

SCIENTIFIC OPINION

23rd list of substances for food contact materials¹

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

Question N° EFSA-Q-2003-199, EFSA-Q-2007-023, EFSA-Q-2008-678

Adopted on 26 March 2009

PANEL MEMBERS

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SUMMARY

Within the general task of evaluating substances intended for use in materials in contact with food according to the Regulation (EC) No.1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with foodstuffs, the CEF Panel evaluated the following substances:

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EFSA Question Number: Ref. No.: Name of the substance: CAS number: SCF_List: Restriction: Remark for Commission:	EFSA-Q2007-023 38550 Bis(4-propylbenzylidene)propylsorbitol 882073-43-0 3 5 mg/kg food including the sum of hydrolysis products, expressed as the parent substance The substance hydrolyses in the presence of acids.
	A conservative estimate of the migration can be received by the sum of the concentration of the parent substance plus three times the concentration of migrated 4-propylbenzaldehyde.
EFSA Question Number:	EFSA-Q-2003-199
Ref. No.:	80077
Name of the substance:	Polyethylene waxes, oxidised
CAS number:	068441-17-8
SCF_List:	2
Restriction:	TDI = 1 mg/kg bw
Remark for Commission:	None
EFSA Question Number:	EFSA-Q-2008-678
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
SCF_List:	3
Restriction:	5 mg/kg food (expressed as the sum of phosphite and phosphate form of the substance and the hydrolysis products)
Remark for Commission:	FRF is applicable

Key words Food Contact Materials, Plastics, Additives, Ref. No. 38550, CAS number 882073-43-0, Bis(4-propylbenzylidene)propylsorbitol; Ref. No. 80077, CAS number 068441-17-8, Polyethylene waxes, oxidised; Ref. No. 92475, CAS number 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.



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 food².

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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^{*} S. Koster declared an interest for the substances REF. No. 38550 and 92475 because his Institute had prepared the evaluation reports under contract with EFSA. He presented the evaluation results and other members of the wg were appointed as rapporteurs to present it to the Panel.

W. Dekant declared an interest for the substance REF. No. 92475 because his Institute had prepared the evaluation report of the substance under contract with EFSA. He presented the evaluation result and another member of the wg was appointed as rapporteur to present it to the Panel.

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



ASSESSMENT

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

The substances examined are listed in ascending order of their Reference Number (REF No.), with their chemical name, Chemical Abstract Number (CAS No.) and classification according to the "SCF list". Since in the past the evaluation of substances used in food contact materials was undertaken by the Scientific Committee on Food (SCF), the same system of classification into a "SCF list" is retained for uniformity purposes. The definitions of the various SCF lists and the abbreviations used are given in the appendix.

The studies submitted for evaluation followed the SCF guidelines for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation (http://ec.europa.eu/food/fs/sc/scf/out82_en.pdf).

EFSA-Q-Nr.:	EFSA-Q2007-023
Ref. No.:	38550
Name of the substance:	Bis(4-propylbenzylidene)propylsorbitol
CAS number:	882073-43-0
Document reference:	SDS EFSA/CEF/FCM/1100-Rev.IIB/38550 of March 2009
General information:	According to the petitioner, the substance is intended to be used in polypropylene homopolymers and high-propylene olefin copolymers up to a maximum concentration of 0.5% w/w as a clarifying agent. Polymers are intended to come into contact with all types of foodstuffs under all time/temperature conditions.
Previous evaluations (by SCF or AFC):	None (new substance)
Available data used for this evaluation:	
Non-toxicity data:	- Data on identity
Ttom toxicity data.	- Data on physical and chemical properties
	- Data on use and authorisation
	- Data on migration
	- Data on actual content
Toxicity data:	 Bacterial gene mutation test <i>In vitro</i> mammalian cell gene mutation test <i>In vitro</i> mammalian chromosome aberration test 90-day oral toxicity study



