



**EUROPEAN COMMISSION**  
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/M91 final  
25 Sept 2002

### **Opinion of the Scientific Committee on Food on the 20<sup>th</sup> additional list of monomers and additives for food contact materials**

- **PM/REF: 16210, 3,3'-Dimethyl-4,4'-diaminodicyclohexyl-methane, CAS No: 6864-37-5**
- **PM/REF: 23070, 2,2'-[1,3-phenylenebis(oxy)]bis-acetic acid (1,3-PDDA),  
CAS No: 102-39-6**
- **PM/REF: 31500, 2-ethylhexyl acrylate- acrylic acid copolymer, CAS No: 25134-51-4**
- **PM/REF: 45640, 2-Cyano-3,3-diphenyl-2-propenoic acid ethyl ester,  
CAS No: 5232-99-5**
- **PM/REF: 71935, Sodium perchlorate monohydrate, CAS No:7601-89-0**
- **PM/REF: 77850, PEG-30 dipolyhydroxystearate, CAS No:70142-34-6**

(Opinion expressed by the SCF on 25 September 2002)

---

B-1049 Bruxelles Brussel - Belgium

Telephone: direct line (+32-2) 295.81.10 / 296.48.70, exchange 299.11.11. Fax: (+32-2) 299.48.91

Telex: COMEU B 21877. Telegraphic address: COMEUR Brussels.

[http://www.europa.eu.int/comm/dg24/health/sc/scf/index\\_en.html](http://www.europa.eu.int/comm/dg24/health/sc/scf/index_en.html)

**Opinion of the Scientific Committee on Food  
on the 20<sup>th</sup> additional list of monomers and additives for food contact materials**

(Opinion expressed by the SCF on 25 September 2002)

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.

Identification of substance/ compound	Assessment
<p><u>PM/REF_n:</u> 16210</p> <p><u>Name of the substance:</u> 3,3'-Dimethyl-4,4'-diaminodicyclohexyl-methane</p> <p><u>CAS number:</u> 6864-37-5</p>	<p style="text-align: right;">SDS CS/PM/ 2997 REV. I / 16210 January 2002</p> <p><u>General information</u> 3,3'-dimethyl-4,4'-diaminodicyclohexyl-methane is a defined mixture of conformational and stereo isomers. The substance is used as a monomer in the manufacture of polyamide for all food types except for foodstuffs containing more than 8% ethanol. The polymer is to be used for long term storage at temperatures below 40°C and for short duration contact of up to one hour at up to 100°C</p> <p><u>Previous evaluations (by SCF)</u> The substance was first evaluated in 1997 on the basis on three mutagenicity studies and a 90-day oral study in rat. The substance was however classified in SCF_Class 7 on the basis of inadequate migration data. (SCF, March 1998). The petitioner provided additional information requested.</p> <p><u>Evaluation</u> 3,3'-dimethyl-4,4'-diaminodicyclohexyl-methane is a defined mixture of conformational and stereoisomers which can be separated partially by chromatographic techniques.</p> <p>Specific migration of 3,3'-dimethyl-4,4'-diaminodicyclohexyl-methane in water, 3% acetic acid, 10% ethanol and iso-octane was found to be not-detectable i.e. &lt; 1.2 µg/dm<sup>2</sup> or &lt; 7 µg/kg food. The substance is not stable in HB307 (synthetic fat simulant) during the migration period. Iso-octane is therefore used as fatty food simulant. The substance is also not stable in 95% ethanol.</p> <p>Recovery of 3,3'-dimethyl-4,4'-diaminodicyclohexyl-methane from food simulants, including the storage period, was approximately 100%, in water, 3% acetic acid, 10% ethanol and iso-octane.</p> <p>3,3'-dimethyl-4,4'-diaminodicyclohexyl-methane was found to be not mutagenic in a gene mutation assay in bacteria, a chromosomal aberration assay in cultured mammalian cells and a gene mutation assay in cultured mammalian cells.</p> <p>In a 90-day oral study in rat, a slight but dose-related reduction in body weight gain was present in females without a concurrently decreased feed consumption. This trend was evident from the lowest dose tested (1.8 mg/kg bw/day). A NOAEL could not be derived.</p>

Conclusion

Based on the above mentioned data the substance is classified:

SCF\_list:3

Restriction: 0.05 mg/kg of food. Based on the reduced core set of toxicological data according to the migration level.

