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Scientific Committee on Food

SCF/CS/PM/GEN/M93 Final

**Opinion of the Scientific Committee on Food
on the 21st additional list of monomers and additives
for food contact materials**

- PM/REF No. 13453 Bis(hydroxyphenyl)methane CAS no. 001333-16-0
- PM/REF No. 17110, 5-Ethylidenebicyclo[2.2.1]hept-2-ene CAS no. 016219-75-3
- PM/REF No. 30340, 12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester, CAS no. 330198-91-9
- PM/REF No. 34240, Alkyl (C10-C20) sulfonic acid, esters with phenol
- PM/REF No. 34650, Aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert.butylphenyl) phosphate CAS no. 151841-65-5
- PM/REF No. 34895, 2-Aminobenzamide, CAS no. 000088-68-6
- PM/REF No. 67896, Myristic acid, lithium salt, CAS no. 020336-96-3
- PM/REF No. 72081/10, Petroleum hydrocarbon resins (hydrogenated), CAS no. 088526-47-0

(Opinion expressed on 5 March 2003)

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**Draft Opinion of the Scientific Committee on Food
on the 21st additional list of monomers and additives for food contact materials**

(Opinion expressed on 5 March 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>Ref. No.: 13453 13455 13457</p> <p>Name of the substance: Bis(hydroxyphenyl)methane</p> <p>CAS number: 001333-16-0 002467-02-9 000620-92-8</p>	<p style="text-align: right;">SDS CS/PM/3381-Rev.IIB/13453 of November 2002</p> <p><u>General information</u> According to the petitioner Bis(hydroxyphenyl)methane (Bisphenol F) is a monomer used in the manufacture of epoxy resins applied in large volume containers. Bis(hydroxyphenyl)methane is a mixture of Bis(2,2'-, 2,4'- and 4,4'-hydroxyphenyl)methane</p> <p><u>Previous evaluations (by SCF)</u> The substance was first evaluated in 2000 (SCF 2000) and classified in SCF_List 7 based on inadequate migration data and equivocal results in mammalian gene mutation assay (needed: repeat of mouse lymphoma assay or in vivo UDS assay).</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, migration and content. - Inadequate calculated worst case migration is 15 ppb <p><u>Toxicity data</u></p> <ul style="list-style-type: none"> - Gene mutation assay in bacteria (negative) - Chromosomal aberration assay in cultured mammalian cells (negative) - Gene mutation assay in cultured mammalian cells (equivocal) - Literature data on oestrogenic activity <i>in vitro</i> - <i>In vivo/in vitro</i> rat liver UDS (negative) <p><u>Evaluation</u> The content of phenolic OH in a typical liquid Bisphenol F based epoxy resin was found to be 20 ppm. The concentration of Bisphenol F diglycidylether in a typical liquid resin was found to be 75%. From these results a worst case calculation of migration of Bisphenol F from a typical epoxy resin was made. In this calculation the mixing with BADGE resin and a hardener as well as a coating thickness of 500 micrometer and a volume/area ratio of a large container was taken into account. In that situation worst case migration was calculated to be 15 ppb. If Bisphenol F is used as hardener, then the worst case migration of Bisphenol F may not be relevant.</p> <p>Bisphenol F was not mutagenic in bacteria and not clastogenic in mammalian cells in vitro. Equivocal results were obtained in a forward mutation test in mammalian cells in vitro, with significant increase in mutant frequencies at high doses associated to exceedingly low survival. Clearly negative results were obtained in the in vitro/in vivo UDS assay in rat liver. It is concluded that Bisphenol F is not genotoxic. In a published study, Bisphenol F showed weak oestrogenic activity in two in vitro assays with human breast cancer cells (Perez et al. 1998).</p> <p><u>Conclusion</u> Based on the above-mentioned data the substance is classified: SCF_List: 7</p> <p><u>Needed data or information:</u> <u>Non-Toxicity Data:</u></p> <ul style="list-style-type: none"> - A properly validated method including data for the determination of Bisphenol F in a typical final product <p>Or</p> <ul style="list-style-type: none"> - A properly validated method including data concerning the specific migration into food simulants of Bisphenol F from a typical final product. <p><u>Toxicity Data:</u> None</p>