EFSA-Q-Nr.:	EFSA-Q2007-023
Ref. No.:	38550
Name of the substance:	Bis(4-propylbenzylidene)propylsorbitol
	- Information on potential for accumulation in man
Evaluation:	Bis(4-propylbenzylidene)propylsorbitol hydrolyses especially under acidic conditions into 4-propylbenzaldehyde, propylsorbitol and mono(p-propylbenzylidene)propylsorbitol.
	The specific migration of bis(4-propylbenzylidene)propylsorbitol into 10% ethanol, 3% acetic acid, and olive oil from a polypropylene sample containing 0.5% w/w of the substance after a contact time of 4 hours at 100°C was 0.361, 0.014 and 2.72 mg/kg food, respectively. The concentration of one of the hydrolysis products, 4-propylbenzaldehyde was 0.15, 0.36 and 0.29 mg/kg food, respectively. Neither a method of analysis nor migration data were provided for the other two hydrolysis products, propylsorbitol and mono(p-propylbenzylidene)propylsorbitol. However, a conservative estimate of the migration of the hydrolysis products can be received by multiplying by a factor of three the concentration of 4-propylbenzaldehyde. This would result in a migration of 1.09 mg/kg for all the hydrolysis products in 3% acetic acid in the migration test referred above.
	 Bis(4-propylbenzylidene)propylsorbitol did not induce mutagenicity in bacteria or gene mutations and chromosomal aberrations in mammalian cells in the absence or presence of S9-mix. Thus, the substance is considered as non-genotoxic. In a 90-day oral toxicity study in rats, the substance induced only minor histopathological changes in the kidneys at a dietary concentration of 20,000 mg/kg food (1698 mg/kg bw/day). The changes were not accompanied by changes in clinical chemistry or haematology. A NOAEL of 5000 mg/kg food (424 mg/kg bw/day) can be derived. Due to a rapid hydrolysis in acidic media and further biotransformation of the formed hydrolysis products to polar compounds, an accumulation of bis(4-propylbenzylidene)propylsorbitol or its hydrolysis products is considered unlikely.
	No specific toxicity data on the hydrolysis products were available. However, the hydrolysis products, 4-propylbenzaldehyde and propylsorbitol are expected to be formed in the S9-mix used for

genotoxicity testing and their genotoxicity is then covered by the data



EFSA-Q-Nr.:	EFSA-Q2007-023
Ref. No.:	38550
Name of the substance:	Bis(4-propylbenzylidene)propylsorbitol
	on the bis(4-propylbenzylidene)propylsorbitol. Moreover they are also expected to be formed in rats stomach in the 90-day study.
Conclusion:	Based on the above mentioned data the substance is classified:
SCF_List:	3
Restriction:	5 mg/kg food including the sum of hydrolysis products, expressed
	as the parent substance
Remark for Commission:	The substance hydrolyses in the presence of acids. A conservative estimate of the migration can be received by the sum of the concentration of the parent substance plus three times the concentration of migrated 4-propylbenzaldehyde.
Needed data or information:	None
References:	Unpublished data submitted by the petitioner in January 2007, April 2008 and August 2008.

EFSA-Q-Nr.:	EFSA-Q-2003-199
Ref. No.:	80077 (80080)
Name of the substance:	Polyethylene waxes, oxidised
CAS number:	068441-17-8
Document reference:	EFSA/CEF/FCM/753-Rev.IVB/80077 (ex 80080) of March 2009
General information:	According to the petitioner, the substance polyethylene waxes oxidised is used as a lubricant at up to 2% for processing of all types of plastics intended for contact with all types of foods up to hot fill temperatures.
Previous evaluations (by SCF or AFC):	 The substance was first evaluated by the Scientific Committee on Food in 2001 (EC, 2001) on the basis of migration data from samples not containing the maximum requested concentration and five 90-day oral studies in rats. It was classified in List 7 with the request for further information as follows: data on the chemical structure of oxidation products with the remark that further toxicity data might be needed, characterisation of the type of PE material used in the migration test,



EFSA-Q-Nr.:	EFSA-Q-2003-199
Ref. No.:	80077 (80080)
Name of the substance:	Polyethylene waxes, oxidised
	- migration tests into olive oil or any other suitable fatty food simulant.
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 Data on identification of oxidation products (Mw<1000 Da) Data on epoxide and peroxide content in the waxes Data on migration of the low molecular weight wax components and identification of migrating species
Toxicity data:	 On the low molecular weight fraction of a representative oxidised polyethylene wax: Bacterial gene mutation test <i>In vitro</i> mammalian chromosome aberration test <i>In vitro</i> mammalian cell gene mutation test On oxidised polyethylene waxes: Five 90-day oral toxicity studies in rats One reproduction/developmental toxicity study
Evaluation:	Polyethylene waxes oxidised is a polymeric additive with up to 29% of a low molecular fraction below 1000 Da.
	Migration of the low molecular weight fraction into isooctane and 95% ethanol in test conditions corresponding to hot fill and long-term storage at room temperature was 7.1 and 12.4 mg/kg respectively. The migrating species include straight chain alkanes with an even number of carbon atoms from C12 – C40, straight chain ketones from C10 to C26, lactones from C9 to C16, and straight chain fatty acids in the range C6 to C34. The waxes had no detectable epoxide content (< 0.5%) and their perovide content was 2.53 mmol/kg. For the other possible oxidation
	peroxide content was 2-53 mmol/kg. For the other possible oxidation products no quantitative data were given.A low molecular weight fraction (Mw < 1500 Da) of a most oxidised (based on the perovide value) polyethylene way had possible results.
	(based on the peroxide values) polyethylene wax had negative results in gene mutation assay with bacteria and mammalian cells and was not clastogenic in mammalian cells. Based on these data, oxidised polyethylene waxes are considered as non-genotoxic <i>in vitro</i> .



