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Scientific Committee on Food

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**Opinion of the Scientific Committee on Food
on the 22nd additional list of monomers and additives
for food contact materials**

- PM/REF No. 16540, Diphenyl carbonate, CAS no. 000102-09-0
- PM/REF No. 18896, 4-(Hydroxymethyl)-1-cyclohexene, CAS no. 001679-51-2
- PM/REF No. 18898, N-(4-Hydroxyphenyl) acetamide, CAS no. 000103-90-2
- PM/REF No. 20440, Methacrylic acid, diester with ethyleneglycol, CAS no. 000097-90-5
- PM/REF No. 21370, Methacrylic acid, 2-sulphoethyl ester, CAS no. 010595-80-9
- PM/REF No. 21400, Methacrylic acid, sulphopropyl ester, potassium salt, CAS no. 054276-35-6
- PM/REF No. 34850, Amines, bis(hydrogenated tallow alkyl) oxidised, CAS no. 143925-92-2
- PM/REF No. 69160, Oleic acid, cobalt salt, CAS no. 014666-94-5
- PM/REF No. 95265, 1,3,5-Tris(4-benzoylphenyl) benzene, CAS no. 227099-60-7

(Opinion expressed on 4 April 2003)

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http://europa.eu.int/comm/food/fs/sc/scf/index_en.html

**Draft Opinion of the Scientific Committee on Food
on the 22nd additional list of monomers and additives for food contact materials**

(Opinion expressed on 4 April 2003)

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>Ref. No.:</u> 16540</p> <p><u>Name of the substance:</u> Diphenylcarbonate</p> <p><u>CAS number:</u> 102-09-0</p>	<p style="text-align: right;">SDS CS/PM/4065-Rev.0B/16540 of January 2003</p> <p><u>General information</u> According to the petitioner, Diphenylcarbonate is used as a monomer in the production of polycarbonate</p> <p><u>Previous evaluations (by SCF)</u> None (new substance)</p> <p><u>Available data</u> <u>Non-toxicity data</u></p> <ul style="list-style-type: none"> - Information concerning identity, physical, chemical data, use, authorisation, and migration data <p><u>Toxicity data</u></p> <ul style="list-style-type: none"> - <i>In vitro</i> gene mutation assays in bacteria - Gene mutation assay in cultured mammalian cells - Chromosomal aberration test <i>in vitro</i> - <i>In vivo</i> rat liver UDS - <i>In vivo</i> micronucleus tests <p><u>Evaluation</u> Migration of Diphenylcarbonate was determined in 3% acetic acid, 10% ethanol and HB 307. Also the migration of Bisphenol A from the test sample and the decomposition product phenol was determined. Diphenylcarbonate hydrolyses in aqueous food simulants into phenol and carbon dioxide. Migration of diphenylcarbonate and bisphenol A was not detectable at levels of approximately 0.05 and 0.2 mg/kg food simulant (6 dm²/kg) respectively. Phenol was detected at 0.16 mg/kg 3% acetic acid and 0.2 mg/kg 10% ethanol after a contact period 2 h at 100°C. Most likely the polymer (polycarbonate) is hydrolysed at the high temperature conditions.</p> <p>Diphenylcarbonate was not mutagenic in gene mutation assays in bacteria and in mammalian cells <i>in vitro</i>. Clear clastogenic activity was observed in a cytogenetic test <i>in vitro</i>, both in presence and absence of metabolic activation. Adequately performed rat liver UDS and mouse bone marrow micronucleus test, with evidence of target cells exposure, gave negative results. It is concluded that the mutagenic properties observed <i>in vitro</i> are not expressed <i>in vivo</i>.</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. Remark for Commission: In the absence of relevant information, the Fat (Consumption) Reduction Factor should not be applied to this substance</p> <p><u>Needed data or information:</u> None</p> <p><u>References:</u> Unpublished data submitted by the petitioner</p>

Ref. No.:
18896

SDS CS/PM/3786-RevIIIB/18896 of January 2003

Name of the substance:
4-(Hydroxymethyl)-1-cyclohexene

General information

4-(Hydroxymethyl)-1-cyclohexene is a monomer, used in the production of an oxygen-scavenging polymer.

