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Opinion of the Scientific Committee on Food on the 10th additional list of monomers and additives for food contact materials

(adopted by the SCF on 22/6/2000)

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Opinion of the Scientific Committee on Food on the 10th additional list of monomers and additives for food contact materials

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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. 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
11500	ACRYLIC ACID, 2-ETHYLHEXYL ESTER	103-11-7	7	Available: 18% hydrolysis in simulated saliva; specific migration in 3% acetic acid, 15% ethanol and 95% ethanol (10 days at 40 °C) < 0.05 mg/kg into food; two gene mutation assays in bacteria (one negative (publication) and one inadequate); limited chromosomal aberration assay in cultured mammalian cells (publication); four gene mutation assays in cultured mammalian cells (one equivocal (publication); one inconclusive (publication); one inadequate and one limited); in vivo chromosomal aberration assay (negative); in vitro micronucleus assay (negative (publication)); limited in vitro UDS assay; inadequate SCE assay; limited mammalian cell transformation assay; limited acute and subacute toxicity studies; two subchronic inhalation toxicity studies (one of which was limited) (NOEL established but not relevant); three dermal long-term toxicity/carcinogenicity studies (one of which was limited) (no NOEL established); limited data on absorption, distribution, metabolism and excretion; four limited sensitisation studies; limited eye irritation study in rabbits. Needed: in vivo UDS assay. RIVM/UK/TNO SDS, February 2000 = CS/PM/3270 REV.II/11500.
13323	1,3-BIS(2-HYDROXY-ETHOXY) BENZENE	102-40-9	5	Genotoxic Available: specific migration < 0.05 mg/kg of food; gene mutation assay in bacteria (negative); two chromosomal aberration assays in cultured mammalian cells (both positive); two gene mutation assays in cultured mammalian cells (one weakly positive and one negative); mouse bone marrow micronucleus assay (equivocal). RIVM/ISS/TNO SDS, February 2000 = CS/PM/2643 REV. II/13323. NOTE: if this substance should be reconsidered the request will be in first instance: • Chromosomal aberration assay in vivo with repeated treatment protocol. • Explanation on the finding/mechanism in the chromosomal aberration assay in cultured mammalian cells.
13453	BIS(HYDROXYPHENYL) METHANE	1333-16-0	7	Available: inadequate calculated worst case migration (= 0.015 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 (equivocal); literature data on endocrine disrupting activity.

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				Needed: • Clarification if bis(hydroxyphenyl)methane is a starting substance used to make the finished epoxy coating OR if bis(hydroxyphenyl)methane is an impurity in one or more of the ingredients mixed and reacted to make the finished coating in this application. • Repeat of mouse lymphoma assay, including proportionate toxic doses (according to OECD 1998) OR an in vivo UDS assay. RIVM/ISS/TNO SDS, January 200 = CS/PM/3381 REV. I/13453.
13932	1-BUTEN-3-OL	598-32-3	L4A	n.d. (DL = 0.01 mg/kg) Available: worst case migration of ≤ 0.008 mg/kg in the case of use as co-monomer of a polymeric additive, made from less then 10% 1-buten-3-ol and used at less then 2.5% in PVC; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive); gene mutation assay in cultured mammalian cells (weakly positive). RIVM/FR SDS, February 2000 = CS/PM/3151 REV. IV/13932. Remark for Commission: only a method for the determination of the residual content is available.
16090.	4,4'-DIHYDROXY-DIPHENYL SULPHONE	80-09-1	3	R = 0.05 mg/kg of food. Available: the substance is used as a comonomer for kitchen utensils, mainly intended for repeated use, and for oven cooking; migration has been tested upto 218 °C and is always below 0.05 mg/kg food (aqueous simulants, HB307); 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/FR/ISS/TNO SDS, February 2000 = CS/PM/2854 REV. II/16090.
16690	DIVINYLBENZENE	1321-74-0	L4A	n.d. (DL = 0.01 mg/kg) 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 (positive); acute toxicity data; skin/eye irritation study. RIVM/ISS/TNO SDS, September 1999 = CS/PM/2959 REV. II/16690. Remark for Commission: • only a method for the determination of the residual content is available. • Petition covers a mixture of substances, specifications needed (and requested by petitioner). Remark: during an earlier meeting it was decided that for the toxicity part, based on the very low migration, there was no need to ask for further data.
18370	1,4-HEXADIENE	592-45-0	7	Available: calculated worst case migration < 0.012 mg/kg food; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive); gene mutation assay in cultured mammalian cells (positive); in vivo micronucleus assay in rats by inhalation (negative); acute toxicity data; two 4-hour inhalation rat studies; 28-day inhalation rat study; metabolism study. Needed: in first instance an in vivo micronucleus assay by an appropriate route (other than inhalation) and if negative an in vivo UDS assay should be performed. RIVM/FR/TNO SDS, February 2000 = CS/'PM/2421 REV. II/18370.
20410	METHACRYLIC ACID DIESTER WITH 1,4-BUTANEDIOL	2082-81-7	3	R = 0.05 mg/kg of food. Available: specific migration data in aqueous simulants and in iso-octane;

