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**SCIENTIFIC COMMITTEE ON FOOD**

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**Opinion  
of the  
Scientific Committee on Food  
on the  
12th additional list of monomers and additives for food contact  
materials**

(adopted on 28 February 2001)

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Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: BE232 - 6/37.

Telephone: direct line (+32-2) 295.81.10 / 296.48.70, exchange 299.11.11. Fax: (+32-2) 299.48.91

Telex: COMEU B 21877. Telegraphic address: COMEUR Brussels.

[http://www.europa.eu.int/comm/dg24/health/sc/scf/index\\_en.html](http://www.europa.eu.int/comm/dg24/health/sc/scf/index_en.html)

## Opinion of the Scientific Committee on Food on the 12th additional list of monomers and additives for food contact materials

(adopted by the SCF on 28 February 2001)

The Committee (re)evaluated a number of monomers and additives for food contact materials. The substances examined are listed in alphabetical order in the Table, with their Reference Number (REF No.), Chemical Abstract Number (CAS No.) and classification in a SCF list. The definition of the SCF lists is given in the Appendix 1. The opinion of the Committee on each of the substances is shown in the same table. Where appropriate, quantitative restrictions (R) on migration in foodstuffs or in the residual quantity in finished products appear in the Table.

**TABLE**

REF_ N	NAME	CAS_N	SCF List	SCF ASSESSMENT
11530	ACRYLIC ACID, 2-HYDROXYPROPYL ESTER	999-61-1	3	<p>R = 0.05 mg/kg of food (for the mixture). Based on the reduced core set of toxicological data according to the migration level, see Appendix 2</p> <p>Available: calculation of worst case migration is &lt; 0.05 mg/kg of food; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive); gene mutation assay in cultured mammalian cells (negative); micronucleus assay (negative). RIVM/ISS/TNO SDS, July 2000 = CS/PM/3117 REV. I/11530.</p> <p>Remark for Commission:</p> <ul style="list-style-type: none"> <li>• Only a residual Q method is available. A QMA of 50 ug/6 dm<sup>2</sup> is proposed.</li> </ul> <p>(Adopted at the 126th SCF meeting, 28 February 2001)</p>
15610	4,4'-DICHLORO-DIPHENYL SULPHONE	80-07-9	3	<p>R = 0.05 mg/kg of food. Based on the reduced core set of toxicological data according to the migration level, see Appendix 2</p> <p>Available: migration data (&lt; 0.05 mg/kg of food); gene mutation assay in bacteria (negative); two gene mutation assays in cultured mammalian cells (one negative and one positive); micronucleus assay (negative, however substance did not reach the bone marrow); in vitro/in vivo UDS assay (negative). RIVM/ISS SDS, May 2000 = CS/PM/3062 REV.I/15610.</p> <p>(Adopted at the 126th SCF meeting, 28 February 2001)</p>
16752	3,4-EPOXY-CYCLO-HEXYLMETHYL-3',4'-EPOXY-CYCLOHEXYL CARBOXYLATE	2386-87-0	7	<p>Available: calculation of worst case migration based on unreliable data of residual ERL-4221 (= 3,4-epoxy-cyclohexylmethyl-3',4'-epoxy-cyclohexyl carboxylate) in a coating; two inadequate gene mutation assays in bacteria (positive); two inadequate gene mutation assays in cultured mammalian cells; inadequate in vitro SCE assay (positive); inadequate in vitro UDS assay (inconclusive); in vivo SCE assay (negative); bone marrow nuclear anomaly test (negative); mouse spot test (negative); morphological transformation assay (inconclusive); UDS assay (negative); micronucleus assay (negative); limited oral 90-day rat study; limited dermal long term carcinogenicity study in mice.</p> <p>Needed: new data concerning the residual content, obtained with a reliable method of analysis. RIVM/ISS/TNO SDS, July 2000 = CS/PM/3064 REV.II/16752.</p>

