

OPINION ON AN ADDITIONAL LIST OF MONOMERS AND ADDITIVES FOR FOOD CONTACT MATERIALS

(expressed on 10 December 1998)

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 No.	NAME	CAS No.	SCF List	SCF Assessment
13210	BIS(4-AMINOCYCLOHEXYL)METHANE	01761-71-3	3	R = 0.05 mg/kg of food. Available: Adequate migration data and analytical report, showing specific migration of bis(4-aminocyclohexyl)methane is < 0.05 mg/kg food; inadequate report of gene mutation test in bacteria; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative). (RIVM/ISS/TNO SDS, April 1998 = CS/PM/ 2852 REV. I /13210). (Adopted at 114th SCF meeting) (10 December 1998)
13720	1,4-BUTANEDIOL	00110-63-4	7	Available: Inadequate migration data in the four official food simulants; three negative mutagenicity studies; 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). Needed: Detailed information concerning establishment of the detection limit; clarification of calculation of recovery of 1,4-butanediol in 15% ethanol and 3% acetic acid from the 1,4-butanediol/DEG ratios reported. (RIVM/UK/TNO SDS, June 1998 =CS/PM/3150 REV.1/13720). (Adopted at 114th SCF meeting) (10 December 1998)
16694	N,N'-DIVINYL-2-IMIDAZOLIDINONE	13811-50-2	3	R = 0.05 mg/kg of food. Available: Adequate analytical method for determination of residual 1,3-divinylimidazolidin-2-one in terpolymer; calculated worst case migration is < 0.08 ppb into food; proposal of petitioner to set restriction of QM = 1 ppm in the polymer; 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); in vivo UDS assay (negative). (RIVM/TNO SDS, March 1998 = CS/PM/3156 /16694). REMARKS for Commission: *Only a method for the determination for the residual content is available. * Substance hydrolyses in acid media. (Adopted at 114th SCF meeting) (10 December 1998)

REF No.	NAME	CAS No.	SCF List	SCF Assessment
18444	HEXAHYDROTEREPHTHALIC ACID	01076-97-7	7	<p>Available: Inadequate migration data; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (equivocal); inadequate gene mutation assay in cultured mammalian cells; limited subacute (28-day) oral study. Needed: identification whether the standard 1,4-CHDA used in the migration testing is representative for the composition of 1,4-CHDA used in the polymerisation process and chromatogram of blank simulant OR identity of interfering component eluting with the same retention time as trans 1,4-CHDA; chromosomal aberration assay in cultured mammalian cells (material which is used should be tested); gene mutation assay in cultured mammalian cells. (RIVM/UK/TNO SDS, June 1998 =CS/PM/3152 REV.1/18444).</p> <p>(Adopted at 114th SCF meeting) (10 December 1998)</p>
18700	1,6-HEXANEDIOL	00629-11-8	7	<p>Available: Inadequate migration data; inadequate data concerning residual content; three negative mutagenicity studies. Needed: Properly described analytical method (preferably according to the standard format) as well as typical chromatograms, calibration procedure and validation of the method, including data to demonstrate suitability and reliability of the migration experiments by carrying out proper recovery tests OR new data on the residual content of 1,6-hexanediol in polymer coating using a suitable analytical method which is properly validated and documented according to SCF guidelines. (RIVM/ISS/TNO SDS, April 1998 = CS/PM/2807 REV. I/18700).</p> <p>(Adopted at 114th SCF meeting) (10 December 1998)</p>
20050	METHACRYLIC ACID, ALLYL ESTER	00096-05-9	3	<p>R : 0.05 mg/kg of food.</p> <p>Available: Adequate migration data and analytical method and stability data in food simulants; three negative mutagenicity studies. (RIVM/DK/TNO SDS, June 1998= CS/PM/3077/Rev.1/20050).</p> <p>(Adopted at 114th SCF meeting) (10 December 1998)</p>
20530	METHACRYLIC ACID, 2-(DIMETHYLAMINO)ETHYL ESTER	02867-47-2	4A	<p>R = not detectable (detection limit = 10 ppb).</p> <p>Available: Hydrolysis data in simulated body fluids; gene mutation assay in bacteria (only a summary available); chromosomal aberration assay in cultured mammalian cells (positive); gene mutation assay in cultured mammalian cells (inconclusive); oral and i.p. acute toxicity data (only summary available); oral subacute (14-day) study (only summary available); inhalation studies (only summary available); dermal toxicity study (only summary available); eye irritation study (only summary available). (RIVM/UK/TNO SDS, June 1998 =CS/PM/3154 REV.1/20530).</p> <p>REMARK for Commission: * No method of analysis is available for the enforcement of an SML. * The substance hydrolyses readily at neutral pH and above and so it will be unstable in many foods. The substance is stable in simulant B and will not hydrolyse in simulant D.</p> <p>(Adopted at 114th SCF meeting) (10 December 1998)</p>
23175	PHOSPHOROUS ACID, TRIETHYL ESTER	00122-52-1	3	<p>QM = n.d. in the polymer (limit of detection = 1 ppm).</p> <p>Available: Adequate analytical method for determination of the residual content; calculation worst case migration; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (positive); in vivo UDS assay in rat liver (negative). (RIVM/ISS/UK SDS, July 1998 = CS/PM/3195/25525).</p> <p>(Adopted at 114th SCF meeting) (10 December 1998)</p>

