Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to

a 2nd list of substances for food contact materials

(Ethylene carbonate, REF. No 16955, Methacrylic acid, 2-sulphoethyl ester, REF. No 21370, Antimony trioxide, REF. No 35760, cis-endo-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, disodium salt, REF. No 38505, Pimelic acid, calcium salt, REF. No 76415)

adopted on 7 January 2004 by written procedure

SUMMARY

Within the general task of evaluating substances intended for use in materials in contact with food according to Council Directive 89/109/EEC of 21 December 1988 relating to materials and articles intended to come into contact with foodstuffs, the AFC Panel evaluated the following substances.

Ref. No.:	16955
Name of the substance:	Ethylene carbonate
Classified in list:	3
Restriction:	Residual content of ethylene carbonate: 5 mg/kg hydrogel at a maximum ratio of 10 g hydrogel/kg food. Specific Migration Limit (SML) for Ethylene glycol: 30 mg/kg food
Ref. No.:	21370
Name of the substance:	Methacrylic acid, 2-sulphoethyl ester
Classified in list:	4A
Restriction:	Substance should not be detectable in food
Ref. No.:	35760
Name of the substance:	Antimony trioxide
Classified in list:	3
Restriction:	0.04 mg/kg of food as Sb
Ref. No.:	38505
Name of the substance:	cis-endo-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, disodium salt
Classified in list:	3
Restriction:	5 mg/kg of food
Ref. No.:	76415
Name of the substance:	Pimelic acid, calcium salt
Classified in list:	3
Restriction:	No special restriction

BACKGROUND

According to Article 3(3) of the Council Directive 89/109/EEC of 21 December 1988 it is necessary to consult the Scientific Committee on Food (SCF) on the risks connected with the migration of substances into food from food contact materials in which they are used. This competence was transferred to the European Food Safety Authority (EFSA) by virtue of the Regulation (EC) 178/2002.The opinion of the EFSA is required before a substance is authorised to be used in food contact materials and be included in a positive list when this is established in the relevant legislation.

TERMS OF REFERENCE

The Commission asks EFSA to carry out risk assessments on:

1. all new substances used in food contact materials before their authorisation and inclusion in a positive list;

2. substances which are already authorised in the framework of Council Directive 89/109/EEC but need to be re-evaluated.

ASSESSMENT

Within this general task the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) (re)evaluated four substances used as additives 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". (Previously the evaluation of substances used in food contact materials was undertaken by the Scientific Committee on Food (SCF).) The definitions of the various SCF lists and the abbreviations used are given in the appendix.

Ref. No.:	**16955**
Name of the substance:	**Ethylene carbonate**
CAS number:	96-49-1
Document reference:	SDS CS/PM/3935-RevIA/16955 of December 2003
General information:	According to the petitioner, ethylene carbonate is a monomer intended to be used in hydrogels consisting of partially neutralised polyacrylates (superabsorbent polymers)
Previous evaluations (by SCF or AFC):	The substance was first evaluated in 2002 (SCF 2002). Based on inadequate method for the determination of the residual content of ethylene carbonate, and on an adequate gene-mutation assay in bacteria, a chromosomal aberration test in cultured mammalian cells, a gene-mutation assay in cultured mammalian cells, an 18 months oral carcinogenicity study in male and female rats (Charles River CD), a teratogenicity study in female rats (Sprague Dawley) and a metabolism study by gavage in male rats (Fisher 344) the substance was listed in SCF L-7.

Ref. No.:	16955
Name of the substance:	Ethylene carbonate

Needed:

- For the determination of residual ethylene carbonate, details on the analytical method (conditions of recovery, detailed GC conditions, representative chromatograms of standard, sample and recovery solutions) should be provided.
- Data on the residual content of ethylene glycol after extraction with a representative aqueous solvent (e.g. 3% acetic acid), in order to exclude the possible generation of ethylene glycol from the cross-linked polyacrylate in the presence of water, should also be provided)

Available data used for this evaluation:

Non-toxicity data: Additional information on the determination of ethylene carbonate. Arguments for the absence of data on ethylene glycol.

Toxicity data No new data

Evaluation:

Additional information to improve the determination of residual ethylene carbonate in the superabsorbent polymer has been provided. Residual content of ethylene carbonate was found to be less than 3.6 mg/kg super absorbent polymer. When used in the ratio of 10 g/kg food the worst case (100%) migration is 0.036 mg/kg food. Determination of ethylene glycol in aqueous simulants was not feasible due to the absorption of the water to the absorbent. However, the possible formation of ethylene glycol by hydrolysis of cross-linked ethylene carbonate is not a cause of concern, being largely covered by the existing SML of ethylene glycol.