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				two gene mutation assays in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive); gene mutation assay in cultured mammalian cells (negative); in vivo micronucleus assay (negative). Acute toxicity test (LD50); three sensitisation tests (two positive and one negative); RIVM/UK/TNO SDS, February 2000 = CS/PM/3219 REV. III/20410.
22337	2-AMINOETHANOL	141-43-5	3	R = 0.05 mg/kg of food. Available: migration data from multilayer bottle and residual content in polymer; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); *in vitro* cell transformation assay (negative); toxicology summary on reproductive toxicity; general toxicological overview on 2-aminoethanol (made by the applicant). RIVM/TNO SDS, August 1999 = CS/PM/3337/22337. Remark: substance evaluated only for the requested use of indirect contact with non-fatty food.
24073	RESORCINOL DIGLYCIDYL ETHER	101-90-6	3	R = 0.005 mg/kg of food; only to be used behind the PET barrier. Available: data on residual content in PHAE polymer, resulting in a worst case migration of 0.001 mg/kg food; gene mutation assay in bacteria (positive); chromosomal aberration assay in cultured mammalian cells (positive); micronucleus assay (negative) (the target organ was not reached); 2-week oral mouse and rat studies; 13-week oral mouse and rat studies; mouse and rat carcinogenicity studies; conclusions made in other scopes. RIVM/TNO SDS, August 1999 = CS/PM/3338/24073. Remark: substance evaluated only for the requested use of indirect contact with non fatty food
34850	AMINES, BIS (HYDROGENATED TALLOW ALKYL) OXIDISED	143925-92-2	7	Available: data on migration of the substance and its transformation products into aqueous and fatty food simulants; analytical methods for the determination in food simulants and in PP and PE; 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 and dog studies; test with 3 migrants for the induction of gene mutations in bacteria and chromosomal aberrations in cultured mammalian cells (negative). Needed: • In-house validation of the analytical method. • Explanation with regard to the migration of the nitrone from LDPE although no nitrone was detected in the polymer. • Explanation with regard to the results for the aldehyde in the migration test and the determination in the polymer • Migration in iso-octane, or justify choice of just ethanol in place of oil. RIVM/DE SDS, February 2000 = CS/PM/3356 REV. I/34850.
35284	N-(2-AMINO ETHYL)-ETHANOLAMINE	111-41-1	3	R = 0.05 mg/kg of food. Available: migration data for multilayer bottle and residual content in the polymer; 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); gene mutation assay in cultured mammalian cells (negative (publication)); in vitro SCE assay (negative (publication)); in vitro UDS assay (negative (publication)); toxicology summary on N-(2-amino ethyl)ethanolamine (made by the applicant). RIVM/TNO SDS, August 1999 = CS/PM/3339/35284. Remark: substance evaluated only for the requested use for indirect contact with non-fatty food.
38840	BIS(2,4-DICUMYL-	154862-	3	R = 5 mg/kg of food.

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
	PHENYL)PENTA-ERYTHRITOL-DIPHOSPHITE	43-8		Available: migration data (<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-diphosphonate); chromosomal aberration assay in cultured mammalian cells (negative; performed with the oxidation product Doverphos S 9228-diphosphonate); gene mutation assay in cultured mammalian cells (negative; performed with the oxidation product Doverphos S 9228-diphosphonate); 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 itself and one of its decomposition products). RIVM/TNO SDS, September 1999 = CS/PM/3222 REV.III/38840.
71935	SODIUM PERCHLORATE MONOHYDRATE	7791-07-3	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: in first instance, recovery experiments of sodium perchlorate monohydrate in food simulants, including the migration period. RIVM/DK/TNO SDS, December 1999 = CS/PM/3377/71935. Remark: literature search concerning thyroid activity and genotoxicity will be made.
86434	SILVER SODIUM HYDROGEN ZIRCONIUM PHOSPHATE	-	7	Available: demonstration of not detectable (<0.004 mg/kg food) migration of Zr and Ag into food simulants under worst-case conditions of reflux; evidence of extensive leaching of silver from the additive into buffers containing sodium ions; two gene mutation assays in bacteria (negative; performed with novaron AG300 (3.8% silver) and novaron AG1100 (10% silver)); gene mutation assay in cultured mammalian cells (equivocal; performed with novaron AG300); in vivo mouse micronucleus assay (negative; performed with novaron AG300); acute toxicity data (performed with novaron AG300 and novaron AG1100); 13-week oral rat study (performed with novaron AG300); teratogenicity study in rats (performed with an experimental mixture of novaron); dermal toxicity (performed with novaron AG300 and AG1100); inhalation toxicity data (performed with an experimental mixture of novaron); eye irritation data (performed with novaron AG300); skin sensitisation data (performed with novaron AG300). Needed: • Migration data from plastic containing the additive, into buffers (simulants) containing sodium ions. • Depending on these results, information on whether or not these migration levels could exert a preservative effect on foodstuffs. RIVM/UK SDS, February 2000 = CS/PM/3382 REV.I/86434.
93930	2,4,4'-TRICHLORO-2'-HYDROXYDIPHENYL-ETHER	3380-34-5	3	R = 5 mg/kg of food. Available: migration data from PP, HDPE and thin PVC films; adequately described test method; tests on the antimicrobial effect; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); in vitro UDS assay (negative); chromosomal aberration assay in vivo (negative); 90-day oral rat study; oral chronic/carcinogenicity

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
				study in rats (no NOAEL established); two-generation reproduction study in rats (no NOAEL established); teratogenicity study in rats; toxicokinetic data. RIVM/DESDS, February 2000 = CS/PM/ REV. IV/93930. Remarks for Commission: • Migration could exceed 5 mg/kg of food. • The use of this compound should not lead to lowering of hygienic standards in food handling.

Previous opinions adopted by the SCF in the area of Food Contact Materials containing lists of assessments of substances (status up to June 2000)

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, ISBN 92-828-5886-3) contains the compilation of the SCF opinions on Food Contact Materials for the period 1974 (the beginning of the existence of the Committee) to March 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:

- 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 dyglicidyl 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 in Forty-third series of Reports of the Scientific Committee for Food, ISBN 92-828-5887-1)

APPENDIX

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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