CAS number:
679-51-2

Previous evaluations (by SCF)

The substance was first evaluated in 2001 (SCF, 2001) and classified in SCF_List 7 based on inadequate non-toxicity and toxicity data.

Needed:

Analytical method and data on residual monomer in polymer, in compliance with requirements according to the Note for Guidance

- Detailed information on GPC measurements performed on the polymer prior to oxidation and after oxidation
- Qualitative and quantitative information on the fraction with Mw<1000 which is extractable from the polymer before and after oxidation
- *In vivo* rat liver UDS assay

Available data:

Non-toxicity data

- Incomplete data on residual monomer in polymer (not oxidised)
- Specific migration into food simulants from oxidised and not oxidised film

Toxicity data

- Gene mutation assay in bacteria
- Chromosomal aberration in cultured mammalian cells
- Gene mutation assay in cultured mammalian cells
- *In vitro/in vivo* rat UDS assay

Evaluation

Specific migration of 4-(Hydroxymethyl)-1-cyclohexene from unoxidised and oxidised samples was determined in 10% ethanol, 3% acetic acid and olive oil. In olive oil, maximum migration from the oxidised sample was found to be 0.068 mg/kg into food.

4-(Hydroxymethyl)-1-cyclohexene is mutagenic in an *in vitro* assay for the detection of gene mutations in cultured mammalian cells.

A gene mutation assay in bacteria and a chromosomal aberration assay in cultured mammalian cells both gave negative results.

In order to rule out significant mutagenicity *in vivo*, an *in vivo* UDS assay was performed.

Based on the negative result observed in the UDS assay it is concluded that the mutagenic properties observed *in vitro* are not expressed *in vivo*.

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: used in oxygen scavenging polymer; no direct food contact (except for dry foods).

Needed data or information: None

References:

Opinion of the Scientific Committee on Food on the safety of 4-(Hydroxymethyl)-1-cyclohexene adopted at the 128th SCF meeting, on 12 July 2001. (14th additional list of Monomers and Additives for food contact materials)

http://europa.eu.int/comm/food/fs/sc/scf/out97_en.pdf

Unpublished data submitted by the petitioner.

<p><u>Ref. No.:</u> 18898</p> <p><u>Name of the substance:</u> N-(4-Hydroxyphenyl) acetamide</p> <p><u>CAS number:</u> 103-90-2</p>	<p style="text-align: right;">SDS CS/PM/3993-RevIB/18898 of January 2003</p> <p><u>General information</u> According to the petitioner N-(4-Hydroxyphenyl) acetamide (APAP) is used in the production of liquid crystal polymers, in direct and indirect food contact applications</p> <p><u>Previous evaluations (by SCF)</u> The substance was evaluated in 2001 (SCF 2001) and classified in SCF_List 3. A request for re-evaluation has been submitted with the objective to establish a “SML of 0.05 mg/kg food” for APAP and the elimination of the present specification: “only to be used in liquid crystals and behind a barrier layer in multilayered plastic”, based on the data in the original submission on APAP.</p> <p><u>Available data:</u> <u>Non-toxicity data</u> – Adequate migration data from monolayer in direct contact with food simulants</p> <p><u>Toxicity data</u> Literature data on: - tests for gene mutation in bacteria, - limited tests for gene mutation in mammalian cells, - tests for chromosomal aberrations and SCE <i>in vitro</i>, - limited tests for chromosomal aberrations and micronuclei <i>in vivo</i>, - study on DNA fragmentation <i>in vivo</i>, - studies on covalent binding to DNA, - NTP carcinogenicity bioassay in mice and rats.</p> <p><u>Evaluation</u> Based on existing migration data which were obtained from migration experiments with direct contact, the use of the test substance in direct food contact applications is acceptable</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> <p><u>References:</u> SCF, 2001: Opinion of the Scientific Committee on Food on the safety of N-(4-Hydroxyphenyl) acetamide adopted on 30 May 2001 (13th additional list of Monomers and Additives for food contact materials): http://europa.eu.int/comm/food/fs/sc/scf/out86_en.pdf</p> <p>Unpublished data submitted by the petitioner.</p>
<p><u>Ref. No.:</u> 20440</p> <p><u>Name of the substance:</u> Methacrylic acid, diester with ethylene glycol</p> <p><u>CAS number:</u> 000097-90-5</p>	<p style="text-align: right;">SDS CS/PM/2461-RevID/20440 of February 2003</p> <p><u>General information</u> According to the petitioner Methacrylic acid, diester with ethylene glycol is used as a monomer in polyacrylates and polymethacrylates</p> <p><u>Previous evaluations (by SCF)</u> The substance was first evaluated in 1994 (SCF, 1999) and classified in SCF_List 7 based on inadequate migration data and incomplete toxicity data.</p> <p><u>Needed:</u> – Migration data – 3 complete mutagenicity studies</p>