Adequate genotoxicity studies indicate that ethylene carbonate is not mutagenic in bacteria or in mammalian cells in vitro, and does not induce chromosomal aberrations in vitro.

Toxicity data indicate low toxicity, and mild/moderate irritating properties. Following oral administration, ethylene carbonate is rapidly metabolised to ethylene glycol. Teratogenic effects in pregnant rats administered a high dose (3000 mg/kg b.w.) of ethylene carbonate are reported in an unpublished (and unreviewed) report. No excess of tumours was observed in a limited oral carcinogenicity study in the rat.

On the basis of the data available, it is concluded that ethylene carbonate is not genotoxic. Information on other toxicological effects are inadequate for a final evaluation. However, the efficient metabolic conversion of ethylene carbonate to ethylene glycol (L2, group-TDI 0.5 mg/kg b.w.) indicates for the former a toxic profile similar to that of ethylene glycol

Conclusion:	Based on the above mentioned data the substance is classified:
SCF list:	**3**
Restriction:	**Residual content of ethylene carbonate: 5 mg/kg hydrogel at a maximum ratio of 10 g hydrogel/kg food. Ethylene glycol: SML = 30 mg/kg food**
Remark for Commission:	No method available for specific migration; only a QM method for the monomer and ethylene glycol (hydrolysis product)
References	- Unpublished data submitted by the petitioner - Opinion of the Scientific Committee on Food on the 19th additional list of monomers and additives for food contact materials (adopted on 26 September 2002) http://europa.eu.int/comm/food/fs/sc/scf/out141_en.pdf

Ref. No.:	**21370**
Name of the substance:	**Methacrylic acid, 2-sulphoethyl ester**
CAS number:	10595-80-9
Document reference:	SDS CS/PM/3220-Rev.IIIB/21370 of November 2003
General information:	According to the petitioner Methacrylic acid, 2-sulphoethyl ester is used as a reactant in thin coatings on polymeric substrates such as PET and Nylon films, and on paper and board.
Previous evaluations (by SCF or AFC):	The substance was first evaluated in 1998 (SCF 1999). Based on inadequate method for the determination of the residual content, and an inconclusive chromosomal aberration assay, the substance was classified in SCF_List 7 (Needed: A proper analytical method and chromosomal aberration assay with an extended harvest period). The substance was then evaluated in April 2003 and again classified in SCF_List 7 (Needed: An assessment of the effect of pH on chromosomal aberration (demonstration, in the same experimental system, of the effect on chromosomal integrity of pH changes similar to those produced by the test article, and the suppression of clastogenicity of Methacrylic acid, 2-sulphoethyl ester after adjustment of pH of culture medium to neutrality)).
Available data used for this evaluation:	
Non-toxicity data:	Information concerning identity, physical chemical data, use, authorisation and content in latex coating. An analytical method for the determination of the residual content
Toxicity data:	Gene mutation assays in bacteria, Gene mutation in mammalian cells, Two chromosomal aberration assays *in vitro*.

Ref. No.:	**21370**
Name of the substance:	**Methacrylic acid, 2-sulphoethyl ester**

Evaluation:

Non toxicity data: Residual content of Methacrylic acid, 2-sulphoethyl ester in latex coatings containing 0.5% of subject substance was found to be not detectable with a limit of detection equivalent to 3 mg of Methacrylic acid, 2-sulphoethyl ester/ kg dried latex.
Worst case migration is calculated to be 16.2 µg/kg food, assuming that 90 g latex/m² film is maximum applied. However the most common film\ thicknesses are varying from 5 – 20 g/m². For those coatings the maximum migration is limited in a range from <0.15 µg /dm² to < 0.6 µg /dm² "equivalent to <0.9 to <3.6 µg/kg food".

