is almost completely oxidised from its phosphite to its phosphate form, namely 3,3’,5,5’-tetrakis(tert-butyl)-2,2'-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl] phosphate. The substance is also hydrolysed in aqueous media, yielding 2,6-di-tert-

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### 17th list of FCM substances

<table>
<thead>
<tr>
<th>Ref. No.:</th>
<th>92475</th>
</tr>
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</table>
| Name of the substance: | 3,3’,5,5’-tetrakis(tert-butyl)-2,2’-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid | butyl-4-(3-hydroxypropyl)phenol and 3,3’,5,5’-tetra-tert-butylbiphenyl-2,2’-diol. A migration study was performed with LDPE made using 0.01% w/w of the substance. Specific migration of the substance (including its oxidation and its hydrolysis products) was not detected after 2 hr at 100°C and 10 days at 40°C, with detection limits ranging from 4 to 10 µg/kg food. The substance was completely hydrolysed in 3% acetic acid and 10% ethanol under the migration conditions. The compound covered by the application, its oxidation and hydrolysis products were not mutagenic in bacteria and did not induce genotoxicity in mammalian cells. Therefore, these compounds are considered as non-genotoxic.

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

- **SCF_List:** 3
- **Restriction:** 0.05 mg/kg food (expressed as the sum of phosphite and phosphate form of the substance)

### Remark for Commission:
Proposed restriction may be exceeded in contact with fatty foods

### References:
- Unpublished data submitted by the petitioner in May of 2007.

<table>
<thead>
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<th>Ref. No.:</th>
<th>94000</th>
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</thead>
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<tr>
<td>Name of the substance:</td>
<td>Triethanolamine</td>
</tr>
<tr>
<td>CAS number:</td>
<td>102-71-6</td>
</tr>
</tbody>
</table>

### General information:
According to the petitioner, triethanolamine (TEA) is intended to be used as a stabiliser in rigid polyvinylchloride (PVC) at a maximum use level of 0.5% w/w. The polymer is intended to come into contact with all types of foodstuffs under the conditions of hot fill followed by long term storage at room temperature.

### Previous evaluations (by SCF or AFC):
None (new substance)

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Ref. No.: 94000
Name of the substance: Triethanolamine

used for this evaluation:
- Data on identity
- Data on physical and chemical properties
- Data on use and authorisation
- Data on migration
- Data on residual content of the substance

Toxicity data:
- Gene mutation assay in bacteria
- In vitro gene mutation assay in mammalian cells
- In vitro chromosomal aberration assay in cultured mammalian cells

Evaluation:
A rigid PVC sample containing 0.5% w/w of the substance was tested for migration into 3% acetic acid and 10% ethanol under conditions of 10 days at 40°C. Based on solubility considerations these two simulants are considered as the most severe. There was no detectable migration with detection limits of 13 and 26 µg/kg, respectively.

Considering the low migration level and the low yield of nitrosation of TEA (Saghir et al., 2005), formation of nitrosamines is not of safety concern.

TEA did not show mutagenic potential in bacteria or in mammalian cells in vitro and it did not induce chromosomal aberrations in vitro. Based on these results the substance is considered to be non-genotoxic.

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

SCF_List: 3
Restriction: 0.05 mg/kg food (including the hydrochloride adduct)

Remark for Commission: None
Needed data or information: None

References:
- Unpublished data submitted by the petitioner in January 2007
- Saghir et al., 2005, Investigation of the formation of N-nitrosodiethanolamine in B6C3F1 mice following topical administration of triethanolamine, Regulatory Toxicology and Pharmacology 43 (2005) 10–18
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 AFC 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 (OM): 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
List of abbreviations:

AFC  Scientific Panel on food additives, flavourings, processing aids and
materials in contact with food
BPIP  N,N’-bis[(2,2,6,6-tetramethyl)-4-piperidinyl]-1,6-hexanediamine
cSt  centistokes
Da  Dalton
DCMT  2,4-dichloro-6-morpholino-1,3,5-triazine
EC  European Commission
EFSA  European Food Safety Authority
EN  European Number
GC-MS  Gas chromatography coupled to high resolution mass spectrometry
LDPE  Low Density Polyethylene
LLDPE  Linear low density polyethylene
MW  Molecular weight
Mw  Weight average molecular weight
NOAEL  No observed adverse effect level
OECD  Organisation for economic co-operation and development
PAO  Polyalphaolefin
PVA  Polyvinyl alcohol
PVC  Polyvinyl chloride
SCF  Scientific Committee on food
TEA  Triethanolamine
UV  Ultra-violet