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

Question N° EFSA-Q-2005-229, EFSA-Q-2006-074, EFSA-Q-2005-111, EFSA-Q-2006-138, EFSA-Q-2006-022, EFSA-Q-2006-058, EFSA-Q-2004-057, EFSA-Q-2004-056, EFSA-Q-2005-228, EFSA-Q-2006-075

Adopted on 29 November 2006

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.:	19180
Name of the substance:	Isophthalic acid dichloride
CAS number:	99-63-8
Classified in list:	3
Restriction:	5 mg/kg food (expressed as isophthalic acid)
Ref. No.:	26305
Name of the substance:	Vinyltriethoxysilane
CAS number:	78-08-0
Classified in list:	3
Restriction:	0.05 mg/kg of food Only to be used as a surface treatment agent
Ref. No.:	48960
Name of the substance:	9,10-dihydroxy stearic acid and its oligomers
CAS number:	
Classified in list:	3
Restriction:	5 mg/kg food
Ref. No.:	53670
Name of the substance:	Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]
CAS number:	32509-66-33
Classified in list:	2

Restriction:	TDI = 0.1 mg/kg bw
Ref. No.:	60025
Name of the substance:	Hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene
CAS number:	-
Classified in list:	3
Restriction:	None
Ref. No.:	72081/10
Name of the substance:	Petroleum Hydrocarbon Resins (hydrogenated)
CAS number:	-
Classified in list:	3
Restriction:	None
Ref. No.:	77732
Name of the substance:	Polyethylene glycol (EO=1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate
CAS number:	-
Classified in list:	3
Restriction:	0.05 mg/kg of food Only for the requested use in PET
Ref. No.:	77733
Name of the substance:	Polyethyleneglycol (EO=1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate
CAS number:	-
Classified in list:	3
Restriction:	0.05 mg/kg food. Only for the requested use in PET
Ref. No.:	79985
Name of the substance:	Poly(ethylene propylene)glycol tridecyl ether
CAS number:	61725-89-1 and 65150-81-4
Classified in list:	3
Restriction:	0.05 mg/kg food To be used only in PTFE items sintered at high temperatures
Ref. No.:	95858
Name of the substance:	Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks
CAS number:	-
Classified in list:	3
Restriction:	0.05 mg/food Not to be used for articles in contact with fatty foods.

KEYWORDS

Food Contact Materials, Plastics, Monomers, Additives, REF. No 19180, CAS No 99-63-8, Isophthalic acid dichloride, REF. No 26305, CAS No 78-08-0, Vinyltriethoxysilane, REF. No 48960, 9,10-dihydroxy stearic acid and its oligomers, REF. No 53670, CAS No. 32509-66-33, Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate] , REF. No 60025, Hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene, REF. No 72081/10, Petroleum Hydrocarbon Resins (hydrogenated), REF. No 77732, Polyethylene glycol (EO=1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate, REF. No 77733, Polyethyleneglycol (EO=1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate, REF. No 79985, CAS No 61725-89-1 and 65150-81-4, Poly(ethylene propylene)glycol tridecyl ether, REF. No 95858, Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks.

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[1].

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.

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

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

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)

Ref. No.:	**19180**
Name of the substance:	**Isophthalic acid dichloride**
CAS number:	99-63-8
Document reference:	SDS EFSA/AFC/FCM/552-Rev.IA/19180 of September 2006
General information:	According to the petitioner isophthalic acid dichloride is used as a co-monomer for the production of polyestercarbonate polymers. The polymer is used in single and repeated use applications. The maximum amount used in polyester carbonate polymers is 20%.
Previous evaluations (by SCF or AFC):	None (new substance)
Available data used for this evaluation:	
Non-toxicity data:	- Data on identity - Data on physical/chemical properties - Data on use - Data on authorisation - Data on hydrolysis in water - Data on residual content of the substance - Information on the possible formation of chlorine containing substances in poly(ester carbonate) polymers
Toxicity data:	- None, complete hydrolysis to authorised substances
Evaluation:	Isophthalic acid dichloride hydrolyses rapidly and completely either in the plastic or in the first contact with food to isophthalic acid (REF No 19150) and hydrochloric acid (REF No. 59990), which have both been authorised for the manufacture of plastics intended to come into contact with food, with a restriction of 5 mg/kg food and no specific restriction respectively (Directive 2002/72/EC). Due to hydrolysis the specific migration of isophthalic acid dichloride in food simulant is not relevant. The residual content of the monomer in polycarbonate was determined. The residual content of isophthalic acid dichloride plus isophthalic acid expressed as isophthalic acid was <60 mg/kg plastic. Based on the residual content the worst case migration for isophthalic acid dichloride was calculated to be < 1.1 mg/kg food. Information was provided on the possible formation of chlorine containing substances during the polymerisation. Due to the alkaline polymerisation conditions no formation of organic chlorinated substances is foreseeable.
Conclusion:	Based on the above-mentioned data the substance is classified:
SCF_List:	**3**