	<p><u>Available data:</u></p> <p><u>Non-toxicity data</u></p> <ul style="list-style-type: none"> - Information concerning identity, physical chemical data, use, authorisation, migration and content. - Adequate migration data in 3%acetic acid, 15% ethanol and 95% ethanol (<0.05 mg/kg into food) <p><u>Toxicity data</u></p> <ul style="list-style-type: none"> - Gene mutation assay in bacteria, - Chromosomal aberration assay in cultured mammalian cells, - Gene mutation assay in cultured mammalian cells, - <i>In vivo</i> micronucleus assay, - <i>In vivo</i> UDS assay. <p><u>Evaluation</u></p> <p>Specific migration of ethylene glycol dimethacrylate into water, 3% acetic acid, 15% ethanol and 95% ethanol after 10 days at 40°C is < 0.05 mg/kg food. Solubility data in olive oil and in 95% ethanol justify the use of ethanol 95% as substitute for food simulants. Recovery of subject substance from food simulants was determined at spiked levels of 0.07 and 0.14 mg/kg, after storage for 10 days at 40°C. In 10% ethanol recovery was found to be 77.6% and 85.5% respectively; In 3% acetic acid and 95% ethanol values of 90.9% - 95.3% were found.</p> <p>Ethylene glycol dimethacrylate was directly clastogenic in an in vitro cytogenetic test in human lymphocytes at the highest (cytotoxic) concentration tested; it was negative in the same assay with metabolic activation. A bacterial mutation test and a gene mutation assay in mouse lymphoma cells gave negative results, with and without metabolic activation. <i>In vivo</i>, negative results were obtained in the rat liver UDS assay and in the mouse bone marrow micronucleus test. In the latter, even though there was no direct evidence of bone marrow exposure (e.g. treatment related toxicity), the clinical signs observed after administration of the test substance indicate significant internal exposure of treated animals. Based on these results it is concluded that the clastogenic activity of ethylene glycol dimethacrylate is not expressed <i>in vivo</i>, and that the substance is not mutagenic <i>in vivo</i>.</p> <p><u>Conclusion</u></p> <p>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> <p><u>References:</u> SCF, 1999: In "Compilation of the evaluations of the Scientific Committee for Food on certain monomers and additives used in the manufacture of plastic materials intended to come into contact with foodstuffs expressed until the 21 March 1997". 42nd Series of Reports of the Scientific Committee for Food. Office of official Publications of the European Communities, Luxembourg, 1999.</p> <p>Unpublished data submitted by the petitioner.</p>
<p><u>Ref. No.:</u> 21370</p> <p><u>Name of the substance:</u> Methacrylic acid, 2-sulphoethyl ester</p>	<p style="text-align: right;">SDS CS/PM/3220-Rev.IIC/21370 of January 2003</p> <p><u>General information</u> According to the petitioner Methacrylic acid, 2-sulphoethyl ester is used as a reactant in thin coatings on polymeric substrates such as PET and Nylon films, and on paper and board.</p>

CAS number:
10595-80-9

Previous evaluations (by SCF)

The substance was first evaluated in 1998 (SCF 1999).