REF No.	NAME	CAS No.	SCF List	SCF Assessment
26155	1-VINYLMIDAZOLE	1072-63-5	3	R = 0.05 mg/kg of food. Available: Adequate analytical method for determination of residual 1-vinylimidazole in terpolymer; calculated worst case migration is < 0.17 ppb into food; three negative mutagenicity studies. (RIVM/TNO SDS, April 1998 = CS/PM/3158 /95805). REMARK for Commission: Only a method for the determination for the residual content is available. (Adopted at 114th SCF meeting) (10 December 1998)
26320	VINYLTRIMETHOXYSILANE	02768-02-7	3	R = 0.05 mg/kg of food Available: Complete hydrolysis in digestive fluid simulants; specific migration in water < 0.006 mg/kg food, in iso-octane < 0.03 mg/kg food; residual content < 50 µg/kg; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive); gene mutation assay in cultured mammalian cells (negative with S9, inconclusive without S9); in vivo micronucleus assay (negative). Remark: given the data on rapid and complete hydrolysis, no further questions concerning genotoxicity are raised. Remark for Commission: Complete and rapid hydrolysis in aqueous food stuff and food simulant. (RIVM/ISS/TNO SDS, July 1998 = CS/PM/3196/26320). (Adopted at 114th SCF meeting) (10 December 1998)
32395	ADIPIIC ACID-DIETHYLENTRIAMINE-EPICHLOROHYDRIN, COPOLYMER	25212-19-5	7	Available: Molecular mass distribution curve, data on use, impurities, residual amounts of starting substances. Needed: In first instance, information on identity of the fraction below 1000 D. DE/TNO SDS, June 1998 = CS/PM/3163 REV.1/32395). (Adopted at 114th SCF meeting) (10 December 1998)
47230	DIBUTYLTINMALEATE	00078-04-6	7	Available: Specific migration of dibutyltinmaleate into 3% acetic acid, 15% ethanol and olive oil is not detectable, i.e. < 0.002 mg/kg food (expressed as tin); gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive); gene mutation assay in cultured mammalian cells (negative). Needed: In first instance, in vivo micronucleus assay or rodent bone marrow metaphase analysis and explanation of the basis for the statement that the compound doesn't hydrolyse. (RIVM/TNO SDS, July 1998 = CS/PM/3197/47230). (Adopted at 114th SCF meeting) (10 December 1998).
53670	ETHYLENEGLYCOL BIS(3,3-BIS(3-tert-BUTYL-4-HYDROXYPHENYL)BUTYRATE)	32509-66-3	2	TDI = 0.1 mg/kg b.w. Available: acute oral toxicity data; 90-day oral rat study; 16-week oral rat study (after in utero exposure); 90-day oral dog study; 2-year oral dog study; 2.5 year oral rat study (combined chronic/carcinogenicity study); one-generation reproduction study with rats; three negative mutagenicity studies. (RIVM SDS, January 1998 = CS/PM/3157/ 53670). REMARK for Commission: No method of analysis is available for the enforcement of an SML. (Adopted at 114th SCF meeting) (10 December 1998)
67170	MIXTURE OF (80-100% W/W) 5,7-DI-tert.BUTYL-3-(3,4-DIMETHYLPHENYL)-3H-BENZOFURAN-2-ONE AND (0-20% W/W) 5,7-DI-tert.BUTYL-3-(2,3-DIMETHYLPHENYL)-3H-BENZOFURAN-2-ONE	181314-48-7	3	R = 5 mg/kg of food. Available: Adequate migration data; log Po/w; three negative mutagenicity studies; 90-day oral rat study (including examination of the activity of the peroxisome associated enzymes); metabolism study (in vitro and in vivo) in rats; in vitro gene mutation assay in bacteria with the dimer (CG33-0941); ADE study. (RIVM/TNO SDS, March 1998 = CS/PM/2965 REV. I/67170). (Adopted at 114th SCF meeting) (10 December 1998)