Genotoxicity: Methacrylic acid, 2-sulphoethyl ester gave negative results in gene mutation assays in bacteria and in cultured mammalian cells. Positive results have been obtained after extended (32–48 hours) treatments only in the absence of S9 in two *in vitro* chromosome aberration assays at doses producing a distinct decrease of pH of culture medium. Considering the lack of genotoxicity of the potassium salt of the structurally related methacrylic acid sulphopropyl ester, it is reasonable to suggest that the clastogenic activity exerted *in vitro* by methacrylic acid sulphoethyl ester is an indirect effect related to pH shift. However, as this hypothesis has not been formally demonstrated, for the sake of caution methacrylic acid 2-sulphoethyl ester should be undetectable as migrant in food or food simulants.

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

SCF list: **4A**

Restriction **Not detectable**

Remark for Commission: Monomer is used in coatings and a specific migration (SM) method is not available. QMA restriction is applicable in this case

References:

Unpublished data submitted by the petitioner.

SCF, 1999: Opinion on an additional list of monomers and additives for food contact materials (expressed on 24 March 1999): http://europa.eu.int/comm/food/fs/sc/scf/out27_en.pdf

Opinion of the Scientific Committee on Food on the 22nd additional list of monomers and additives for food contact materials (expressed on 4 April 2003) http://europa.eu.int/comm/food/fs/sc/scf/out180_en.pdf

Ref. No.:	**35760**
Name of the substance:	**Antimony trioxide**
CAS number:	001309-64-4
Document reference:	SDS CS/PM/3254-Rev.IIIB/35760 of December 2003

General information: According to the petitioner antimony trioxide is used as additive and initiator in the manufacture of PET and other polymers, at the maximum percentage of 0.035 % (as Sb).

Previous evaluations (by SCF or AFC): The substance was first evaluated in 1999 (SCF, 1999) and classified in SCF_List 3 with a restriction of 0.01 mg/kg, SML 0.02 mg/kg (expressed as Sb including analytical tolerance).

Available data used for this evaluation:

Non-toxicity data: Solubility in synthetic gastric juice

Toxicity data:
- Assessment of genotoxicity (Eliot et al., 1998)
- Review of subchronic studies (Lynch et al., 1999)
- Revised document for WHO, drinking water guidelines, 3rd edition

Evaluation: Highest migration was detected in 3 % acetic acid. For PET samples containing 350 mg Sb/kg (maximum Sb content), migration amounted to 31.8 µg (as Sb)/kg of food simulant.
Antimony trioxide has been shown to be clastogenic *in vitro* but not mutagenic in gene mutation assays in bacteria and in cultured mammalian cells. A clastogenic effect in mouse bone marrow was reported in a published study with a sample of antimony trioxide of unspecified purity and high toxicity. On the other hand, no genotoxicity was observed *in vivo* (single and repeat dose mouse bone marrow micronucleus tests and rat liver unscheduled DNA synthesis assay). Based on these results it is concluded that the clastogenic effect of antimony trioxide observed *in vitro* is not expressed *in vivo*.(Gurnani et al, 1992; Kuroda et al, 1991)

Antimony trioxide is classified as a category 2B carcinogen by the International Agency for Research on Cancer, based on the induction of lung tumours in rodents following chronic inhalational exposure. No long-term studies by the oral route are available on antimony trioxide, while no evidence of carcinogenic potential was observed in an oral study with antimony potassium tartrate. The data were deemed inadequate to evaluate cancer risk following oral exposure to antimony.

Ref. No.:	**35760**
Name of the substance:	**Antimony trioxide**

Based on a re-evaluation of results from a subchronic drinking water study with potassium antimony tartrate a NOAEL of 6.0 mg Sb/kg bw/day was recently proposed. Using this NOAEL and an uncertainty factor of 1000 (100 for intra and interspecies variation, and 10 for the use of a subchronic study), a TDI of 0.006 mg Sb/kg bw/day (or 0.36 mg Sb/person/day) was derived by WHO (draft WHO drinking water guidelines, 3rd edition, 2003).

Based on the above data and considering various exposures, a Restriction of 0.04 mg/kg of food (as Sb) is applied. This restriction would allow for 10% of the TDI being allocated to food contact materials.

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

SCF list: **3**

Restriction **0.04 mg/kg of food (as Sb)**

Remark for Commission: Migration limit might be exceeded at very high temperature.