Based on inadequate method for the determination of the residual content, and an inconclusive chromosomal aberration assay, the substance was classified in SCF_List 7 (Needed: A proper analytical method and chromosomal aberration assay with an extended harvest period).

Available data:

Non-toxicity data

Information concerning identity, physical chemical data, use, authorisation and content in latex coating.

Toxicity data

- Gene mutation assays in bacteria,
- Gene mutation in mammalian cells,
- Two chromosomal aberration assays *in vitro*.

Evaluation:

Residual content of Methacrylic acid, 2-sulphoethyl ester (2-SEM) in latex coatings containing 0.5% of subject substance was found to be not detectable with a limit of detection equivalent to 3 mg 2-SEM/ kg dried latex. Worst case migration is calculated to be 32.4 µg/kg food, assuming that 180 g latex/m² film is maximum applied.

Sodium 2-sulfoethyl methacrylate (2-SEM) gave negative results in gene mutation assays in bacteria and in cultured mammalian cells. Positive results have been obtained after extended (32–48 hours) treatments in the absence of S9 in two *in vitro* chromosome aberration assays. As the test article induced a distinct decrease of pH of culture medium, the clastogenic effect observed may be the result of unspecific effects related to pH change. However, further experimental evidence is necessary to prove this possibility, namely the demonstration, in the same experimental system, of the effect on chromosomal integrity of pH changes similar to those produced by the test article, and the suppression of clastogenicity of 2-SEM after adjustment of pH of culture medium to neutrality.

Conclusion

Based on the above-mentioned data the substance is classified:
SCF_List: 7

Remark for Commission: Monomer is used in coatings and an SM method is not available. QMA restriction is applicable in this case

Needed data or information:

An assessment of the effect of pH on chromosomal aberration (demonstration, in the same experimental system, of the effect on chromosomal integrity of pH changes similar to those produced by the test article, and the suppression of clastogenicity of 2-SEM after adjustment of pH of culture medium to neutrality).

References:

Unpublished data submitted by the petitioner.

SCF, 1999: Opinion on an additional list of monomers and additives for food contact materials (expressed on 24 March 1999):

http://europa.eu.int/comm/food/fs/sc/scf/out27_en.pdf

<p><u>Ref. No.:</u> 21400</p> <p><u>Name of the substance:</u> Methacrylic acid, sulphopropyl ester, potassium salt</p> <p><u>CAS number:</u> 054276-35-6</p>	<p style="text-align: right;">SDS CS/PM/2790-RevIIC/21400 of January 2003</p> <p><u>General information</u> According to the petitioner the substance (SPM) is used as a co-monomer for acrylate based coatings.</p> <p><u>Previous evaluations (by SCF)</u> The substance has been evaluated in 1994 (toxicity) and in 1996 (identity, use and migration). While the toxicity data was found adequate further data was requested on the types of materials where the substance is to be used, on migration and on residual amount of the substance in the Food contact materials. The substance was therefore listed in SCF_List 7 (SCF 1999). New information was supplied in 2002.</p> <p>Methacrylic acid, sulphopropyl ester was tested under <i>in vitro</i> conditions in the Ames test, chromosomal aberration assay and the gene mutation assay in cultured mammalian cells. The test substance was negative in these three tests.</p> <p><u>Available data:</u> <u>Non-toxicity data</u></p> <ul style="list-style-type: none"> - Information on identity, chemical and physico-chemical properties, use, authorisation, migration, and residual content - Information on analytical method (with a detection limit 0,008 mg/6 dm²) to verify the residual content. <p><u>Toxicity data</u></p> <ul style="list-style-type: none"> - Gene mutation Ames test, - Chromosomal aberration assay in mammalian cells <i>in vitro</i>, - Gene mutation assay in cultured mammalian cells. <p><u>Evaluation</u> The substance has been shown to be not detectable in an acrylate-based coating, with a detection limit corresponding to 0.008 mg/6 dm² and to a worst-case migration of 0.008 mg/kg food. These coatings are intended to be in contact with dry foods. This latter information allows evaluating the worst-case migration of the substance, and migration data are no longer needed.</p> <p>Methacrylic acid, sulphopropyl ester, potassium salt did not show genotoxic properties in the three <i>in vivo</i> mutagenicity studies required by the SCF Guidelines on food contact materials.</p> <p><u>Conclusion</u> Based on the above mentioned data the substance is classified: SCF_List: 3 Restriction: R = 0.05 mg/kg food. Based on the reduced core set of toxicological data and on the very low migration.</p> <p><u>Remark for Commission:</u> None</p> <p><u>Needed data or information:</u> None</p> <p><u>References:</u> SCF (1999): In "Compilation of the evaluations of the Scientific Committee for Food on certain monomers and additives used in the manufacture of plastic materials intended to come into contact with foodstuffs until the 21 March 1997". 42nd Series of Reports of the Scientific Committee for Food. Office of official Publications of the European Communities, Luxembourg, 1999.</p> <p>Unpublished data submitted by the petitioner.</p>
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REF. N.:
34850