REF No.	NAME	CAS No.	SCF List	SCF Assessment
76780	POLYESTER OF ADIPIC ACID WITH 1,3-BUTANEDIOL	24937-93-7	2	Group-TDI = 0.5 mg/kg .b.w. (with PM/REF Nos. 76790, 76865 and 80820). Same references as 76865. (Adopted at 114th SCF meeting) (10 December 1998)
76790	POLYESTER OF ADIPIC ACID WITH 1,3- AND/OR 1,4-BUTANEDIOL AND/OR 1,2-PROPANEDIOL, WITH FREE HYDROXYL GROUPS ACETYLATED	- . -	2	Group-TDI = 0.5 mg/kg .b.w. (with PM/REF Nos. 76780, 76865 and 80820). Same references as 76865. (Adopted at 114th SCF meeting) (10 December 1998)
76830	POLYESTER FORMED FROM ADIPIC,AZELAIC,DECA NEDI-CARBOXYLIC,GLUTARIC,MALEIC,PHTHALIC,SEBACIC,SUCCINIC ACIDS WITH ONE OR MORE DIOLS (C2-C6),GLYCEROL,MANNITOL,2,2-BIS(4-HYDROXYPHENYL)PROPANE,PENTAERYTHRITOL SORBITOL, THE TERMINAL GROUP MAY BE ESTERIFIED BY MONOCARBOXYLIC ACIDS OR MONFUNCTIONAL ALCOHOLS	- . -	7	Needed: Specification of the polyesters in actual use, migration and toxicity data on representative esters based on other acids than adipic acid. (Adopted at 114th SCF meeting) (10 December 1998)
76865	POLYESTERS OF 1,2-PROPANEDIOL AND/OR 1,3- AND/OR 1,4-BUTANEDIOL AND/OR POLYPROPYLENEGLYCOL WITH ADIPIC ACID, ALSO ENDCAPPED WITH ACETIC ACID OR FATTY ACIDS C12-C18 OR n.OCTANOL AND/OR n.DECANOL	- . -	2	Group-TDI = 0.5 mg/kg .b.w. (with PM/REF Nos. 76780, 76790 and 80820). Remark: The group TDI is based on analytical and toxicological studies carried out with different polyesters covered by the general description of PM Ref. N. 76865. Available: Migration data under conditions simulating contact with fresh meat; adequately described test method; three (negative) mutagenicity studies; acute toxicity data; absorption/ metabolism/excretion; 28-day oral rat study; 90-day oral rat study; 2-year oral rat study; 2-year oral dog study; 3-generation reproduction study on different polyesters out of the group. (UK SDS, May 1995 = CS/PM/2592; RIVM/DE SDS, September 1998= CS/PM/3128 REV.III/76865). (Adopted at 114th SCF meeting) (10 December 1998)
77895	POLYETHYLENEGLYCOL (EO= 2-6)MONOALKYL(C16-C18) ETHER	68439-49-6	3	R = 0.05 mg/kg of food. Available: Adequate migration data; inadequate gene mutation assay in bacteria; incomplete chromosomal aberration assay in cultured mammalian cells (missing odd pages of the report); gene mutation assay in bacteria (negative); gene mutation assay in cultured mammalian cells (negative); chromosomal aberration assay in mammalian cells (negative). (RIVM/ISS/TNO SDS, April 1998 = CS/PM/2859 REV.II/77895). REMARK: The sum of all components present in Marlipal 1618/1 was determined in the migration experiments. A shift of the quantitative composition of the components migrated into the food simulants related to the initial composition of Marlipal 1618/1 was observed. The method is suitable to determine the sum of free fatty alcohol and the homologues of ethylene glycol ethers. REMARK :The toxicity studies were performed with Marlipal 1618/1 (commercial product with the specifications as given in the dossier). (Adopted at 114th SCF meeting) (9-10 December 1998)