References:

- Unpublished data submitted by the petitioner.
- Elliot BM, Mackay JM, Clay P, Ashby J (1998) An assessment of the genetic toxicology of antimony trioxide. Mut.Res. 415: 109-117.
- Gurnany N, Sharma A, Talukder G (1992) Comparison of the clastogenic effects of antimony trioxide on mice in vivo following acute and chronic exposure. Biometals 5: 47-50.
- International Agency for Research on Cancer. Some organic solvents, resin monomers and related compounds, pigments and occupational exposures in paint manufacture and painting. Lyon, 1989:291-305 (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 47).
- Kuroda K, Endo G, Okamoto A, Yoo YS, Horiguchi S (1991) Genotoxicity of beryllium, gallium and antimony in short-term assays. Mutation research 264, 163-170.
- Lynch BS, Capen CC, Nestmann ER, Veenstra G and Deyo A (1999) Review of subchronic/chronic toxicity of antimony trioxide potassium tartrate. Reg.Toxicol.Pharmacol. 30: 9-17.
- Opinion of the Scientific Committee on Food on an additional list on monomers and additives for food contact materials (Adopted at the 119th SCF meeting) (2 December 1999) http://europa.eu.int/comm/food/fs/sc/scf/out50_en.pdf
- Antimony - revised document prepared for WHO, drinking water guidelines, 3rd edition.

http://www.who.int/docstore/water_sanitation_health/GDWQ/draftchemicals/antimony2003.pdf

Ref. No.:	**38505**
Name of the substance:	***cis-endo*-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, disodium salt**

CAS number: 351870-33-2
Document reference: SDS CS/PM/4118-Rev.0B/38505 of November 2003

General information: According to the petitioner, *cis-endo*-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, disodium salt is a nucleating agent for polypropylene and polyethylene. It reduces the processing cycle time of polyolefin articles, and improves physical properties (stiffness, haze, clarity). It is intended to be used with polypropylene (all types of foods [dry, aqueous, fatty, acidic and alcoholic], in any conditions of use [max. realistic temperature 121 °C]), and for polyethylene (dry, aqueous, fatty, alcoholic foods, in any conditions of use [max. realistic temperature for this polymer is 100 °C]).
The substance is specified to be at least 96 % pure, the impurities are residues of starting substances or reagents, or side products. All the batches analysed were at least 98.8 % pure, and included 0.3-0.5 % water.

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

Available data used for this evaluation:

Non-toxicity data:
- identity
- purity
- migration data

Toxicity data:
- Bacterial reverse mutation assay
- Mouse lymphoma mutation assay
- Human lymphocyte chromosome aberration test
- Rat 28 day oral subacute toxicity study
- Mouse 90 day oral subchronic toxicity study

Evaluation: The migration of the substance was properly determined, in worst case likely conditions of use. The analytical method was well described. Migration was highest for acetic acid, most likely because the slightly basic character of the substance (as a carboxylate) improves its solubility in this test medium. Migration in all other simulants (including 95 % ethanol) was much lower. With polypropylene, the migration reached 3.3 mg/kg food (2h at 121 °C + 238 h at 40 °C) with 3 % acetic acid. With polyethylene, the petitioner rules out the contact with acidic foodstuffs.

Ref. No.:	38505
Name of the substance:	***cis-endo*-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, disodium salt**

Adequate genotoxicity studies indicate that *cis-endo*-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, disodium salt is not mutagenic in bacteria and in mammalian cells *in vitro*, and does not induce chromosomal aberrations *in vitro.* On the basis of the data available, it is concluded that *cis-endo*-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, disodium salt is not genotoxic.

Dose-related stomach and caecum changes in male and female animals were reported in a 28-day study in rats treated with *cis-endo*-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid by oral intubation. *Stomach* : mucosal changes for animals of either sex treated with the two highest doses (250 and 1000 mg/kg bw/day). Partial regression was observed among recovery 1000 mg/kg/day animals. *Caecum* : an increase in the severity of mononuclear cell infiltrates in the lamina propria was observed in relation to treatment for animals of either sex dosed with 1000 mg/kg bw/day. This effect was not observed in animals of the 1000 mg/kg/day recovery group. No such effects were detected in animals treated with 50 mg/kg bw/day; therefore the NOAEL was considered to be 50 mg/kg bw/day. Note: this NOAEL was derived from a gavage study, that represents a worst case compared to the dietary exposure expected for food contact materials

The test substance (*cis-endo*-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, disodium salt) was administered to CD-1 mice by dietary admixture at ~~dose~~ levels of 500, 2000 and 10000 ppm (78, 332 and 1419 mg/kg bw/day respectively) for 90 days. There were no treatment-related changes in the recorded parameters during the study. The NOEL was therefore considered to be at least 1400 mg/kg bw/day.