SDS CS/PM/3356-Rev.IVC/34850 of February 2003

Name of the substance:
Amines,
bis(hydrogenated
tallow alkyl) oxidised

General information

According to the petitioner amines, bis(hydrogenated tallow alkyl)oxidised is used as a processing stabiliser in polyolefins at concentrations up to 0.1% and in polyethyleneterephthalate up to 0.25%. It is a product by process composed as follows:

Bis(hydrogenated tallow, C16-C18, alkyl) hydroxylamine	63 – 80 %
Bis(hydrogenated tallow, C16-C18, alkyl) amine	12 – 20 %
Bis(hydrogenated tallow, C16-C18, alkyl) nitrones	2 – 10 %
(Hydrogenated tallow, C16-C18, alkyl) oximes	2 – 10 %
Fatty acids (C16-C18)	0 - 5 %
(C16-C18) secondary amides	0 - 7 %

CAS number:
143925-92-2

Previous evaluations (by SCF)

The substance was first evaluated in 2000 (SCF, 2000) and classified in SCF_List 7 based on inadequate migration data.

Needed :

- In-house validation of the analytical method
- Explanation with regard to the migration of the nitron from LDPE although no nitron was detected in the polymer
- Explanation with regard to the results for the aldehyde in the migration test and the determination in the polymer
- Migration in iso-octane, or justify choice of just ethanol in place of oil. These data have now been provided.

The substance was re-evaluated in 2001 (SCF, 2001) and again classified in SCF-List 7.

Needed: in-house validation of the analytical method to determine the QM in finished articles.

Available data:

Non-toxicity data

- Data on migration of the substance and its transformation products from polyolefins into aqueous and fatty food simulants, and from PET in aqueous food simulants.
- Analytical methods for the determination in food simulants and in PP and PE
- Method for the determination of the substance in polyolefins

Toxicity data

- Gene mutation assay in bacteria,
- Chromosomal aberration assay in cultured mammalian cells,
- Gene mutation assay in cultured mammalian cells,
- 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,
- 28-day oral rat study with Bis(hydrogenated tallow, C16-C18, alkyl) hydroxylamine.

