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Opinion of the Scientific Committee on Food
on
the 9th 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 9th additional list of monomers and additives
for food contact materials**

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

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
13395	2,2-BIS(HYDROXY-METHYL) PROPIONIC ACID	4767-03-7	3	R = 0.05 mg/kg of food. Available: calculation of worst case migration based on extraction values; analytical method for quantification in aqueous simulants and in 95% ethanol is properly described; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative). RIVM/FR SDS, November 1999 = CS/PM/3358 REV. I/13395. Remark for Commission: No method of analysis in olive oil is available. A QMA would be indicated.
22390	2,6-NAPHTHALENE-DICARBOXYLIC ACID, DIMETHYL ESTER	840-65-3	7	Available: specific migration < 0.024 mg/kg food in water and 15% ethanol and <0.24 mg/kg food in 3% acetic acid and olive oil; hydrolysis data; acute toxicity data; 90-day 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); micronucleus assay (negative). Needed: information on the absence of accumulation of the compound. RIVM/TNO SDS, September 1999 = CS/PM/3085 REV. I/22390.
22900	1-PENTENE	109-67-1	3	R = 5 mg/kg of food. Available: migration data showing specific migration < 0.05 mg/kg in food; log Po/w; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); two gene mutation assays in cultured mammalian cells (one inadequate and one negative); 90-day oral rat study. RIVM/TNO/ISS SDS, October 1999 = CS/PM/2855 REV. IV/22900.

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
12765 former PM/ REF N. 35180	N-(2-AMINOETHYL)-beta-ALANINE MONOSODIUM SALT	84434-12-8	3	<p>R = 0.05 mg/kg of food</p> <p>Available: specific migration in 3% acetic acid, 15% ethanol and 95% ethanol < 0.03 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) RIVM/ISS/TNO SDS, November 1999 = CS/PM/3352 REV. I/35180.</p> <p>Remark for Commission:</p> <ul style="list-style-type: none"> • Send a letter to the applicant, concerning the "preparation" of the petition (poor quality of the dossier) • The commercial product (as 40% aqueous solution) is tested in the mutagenicity assays

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 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 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.