Restriction:	**5 mg/kg food (expressed as isophthalic acid)**
Remark for Commission:	None
Needed data or information	None
References:	- Unpublished data submitted by the petitioner in September 2005 and May 2006. - Commission Directive 2002/72/EC of 6 August 2002 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*

Ref. No.:	**26305**
Name of the substance:	**Vinyltriethoxysilane**
CAS number:	78-08-0
Document reference:	SDS EFSA/AFC/FCM/711-Rev.0A/26305 of November 2006
General information:	According to the petitioner vinyltriethoxysilane (VTEO) is used as a coupling agent on inorganic materials (fillers) which are blended into polymers, acting as an adhesion promoter, crosslinker and/or surface modifier. Percentage of use is 0.1-1 % w/w filler. VTEO may also be used for the preparation of different polymers, destined for general use.
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, - hydrolysis studies, - data on the intended use and authorisation, - quantification of migrateable oligomers, - determination of residual content - worst case calculation of specific migration
Toxicity data	- Bacterial reversion assays with vinyltriethoxysilane (VTEO); - Tk+/- assay in mouse lymphoma cells with VTEO; - HPRT assay in CHO cells with vinyltrimethoxysilane (VTMO); - Chromosomal aberrations in CHO cells with VTMO; - Micronucleus test in mouse peripheral blood with VTMO

Evaluation:	Specific migration of VTEO in food simulants was not determined but worst case migration was calculated on the basis of the residual content. To this aim, the residual amount of VTEO in a worst case sample (filler treated with 1% VTEO) was determined by a properly validated analytical method (hexane extraction and Gas Chromatographic/Mass Spectrometric analysis). No residual amount of VTEO was detected with a detection limit of 1.16 µg VTEO/g filler. The calculated worst case migration was found to be lower than 31 µg/kg food. Migration of non-volatile oligomers and reaction products, determined by ethanol extraction, was in the range of untreated samples. Hydrolysis studies in gastric juice simulants showed complete hydrolysis of VTEO after 1 hour at 37°C to insoluble polysiloxanes and ethanol. Vinyltriethoxysilane (VTEO) was non-mutagenic in bacterial reversion tests and in the forward mutation assay in mouse lymphoma cells, which detects clastogenic effects as well as gene mutations. No further toxicity data on VTEO are available. However, as VTEO and VTMO (vinyltrimethoxysilane) hydrolyse completely in body fluids forming identical polysiloxanes, it is considered appropriate to read across from the genotoxicity studies performed on VTMO. In studies in cultured mammalian cells, VTMO was negative in a limited forward mutation test at the HPRT locus, while it increased the incidence of structural chromosomal aberrations, both with and without exogenous metabolism. The clastogenic potential of VTMO *in vivo* was assessed in the micronucleus test in mouse peripheral blood: in this study VTMO, administered at doses close to the LD50, provided negative results, indicating that the clastogenic activity of VTMO observed *in vitro* is not expressed *in vivo*. Based on the negative results of the studies on VTEO, and the fact that genotoxicity of VTMO is not expressed *in vivo*, it is concluded that VTEO does not raise concern for genotoxicity.
Conclusion:	Based on the above-mentioned data the substance is classified:
SCF_List:	**3**
Restriction:	**0.05 mg/kg of food** **Only to be used as a surface treatment agent**
Remark for Commission:	Only method of analysis for the determination of the residual monomer on the treated surface (QMA) is provided.
Needed data or information	None