Evaluation

During polymer processing transformation reactions occur, the hydroxylamine disappears and as potential migrants the amine, nitron, oxime, and fatty aldehyde are available. Migration was analysed from PP and HDPE (0,1% FS-042) and LDPE (0,05% FS-042). The hydroxylamine was not found, migration of the transformation products was detected in 95% ethanol only (max. 1,86ppm oxime, 1,14ppm amine, 1,00ppm aldehyde respectively). In the case of LDPE also the nitron migrates (max. 2,54ppm) although it was not detected in the polymer. Migration from PET containing 0.25% FS-042 in aqueous food simulants was not detectable at a level of 0.5 mg/kg. Specific and a-specific analytical methods for migration testing and for the determination of FS-042 and its transformation products in the polymers are provided. The use of 95% ethanol instead of olive oil as substitute for simulant D was justified. The different substance pattern in the migration tests and in the data on residual content of FS 042 and its transformation products are explained by additional transformation processes under the conditions of polymer extraction with hot solvent. Requested data on in-house validation of the analytical methods had not been provided. The actual amount of FS-042 in polyolefins and PET was determined, using HPLC and nitrogen determination respectively.

Bis(hydrogenated tallow alkyl) amines, oxidised (TKA 40082 or CGA 042) did not show genotoxic properties in the three *in vitro* mutagenicity studies required by the SCF Guidelines on food contact materials.

Bis(hydrogenated tallow alkyl) amines, oxidised (TKA 40082 or CGA 042) were tested in oral a 90-day (+ 4-week recovery period) rat study and a 90-day dog study. The NOEL in these studies were 50 mg/kg bw. for rats and 200 mg/kg bw. for dogs.

Bis(hydrogenated tallow, C16-C18, alkyl) amine, Bis(hydrogenated tallow, C16-C18, alkyl) nitrones, and (Hydrogenated tallow, C16-C18, alkyl) oximes did not induce gene mutations in bacteria and chromosome aberrations *in vitro*.

Purified Bis(hydrogenated tallow, C16-C18, alkyl) hydroxylamine was also tested in a 28-day feeding study (intended by petitioner to demonstrate that the toxicity of the stabiliser was attributed mainly to the hydroxylamine). However, this study was regarded as inappropriate for this purpose because no NOEL but also no dose-effect relationship could be established and at the top dose no effects at all were observed.

With the exception of (hydrogenated tallow, C16-C18, alkyl) aldehyde the other migrants are constituents of the mixture used in the subchronic rat study. The aldehyde is of minor toxicological relevance because it is easily converted to the corresponding fatty acid or the fatty alcohol. Between the amount of Bis(hydrogenated tallow, C16-C18, alkyl) amine and its corresponding part of the NOEL is a sufficient margin of safety. However, for bis(hydrogenated tallow, C16-C18, alkyl) nitrones and (hydrogenated tallow, C16-C18, alkyl) oximes, the other migrants, the highest measured migration leaves no sufficient safety margin (60 for the oxime and 35 for the nitron) to their corresponding part of the NOEL in the 90-day oral rat study. Therefore, this stabiliser should only be used in polyolefins in contact with non-fatty foods. Because the main component of this stabiliser, bis(hydrogenated tallow, C16-C18, alkyl) hydroxylamine, does not migrate and the migration of other components and/or reaction products from different types of polyolefins under different time/temperature conditions does not follow a uniform pattern it is impossible to set restrictions on a SML basis.

To make sure that also for the migration of Bis(hydrogenated tallow, C16-C18, alkyl) nitrones and (Hydrogenated tallow, C16-C18, alkyl) oximes into fatty foods a sufficient safety margin to the NOEL in the subchronic oral rat study exists the following restriction is proposed: QM 0,1 % in polyolefins, not for fatty foods with a Reduction Factor < 3.

Conclusion

Based on the above-mentioned data the substance is classified:

SCF_List: 3

Restriction:

Only to be used:

- in polyolefins at 0.1 % (w/w) and not for fatty food with a simulant D Reduction Factor less than 3
- in PET at 0.25% (w/w) and only for food for which simulant D is not required.

Remark for Commission:

To make sure that also for the migration of Bis(hydrogenated tallow, C16-C18, alkyl) nitrones and (Hydrogenated tallow, C16-C18, alkyl) oximes into fatty foods a sufficient safety margin to the NOEL in the subchronic oral rat study exists the following restriction is proposed: Qm 0,1 % in polyolefins, not for fatty foods with a Reduction Factor < 3.

