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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions

**C2 - Management of scientific committees; scientific co-operation and networks**

**SCIENTIFIC COMMITTEE ON FOOD**

SCF/CS/PM/GEN/M87 Final  
18 December 2001

**Opinion  
of the  
Scientific Committee on Food  
on the  
15th additional list of monomers and additives  
for food contact materials**

- **PM/REF No. 13323 (1,3-bis(2-hydroxyethoxy)benzene; CAS no. 102-40-9**
- **PM/REF No. 34850 (Amines, bis(hydrogenated tallow alkyl) oxidised; CAS no. 143925-92-2**
- **PM/REF No. 66930 (methylsilsesquioxane); CAS no. 68554-70-1**
- **PM/REF No. 68860 (n-octylphosphonic acid); CAS no. 4724-48-5**

(adopted by the SCF on 13 December 2001)

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**Opinion of the Scientific Committee on Food  
on the 15th additional list of monomers and additives for food contact materials**

(adopted by the SCF on 14 December 2001)

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 1. 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
13323	1,3-BIS(2-HYDROXY ETHOXY) BENZENE	102-40-9	7	<p>Available : migration data ; gene mutation assay in bacteria (negative) ; two gene mutation assays in cultured mammalian cells (one negative, one weakly positive) ; two chromosomal aberration assays in cultured mammalian cells (both positive) ; mouse bone marrow micronucleus assay (equivocal) ; rat bone marrow chromosomal aberration assay (negative).</p> <p>Needed : data on levels of 1,3-bis(2-hydroxyethoxy)benzene (BHEB) and related compounds in blood in the rat cytogenetic study. RIVM/ISS/TNO SDS, April 2001 = CS/PM/2643 REV. III/13323.</p> <p>Remark : substance was moved from list 5 into list 7, because there is indication that the substance does not induce genotoxic effects in vivo and therefore list 5 was not tenable anymore.</p> <p>(Adopted at the 130<sup>th</sup> SCF meeting, 13 December 2001)</p>
34850	AMINES, BIS (HYDROGENATED TALLOW ALKYL) OXIDISED	143925-92-2	7	<p>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 ; tests with 3 migrants for the induction of gene mutations in bacteria and chromosomal aberrations in cultured mammalian cells (negative) ; 28-day oral rat study with bis(hydrogenated tallow, C16-C18, alkyl) hydroxylamine.</p> <p>Needed : in-house validation of the analytical method to determine the QM in finished articles. RIVM/DE SDS, June 2001 = CS/PM/3356 REV. III/34850.</p> <p>Remark : if the in-house validation of the analytical method to determine the QM in finished articles has been provided the following classification is possible, i.e. L3 QM = 0.1% in polyolefins. Not for fatty foods with a reduction factor &lt;3.</p> <p>(Adopted at the 130<sup>th</sup> SCF meeting, 13 December 2001)</p>

REF_N	NAME	CAS_N	SCF List	SCF ASSESSMENT
66930	METHYLSILSESQUIOXANE	68554-70-1	7	<p>Available : migration data from oriented polypropylene (OPP).</p> <p>Needed : mutagenicity data on the monomer (methyltrimethoxysilane), according to the guidelines. RIVM/DE SDS, June 2001 = CS/PM/3828 REV. I/66930.</p> <p>(Adopted at the 130<sup>th</sup> SCF meeting, 13 December 2001)</p>
68860	N-OCTYLPHOSPHONIC ACID	4724-48-5	3	<p>R = 0.05 mg/kg of food. Based on the reduced core set of toxicological data according to the migration level.</p> <p>Available : migration data (SM &lt; 15 ppb) ; gene mutation assay in bacteria (negative) ; chromosomal aberration assay in cultured mammalian cells (negative) ; gene mutation assay in cultured mammalian cells (negative). RIVM/TNO SDS, June 2001 = CS/PM/3847 REV. I/68860.</p> <p>(Adopted at the 130<sup>th</sup> SCF meeting, 13 December 2001)</p>

## **Previous opinions adopted by the SCF in the area of Food Contact Materials (status up to May 2001)**

### 1) Evaluations of individual substances

The 42<sup>nd</sup> 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, in press) contains the compilation of the SCF opinions on Food Contact Materials for the period 1974 (the beginning of the existence of the Committee) to May 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, in the Europe server, [www.europa.eu.int](http://www.europa.eu.int)):

- Statement on a recent report on primary aromatic amines in food and packaging samples in a Danish magazine (expressed on 26 September 2001)
- Opinion on the 14th additional list of monomers and additives for food contact materials (10 compounds) (expressed on 30th May 2001)
- Opinion on the 13th additional list of monomers and additives for food contact materials (18 compounds) (expressed on 30th May 2001)
- Opinion on the 12th additional list of monomers and additives for food contact materials (10 compounds) (expressed on 28th February 2001)
- Opinion on the 11th additional list of monomers and additives for food contact materials (11 compounds) (expressed on 19 October 2000)
- Opinion on the 10th additional list of monomers and additives for food contact materials (29 compounds) (expressed on 22 June 2000)
- Opinion on the 9th additional list of monomers and additives for food contact materials (4 compounds) (expressed on 22 June 2000)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (10 compounds) (expressed on 2 December 1999)
- Statement on the use of Novolac glycidyl ethers (NOGE) as additives in food contact materials. Minutes of the 119<sup>th</sup> 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 119<sup>th</sup> 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 compounds) (expressed on 23 September 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (11 compounds) (expressed on 17 June 1999)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (6 compounds) (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 compounds) (expressed on 10 December 98)

- Opinion on an additional list of monomers and additives intended to be used for food contact materials (13 compounds) (expressed on 17 September 1998)
- Opinion on an additional list of monomers and additives intended to be used for food contact materials (37 compounds) (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 compounds) (adopted during the SCF meeting of 12 and 13 June 1997). Also appearing in the Forty-third series of Reports of the Scientific Committee for Food, ISBN 92-828-5887-1)

## 2) Guidelines

The Committee has adopted also "**Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation**", on 22 November 2000. These guidelines are an update from the earlier ones published in the 26<sup>th</sup> series of the reports of the SCF.

## **APPENDIX 1**

### **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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## **APPENDIX 2**

### **Extract of the "Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation"**

These guidelines establish the general requirements of data to be submitted. As a general principle, the greater the exposure through migration, the more toxicological information will be required. In case of high migration (i.e. 5 - 60 mg/kg/food) an extensive data set is needed to establish the safety. In case of migration between 0.05 – 5 mg/kg food a reduced data set may suffice. If the data are appropriate, a restriction of 5 mg/kg of food is attributed to the substance. In case of low migration (i.e. <0.05 mg/kg food) only a limited data set is needed. If the data are appropriate, also in this case a restriction of 0.05 mg/kg of food is attributed to the substance. The full text of the guidelines provides a more detailed explanation. The guidelines are available at the webpages of the Committee.