Remark for Commission: substance is not stable in fat simulant. Only to be used in polyamides

Needed data or information:

None.

References:

- Scientific Committee on Food, 111<sup>th</sup> meeting, 18-19 March 1998 ([http://europa.eu.int/comm/food/fs/sc/scf/out10\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scf/out10_en.pdf))
- Unpublished data submitted by the petitioner.

(Opinion expressed by the SCF on 25 September 2002, 134th meeting of the SCF)

Identification of substance/ compound	Assessment
<p><u>PM/REF_n:</u> 23070</p> <p><u>Name of the substance:</u> 2,2'-[1,3-phenylenebis(oxy)]bis-acetic acid (1,3-PDDA)</p> <p><u>CAS number:</u> 102-39-6</p>	<p style="text-align: right;">SDS CS/PM/ 3916/23070 December 2001</p> <p><u>General information</u> According to the petitioner 1,3-PDDA is used as a co-monomer to make modified polyester (PET) articles. The plastic is to be used for all types of food and beverages with contact up to 100°C for hot fill with contact times up to 2 years for storage at ambient temperature.</p> <p><u>Previous evaluations (by SCF)</u> None (new substance)</p> <p><u>Evaluation</u> An amorphous polyester sample using 1,3-PDDA was tested for residual 1,3-PDDA. None was detected using a method with a detection limit of 2 mg/kg polymer. A worst -case calculation assuming 100% migration from 0.25 mm thickness of plastic with 6 dm<sup>2</sup> in contact with 1 kg food/simulant gives a maximum migration value of 40 µg/kg food/simulant.</p> <p>1,3-PDDA and its sodium salt was inactive in bacteria reversion assays and in gene mutation and chromosomal aberration assays in mammalian cells <i>in vitro</i>. On the basis of the information available 1,3-PDDA is evaluated as non-genotoxic. In a 28 days rat oral study, two different kidney lesions were observed in two different animals at the highest dose tested (1000 mg/kg bw). No histopathological lesions were observed at the next lower dose level (140 mg/kg bw).</p> <p><u>Conclusion</u> Based on the above mentioned data the substance is classified: SCF_list:3 Restriction: 0.05 mg/kg of food. Based on the reduced core set of toxicological data according to the migration level.</p> <p>Remark for Commission: No method of analysis for specific migration available. QMA= 0.05mg/6dm<sup>2</sup></p>

Needed data or information:

None.

References:

- Unpublished data submitted by the petitioner.

(Opinion expressed by the SCF on 25 September 2002, 134th meeting of the SCF)

Identification of substance/ compound	Assessment
<p><u>PM/REF_n:</u> 31500</p> <p><u>Name of the substance:</u> 2-ethylhexyl acrylate- acrylic acid copolymer</p> <p><u>CAS number:</u> 25134-51-4</p>	<p style="text-align: right;">SDS CS/PM/ 3931/31500 January 2002</p> <p><u>General information</u> According to the petitioner the copolymer of acrylic acid and 2-ethylhexyl acrylate is a suspension agent used in the suspension polymerisation of all types of polystyrene. The final articles are intended for use with all types of liquid foodstuffs.</p> <p><u>Previous evaluations (by SCF)</u> None (new substance)</p> <p><u>Evaluation</u> The average molecular weight of the substance is given as 1.600.000 D; The percentage of constituents with a MW &lt; 1000 D is &lt; 0.6%. The worst case migration (100%) calculated for the fraction with molecular weight below 1000 D is 12.5 µg/dm<sup>2</sup> (equal to 75µg/kg food) and for 2-ethylhexyl acrylate is 0.026 µg/dm<sup>2</sup> (equal to 0.156 µg/kg food).</p> <p>Due to the high average molecular mass of the copolymer no toxicological data on the copolymer itself are requested. However one of the starting substances (2-ethylhexyl acrylate, PM/REF 11500) is still in list 7 (SCF, 2000). An <i>in vivo</i> UDS assay has been requested for 2-ethylhexyl acrylate</p> <p><u>Conclusion</u> Based on the above mentioned data the substance is classified: SCF_list:7 Restriction: not applicable Remark for Commission: none</p> <p><u>Needed data or information:</u> <i>In vivo</i> UDS assay for 2-ethylhexyl acrylate .</p> <p><u>References:</u> - Unpublished data submitted by the petitioner. - Scientific Committee on Food, 2000. Opinion of the Scientific Committee on Food on the 10th additional list of monomers and additives for</p>