References:	Unpublished data provided by the petitioner in August 2006

Ref. No.:	**48960**
Name of the substance:	**9,10-dihydroxy stearic acid and its oligomers**
CAS number:	
Document reference::	EFSA/AFC/FCM/504-Rev.IIC/48960 of November 2006
General information:	According to the petitioner 9,10-dihydroxystearic acid and its oligomers is a defined mixture of monomer, dimer, trimer and tetramer of 9,10-dihydroxystearic acid derived from natural fats and oils. The ammonium salt of the substance is used as an emulsifier for the polymerisation of PVC.
Previous evaluations (by SCF or AFC):	The substance was first evaluated by the EFSA/AFC Panel in 2003 (EFSA/AFC, 2003) and it was classified in List 7 with the following request for additional data: - Specification of the actual substance. - Information on the actual substance used for the determination of the solubility. - Confirmation whether iso-octanol or iso-octane is used in the determination of the solubility. - Confirmation of the detection limit (μg/dm²) supported by convincing chromatograms to establish the detection limit. - Data on the actual amount of 9,10-dihydroxystearic acid recovered from simulants to which the substance has been added at a relevant concentration and stored for 10 d at 40°C, in accordance with the Note for Guidance. - Detailed data to evaluate the reliability of the migration results presented - A complete chromosomal aberration assay in mammalian cells including data without metabolic activation (S9).
Available data used for this evaluation:	
Non-toxicity data:	- Data on identity - Data on physical/chemical properties including Log Po/w values - Data on use and authorisation - Data on migration from PVC - Data on residual amount of 9,10-dihydroxystearic acid in PVC.

Ref. No.:	**48960**
Name of the substance:	**9,10-dihydroxy stearic acid and its oligomers**
Toxicity data:	- Gene mutation assay in bacteria. - Gene mutation assay in mammalian cells. - Chromosomal aberration assay in cultured mammalian cells (incomplete, data only with S9). - A complete chromosomal aberration assay in mammalian cells including data without metabolic activation (S9) - Micronucleus assay in bone marrow cells of the mouse - 90-day oral toxicity study with reversibility in rats - Bioavailability study
Evaluation:	Migration of 9,10-dihydroxystearic acid from two PVC samples containing 0.03 and 0.07% of the test substance was determined. Migration from the sample containing 0.03 % of the substance was not detectable in aqueous food simulants and was 63 µg/kg in 100% ethanol. From the sample containing 0.07% of the substance migration after a contact period of 10 days at 40°C into water, 3% acetic acid, 15% ethanol and 100% ethanol of 9,10-dihydroxystearic acid was found to be <16, 27, 27 and 216 µg/kg respectively. A second set of migration data, including proper validation, was provided using the sample with 0.03% of 9,10-dihydroxystearic acid. Results confirmed earlier findings. Migration in 3% acetic acid, 10% ethanol and 95% ethanol was 12, 14 and 42 µg/kg respectively. The test substance was negative in the two requested gene mutation assays (in bacteria and in mammalian cells). The results of the two chromosomal aberration assays with S9 mix are not in agreement and the results of the only one study including exposure without S9 remains equivocal. However, the *in vivo* micronucleus assay was negative. Based on the available genotoxicity data the substance is considered as non genotoxic. An oral 90-day study has been performed. The doses used were up to 1000 mg/kg b.w/day. The usual monitored parameters were not significantly modified by the treatment at any dose. A no-observed-adverse-effect-level (NOAEL) greater than 1000 mg/kg bodyweight/day, the highest dose level tested, can be foreseen on the basis of this study. The toxicokinetic study indicates a low bioavailability of 9,10-dihydroxystearate after oral administration and suggests a rapid metabolism of 9,10-dihydroxystearate. These data demonstrate the absence of a potential for bioaccumulation.
Conclusion:	Based on the above-mentioned data the substance is classified

Ref. No.:	**48960**
Name of the substance:	**9,10-dihydroxy stearic acid and its oligomers**
SCF list:	**3**
Restriction	**5 mg/kg food**
Needed data or information	None
Remark for Commission:	None
References:	- Unpublished data submitted by the petitioner - EFSA/AFC opinion on a 1st list of substances for food contact materials, adopted on the 1st October 2003 http://www.efsa.eu.int/science/afc/afc_opinions/195_en.html

Ref. No.:	**53670**
Name of the substance:	**Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]**
CAS number:	32509-66-33
Document reference:	EFSA/AFC/FCM/749-Rev.IA/53670 of November 2006
General information:	According to the petitioner ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate] is intended to be used as a long term antioxidant in the manufacture of plastics. Maximum percentage in formulation is 0.115%.
Previous evaluations (by SCF or AFC):	The substance was first evaluated by the SCF in 1998 (SCF, 1998) and it was allocated a TDI of 0.1 mg/kg bw on the basis of the following toxicity studies: acute oral toxicity data; 90-day oral rat study; 16-week oral rat study (after in utero exposure); 90-day oral dog study; 2-year oral dog study; 2.5 year oral rat study (combined chronic/carcinogenicity study); one-generation reproduction study with rats; three negative mutagenicity studies. REMARK for Commission: No method of analysis is available for the enforcement of an SML.
Available data used for this evaluation:	
Non-toxicity data:	- Data on identity - Data on physical/chemical properties - Data on use - Data on authorisation

