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SCIENTIFIC COMMITTEE ON FOOD

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**Opinion
of the
Scientific Committee on Food
on the
13th additional list of monomers and additives for food contact
materials**

(Adopted by the SCF on 30 May 2001)

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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
13620	BORIC ACID	10043-35-3	2	<p>Re-evaluation on the basis of an opinion of the SCF in another context.</p> <p>Group-TDI = 0.1 mg/kg b.w. (as B) (with REF_n. 36840, 40320 and 87040).</p> <p>The TDI is based on the No Adverse Effect Level (NOAEL) of 9.6 mg/kg b.w./day for effects on fetal body weight and skeletal anomalies in the rat developmental study. A Safety Factor (SF) of 100 is used.</p> <p>“Opinion of the Scientific Committee on Food on Arsenic, Barium, Fluoride, Boron and Manganese in Natural Mineral Waters (expressed on 13 December 1996, 105th plenary meeting of the SCF, completed on 13 June 1997 at the 107th plenary meeting of the SCF; 43rd Series of Reports of the SCF, 2000”. This opinion is also available on Internet.</p> <p>(Adopted by the SCF at the 127th meeting, 30 May 2001)</p>
13720	1,4-BUTANEDIOL	110-63-4	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 aqueous food simulants 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); acute and 28-day oral studies (original reports are not available); teratogenicity study (original report is not available); distribution, metabolism and excretion studies (original reports are not available); dermal toxicity study (original report is not available); inhalation study (original report is not available). RIVM/UK/TNO SDS, September 2000 = CS/PM/3150 REV. II/13720.</p> <p>(Adopted by the SCF at the 127th meeting, 30 May 2001)</p>
15355	TRIMETHYLHEXA-METHYLENEDIAMINE	25513-64-8	3	<p>Re-evaluation to align this evaluation with other evaluations done by the SCF.</p> <p>R = 5 mg/6 dm².</p>

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
				<p>Remark for Commission: A QM would be indicated. The choice of a QM instead of SML is due to the reactivity of the substance with fat simulant.</p> <p>Available: migration data; three negative mutagenicity studies; 90-day oral rat study; 2-generation reproduction study (rat); two teratogenicity studies (rat and rabbit). RIVM/TNO SDS, November 2000 = CS/PM/2914/15355.</p> <p>(Adopted by the SCF at the 127th meeting, 30 May 2001)</p>
15370	1,6-DIAMINO-2,2,4-TRIMETHYLHEXANE	3236-53-1	3	<p>R = 5 mg/6dm². Same references as for REF_N. 15355.</p> <p>(Adopted by the SCF at the 127th meeting, 30 May 2001)</p>
15400	1,6-DIAMINO-2,2,4-TRIMETHYLHEXANE	3236-54-2	3	<p>R = 5 mg/6dm². Same references as for REF_N. 15355.</p> <p>(Adopted by the SCF at the 127th meeting, 30 May 2001)</p>
16697	n-DODECANEDIOIC ACID	693-23-2	3	<p>Toxicologically acceptable.</p> <p>Available: migration data in food simulants; gene mutation assay in bacteria (negative); gene mutation assay in cultured mammalian cells (negative); micronucleus assay (negative); 90-day oral rat study. RIVM/DK/TNO SDS, November 2000 = CS/PM/3793/16697.</p> <p>Remark: A high log Po/w of 3.17 can indicate the potential for accumulation but as the substance is readily metabolised by the normal fat metabolising route this is not the case for DDDA. For this reason there is also no reason for specifying a migration limit.</p> <p>(Adopted by the SCF at the 127th meeting, 30 May 2001)</p>
18430	HEXAFLUOROPROPYLENE	116-15-4	4A	<p>Not detectable.</p> <p>Available: gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive); gene mutation assay in cultured mammalian cells (negative); micronucleus assay (positive); UDS assay (negative). RIVM SDS, October 2000 = CS/PM/923 REV. I/18430.</p> <p>(Adopted by the SCF at the 127th meeting, 30 May 2001)</p>
18898	N-(4-HYDROXYPHENYL)-ACETAMIDE	103-90-2	3	<p>Only to be used in liquid crystal; polymers used in indirect food contact.</p> <p>Available: migration data from monolayer in direct contact with food simulants; literature data on: 7 gene mutation assays in bacteria (negative); 2 limited gene mutation assays in cultured mammalian cells; 5 assays for chromosomal aberrations and SCE in vitro (positive); 2 limited assays for chromosomal aberrations and micronuclei in vivo (mainly negative; one poorly reported and one study only cited in); assay on DNA fragmentation in vivo (positive); 2 studies on covalent binding to DNA (showing no or marginal binding); NTP carcinogenicity bioassay in mice and rats (equivocal in female rats and no evidence of carcinogenic activity in mice (both sexes) and male rats); 3 human volunteer studies detecting chromosomal aberrations and SCE (mainly positive) (therapeutic dose). RIVM/ISS/TNO SDS, October 2000 = CS/PM/3791/18898.</p> <p>Remark for Commission: indirect food contact; behind a barrier layer in multilayer packaging structures. But migration in direct contact is not detectable at < 50 ug/kg.</p> <p>(Adopted by the SCF at the 127th meeting, 30 May 2001)</p>