food contact materials. Adopted by the SCF on 22/6/2000 at 121st plenary meeting. CS/PM/GEN/M82 final).  
[http://europa.eu.int/comm/food/fs/sc/scf/out62\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scf/out62_en.pdf)

(Opinion expressed by the SCF on 25 September 2002, 134th meeting of the SCF)



Identification of substance/ compound	Assessment
<p><u>PM/REF_n.:</u> 45640</p> <p><u>Name of the substance:</u> 2-Cyano-3,3-diphenyl-2-propenoic acid ethyl ester</p> <p><u>CAS number:</u> 5232-99-5</p>	<p style="text-align: right;">SDS CS/PM/ 3959/45640 April 2002</p> <p><u>General information</u> According to petitioner 2-Cyano-3, 3-diphenyl-2-propenoic acid ethyl ester is an UV light stabiliser for all kind of plastic materials (films for agriculture, green houses storage and transport vessels). The material is to be used for long time contact at temperatures between + 50°C and – 25°C and short time exposure (up to 15 minutes) to temperatures between 70 °C and 100 °C.</p> <p><u>Previous evaluations (by SCF)</u> None (new substance)</p> <p><u>Evaluation</u> Specific migration of the compound was determined in 3% acetic acid, 10% ethanol and HB307. Specific migration was found to be not detectable in all food simulants with a detection limit of the analytical method ranging from 0.018 to 0.024 mg/kg food.</p> <p>Toxicological evaluation was based on a gene mutation assay in bacteria; an <i>in vitro</i> gene mutation assay in mammalian cells with and without metabolic activation; two <i>in vitro</i> chromosomal aberration assays in cultured mammalian cells. Gene mutation and chromosomal aberration tests were shown to be negative.</p> <p><u>Conclusion</u> Based on the above mentioned data the substance is classified: SCF_list:3 Restriction: 0.05 mg/kg of food. Based on the reduced core set of toxicological data according to the migration level.</p> <p>Remark for Commission: None.</p> <p><u>Needed data or information:</u> None.</p>

References:

- Unpublished data submitted by the petitioner.

(Opinion expressed by the SCF on 25 September 2002, 134th meeting of the SCF)

Identification of substance/ compound	Assessment
<p><u>PM/REF_n.:</u> 71935</p> <p><u>Name of the substance:</u> Sodium perchlorate monohydrate</p> <p><u>CAS number:</u> 7601-89-0</p>	<p style="text-align: right;">SDS CS/PM/ 3377 REV. II / 71935 January 2002</p> <p><u>General information</u> According to the petitioner sodium perchlorate monohydrate is used as a heat stabiliser during the processing of PVC.</p> <p><u>Previous evaluations (by SCF)</u> The substance was first evaluated in 2000 (SCF, 2000) and was classified in SCF_List 7 based on inadequate migration data and inadequate recovery experiments of the substance in food simulants, including the migration period. The substance was re-evaluated in 2001 and again classified SCF_List 7 because data on the recovery of the substance from food simulants were still not submitted and because the experiments and the additional data provided by the petitioner were not in compliance with the requirements according to 'Note for Guidance' of the SCF regarding the testing of food contact materials. These data were now provided.</p> <p><u>Evaluation</u> Specific migration of Sodium perchlorate monohydrate in 10% ethanol, 3% acetic acid and HB307 from PVC plates ranged from not detectable to maximum 32.4 µg/kg food. Recovery of the substance from olive oil, added at a level of 50 µg/kg, was found to be poor (&lt; 60%). Therefore a saturated fat shall be used for the determination of the specific migration of the substance in fatty food simulants.</p> <p>Sodium perchlorate monohydrate was tested <i>in vitro</i> in a gene mutation assay in bacteria; a chromosomal aberration assay in cultured mammalian cells and in a gene mutation assay in cultured mammalian cells. The substance did not show genotoxic properties.</p> <p><u>Conclusion</u> Based on the above mentioned data the substance is classified: SCF_list:3 Restriction: 0.05 mg/kg of food. Based on the reduced core set of toxicological data according to the migration level.</p> <p>Remark for Commission: for fatty food method only applicable with saturated fatty food simulant (e.g. HB307, Mygliol).</p>