Needed data or information: None

References:

Opinion of the Scientific Committee on Food on a 10th additional list of Monomers and Additives adopted by the SCF at the 120th meeting, 22 June 2000

http://europa.eu.int/comm/food/fs/sc/scf/out62_en.pdf

Opinion of the Scientific Committee on Food on a 15th additional list of Monomers and Additives adopted by the SCF at the 130th meeting, 13 December 2001,

http://europa.eu.int/comm/food/fs/sc/scf/out114_en.pdf

Unpublished data submitted by the petitioner.

<p><u>REF. N.:</u> 69160</p> <p><u>Name of the substance:</u> Oleic acid, cobalt salt</p> <p><u>CAS number:</u> 014666-94-5</p>	<p style="text-align: right;">SDS CS/PM/3934-Rev0B/69160 of January 2003</p> <p><u>General information</u> According to the petitioner, Cobalt oleate is used as an additive along with a photoinitiator, which activates an oxygen-scavenging polymer. Cobalt oleate is added together with a photoinitiator to the finished polymer in the form of a masterbatch at the point of extrusion. The photoinitiator, upon a brief activation with UV light in the presence of Cobalt oleate, can trigger the selective and engineered oxidation of the polymer, and such results in the absorption of the oxygen present in the headspace of the package.</p> <p><u>Previous evaluations (by SCF)</u> None (new substance) Cobalt was evaluated in 1992 (SCF, 1999) and classified in SCF_List 3 with a restriction of 0.05 mg/kg of food. Oleic acid was evaluated in 1990 (SCF, 1991) as a food additive and an “ADI not specified” was allocated.</p> <p><u>Available data:</u> <u>Non-toxicity data</u> Information concerning identity, physical chemical data, use, authorisation, and migration, but inadequate data on the actual content of Co-oleate in the test samples.</p> <p><u>Toxicity data</u> See (SCF, 1991) and (SCF, 1999)</p> <p><u>Evaluation</u> Specific migration of Cobalt in 10% ethanol and 95% ethanol is < 50 µg/kg food.</p> <p><u>Conclusion</u> Based on the above-mentioned data the substance is classified: SCF_List: 7</p> <p>Remark for the Commission : Intended to be used in active packaging</p> <p><u>Needed data or information:</u> – Data on the actual content of Co-oleate in the test samples</p> <p><u>References:</u> SCF (1991): Reports of the Scientific Committee for Food. 25th report series. First series of food additives of various technological functions. Opinion expressed on 18 May 1990. Directorate General Internal market and Industrial Affairs 1991 SCF (1999): In “Compilation of the evaluations of the Scientific Committee for Food on certain monomers and additives used in the manufacture of plastic materials intended to come into contact with foodstuffs until the 21 March 1997”. 42nd Series of Reports of the Scientific Committee for Food. Office of official Publications of the European Communities, Luxembourg, 1999.</p> <p>Unpublished data submitted by the petitioner.</p>
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<p><u>REF. N.:</u> 95265</p> <p><u>Name of the substance:</u> 1,3,5-Tris(4-benzoylphenyl)</p> <p><u>CAS number:</u> 227099-60-7</p>	<p style="text-align: right;">SDS CS/PM/3929-Rev0B/95265 of January 2003</p> <p><u>General information</u> According to the petitioner, 1,3,5-Tris(4-benzoylphenyl)benzene is a photoinitiator, which in the presence of a catalyst, activates an oxygen scavenging polymer.</p> <p><u>Previous evaluations (by SCF)</u> None (new substance).</p> <p><u>Available data:</u> <u>Non-toxicity data</u></p> <ul style="list-style-type: none"> - Inadequate migration data from multi-layer film samples; maximum migration 38.9 µg/kg food in olive oil. However these data could not be evaluated properly. <p><u>Toxicity data</u></p> <ul style="list-style-type: none"> - Bacterial reverse mutation assay, - Chromosomal aberrations in cultured human peripheral blood lymphocytes, - L5178Y TK^{+/−} mouse lymphoma forward mutation assay with a confirmatory assay. <p><u>Evaluation</u> Specific migration of 1,3,5-Tris(4-benzoylphenyl)benzene into 10% ethanol and 3% acetic acid was found to be not-detectable or < 23.25 µg/kg food. In olive oil, maximum migration was found to be 38.9 µg/kg food.</p> <p>1,3,5-Tris(4-benzoylphenyl)benzene did not show genotoxic properties in the three <i>in vitro</i> mutagenicity studies required by the SCF Guidelines on food contact materials</p> <p><u>Conclusion</u> Based on the above-mentioned data the substance is classified: SCF_List: 7 Restriction: None</p> <p>Remark for Commission: This substance is considered lipophilic and, therefore the Fat (consumption) Reduction Factor may be applied.</p> <p><u>Needed data or information:</u></p> <ul style="list-style-type: none"> - Analytical method for the determination of the specific migration of 1,3,5-tris(4-benzoylphenyl)benzene in food simulants, in compliance with requirements according to the Note for Guidance; - Recovery data of 1,3,5-Tris(4-benzoylphenyl)benzene from food simulants, after storage according to the migration conditions; - Data demonstrating the actual content of 1,3,5-Tris(4-benzoylphenyl)benzene in the test samples; - Explanation of the working mechanism of the photoinitiator in the oxygen scavenging system, and evidence or proper information of the absence of reaction product. <p><u>References:</u> Unpublished data submitted by the petitioner.</p>
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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

