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SCIENTIFIC COMMITTEE ON FOOD

SCF/CS/PM/r77 final
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OPINION
ON AN ADDITIONAL LIST OF MONOMERS AND ADDITIVES FOR FOOD CONTACT MATERIALS

(expressed on 24 March 1999)

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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_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.

TABLE

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
13932	1-BUTEN-3-OL	00598-32-3	4A	n.d. (DL = 0.01 mg/kg) Available: worst case exposure 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 than 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) Needed: statement on all possible uses of the substance and data on the polymeric additives which are made from 1-buten-3-ol. (RIVM/FR SDS, December 1998 = CS/PM/3151 REV.I/13932). Remark: only for the production of a polymeric additive. Remark for Commission: no method of analysis for the determination of an SML is available. (Adopted at 116th SCF meeting) (24 March 1999)

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
21370	METHACRYLIC ACID, 2-SULPHOETHYL ESTER	10595-80-9	7	Available: Method for determination of residual content of 2-SEM in resins (insufficient); gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (inconclusive); gene mutation assay in cultured mammalian cells (negative). Needed: Information on the use of the polymers containing the substance. Information should be provided whether polymers containing the substance are used in the manufacture of final food contact materials (if so the type of food contact materials should be indicated), in coatings on substrates, or both. Information should be provided on the intended thickness of coatings in various products to allow a worst case calculation; information of the initial content of methacrylic acid, 2-sulphoethylester in resins; data on residual content obtained with a reliable method suitable to obtain the required detection limit. The method shall be described properly following the standard format. The method shall be properly validated, and recovery shall be determined at the relevant level. All according to the SCF-WG-explanatory guidance of the SCF guidelines for food contact materials; chromosomal aberration assay in cultured mammalian cells with an extended harvest period. (RIVM/UK/TNO SDS, December 1998 = CS/PM/3220 REV. I/21370). (Adopted at 116th SCF meeting) (24 March 1999)
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 ug/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). (RIVM/ISS/TNO SDS, October 1998 = CS/PM/3196 REV. I/26230). 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 foodstuff and food simulants. (Adopted at 116th SCF meeting) (24 March 1999)

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
38840	BIS(2,4-DICUMYLPHENYL)PENTAERYTHRITOL_DIPHOSPHITE	154862-43-8	7	Available: adequate migration data and actual content in polymer; acute toxicity data (performed with stabiliser itself and with one of its decomposition products); 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 an two of its decomposition products); neurotoxicity study (performed with a mixture of the stabiliser itself and one of its decomposition products); gene mutation assay in bacterial (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). Needed: mutagenicity studies according to SCF guidelines on the hydrolysis product (2,4-diicumylphenol). (RIVM/TNO SDS, December1998 = CS/PM/3222 REV.I/38840). NOTE: an Ames report on the hydrolysis product (2,4-dicumylphenol) was provided (13-11-1998). Due to the considerable migration there is still a need for a chromosomal and a gene mutation assay in cultured mammalian cells, on the hydrolysis product. (Adopted at 116th SCF meeting) (24 March 1999)
39925	3,3-BIS(METHOXY-METHYL) 2,5-DIMETHYL-HEXANE	129228-21-3	3	R = 0.05 mg/kg of food. Available: worst case migration levels based on compositional analysis and assumption of 1000% migration from 250 um layer thickness; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); two gene mutation assays in cultured mammalian cells (positive); in vivo UDS assay in rat liver (negative); in vivo micronucleus assay (negative). (RIVM/ISS/UK SDS, November 1998 = CS/PM/3223 REV. I/39925). Remark for Commission: No method of analysis for the determination of an SML is available. (Adopted at 116th SCF meeting) (24 March 1999)

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
95270	2,4,6-TRI-TERT-BUTYLPHENYL-2-BUTYL-2ETHYL-1,3-PROPANEDIOL PHOSPHITE	16717-32-4	3	R = 0.05 mg/kg of food (sum of phosphate, phosphite and the hydrolysis product (TTBP). Available: 100% hydrolysis of 2,4,6-TRI-TERT-BUTYLPHENYL-2-BUTYL-2ETHYL-1,3-PROPANEDIOL in 10% ethanol (aqueous foods); migration of the substance from HDPE and PP into 95% ethanol maximum 2.73 mg/kg food; migration of 2,4,6-TRI-TERT-BUTYLPHENYL-2-BUTYL-2ETHYL-1,3-PROPANEDIOL -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; solubility in 95% ethanol 0.2%, in iso-octane 12%, in olive oil 4%; 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); 28-day oral rat study (no NOAEL established); 90-day oral rat study (no NOAEL established); delayed neurotoxicity study. (RIVM/DE/TNO SDS, October 1998 = CS/PM/3198 REV.II/95270). Remark: 1) There is no need for mutagenicity studies on the hydrolysis product (TTBP) because of its resemblance with BHT and BHA. 2) There is no expectation for accumulation in view of its easy hydrolysis. Remark for Commission : 1) Since high migration into fat has been demonstrated the Committee recommends that the Commission take the necessary measures so that the restriction proposed is not exceeded. 2) 95% ethanol is not the appropriate substitute simulant for olive oil. (Adopted at 116th SCF meeting) (24 March 1999)

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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