EFSA-Q-Nr.:	EFSA-Q-2003-199
Ref. No.:	80077 (80080)
Name of the substance:	Polyethylene waxes, oxidised
	The same most oxidised PE wax did not induce treatment-related effects in a reproduction/developmental toxicity study at the highest dose of 1000 mg/kg bw/day. Five different commercial products of polyethylene oxidised waxes have been tested in 90-day studies in rats. Considering the variability in the chemical composition of the waxes, the lowest NOAEL of 500 mg/kg bw/day in these studies was used for the derivation of a TDI. The Panel noted that no data on the low molecular weight fraction was available for subchronic toxicity. Taking this into account and the absence of any chronic study an additional factor of 5 is applied to the usual uncertainty factor of 100 to this NOAEL to derive a TDI. Accordingly, the TDI value is 1 mg/kg bw. No precipitation of the oxidised polyethylene waxes was observed in liver and lymph nodes and therefore no accumulation in man is anticipated.
Conclusion: SCF_List: Restriction: Remark for Commission: Needed data or information:	Based on the above-mentioned data the substance is classified: 2 TDI= 1 mg/kg bw None None
References:	 Unpublished data submitted by the petitioner in December 199, January 2000, December 2002, September 2006 and July 2008. EC (European Commission), 2001. Opinion of the Scientific Committee on Food on the 13th additional list on monomers and additives for food contact materials, <u>http://europa.eu.int/comm/food/fs/sc/scf/out86_en.pdf</u>.

EFSA-Q-Nr.:	EFSA-Q-2008-678
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
Document reference:	SDS EFSA/CEF/FCM/1022-Rev.IB/92475 of March 2009



EFSA-Q-Nr.:	EFSA-Q-2008-678
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
General information:	According to the petitioner, 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 is intended to be used as an antioxidant in the manufacture of polyolefins for contact with all types of foodstuffs (including fatty foods) at the maximum use level of 0.01% w/w.
Previous evaluations (by SCF or AFC):	The substance was evaluated by EFSA (EFSA, 2007) for the use as an antioxidant in polyolefins intended to be in contact with aqueous, acidic and alcoholic foodstuff. It was classified in SCF list 3 with the restriction 0.05 mg/kg food (expressed as the sum of phosphite and phosphate form of the substance).
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 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 substance covered by the application, its oxidation and its hydrolysis products: Bacterial gene mutation test In vitro mammalian chromosome aberration test In vitro mammalian cell gene mutations test For the substance covered by the application: 90-day oral toxicity study in Rodents Absorption, distribution, metabolism and excretion (ADME) after single oral administration Neurotoxicity data (effects on cholinesterase activities in rats)
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-



EFSA-Q-Nr.:	EFSA-Q-2008-678
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
	methylphenyl)propyl] phosphate (NP-2018).
	The stability of the substance was tested in food simulants. In 3% acetic acid and 10% ethanol under the migration conditions, the substance was completely hydrolysed into benzenepropanol, 3-(1,1-dimethylethyl)-4-hydroxy-5-methyl- (MOH) and 6-hydroxy-2,4,8,10-tetra-tert-butyldibenzo[d,f][1,3,2]dioxaphosphepin (NP-1907). The hydrolysis product NP-1907 is further hydrolyzed into 2-phosphinic acid 2'-hydroxy-3,3'',5,5'-tetra-tert-butylbiphenyl ester (NP-2017) then into 3,3',5,5'-tetra-tert-butylbiphenyl-2,2'-diol (TBPH). In 50% ethanol the substance shows strong hydrolysis. In 95% ethanol, the
	substance is partly hydrolyzed and oxidized while in iso-octane the substance shows partially oxidation.
	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) in 3% acetic acid and 10% ethanol was not detected after 2 hr at 100°C and 10 days at 40°C, with detection limits ranging from 4 to 10 μ g/kg food. In 50% ethanol and in the substitute fatty food simulants, 95% ethanol and iso-octane, specific migration of the substance and of the hydrolysis products NP-1907, NP2017 and TBPH was not detectable, with a detection limit ranging from of 8 to 12 μ g/kg food. Specific migration of the hydrolysis product MOH was not detectable in 50% ethanol and 95% ethanol with a detection limit of 9 μ g/kg food, and was found at 18 μ g/kg food in iso-octane after 2 days 20°C (as impurity migrated from the plastic). Migration of the oxidation product into fatty foods simulants was up to 1.2 mg/kg.
	The substance covered by the application, its oxidation and hydrolysis products were not mutagenic in bacteria and did not induce gene mutations or chromosomal aberrations in mammalian cells. Therefore, these substances are considered as non-genotoxic. According to an ADME study, the oxidation product was found to be the primary metabolite of the substance. In the same study the substance covered by the application was rapidly eliminated with faeces, only low levels of radioactivity were retained 168 hours after administration. Thus the substance is not expected to accumulate in