Ref. No.:	**53670**
Name of the substance:	**Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]**
	- Data on migration - Data on residual content of the substance
Toxicity data	This aspect has been evaluated by the SCF (SCF, 1998)
Evaluation:	An adequate method of analysis has been provided by the petitioner. Specific migration tests were performed on a LDPE containing 0.115% of the antioxidant. Tests were performed by total immersion in 3% acetic acid, 10% ethanol, 95% ethanol and iso-octane for 10 days 40°C and 2 days 20°C (iso-octane). Specific migration of ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate] was found to be not detectable in the aqueous simulants and in 95% ethanol, with a detection limit for these simulants of 0.46 mg/kg food. In isooctane, specific migration was found to be 0.20 mg/kg food. The method is properly described. Recovery experiments showed that the substance is stable in 10% ethanol, 95% ethanol and isooctane, under the test conditions applied. In 3% acetic acid, recovery was found to be <43%, due to acid catalysed hydrolysis.
Conclusion:	Based on the previous evaluation by the SCF (SCF, 1998) and the currently provided analytical data the substance remains classified in:
SCF_List:	**2**
Restriction:	**TDI = 0.1 mg/kg bw**
Remark for Commission:	FRF is applicable
Needed data or information	None
References:	- Unpublished data submitted by the petitioner on 19/09/2006 - Scientific Committee on Food, opinion on an additional list on monomers and additives for food contact materials (expressed on 10 December 1998) http://europa.eu.int/comm/food/fs/sc/scf/out20_en.pdf

Ref. No.:	**60025**
Name of the substance:	**Hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene**
CAS number:	-
Document reference:	EFSA/AFC/FCM/755-Rev.IA/60025
General information:	According to the petitioner homopolymers and/or copolymers made

Ref. No.:	**60025**
Name of the substance:	**Hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene**
	of 1-decene and/or 1-dodecene and/or 1-octene (PAOs) are added to polypropylene to improve the polymer's desirable properties, such as melting point, crystallization rate, and optical properties. Average molecular mass of the PAOs ranges from 450-7000 Daltons depending on the type of PAOs. The substance is intended to be used in propylene homopolymers and copolymers in contact with aqueous, acidic, and low-alcohol (up to 10% ethanol) foods under all temperature conditions. Maximum amount of PAOs use in polypropylene is 10%.
Previous evaluations (by SCF or AFC):	None (new substance)
Available data used for this evaluation:	
Non-toxicity data:	- Data on identity - Data on physical and chemical properties - Data on the intended use and authorisation of the substance - Data on migration of the substance - Data on the residual content of the substance
Toxicity data	- gene mutation in bacteria - chromosomal aberrations in cultured mammalian cells - *in vivo* mouse bone marrow micronucleus studies - subchronic (90-day) oral toxicity studies in rats - acute oral toxicity studies in rats - predictions on absorption, distribution, metabolism and excretion based on the SCF opinion on hydrogenated poly-1-decene
Evaluation:	The migration of PAOs with low viscosity from a polypropylene sample containing the maximum foreseeable amount of PAOs has been determined into 10% ethanol and using the contact conditions of 2 hours at 66°C followed by 238 hours at 40°C. The migration was not detectable at the level of 0.2 mg/kg. The calculated worst case migration of the main impurities are < 0.014 mg/kg for the monomers 1-octene, 1-decene 1-dodecene and <0.00085 mg/kg for organic chlorides assuming that the organic chlorides migrate at levels proportional to that of the PAOs. The PAOs tested did not induce mutagenicity in bacteria and did not induce chromosome aberrations in cultured mammalian cells. Moreover, representative compounds for the group did not induce