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
34650	ALUMINIUM HYDROXYBIS [2,2'-METHYLENEBIS (4,6-DI-TERT.BUTYLPHENYL) PHOSPHATE	151841-65-5	W7	<p>Available: migration data in aqueous food simulants and 95% ethanol; gene mutation assay in bacteria (negative); limited chromosomal aberration assay in cultured mammalian cells (inconclusive); gene mutation assay in cultured mammalian cells (negative); 28-day oral gavage toxicity study (with recovery) in rats; 90-day oral gavage toxicity study in rats; acute oral toxicity study in rats; acute dermal toxicity study in rats; skin irritation study in New Zealand White rabbits; eye irritation study in Zealand white rabbits; skin sensitisation study in guinea pigs</p> <p>Needed:</p> <ul style="list-style-type: none"> - Clarification on unexpected results of migration in 95% ethanol, iso-octane and olive oil; - In first instance, clarification of the choice of solvents and doses used in the submitted mutagenicity studies; - Documentation on the absence of potential for accumulation. <p>RIVM/UK/TNO SDS, October 2000 = CS/PM/3792/34650.</p> <p>(Adopted by the SCF at the 127th meeting, 30 May 2001)</p>
36840	BARIUM TETRABORATE	12007-55-5	2-3	<p>Re-evaluation on the basis of an opinion of the SCF in another context.</p> <p>List 3 for Barium. R = 1 mg/kg (as Ba in food). RIVM SDS, May 1992 = CS/PM/1584.</p> <p>List 2 for Borate. Group-TDI = 0.1 mg/kg b.w. (as B) (with REF_n. 36840, 40320 and 87040).</p> <p>The TDI is based on the No Adverse Effect Level (NOAEL) of 9.6 mg/kg b.w./day for effects on fetal body weight and skeletal anomalies in the rat developmental study. A Safety Factor (SF) of 100 is used.</p> <p>"Opinion of the Scientific Committee on Food on Arsenic, Barium, Fluoride, Boron and Manganese in Natural Mineral Waters (expressed on 13 December 1996, 105th plenary meeting of the SCF, completed on 13 June 1997 at the 107th plenary meeting of the SCF; 43rd Series of Reports of the SCF, 2000". This opinion is also available on Internet.</p> <p>(Adopted by the SCF at the 127th meeting, 30 May 2001)</p>
39090	N,N bis(2-HYDROXY ETHYL) ALKYL (C8-18) AMINE		2	<p>Nota bene</p> <p>Substance evaluated in the past (Additional List of Monomers and Additives Evaluated by the WG "Food Contact Materials" of the SCF During the 69th-70th Meetings (adopted during the 107th SCF meeting of 12 and 13 June 1997 see http://europa.eu.int/comm/food/fs/sc/oldcomm7/out12_en.html)</p> <p>Only a clarification of the expression "free amine" appearing in the SCF restrictions of the substance 39120 (see below) was requested to the SCF. Therefore, this is not a re-evaluation of the substance because of new data.</p> <p>Group t-TDI = 0.02 mg/kg b.w. (with REF-n. 39120).</p> <p>Needed: three in vitro mutagenicity studies according to guidelines on either REF_N. 39090 or 39120.</p> <p>Remark: on the basis of the available studies it remains included in the group t-TDI pending the results of the required mutagenicity studies. If negative it will be classified in L3 with a restriction of 5 mg/kg of food. NOTE: both substances are covered when the mutagenicity studies are submitted.</p> <p>(Adopted by the SCF at the 127th meeting, 30 May 2001)</p>

