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SCIENTIFIC COMMITTEE ON FOOD

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**Opinion
of the
Scientific Committee on Food
on the
14th additional list of monomers and additives for food contact
materials**

- **PM/REF No. 14650 (chlorotrifluoroethylene); CAS no. 79-38-9**
- **PM/REF No. 16650 (diphenyl sulphone); CAS no. – 127-63-9**
- **PM/REF No. 16690 (divinylbenzene); CAS no. 1321-74-0**
- **PM/REF No. 18896 (4-(hydroxymethyl)-1-cyclohexene; CAS no. 1679-51-2**
- **PM/REF No. 18897 (2-hydroxy-6-naphtoic acid); CAS no. 16712-64-4**
- **PM/REF No. 40120 (bis(polyethyleneglycol)hydroxymethylphosphonate);
CAS no. 68951-50-8**
- **PM/REF No. 45650 (2-cyano-3,3-diphenyl-2-propenoic acid 2-ethylhexyl
ester);
CAS no. 6197-30-4**
- **PM/REF No. 71670 (pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate);
CAS no. 178671-58-4**
- **PM/REF No. 71935 (sodium perchlorate monohydrate); CAS no. 7601-89-0**
- **PM/REF No. 79550 (polyethyleneglycol 2,4,7,9-tetra-methyl-5-decyn-4,7-diol
ether); CAS no. 9014-85-1**

(adopted by the SCF on 11 July 2001)

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**Opinion of the Scientific Committee on Food
on the 14th additional list of monomers and additives for food
contact materials**

(adopted by the SCF on 11 July 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
14650	CHLOROTRIFLUORO-ETHYLENE	79-38-9	3	<p>R = 0.5 mg/6 dm². Based on the reduced core set of toxicological data according to the migration level.</p> <p>The substance is extremely volatile and the toxicity data support an R = 0.05 mg/kg food. However this is analytically not enforceable due to the lack of a method for an SML. The residual content QM = 0.05 mg/6dm², assuming 100% migration, is raised 10-fold as it has been demonstrated that more than 95% of migrants appear in the headspace because of the extreme volatility of the additive.</p> <p>Available: data on residual content of chlorotrifluoroethylene (CTFE); poor recovery of CTFE from food simulants; liquid/vapour partitioning data of CTFE in food simulants; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); limited in vivo SCE assay (negative).</p> <p>RIVM/IT/TNO SDS, March 2001 = CS/PM/2795 REV. II/14650.</p> <p>(Adopted at the 128th SCF meeting, 12 July 2001)</p>
16650	DIPHENYL SULPHONE	127-63-9	3	<p>R = 3 mg/kg food (same reference as REF_N. 51570).</p> <p>Remark : the same substance was previously evaluated as an additive (see Opinion on an additional list of monomers and additives for food contact materials expressed on 23 September 1999, at the 118th meeting of the SCF) and the same evaluation is extended now to its requested use as monomer.</p> <p>(Adopted at the 128th SCF meeting, 12 July 2001)</p>
16690	DIVINYLBENZENE	1321-74-0	4A	<p>R = Not detectable. Sum of divinylbenzene and ethylvinylbenzene (DL = 0.01 mg/kg).</p> <p>Available: calculated worst case migration < 1.3 ug/kg food, based on the determination of the residual content; two gene mutation assays in bacteria (negative); mouse inhalation study (shows weak clastogenic activity); acute toxicity data; skin/eye irritation study.</p> <p>RIVM/ISS/TNO SDS, February 2001 = CS/PM/2959 REV. III/16690.</p> <p>Remark for Commission:</p> <ul style="list-style-type: none"> - Only a method for the determination of the residual content is available

