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SCIENTIFIC COMMITTEE ON FOOD

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

(expressed on 23 September 1999)

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

(expressed on 23 September 1999)

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_N), Chemical Abstract Number (CAS_N.) 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.

The substances appearing in this table have been examined during the 79th meeting of the Working Group Food Contact Materials on 27-29 April 1999.

TABLE

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
14260	CAPROLACTONE	502-44-3	7	<p>Available: specific migration in four simulants; maximum in 15% ethanol after 10 days 40 °C 0.012 mg/kg into food; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (inadequate); gene mutation assay in cultured mammalian cells (inadequate).</p> <p>Needed: additional data concerning recovery and stability of caprolactone from food simulants, including migration period and complete sample work-up; chromosomal aberration assay in cultured mammalian cells; gene mutation assay in cultured mammalian cells. (RIVM/ISS/TNO SDS, April 1999 = CS/PM/1585 REV. I/14260).</p> <p>(Adopted at the 118th SCF meeting) (23 September 1999)</p>
15310	2,4-DIAMINO-6-PHENYL-1,3,5-TRIAZINE	91-76-9	7	<p>Available: migration data; 3-month oral rat study; oral carcinogenicity studies in mice and rats (inadequate); gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive); gene mutation assay in cultured mammalian cells (positive); micronucleus assay (equivocal); bioaccumulation data.</p> <p>Needed: new mouse bone marrow micronucleus assay with an extended sampling time (72 hours) and scoring of at least 2000 PCE's per animal. (RIVM/ISS/TNO SDS, March 1999 = CS/PM/2526 REV. I/15310).</p> <p>(Adopted at the 118th SCF meeting) (23 September 1999)</p>

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
22360	2,6-NAPHTHALENE DICARBOXYLIC ACID	1141-38-4	3	<p>R = 5 mg/kg of food</p> <p>Available: migration tests according to EU directives; extraction tests according to FDA; log Po/w; acute toxicity data; skin and eye irritation studies; gene mutation assay in bacteria (negative); two chromosomal aberration assays in cultured mammalian cells (one positive and one inadequate); gene mutation assay in cultured mammalian cells (negative); micronucleus assay (negative); 90-day oral rat study. (RIVM/ISS/TNO SDS, April 1999 = CS/PM/2220 REV. II/22360).</p> <p>(Adopted at the 118th SCF meeting) (23 September 1999)</p>
50480/ 67760	DI-n-OCTYL TIN BIS(2-ETHYLHEXYL MERCAPTOACETATE) AND MONO-n-OCTYL TIN TRIS (2-ETHYLHEXYL MERCAPTOACETATE) AS AN EXAMPLE FOR DI-n-OCTYL TIN-STABILISERS (SEE REF_No. 50480) AND FOR MONO-n-OCTYL TIN-STABILISERS (SEE REF_No. 67760)	26401-97-8 (REF_N 50480) 26401-86-5 (REF_N 67760)	2	<p>Group-TDI = 0.6 ug Sn/kg b.w. for dioctyltin stabilisers (REF_N 50480) Group-TDI = 20 ug Sn/kg b.w. for monoctyltin stabilisers (REF_N 67760)</p> <p>Available: migration data; several subacute studies in rats and dogs (performed with MOTTG, DOTTG, MOTC, DOTC and formulation of MOTC and DOTC); several semichronic studies in rats and dogs (performed with MOTTG, DOTTG and formulation of MOTTG and DOTTG); 2-year rat and dog studies (performed with DOTTG and formulation of MOTC and DOTC); gene mutation assays in bacteria (negative) (performed with MOTC, DOTC and formulation of MOTTG and DOTTG); gene mutation assays in cultured mammalian cells (negative) (performed with MOTC and DOTC); in vitro UDS assay (negative) (performed with DOTC); in vitro covalent DNA binding assay (negative) (performed with DOTC); micronucleus assays (negative; however, it was noted that no cytotoxicity was observed when performed with MOTC) (negative with formulation with MOTTG and DOTTG); in vivo SCE assay (negative) (performed with DOTC); 2-generation reproduction study in rats (performed with formulation of MOTTG and DOTTG); teratogenicity study in rats (performed with formulation of MOTTG and DOTTG); teratogenicity study in rabbits (performed with formulation of MOTTG and DOTTG). (RIVM SDS, October 1998 = CS/PM/3255/50480/67760).</p> <p>Remark for Commission: no analytical method is available.</p> <p>(Adopted at the 118th SCF meeting) (23 September 1999)</p>
51570	DIPHENYL SULPHONE	127-63-9	3	<p>R = 3 mg/kg of food</p> <p>Available: migration data; log Po/w; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); 4-week oral rat study; 3-months oral rat study. (RIVM/TNO SDS, April 1999 = CS/PM/2651 REV. II/51570).</p> <p>(Adopted at the 118th SCF meeting) (23 September 1999)</p>
52645	CIS-11-EICOSENAMIDE	10436-08-5	3	<p>Hydrolyses to innocuous substances.</p> <p>Available: specific migration in 3% acetic acid and 15% ethanol < 0.04 mg/kg, in olive oil maximum 2.8 mg/kg into food; comparable with oleamide and erucamide and thus complete hydrolysis to be expected in intestinal fluid in fatty acid and ammonia; gene mutation assay in bacteria (negative). (RIVM/TNO SDS, March 1999 = CS/PM/3269/52645).</p> <p>(Adopted at the 118th SCF meeting) (23 September 1999)</p>

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
63940	LIGNOSULPHONIC ACID	8062-15-5	3	<p>R = 0.04 mg/dm² = 0.24 mg/kg of food for the requested use, i.e. as dispersant for plastics dispersions.</p> <p>Available: molecular mass distribution curve; calculation of worst case migration assuming 100% transfer into food; gene mutation assay in bacteria (negative) and 16-week oral rat study. (RIVM/DE SDS, May 1999 = CS/PM/3284 REV. I/63940).</p> <p>Remark for Commission: No analytical method is available.</p> <p>(Adopted at the 118th SCF meeting) (23 September 1999)</p>
68400	OCTADECYLERUCAMIDE	10094-45-8	3	<p>R = 5 mg/kg of food</p> <p>Available: specific migration in aqueous food simulants <0.4 mg/kg, in HB307 1.8 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 (no NOAEL established). (RIVM/UK/TNO SDS, May 1999 = CS/PM/3273 REV. I/68400).</p> <p>(Adopted at the 118th SCF meeting) (23 September 1999)</p>
95600	1,1,3-TRIS(2-METHYL-4-HYDROXY-5-tert-BUTYLPHENYL)BUTANE	18436-03-4	3	<p>R = 5 mg/kg of food</p> <p>Available: adequate migration data (SM 0.003-1.8 mg/dm²); log Po/w; acute toxicity data; inadequate 90-day oral dog study; inadequate 12-week oral rat study; 13-week oral rat study; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); excretion studies. (RIVM/TNO SDS, April 1999 = CS/PM/2905 REV. I/95600).</p> <p>(Adopted at the 118th SCF meeting) (23 September 1999)</p>

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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.