Taking into account the results from the most sensitive species, the overall NOAEL is 50 mg/kg bw/day.

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

SCF list: **3**

Restriction: **5 mg/kg of food (based on a daily consumption of 1 kg of packaged food per person.** This restriction would correspond to a maximum intake of 0.1 mg *cis-endo*-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, disodium salt /kg b.w./day Such figure is at least two orders of magnitude lower than the NOAEL which can be extrapolated from the results on the most sensitive species.)

Ref. No.:	**38505**
Name of the substance:	***cis-endo*-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, disodium salt**

Remark for Commission: Not to be used with polyethylene in contact with acidic foods
Hydrophilic substance (based on log$P_{o/w}$, and on highest migration into acidic foods)
The purity of the substance tested was ≥ 98.8%
The petitioner applies only for polypropylene (all food types) and polyethylene (non acidic foods)

References: -Unpublished data submitted by the petitioner.

Ref. No.:	**76415**
Name of the substance:	**Pimelic acid, calcium salt**

CAS number: 19455-79-9
Document reference: SDS CS/PM/4119-Rev.0C/76415 of November 2003

General information: According to the petitioner, Pimelic acid, calcium salt is used as a nucleating agent in polypropylene products at the highest concentration of 0.15 %. It functions due to its high melting point (> 300 °C) and favours the β-modification (crystalline type) of polypropylene during cooling of the melt. The β-modification has better mechanical properties such as higher tensile strength and an improved impact strength.

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

Available data used for this evaluation:

Non-toxicity data: Properties, legal status, migration data

Toxicity data: Bacterial reverse mutation assay
Mouse lymphoma mutation assay
Chinese hamster V79 cells chromosome aberration test
Rat 28 day oral subacute toxicity study

Evaluation:

Non-toxicity data: Calcium pimelate is well soluble in water. It is stable up to 300°, which is well above the processing temperature of polypropylene It is intended to be used for polypropylene, with any type of food, at temperatures at or below room temperature, sometimes with sterilization at 121°C.
Its migration has been determined in the corresponding official test conditions: 2 hours at 121°C followed by 238 h at 40°C. The highest

Ref. No.:	76415
Name of the substance:	Pimelic acid, calcium salt

migration was observed into 3 % acetic acid (0.37 mg/kg food), whereas migration was much lower into 10 % ethanol (0.06 mg/kg food stimulant) and in synthetic fat HB 307 (<0.062 mg/kg food). The content in the material was also determined, and fitted with the intended content. It corresponded to 20 mg/6 dm².

Toxicity data: Adequate genotoxicity studies indicate that pimelic acid, calcium salt is not mutagenic in bacteria and in mammalian cells *in vitro*, and does not induce chromosomal aberrations *in vitro.* On the basis of the data available, it is concluded that pimelic acid, calcium salt is not genotoxic.
Oral administration of the test material to Wistar rats for a period of 28 consecutive days at dose level up to 1000 mg/kg bw/day resulted in no treatment-related change. Therefore, a NOAEL of at least 1000 mg pimelic acid/kg bw/day could be derived from this study.
The test substance, as others dicarboxylic acid salts, is extensively metabolised by β-oxidation (serum $t_{1/2}$ is about 3 hours).
Consequently, pimelic acid, the C7 straight chain dicarboxylic acid, is the the β-oxidation proximate metabolite of azelaic acid for which a large amount of toxicological data are available (Mingrone et al., 1983). From this literature, it is possible to conclude that :
- an accumulation of pimelic acid is unlikely to occur,
- the 90 day oral gavage NOAEL (280 mg/kg bw) for azelaic acid could be extrapolated to pimelic acid (250 mg/kg bw).

Conclusion:

SCF_List: **3**
Restriction: **None (the substance is a metabolite of a non toxic fatty acid)**
Remark for Commission: None

References:

- Unpublished data submitted by the petitioner.
- A. Bertuzzi et al., 1991, Pharmacokinetic analysis of azelaic sodium salt, Clin. Pharmacokinet., 20 (5), 411-419.
- G. Mingrone et al., 1983, Toxicology of azelaic acid, Drugs Exptl. Clin. Res., IX(6), 447-455.

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APPENDIX

DEFINITION OF THE SCF LISTS

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 of abbreviations :

QMA = maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm^2 of the surface in contact with foodstuffs

SM = Specific migration

SML = Specific migration limit