Needed data or information: None.

References:

- Unpublished data submitted by the petitioner.
- Scientific Committee on Food, 2000. Opinion of the Scientific Committee on Food on the 10th additional list of monomers and additives for food contact materials (adopted by the SCF on 22/6/2000). CS/PM/GEN/M82. [http://europa.eu.int/comm/food/fs/sc/scf/out62\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scf/out62_en.pdf)

Identification of substance/ compound	Assessment
<p><u>PM/REF_n.:</u> 77850</p> <p><u>Name of the substance:</u> PEG-30-dipolyhydroxystearate</p> <p><u>CAS number:</u> 70142-34-6</p>	<p style="text-align: right;">SDS CS/PM/3930/77850 Dated January 2001.</p> <p><u>General information</u> According to the petitioner, this substance is a polymeric additive and is used as an emulsifier in the manufacture of expanded polystyrene up to 0.5%. The final articles are intended for use with all types of foodstuffs from cold storage and long term storage at room temperature up to brief contact at temperatures of 75 to 80 °C.</p> <p><u>Previous evaluations (by SCF)</u> None (new substance)</p> <p><u>Evaluation</u> The molecular weight is given as 6970 D and the percentage of constituents with MW &lt;1000 D is 0.22%. Data on molecular weight distribution and on MS spectra are incomplete.</p> <p><u>Conclusion</u> Based on the abovementioned data the substance is classified: SCF_list: 7 Restriction: none. Remark for Commission: none</p> <p><u>Needed data or information:</u></p> <ul style="list-style-type: none"> <li>- Molecular weight distribution curve (differential and cumulative)</li> <li>- Details on MS spectra</li> <li>- Clarification of the inconsistency in the data from the petitioner in respect to the solubility of the test compound in various solvents.</li> </ul> <p><u>References:</u> - Unpublished data submitted by the petitioner.</p> <p>(Opinion expressed by the SCF on 25 September 2002, 134th meeting of the SCF)</p>

## **Previous opinions adopted by the SCF in the area of Food Contact Materials (status up to August 2002)**

### 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, 2000) 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 Europa server, [www.europa.eu.int](http://www.europa.eu.int)):

- Opinion on the 19th additional list of monomers and additives for food contact materials (expressed on 25 September 2002)
- Opinion on the 18th additional list of monomers and additives for food contact materials (expressed on 24 September 2002)
- Opinion on the 17th additional list of monomers and additives for food contact materials (expressed on 27 February 2002)
- Opinion on the 16th additional list of monomers and additives for food contact materials (expressed on 13th December 2001)
- Opinion on the 15th additional list of monomers and additives for food contact materials (expressed on 13th December 2001)
- 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 (expressed on 30th May 2001)
- Opinion on the 13th additional list of monomers and additives for food contact materials (expressed on 30th May 2001)
- Opinion on the 12th additional list of monomers and additives for food contact materials (expressed on 28th February 2001)
- Opinion on the 11th additional list of monomers and additives for food contact materials (expressed on 19 October 2000)
- Opinion on the 10th additional list of monomers and additives for food contact materials (expressed on 22 June 2000)
- Opinion on the 9th additional list of monomers and additives for food contact materials (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)
- Statements 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**". These guidelines have been modified for the last time on 13 December 2001. (Document SCF/CS/PLEN/GEN/100 Final).

## **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 this Committee has established a TDI or a t-TDI.

#### **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 that 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.

\*\*\*\*\*

## **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 web pages of the Committee.