REF No.	NAME	CAS No.	SCF List	SCF Assessment
81820	1,3-PROPANEDIAMINE,N,N "1,2-ETHANEDIYLBIS-,POLYMER WITH N-BUTYL-2,2,6,6-TETRAMETHYL-4-PIPERIDINAMINE AND 2,4,6-TRICHLORO-1,3,5-TRIAZINE	120498-03-5	3	R = 5 mg/kg of food. Available: Specific migration is 0.1-0.6 mg/kg food; three negative mutagenicity studies; acute toxicity data; 90-day rat gavage study (no NOAEL); skin/eye irritation studies; 90-day oral rat study. (RIVM/TNO SDS, March 1998 = CS/PM/2805 REV. I/81820). (Adopted at 114th SCF meeting) (10 December 1998)
86430	SILVER CHLORIDE (20% W/W) COATED ON TITANIUM DIOXIDE (80% W/W)	-	W7	Available: Inadequate migration data, worst case calculation of migration of 2.45 ug silver per dm ² of coated paper; four (negative) in vitro mutagenicity studies; acute toxicity data; 28-day oral rat study. Needed: Confirmation of the figure of 27.2 mg/m ² paper (paragraph 5.1.2 of the SDS); properly described analytical method with sufficient data on calibration and detection limit. Remark: Change name in: silver chloride, coated on a substrate, e.g. titanium oxide. (RIVM/DE/TNO SDS, October 1998 = CS/PM/3067REV. II/86430). (Adopted at 114th SCF meeting) (10 December 1998)
95270	2,4,6-TRIS(tert-BUTYL)PHENYL 2-BUTYL-2-ETHYL-1,3-PROPANEDIOL PHOSPHITE	161717-32-4	W7	Available: 100% hydrolysis of Ultranox®640 in 10% ethanol (aqueous foods); migration of Ultranox®640 from HDPE and PP into 95% ethanol maximum 2.73 mg/kg food; migration of Ultranox®640-phosphate from HDPE and PP into 95% ethanol maximum 0.1 mg/kg food; migration of the hydrolysis product 2,4,6-tri-tert-butyl phenol from HDPE and PP maximum 0.34 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); in vivo micronucleus assay (negative); 28-day oral rat study (no NOAEL established); 90-day oral rat study (no NOAEL established); delayed neurotoxicity study; no data available to show the absence of accumulation; WG didn't agree with the extrapolation to a NOEL in the 90-day study. Needed: Solubility data of Ultranox®640 and Ultranox®640-phosphate in fat simulant compared to 95% ethanol and iso-octane. (RIVM/DE/TNO SDS, September 1998 = CS/PM/3198 REV.1/95270). REMARK: There is no expectation for accumulation given the substance is an ester (it will be broken down by esterases in the body). (Adopted at 114th SCF meeting) (10 December 1998)

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.