Previous opinions adopted by the SCF in the area of Food Contact Materials (status up to March 2003)

1) Evaluations of individual substances

The 42nd Series of Reports of the SCF 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. ("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, Office of Official Publications of the European Communities, Luxembourg 1999" http://europa.eu.int/comm/food/fs/sc/scf/reports_en.html)

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, http://europa.eu.int/comm/food/fs/sc/scf/outcome_en.html)

- Opinion on the 21st additional list of monomers and additives for food contact materials (expressed on 5 March 2002)
- Opinion of the Scientific Committee on Food on Potential risks from organotin compounds used as catalysts in silicone-coated baking papers (expressed on 5 March 2002)
- Statement on the re-allocation of some substances for consistency with new SCF guidelines for food contact materials (expressed on 4 December 2002)
- Statement of the Scientific Committee on Food on 1,6-Diamino-2,2,4-trimethylhexane (PM/REF.N. 15370), 1,6-Diamino-2,4,4- trimethylhexane (PM/REF.N 15400) and on their mixture of (40% w/w) 1,6- diamino-2,2,4-trimethylhexane and (60% w/w)1,6-diamino-2,4,4-trimethylhexane (PM/REF. N. 22331, previously mentioned as PM/REF.N. 15355) (expressed on 4 December 2002)
- Statement of the Scientific Committee on Food on 1,6-Diamino-2,2,4-trimethylhexane (PM/REF.N. 15370), 1,6-Diamino-2,4,4- trimethylhexane (PM/REF.N 15400) and on their mixture of (40% w/w) 1,6- diamino-2,2,4-trimethylhexane and (60% w/w)1,6-diamino-2,4,4-trimethylhexane (PM/REF. N. 22331, previously mentioned as PM/REF.N. 15355) (expressed on 4 December 2002)
- Opinion on the introduction of a Fat (Consumption) Reduction Factor (FRF) in the estimation of the exposure to a migrant from food contact materials (expressed on 4 December 2002)
- Statement on Bisphenol A diglycidyl ether (BADGE) (expressed on 4 December 2002)
- Opinion on the 20th additional list of monomers and additives for food contact materials (expressed on 25 September 2002)
- 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 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 119th 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 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 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: http://europa.eu.int/comm/food/fs/sc/scf/out82_en.pdf).

Extract of the Guidelines:

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.