EFSA-Q-Nr.:	EFSA-Q-2008-678
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
	man. In a 90-day oral toxicity study in rats, the substance covered by the application induced mild increased relative liver and kidney weights at the dose higher than 100 mg/kg bw/day. These effects were not linked to any histopathological changes. Therefore, a NOEL of 100 mg/kg bw/day can be derived. Considering the above ADME study, it is concluded that this 00 day study also covers the potential toxicity of
	concluded that this 90-day study also covers the potential toxicity of the oxidation product which was found to migrate into food. No indication for neurotoxicity of the substance covered by the application and its oxidation product was observed in rats when tested for cholinesterase activity after a single oral dose (2000 mg/kg bw).
Conclusion:	Based on the above-mentioned data the substance is classified:
SCF_List:	3
Restriction:	5 mg/kg food (expressed as the sum of phosphite and phosphate form of the substance and the hydrolysis products)
Remark for Commission: Needed data or information:	FRF is applicable None
References:	 Unpublished data submitted by the petitioner in August 2008. EFSA (European Food Safety Authority), 2007. 17th list of substances for food contact materials - Scientific Opinion of the Panel on food additives, flavourings, processing aids and materials in contact with food (AFC); the EFSA Journal (2007) 601-609, 1-24; http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178675761369.htm.



APPENDIX

DEFINITION OF THE SCF LISTS

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

- **List 0** Substances, e.g. foods, which may be used in the production of plastic materials and articles, e.g. food ingredients and certain substances known from the intermediate metabolism in man and for which an ADI need not be established for this purpose.
- List 1 Substances, e.g. food additives, for which an ADI (=Acceptable Daily Intake), a t-ADI (=temporary ADI), a MTDI (=Maximum Tolerable Daily Intake), a PMTDI (=Provisional Maximum Tolerable Daily Intake), a PTWI (=Provisional Tolerable Weekly Intake) or the classification "acceptable" has been established by this Committee or by JECFA.
- **List 2** Substances for which this Committee has established a TDI or a t-TDI.
- **List 3** Substances for which an ADI or a TDI could not be established, but where the present use could be accepted.

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

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

List 4 (for monomers)

- **4A** Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method.
- **4B** Substances for which an ADI or TDI could not be established, but which could be used if the levels of monomer residues in materials and articles intended to come into contact with foodstuffs are reduced as much as possible.
- List 4 (for additives)



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

- List 5 Substances that should not be used.
- List 6 Substances for which there exist suspicions about their toxicity and for which data are lacking or are insufficient. The allocation of substances to this list is mainly based upon similarity of structure with that of chemical substances already evaluated or known to have functional groups that indicate carcinogenic or other severe toxic properties.
 - **6A** Substances suspected to have carcinogenic properties. These substances should not be detectable in foods or in food simulants by an appropriate sensitive method for each substance.
 - **6B** Substances suspected to have toxic properties (other than carcinogenic). Restrictions may be indicated.
- **List 7** Substances for which some toxicological data exist, but for which an ADI or a TDI could not be established. The required additional information should be furnished.
- **List 8** Substances for which no or only scanty and inadequate data were available.
- List 9 Substances and groups of substances which could not be evaluated due to lack of specifications (substances) or to lack of adequate description (groups of substances). Groups of substances should be replaced, where possible, by individual substances

actually in use. Polymers for which the data on identity specified in "SCF Guidelines" are not available.

List W "Waiting list". Substances not yet included in the Community lists, as they should be considered "new" substances, i.e. substances never approved at national level. These substances cannot be included in the Community lists, lacking the data requested by the Committee.

Term used relevant to migration:

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

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



List of abbreviations:

AFC	Scientific Panel on additives, flavourings, processing aids and materials in contact with food
ADME	Absorption, distribution, metabolism, and excretion
bw	Body weight
CAS	Chemical abstracts service
CEF	Scientific Panel on food contact materials, enzymes, flavourings and processing
	aids
Da	Dalton
EC	European Commission
EFSA	European Food Safety Authority
FCM	Food Contact Material(s)
LDPE	Low density polyethylene
Mw	Weight average molecular weight
NOAEL	No observed adverse effect level
NOEL	No observed effect level
PE	Polyethylene
REF No	Reference Number
SCF	Scientific Committee on food
TDI	Tolerable daily intake
w/w	Weight by weight