Ref. No.:	**60025**
Name of the substance:	**Hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene**
	micronucleus formation in the bone marrow of mice treated according to OECD-guidelines with high doses. Therefore, the tested substance is thus considered as non-genotoxic. In adequate 90-day oral feeding studies in rats, only marginal effects on some clinical chemistry parameters (not dose related) were observed. The NOAEL was 20000 mg/kg in food (approximately 1200 mg/kg bw/day). NOAELs of more than 1000 mg/kg bw/day were also observed in four 28-day studies with different representatives of polyalphaolefins. Due to a poor gastrointestinal absorption of structurally related compounds including poly-1-decene which is an authorised food additive (Commission, 2003) evaluated by the SCF in 2001 (SCF, 2001) only a low potential for bioaccumulation is predicted for the polyalphaolefins. Based on the toxicological data provided there are no safety concerns.
Conclusion:	
SCF_List:	**3**
Restriction:	**None**
Remark for Commission:	Migration in fatty foods may exceed the overall migration limit Specifications: - Minimum viscosity (at 100°C) = 3.8 cSt - Average Mw>450 Dalton
Needed data or information	None
References:	- Unpublished data submitted by the petitioner in February and September 2006 - Commission Directive of the European Parliament and of the Council of 22 December 2003, amending Directive 95/2/EC on food additives other than colours and sweeteners - http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/l_024/l_02420040129en00580064.pdf - Scientific Committee on Food opinion on hydrogenated poly-1-decene, 11 July 2001 http://europa.eu.int/comm/food/fs/sc/scf/out95_en.pdf

Ref. No.:	**72081/10**
Name of the substance:	**Petroleum Hydrocarbon Resins (hydrogenated)**
CAS number:	-
Document reference:	EFSA/AFC/FCM/96-Rev.VIA/72081/10 of September 2006
General information:	According to the petitioner the petroleum hydrocarbon resins (hydrogenated) are used as a polymeric additive mainly in polyethylene and polypropylene but also in adhesives to improve processability, gas/vapour permeability, transparency, stiffness, sealing and adhesion properties.
Previous evaluations (by SCF or AFC):	The substance was first evaluated in 1998 (SCF 1998) on the basis of three mutagenicity studies (performed with the hydrogenated hydrocarbon resin) but was classified in SCF_List 7 on the basis of inadequate migration data. (Needed: In first instance, migration data on the polymeric additive; explanation why the residual amount of the hydrogenated monomers and unpolymerisable components are rather high (in the product), more information on specification, i.e. information on hydrogenation, purification and viscosity of final product). The substance was again evaluated in 2000 (SCF 2000). Because of the high migration to be expected in fatty food the substance was again classified in SCF_List 7, requesting in first instance reduction of the residues of the hydrogenated monomers and non-polymerisable components (by technical processing). In the 3rd evaluation (SCF, 2002), an accumulation study with a representative sample of hydrocarbon resins was requested. In the 4th evaluation (EFSA, 2005), based on the data from an accumulation study and the package of toxicological studies available a restriction of 5 mg/kg food was proposed.
Available data used for this evaluation:	
Non-toxicity data:	- See SCF 1998, 2000 and 2003
Toxicity data:	- See SCF 1998, 2000, 2003 and EFSA 2005 - Pharmacokinetic modelling of the accumulation data on a representative sample of hydrocarbon resins
Evaluation:	Considering the high migration from a PP with 10% resin into olive oil and 95% ethanol (51 mg/kg and 11.6 mg/kg respectively) the potential accumulation of Petroleum hydrocarbon resins (hydrogenated) in man was re-evaluated using new data from a pharmacokinetic modelling of a bio-accumulation study in rats. The study was performed with [3H]-labelled polycyclopentadiene (REF No 76680) as a representative sample of hydrocarbon resins.

	Following the administration of 14 daily oral doses of 10 mg [3H]-polycyclopentadiene/kg, only a low amount of [3H]-labelled material was distributed into the tissues (0.69%) with the highest concentrations in liver and mesenteric lymph nodes. The terminal elimination of [3H]-material from tissues was slow, particularly from fat and mesenteric lymph nodes. According to the pharmacokinetic modelling of the bio-accumulation study the steady state levels of [^{3}H]-polycyclopentadiene would have been attained in mesenteric lymph nodes and in fat after approximately 55 and 80 days of daily dosing, respectively. Based on the estimates of model parameters the dissipation half-lives of most tissues were in the range of 3.6 – 5.9 days, but longer for mesenteric lymph nodes (10.8 days) and for abdominal fat (18.1 days). Based on the pharmacokinetic modelling, the absence of toxicity in the 90-day study and low oral absorption, the accumulation potential of polycyclopentadiene is considered to be negligible. Based on these results and considering the absence of genotoxicity and adverse effects in the 90-day oral rat study (including an in utero exposure phase) up to 1800 mg/kg bw/d (SCF, 2003) the Panel noted that also without a specific restriction for petroleum hydrocarbon resins (hydrogenated) in food the margin of safety with regard to possible adverse effects in man would be large.
Conclusion:	Based on the above-mentioned data the substance is classified:
SCF_List:	**3**
Restriction:	**None**
Remark for Commission:	• Migration in fatty foods may exceed overall migration limit • Specifications: Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermal polymerisation of dienes and olefins of the aliphatic, alicyclic and monobenzenoid arylalkene types from distillates of cracked petroleum stocks with a boiling range not greater than 220°C, as well as the pure monomers found in these distillation streams, subsequently followed by distillation, hydrogenation and additional processing Properties Viscosity: > 3 Pa.s at 120 °C. Softening point > 95 °C as determined by ASTM Method E 28-67. Bromine number < 40 (ASTM D1159) . The color of a 50% solution in toluene < 11 on the Gardner scale Residual aromatic monomer ≤ 50 ppm These specifications cover also the substances: - polycyclopentadiene hydrogenated, - dicyclopentadiene-indene-styrene-alpha.methylstyrene-