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
39120	N,N-bis (2-HYDROXYETHYL)ALKYL C8-18 AMINE HYDROCHLORIDES		2	Group t-TDI = 0.02 mg/kg b.w. expressed as tertiary amine (expressed excluding HCl) (with REF_n. 39090). (Adopted by the SCF at the 127 th meeting, 30 May 2001)
40320	BORIC ACID	10043-35-3	2	Re-evaluation on the basis of an opinion of the SCF in another context. Group-TDI = 0.1 mg/kg b.w. (as B) (with REF_n. 36840, 40320 and 87040). The TDI is based on the No Adverse Effect Level (NOAEL) of 9.6 mg/kg b.w./day for effects on fetal body weight and skeletal anomalies in the rat developmental study. A Safety Factor (SF) of 100 is used. "Opinion of the Scientific Committee on Food on Arsenic, Barium, Fluoride, Boron and Manganese in Natural Mineral Waters (expressed on 13 December 1996, 105 th plenary meeting of the SCF, completed on 13 June 1997 at the 107 th plenary meeting of the SCF; 43 rd Series of Reports of the SCF, 2000". This opinion is also available on Internet. (Adopted by the SCF at the 127 th meeting, 30 May 2001)
40580	1,4-BUTANEDIOL	110-63-4	3	Same reference as 13720. (Adopted by the SCF at the 127 th meeting, 30 May 2001)
80000	POLYETHYLENE WAX	9002-88-4	7	Available: migration data from PE, PS and PVC (samples do not contain the maximum indicated concentration of the additive). Needed: <ul style="list-style-type: none"> - characterisation of the type of PE material used in the migration test; - migration data into olive oil or a suitable alternative fatty food simulant. RIVM/DE SDS, June 2000 = CS/PM/3787/80000. (Adopted by the SCF at the 127 th meeting, 30 May 2001)
80077	POLYETHYLENE, OXIDISED	68441-17-8	7	Available: migration data from PE, PS and PVC (samples do not contain the maximum indicated concentration of the additive); 5 90-day oral rat studies. Needed: <ul style="list-style-type: none"> - information on the chemical structure of oxidation products, especially for epoxides and peroxide components; - characterisation of the type of PE material used in the migration test; - migration data into olive oil or a suitable alternative fatty food simulant; • in second instance, only if an SML was set: migration data from a material expected to give the highest migration with the maximum intended use concentration under worst case conditions. Remark: <ul style="list-style-type: none"> - No mutagenicity studies are asked for at the moment. However, based on the requested information concerning the chemical structure of the oxidation products further toxicity data might be requested. - No log Po/w is requested because it can be assumed that the potential for bioaccumulation of polyethylene, oxidised is lower than that of the un-oxidised polyethylene wax (REF_N. 80000). RIVM/DE SDS, December 2000 = CS/PM/3789 REV. I/80077. (Adopted by the SCF at the 127 th meeting, 30 May 2001)

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
81060	POLYPROPYLENE WAX	9003-07-0	7	<p>Available: migration data from PE and PVC (samples do not contain the maximum indicated concentration of the additive).</p> <p>Needed:</p> <ul style="list-style-type: none"> - characterisation of the type of PE material used in the migration test; - migration data into olive oil or a suitable alternative fatty food simulant. <p>RIVM/DE SDS, December 2000 = CS/PM/3788 REV. I/81060.</p> <p>(Adopted by the SCF at the 127th meeting, 30 May 2001)</p>
87040	SODIUM TETRABORATE	1330-43-4	2	<p>Re-evaluation on the basis of an opinion of the SCF in another context.</p> <p>Group-TDI = 0.1 mg/kg b.w. (as B) (with REF_n. 36840, 40320 and 87040).</p> <p>The TDI is based on the No Adverse Effect Level (NOAEL) of 9.6 mg/kg b.w./day for effects on fetal body weight and skeletal anomalies in the rat developmental study. A Safety Factor (SF) of 100 is used.</p> <p>“Opinion of the Scientific Committee on Food on Arsenic, Barium, Fluoride, Boron and Manganese in Natural Mineral Waters (expressed on 13 December 1996, 105th plenary meeting of the SCF, completed on 13 June 1997 at the 107th plenary meeting of the SCF; 43rd Series of Reports of the SCF, 2000”. This opinion is also available on Internet.</p> <p>(Adopted by the SCF at the 127th meeting, 30 May 2001)</p>
93970	TRICYCLODECANE DIMETHANOL-bis-(HEXA-HYDROPTHTALATE	-	7	<p>Available: migration data in aqueous food simulants and 50% ethanol; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive; at highly toxic doses); gene mutation assay in cultured mammalian cells (negative); in vivo micronucleus assay (negative); acute toxicity data; 30-day oral rat study.</p> <p>Needed:</p> <ul style="list-style-type: none"> - information on the proportion of the five main isomers that comprise 95.7% of the names substance, along with information on the impurities <p>RIVM/TNO SDS, October 2000 = CS/PM/3790 REV. I/93970.</p> <p>(Adopted by the SCF at the 127th meeting, 30 May 2001)</p>

Previous opinions adopted by the SCF in the area of Food Contact Materials (status up to 29 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 12th additional list of monomers and additives for food contact materials (10 substances) (expressed on 28th February 2001)
- 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 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 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.

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.