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
				(Adopted at the 126th SCF meeting, 28 February 2001)
17110	ETHYLIDENE NORBORNENE	16219-75-3	7	<p>Available: proper substance description; analytical method for the determination of the substance in terpolymers; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); in vitro SCE assay (negative); dominant lethal assay (negative); 90-day rat inhalation study; morphometric evaluation of the thyroid glands of rats after 14-week exposure; developmental vapour inhalation toxicity study with rats.</p> <p>Needed:</p> <ul style="list-style-type: none"> <li>• Calibration curve</li> <li>• Specification of the use of the substance</li> <li>• Explanation of the following statement (made by the petitioner): "other results may be obtained in other application situations, and for other polymer grades, e.g. when used in plastic polymer blends, as polymer modifier. etc."</li> </ul> <p>RIVM/FR SDS, July 2000 = CS/PM/3414/17110.</p> <p>Remark: in case the migration exceeds the 0.05 mg/kg of food, additional data according to SCF guidelines are needed.</p> <p>(Adopted at the 126th SCF meeting, 28 February 2001)</p>
20260	CYCLOHEXYL METHACRYLATE	101-43-9	3	<p>R = 0.05 mg/kg of food. Based on the reduced core set of toxicological data according to the migration level, see Appendix 2</p> <p>Available: migration data in deionised water, 3% acetic acid, 15% ethanol and isooctane (&lt; 0.05 mg/kg of food); gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative). RIVM/DE SDS, July 2000 = CS/PM/3078 REV. II/20260.</p> <p>Remark for Commission: Method available for the determination of specific migration in aqueous and substitute food simulants (iso-octane).</p> <p>(Adopted at the 126th SCF meeting, 28 February 2001)</p>
22932	PERFLUOROMETHYL PERFLUOROVINYL ETHER	1187-93-5	7	<p>Available: inadequate migration data; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); micronucleus assay (negative).</p> <p>Needed:</p> <ul style="list-style-type: none"> <li>• Clarification concerning initial amount of subject substance in relation to chemical structure of the polymer</li> <li>• Examples of typical food contact materials</li> <li>• Detailed information concerning actual conditions of migration experiments, i.e. whether tests were carried out in a gas-tight system, dimensions of test samples to justify surface/volume ratio 1</li> <li>• Recovery experiments in food simulants, including migration period.</li> </ul> <p>RIVM/ISS/TNO SDS, July 2000 = CS/PM/3454/22932.</p> <p>Remark for Commission: need of notification was raised.</p> <p>(Adopted at the 126th SCF meeting, 28 February 2001)</p>
25450	TRICYCLO (5.2.1.0 <sup>2,6</sup> ) DECANEDIMETHANOL	26896-48-0	3	<p>R = 0.05 mg/kg of food. Based on the reduced core set of toxicological data according to the migration level, see Appendix 2</p> <p>Available: adequate information on the identity of the substance; incomplete specific migration data in ethanol instead of olive oil; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative). RIVM/FR SDS, July 2000 = CS/PM/3253 REV. II/25450.</p>

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
38840	BIS (2,4-DICUMYL-PHENYL) PENTAERYTHRITOL-DIPHOSPHITE	154862-43-8	3	<p>R =5 mg/kg of food (assigned to Doverphos S-9228 including the stabiliser itself, its oxidised form bis (2,4-dicumylphenol) pentaerythritol-phosphate and its hydrolysed product (2,4-dicumylphenol). Based on the reduced core set of toxicological data according to the migration level, see Appendix 2</p> <p>Available: migration data (&lt;0.05 mg/kg of food) and actual content in polyolefins, polycarbonate and PET; acute toxicity data (performed with stabiliser itself and with one of its decomposition products); gene mutation assay in bacteria (negative; performed with stabiliser itself); chromosomal aberration assay in cultured mammalian cells (negative; performed with stabiliser itself); gene mutation assay in cultured mammalian cells (negative; performed with stabiliser itself); gene mutation assay in bacteria (negative; performed with the oxidation product Doverphos S 9228-diphosphate); chromosomal aberration assay in cultured mammalian cells (negative; performed with the oxidation product Doverphos S 9228-diphosphate); gene mutation assay in cultured mammalian cells (negative; performed with the oxidation product Doverphos S 9228-diphosphate); gene mutation assay in bacteria (negative; performed with the hydrolysis product 2,4-dicumylphenol); chromosomal aberration assay in cultured mammalian cells (negative; performed with the hydrolysis product 2,4-dicumylphenol); gene mutation assay in cultured mammalian cells (negative; performed with the hydrolysis product 2,4-dicumylphenol); 28-day oral rat study (performed with stabiliser itself); 90-day oral rat study (performed with a mixture of the stabiliser itself and two of its decomposition products); 90-day oral dog study (performed with a mixture of the stabiliser itself and two of its decomposition products); neurotoxicity study (performed with a mixture of the stabiliser and one of its decomposition products). RIVM/TNO SDS, November 2000 = CS/PM/3222 REV.IV/38840.</p> <p>(Adopted at the 126th SCF meeting, 28 February 2001)</p>
68078	NEODECANOIC ACID COBALT SALT	27253-31-2	3	<p>List 3 for neodecanoic acid. R: 0.05 mg/kg of food for neodecanoic acid. Not for fatty foods.</p> <p>Available: 3 negative mutagenicity tests and migration data for non-fatty foods for neodecanoic acid.</p> <p>List 3 for Cobalt. R: 0.05 mg/kg of food (as Co). (RIVM, summary data, October 1992=CS/PM/1707)."</p> <p>(Adopted at the 126th SCF meeting, 28 February 2001)</p>
73160	PHOSPHORIC ACID, MONO- AND DIESTERS WITH CETYL- AND STEARYL ALCOHOL		3	<p>All 4 constituents of the mixture are allocated in List 3 with R = 0.05 mg/kg of food.</p> <p>The four constituents of the mixture are:</p> <ul style="list-style-type: none"> <li>• Phosphoric acid, mono-octadecyl ester (CAS no. 2958-09-9)</li> <li>• Phosphoric acid, di-octadecyl ester (CAS no. 3037-89-6)</li> <li>• Phosphoric acid, mono-hexadecyl ester (CAS no. 3539-43-3)</li> <li>• Phosphoric acid, di-hexadecyl ester (CAS no. 2197-63-9)</li> </ul> <p>(Adopted at the 126th SCF meeting, 28 February 2001)</p>