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
				<p>– Petition covers a mixture of substances of divinylbenzene and ethylvinylbenzene</p> <p>(Adopted at the 128th SCF meeting, 12 July 2001)</p>
18896	4-(HYDROXYMETHYL)-1-CYCLOHEXENE	1679-51-2	7	<p>Available: incomplete data on residual monomer in polymer (not oxidised); gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (weakly positive).</p> <p>Needed:</p> <ul style="list-style-type: none"> – Analytical method and data on residual monomer in polymer, in compliance with requirements according to the Note for Guidance – Detailed information on GPC measurements performed on the polymer prior to oxidation and after oxidation – Qualitative and quantitative information on the fraction with Mw<1000 which is extractable from the polymer before and after oxidation – In vivo rat liver UDS assay <p>RIVM/TNO SDS, March 2001 = CS/PM/3786 REV. II/18896.</p> <p>(Adopted at the 128th SCF meeting, 12 July 2001)</p>
18897	2-HYDROXY-6-NAPHTHOIC ACID	16712-64-4	3	<p>R = 0.05 mg/kg food</p> <p>Available: migration data from monolayer in direct contact with food simulants (SM < 0.046 mg/kg food); gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive); gene mutation assay in cultured mammalian cells (negative); in vivo micronucleus assay (negative).</p> <p>RIVM/TNO SDS, December 2000 = CS/PM/3812/18897.</p> <p>(Adopted at the 128th SCF meeting, 12 July 2001)</p>
40120	BIS (POLYETHYLENE-GLYCOL) HYDROXY-METHYLPHOSPHONATE	68951-50-8	3	<p>R = 0.6 mg/kg food</p> <p>Available: migration data (< 0.1 mg/kg); gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); 90-day oral rat study.</p> <p>Remark: no accumulation is expected. RIVM SDS, November 2000 = CS/PM/3813/40120.</p> <p>Remark (reasoning for calculating the restriction): Current approach is not setting a TDI based on abovementioned data-package. The restriction is calculated based on the "LOAEL" of 5 mg/kg b.w. (90-day study; change in thymus weight and liver changes) and making use of a safety factor of 500 (10 for intraspecies; 10 for interspecies and 5 for LOAEL to NOAEL). Body weight of 60 kg is used in the calculation.</p> <p>(Adopted at the 128th SCF meeting, 12 July 2001)</p>
45650	2-CYANO-3,3-DIPHENYL-2-PROPENOIC ACID 2-ETHYLHEXYL ESTER	6197-30-4	3	<p>R = 0.05 mg/kg food.</p> <p>Available: migration data (< 0.05 mg/kg food); 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); acute toxicity data; 90-day oral rat study; teratogenicity study with rats. RIVM/TNO SDS, January 2001 = CS/PM/3818/45650.</p> <p>Remark: If data on the absence of potential for accumulation were available then a restriction of 5 mg/kg food could be assigned to this substance.</p> <p>(Adopted at the 128th SCF meeting, 12 July 2001)</p>
71670	PENTAERYTHRITOL TETRAKIS (2-CYANO-	178671-58-4	3	<p>R = 0.05 mg/kg food.</p>

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
	3,3-DIPHENYL ACRYLATE)			Available: migration data (< 0.05 mg/kg food); gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); acute toxicity data; 4-week oral rat study. RIVM/TNO SDS, January 2001 = CS/PM/3819/71670. (Adopted at the 128 th SCF meeting, 12 July 2001)
71935	SODIUM PERCHLORATE MONOHYDRATE	7601-89-0	7	Available: inadequate migration data in 3% acetic acid, 10% ethanol and olive oil; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative). Needed: – Recovery of sodium perchlorate monohydrate from food simulants. Experiments and data provided shall be in compliance with the requirements according to the Note for Guidance. RIVM/DK/TNO SDS, January 2001 = CS/PM/3377 REV. I/71935. Remark: literature search concerning thyroid activity has been made. (Adopted at the 128 th SCF meeting, 12 July 2001)
79550	POLYETHYLENEGLYCOL 2,4,7,9-TETRAMETHYL-5-DECYN-4,7-DIOL ETHER	9014-85-1	3	Only to be used for no-stick polytetrafluoroethane (PTFE) coatings manufactured by sintering. Available: information on the nature of the decomposition residue of the substance (S-440); calculated worst case migration is 0.002 mg residue/dm ² from the final PTFE coating, assuming 100% migration of the solid residue; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); acute toxicity data; limited 28-day range-finding study; inadequate 90-day oral rat study; inadequate one-generation reproduction study. RIVM/TNO SDS, January 2001 = CS/PM/2906 REV. I/79550. (Adopted at the 128 th SCF meeting, 12 July 2001)

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

1) Evaluations of individual substances

The 42nd 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 Europe server, www.europa.eu.int):

- Opinion on the 13th additional list of monomers and additives for food contact materials (18 compounds) (expressed on 30th May 2001)
- Opinion on the 12th additional list of monomers and additives for food contact materials (10 compounds) (expressed on 28th February 2001)
- Opinion on the 11th additional list of monomers and additives for food contact materials (11 compounds) (expressed on 19 October 2000)
- Opinion on the 10th additional list of monomers and additives for food contact materials (29 compounds) (expressed on 22 June 2000)
- Opinion on the 9th additional list of monomers and additives for food contact materials (4 compounds) (expressed on 22 June 2000)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (10 compounds) (expressed on 2 December 1999)
- Statement on the use of Novolac glycidyl ethers (NOGE) as additives in food contact materials. Minutes of the 119th 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 119th 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 compounds) (expressed on 23 September 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (11 compounds) (expressed on 17 June 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (6 compounds) (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 compounds) (expressed on 10 December 98)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (13 compounds) (expressed on 17 September 1998)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (37 compounds) (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 compounds) (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 "**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. These guidelines are an update from the earlier ones published in the 26th series of the reports of the SCF.

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.

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 provides a more detailed explanation. The guidelines are available at the webpages of the Committee.