	vinyltoluene-isobutylene, copolymer, hydrogenated - alpha-Methylstyrene-styrene, copolymer, hydrogenated - alpha-Methylstyrene-vinyltoluene, copolymer, hydrogenated
Needed data or information:	
References:	Unpublished data submitted by the petitioner. SCF (1998 and 2000): Opinion of the Scientific Committee on Food on the 11th additional list of monomers and additives for food contact materials (expressed on 19 October 2000) http://ec.europa.eu/comm/food/fs/sc/scf/out76_en.pdf SCF (2003): Opinion of the Scientific Committee on Food on the 21st additional list of monomers and additives for food contact materials (expressed on 5 March 2003) http://ec.europa.eu/comm/food/fs/sc/scf/out172_en.pdf EFSA (2005) Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 9th list of substances for food contact materials (adopted on 29 June 2005) http://www.europa.eu./science/afc/afc_opinions/1056_en.html

Ref. No.:	**77732**
Name of the substance:	Polyethylene glycol (EO=1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate
CAS number:	-
Document reference:	*EFSA/AFC/FCM/353-Rev.I/77732 of November 2006*
General information:	The test substance is a non-defined mixture. It is intended to be used as an additive in PET plastics at typically 2,000 mg/kg. Its function is to act as a light absorber to protect the packaged food or beverage.
Previous evaluations (by SCF or AFC):	None
Available data used for this evaluation:	
Non-toxicity data:	- Data on identity and purity - Data on physical and chemical properties - Data on the intended use and authorisation - Data on hydrolysis in food simulants

Ref. No.:	**77732**
Name of the substance:	Polyethylene glycol (EO=1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate
	- Migration data for the test substance and for two hydrolysis products, one of which is also an impurity in the test substance - Calculation by mathematical modelling, of the migration levels expected for a dimeric impurity
Toxicity data:	- Gene mutation in bacteria - *In vitro* mammalian cell gene mutation test - *In vitro* chromosome aberration test
Evaluation:	The test substance hydrolyses in aqueous media. Migration of the test substance, as such or monitored via its hydrolysis product polyethoxylated (typically n=6) vanillin, was not detectable with a detection limit of 5 to 9 microg/kg into all simulants. Specific migration of butyl cyanoacetate (an impurity in the test substance and also a hydrolysis product) was detectable at 2.7 microg/kg using worst-case conditions of test. Specific migration of the dimer was estimated using verified migration modelling to be 1 microg/kg.
	Polyethylene glycol (EO=1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate was consistently negative in *in vitro* genotoxicity studies performed under appropriate quality control.
Conclusion:	Based on the above-mentioned data the substance is classified:
SCF_List:	**3**
Restriction:	**0.05 mg/kg food.** **Only for the requested use in PET**
Remark for Commission:	None
Needed data or information	None
References:	Unpublished data provided by the petitioner, April 2004 and July 2006.

Ref. No.:	**77733**
Name of the substance:	**Polyethyleneglycol (EO=1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate**
CAS number:	-
Document reference:	*EFSA/AFC/FCM/354-Rev.I/77733 of November 2006*
General information:	The test substance is a non-defined mixture. It is intended to be used as an additive in PET plastics at typically 2,000 mg/kg. Its