## **Previous opinions adopted by the SCF in the area of Food Contact Materials (status up to February 2001)**

### 1) Evaluations of individual substances

The 42<sup>nd</sup> Series of Reports of the SCF (Compilation of the evaluations of the Scientific Committee for Food on certain monomers and additives used in the manufacture of plastics materials intended to come into contact with foodstuffs expressed until 21st March 1997, in press) contains the compilation of the SCF opinions on Food Contact Materials for the period 1974 (the beginning of the existence of the Committee) to May 1997.

Following this compilation, the Committee has evaluated or re-evaluated a number of substances. All these opinions have been published on the Internet (at the webpages of the Committee, in the Europa server, [www.europa.eu.int](http://www.europa.eu.int)):

- Opinion on the 11th additional list of monomers and additives for food contact materials ( 11 substances) (expressed on 19 October 2000)
- Opinion on the 10th additional list of monomers and additives for food contact materials ( 29 substances) (expressed on 22 June 2000)
- Opinion on the 9th additional list of monomers and additives for food contact materials ( 4 substances) (expressed on 22 June 2000)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (10 substances) (expressed on 2 December 1999)
- Statement on the use of Novolac glycidyl ethers (NOGE) as additives in food contact materials. Minutes of the 119<sup>th</sup> meeting of the SCF (1st/2nd December 1999)
- Statement on a recent survey on Bisphenol A diglycidyl ether (BADGE) and Bisphenol F diglycidyl ether (BFDGE) in canned food. Minutes of the 119<sup>th</sup> meeting of the SCF (1st/2nd December 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (9 substances) (expressed on 23 September 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (11 substances) (expressed on 17 June 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (6 substances) (expressed on 24 March 1999)
- Opinion on Bisphenol A diglycidyl ether (expressed on 24 March 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (23 substances) (expressed on 10 December 98)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (13 substances) (expressed on 17 September 1998)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (37 substances) (expressed on 19 March 1998)
- Additional list of monomers and additives evaluated by the WG "Food Contact Materials" of the SCF during the 69th-70th meetings. (16 substances) (adopted during the SCF meeting of 12 and 13 June 1997). Also appearing in the Forty-third series of Reports of the Scientific Committee for Food, ISBN 92-828-5887-1)

## 2) Guidelines

The Committee has adopted also updated "**Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation**", on 22 November 2000.

## **APPENDIX 1**

### **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 a TDI or a t-TDI has been established by this Committee.

#### **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.

#### **LIST 4 (for monomers)**

##### **Section 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.

##### **Section 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 which 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.

**Section 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.

**Section 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.

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## **APPENDIX 2**

### **Extract of the "Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation"**

These guidelines establish the general requirements of data to be submitted. As a general principle, the greater the exposure through migration, the more toxicological information will be required. In case of high migration (i.e. 5 - 60 mg/kg/food) an extensive data set is needed to establish the safety. In case of migration between 0.05 – 5 mg/kg food a reduced data set may suffice. If the data are appropriate, a restriction of 5 mg/kg of food is attributed to the substance. In case of low migration (i.e. <0.05 mg/kg food) only a limited data set is needed. If the data are appropriate, also in this case a restriction of 0.05 mg/kg of food is attributed to the substance. The full text of the guidelines provide a more detailed explanation. The guidelines are available at the webpages of the Committee.