Ref. No.:	**77733**
Name of the substance:	**Polyethyleneglycol (EO=1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate**
	function is to act as a light absorber to protect the packaged food or beverage.
Previous evaluations (by SCF or AFC):	None
Available data used for this evaluation:	
Non-toxicity data:	- Data on identity and purity - Data on physical and chemical properties - Data on the intended use and authorisation - Data on hydrolysis in food simulants - Migration data for the test substance and for two hydrolysis products, one of which is also an impurity in the test substance - Calculation by mathematical modelling, of the migration levels expected for a dimeric impurity
Toxicity data:	- Gene mutation in bacteria - *In vitro* mammalian cell gene mutation test - *In vitro* chromosome aberration test
Evaluation:	The test substance hydrolyses in aqueous media. Migration of the test substance, as such or monitored via its hydrolysis product polyethoxylated (typically n=5) hydroxybenzaldehyde, was not detectable with a detection limit of 5 to 9 microg/kg into all simulants. Specific migration of butyl cyanoacetate (an impurity in the test substance and also a hydrolysis product) was detectable at 3.9 microg/kg using worst-case conditions of test. Specific migration of the dimer was estimated using verified migration modelling to be 1.3 microg/kg. Polyethylene glycol (EO=1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxyphenyl) acrylate was consistently negative in *in vitro* genotoxicity studies performed under appropriate quality control.
Conclusion:	Based on the above-mentioned data the substance is classified:
SCF_List:	**3**
Restriction:	**0.05 mg/kg food.** **Only for the requested use in PET**
Remark for Commission:	None
Needed data or information	None

Ref. No.:	**77733**
Name of the substance:	**Polyethyleneglycol (EO=1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate**
References:	Unpublished data provided by the petitioner, April 2004 and July 2006.

Ref. No.:	**79985**
Name of the substance:	**Poly(ethylene propylene)glycol tridecyl ether**
CAS number:	61725-89-1 and 65150-81-4
Document reference:	SDS EFSA/AFC/FCM 549-Rev.IA/79985 of September 2006
General information:	According to the petitioner poly(ethylene propylene)glycol tridecyl ether is used as a wetting agent and to improve the stability of polytetrafluorothylene (PTFE) in aqueous dispersion during transport and storage. Maximum addition level is 10% in aqueous PTFE dispersions. The food contact material is glass cloth or metal substrates coated with PTFE. The food contact materials are intended to be used with all types of food at all temperatures under conditions of repeat brief contact e.g. conveyor belts, cooking pans. The substance is not expected to be present in the final food contact material as final materials are sintered at high temperatures above the decomposition temperature of the substance. The decomposition products are also expected to burn off during this process.
Previous evaluations (by SCF or AFC):	None (new substance)
Available data used for this evaluation:	
Non-toxicity data:	- Identity of the substance - Chemical and physical properties - Intended use - Authorisation of the substance - Overall migration tests from coatings to water, 10% ethanol, 95% ethanol, iso-octane and MPPO - Determination of the residual content in coatings - Calculation of worst case migration assuming 100% migration of residual content - Information on the sintering temperature and conditions of the test samples - Supporting documents on the analytical method like a calibration curve and typical chromatograms of sample extracts - Data on the presence and identity of any decomposition and/or reaction product of the substance in a final article, manufactured under conditions of minimum and maximum sintering

Ref. No.:	**79985**
Name of the substance:	**Poly(ethylene propylene)glycol tridecyl ether**
	temperatures.
Toxicity data:	- Gene mutation in bacteria on tridecyl alcohol (CAS No. 27458-92-0)
Evaluation:	The substance has two trade names and CAS No's because there are two different manufacturers but the additive is essentially the same with slightly different average ratios of ethylene oxide and propylene oxide and alcohol branching. The average molecular mass of the substance is 960/970 D. The fraction with MW below 1000D is 56%. Thermogravimetric analysis performed under conditions of manufacture of the food contact material (including the final sintering stage at 410°C) shows that the substance indeed decomposes during the sintering process. Overall migration in water, 10% ethanol, 95% ethanol, iso-octane from test samples consisting of aluminium foil coated on both sides with a PTFE dispersion containing 6% of the additive ranged from 0.9 – 3.6 mg/kg food. Specific migration tests have not been performed. The residual level of poly(ethylene propylene)glycol tridecyl ether in PTFE coatings was found to be 4 mg/kg polymer. The average worst case migration was calculated taking into account the lifetime of a conveyor belt and a coated pan and the total amount of food in contact with the article under real use conditions. For the conveyor belt and the coated pan the average migration was 0.01µg/kg and 0.07µg/kg food respectively. Calculation of the worst case migration was found to be 0.012 mg/6dm². This does not take into account a reduced migration upon repeated use. The presence and identity of the decomposition and/or reaction products of the substance in a sample equivalent to a final article, sintered at 380°C and 420°C was determined. No volatile components were found in the sample extracts. The main components in the extracts were low molecular weight oligomers of poly(ethylene propylene)glycol tridecyl ether. Additional components present at lower levels were also oligomeric ethoxylate, presumably oxidized/degraded starting surfactant. Worst case migration of these oxidized by-products is calculated to be less than 1 µg/kg food or <1 µg/6 dm², taking into account repeated use contact. Two of the monomers for this additive, REF No. 17020 ethylene oxide and REF No. 24010 propylene oxide, have been authorized for the manufacture of plastics intended to come into contact with

Ref. No.:	**79985**
Name of the substance:	**Poly(ethylene propylene)glycol tridecyl ether**
	food, with a restriction of 1 mg/kg in the final article (Directive 2002/72/EC). The third monomer, tridecyl alcohol, is not listed in the positive list of authorised substances of the above mentioned Directive. For the two different branched isomers of tridecyl alcohol, CAS No. 68526-86-3 and 27458 -92-0, which are used by the two manufacturers, only limited genotoxicity data are available; just one negative gene mutation study in bacteria with one of the isomers (CAS No 27458 -92-0). Considering the high temperature at which the final item is sintered, the monomers are not likely to be present in the final product. Therefore no further toxicity data are deemed necessary for the monomers. In addition, the substance polyethyleneglycol tridecyl ether phosphate, REF No. 79600, has been evaluated by EFSA in 2004 (EFSA, 2004) and a SML of 5 mg/kg was assigned.
Conclusion:	Based on the above-mentioned data the substance is classified:
SCF_List:	**3**
Restriction:	**0.05 mg/kg food** **To be used only in PTFE items sintered at high temperatures**
Remark for Commission:	Only a method for the determination of the residual content is available.
Needed data or information	None
References:	- Unpublished data submitted by the petitioner in September 2005 and May 2006 - - Commission Directive 2002/72/EC of 6 August 2002 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 - EFSA, 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 6th list of substances for food contact materials, adopted on 8/12/2004 http://www.efsa.eu.int/science/afc/afc_opinions/768_en.html

Ref. No.:	**95858**
Name of the substance:	**Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks**
CAS number:	-
Document reference:	EFSA/AFC/FCM/758-Rev.0A/95858 of November 2006.
General information:	According to the petitioner waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks are intended for use as lubricants in all kinds of polymers in amounts up to 3 %. The finished materials are intended for long term storage of food at ambient temperatures. Paraffin waxes are not intended for articles in contact with fatty foods.
Previous evaluations (by SCF or AFC):	None
Available data used for this evaluation:	
Non-toxicity data:	- Data on identity - Data on physical/chemical properties - Data on use - Data on authorisation - Data on migration in aqueous food simulants - Data on residual content
Toxicity data	- Gene mutation in bacteria - *In vitro* mammalian cell gene mutation test - *In vitro* chromosome aberration test
Evaluation:	Migration from LDPE manufactured with and without a wax representing the lower range of the specification was tested into water, 3% acetic acid and 10 % ethanol for 10d/40°C by total immersion. No detectable migration related to the wax was found at a detection limit of 15 microg/kg. Actual content of the waxes in the sample used for migration testing was determined to be 2.4%. Analytical methods are properly described and validated. (DMSO) extracts of paraffinic waxes did not show mutagenic potential in bacteria and in mammalian cells and it did not induce chromosome aberrations *in vitro*. Therefore, based on the three performed *in vitro* tests there is no evidence for a genotoxic potential of the tested extracts of paraffinic waxes.
Conclusion:	Based on the above-mentioned data the substance is classified:
SCF_List:	**3**
Restriction:	**0.05 mg/kg food** **Not to be used for articles in contact with fatty foods.**

Ref. No.:	**95858**
Name of the substance:	**Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks**
Remark for Commission:	Specifications: - Average molecular weight not less than 350 - Viscosity at 100°C min 2.5 cSt - Content of hydrocarbons with carbon number less than 25, not more than 40%(w/w).
Needed data or information	
References:	Unpublished data submitted by the petitioner in July 2006.

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LIST OF ABBREVIATIONS:

bw	Body weight
D	Dalton
FRF	Fat (consumption) Reduction Factor
MW	Molecular weight
NOAEL	No observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PAO	Poly alpha-olefin
PTFE	Polytetrafluorothylene
QMA	Maximum permitted quantity of the substance in the finished material or article expressed as mg per dm^2 of the surface in contact with food
SML	Specific migration limit
TDI	Tolerable daily intake

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.