	<p><u>References:</u> Unpublished data submitted by the petitioner.</p> <p>P.Perez, R.Pulgar, F. Olea-Serrano, M.Villabona, A.Rivas, M.Metzler, V.Pedraza, N.Olea (1998) The estrogenicity of bisphenol A-related diphenylalkanes with various substituents at the central carbon and the hydroxy groups. Environmental Health Perspectives, 106, 167-174.</p> <p>SCF (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 June 2000) http://europa.eu.int/comm/food/fs/sc/scf/out62_en.pdf</p>
<p><u>Ref. No.:</u> 17110</p> <p><u>Name of the substance:</u> 5-Ethylidenebicyclo [2.2.1]hept-2-ene</p> <p><u>CAS number:</u> 016219-75-3</p>	<p style="text-align: right;">SDS CS/PM/3414-RevIB/17110 of November 2002</p> <p><u>General information</u> According to the petitioner, 5-Ethylidenebicyclo(2.2.1)hept-2-ene (ENB, ethylenenorbornene, mixture of two stereoisomers) is a monomer used in terpolymers, usually with ethylene and propylene, to produce elastomeric materials. These are typically used for seals (long times of contact at room temperature) or tubes and hoses (short times at high temperatures, e.g. for hot water applications). The maximum percentage in the formulation is 12 % ENB. These elastomeric polymers are intended for all types of food.</p> <p><u>Previous evaluations (by SCF)</u> ENB was evaluated in 1992 and was classified in SCF_List 8 (SCF, 1999) based on inadequate data. When re-evaluated in 2000 it was classified in SCF_List 7 (SCF 2000) based on the need of non-tox data: Calibration curve for the determination of the substance in polymers; Specification of the use of the substance, as the actual surface / volume ratio and the thickness of the real materials strongly influence the calculated worst case migration scenario; Explanation of the following statement (made by the petitioner): "other results may be obtained in other application situations, and for other polymer grades, e.g. when used in plastic polymer blends, as polymer modifier.....".</p> <p><u>Available data:</u> <u>Non-toxicity data</u></p> <ul style="list-style-type: none"> - Proper substance description - Analytical method for the determination of the substance in terpolymers <p><u>Toxicity data</u></p> <ul style="list-style-type: none"> - Gene mutation test in bacteria (negative) - Chromosomal aberration in cultured mammalian cells (negative) - Gene mutation in cultured mammalian cells (negative) - In vitro SCE assay (negative) - Dominant lethal assay (negative) - 28- day rat subacute study with oral administration (only the summary was provided. - 90-day rat inhalation study - Morphometric evaluation of the thyroid glands after 14-week exposure - Developmental vapour inhalation toxicity study with rats - Reproduction study (45 days) with oral administration (only the summary was provided.) <p><u>Evaluation</u> Migration was not determined, and was replaced by a worst case 100 % migration assumption. It can be accepted that the substance is to be used only in situations corresponding to low surface plastic / volume (S/V) of food ratios, where the worst case 100 % migration assumption gives figures below 50 µg/kg food. For uses where the S/V ratio exceeds 2 dm²/kg food, no evidence is available that migration would not exceed 50 µg/kg food. From the different provided genotoxicity assays it can be concluded that the substance is not genotoxic. All the in-vivo studies, submitted in full, have been performed using the inhalation route and cannot be considered as totally relevant for this kind of applications and are not sufficient basis for allocating an ADI. Except for reduced body weight or body weight gain, the in-vivo inhalation studies indicate in all cases and for all used doses a thyroid effect. Based on this effect, the NOEL was less than 5 ppm for males and 5 ppm for females. A morphometric study on the thyroid gland tissue was performed and concludes to a significant statistical decrease in average colloid</p>

	<p>area per follicle at 25 ppm dosing (5ppm dose was not included in this study). This effect was absent after the 4-week recovery period following the 14-week exposure regimen. A sub-acute (28-day) toxicity study and a reproduction toxicity study using oral administration have been performed but the results only presented as a summary and it was not possible to include the data in the evaluation.</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: Only a QM method is available, therefore a QMA limit is applicable.</p> <p><u>Needed data or information:</u> None</p> <p><u>References:</u> Unpublished data submitted by the petitioner.</p> <p>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>SCF (2000): Opinion of the Scientific Committee on Food on the 12th additional list of monomers and additives for food contact materials (adopted on 28 February 2001) Http://europa.eu.int/comm/food/fs/sc/scf/out84_en.pdf</p>
<p><u>Ref. No.:</u> 30340</p> <p><u>Name of the substance:</u> 12-(Acetoxy)-stearic acid, 2,3-bis(acetoxy)propyl ester</p> <p><u>CAS number:</u> 330198-91-9</p>	<p style="text-align: right;">SDS CS/PM/3991-Rev.0D/30340 of November 2002</p> <p><u>General information</u> According to the petitioner 12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester (TS-ED 532) is used mainly as plasticizer in PVC film.</p> <p><u>Previous evaluations</u> (by SCF) None (new substance)</p> <p>A review of the toxicity of 12-hydroxy-octadecanoic acid, 12-acetoxyoctadecanoic acid and the systemic toxicity of acetic acid was also submitted.</p> <p><u>Available data:</u> <u>Non-toxicity data</u></p> <ul style="list-style-type: none"> - Hydrolysis data in three digestive fluid simulants (complete hydrolysis in intestinal fluid) - Specific migration from PVC film in 3% acetic acid, 15% ethanol (0.06 mg/kg food) and sunflower oil (61 mg/kg food) <p><u>Toxicity data</u></p> <ul style="list-style-type: none"> - gene mutation assays in bacteria (negative) - chromosomal aberration assay in cultured mammalian cells (incomplete) - gene mutation assay in cultured mammalian cells (negative) - 2-week palatability study - 13-week gavage toxicity study (with further analysis of data) - peroxisome proliferation - review of the metabolism of triacylglycerols with specific reference to the test substance - a review of the toxicity of 12-hydroxy-octadecanoic acid, 12-acetoxyoctadecanoic acid and the systemic toxicity of acetic acid <p><u>Evaluation</u> Specific migration of 12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester into 3% acetic acid and 15% ethanol from PVC film was found to be 0.06 mg/kg food. Migration into</p>

	<p>sunflower oil was higher and found to be 10.3 mg/dm² or 61.8 mg/kg into food. 12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester is not significantly hydrolysed by either saliva simulant or gastric juice simulant. The test substance is extensively hydrolysed by intestinal fluid simulant. Major hydrolysis product is stearic acid, 12 (acetyloxy).</p> <p>The test substance produced negative results in assays for the induction of gene mutations in bacteria and cultured mammalian cells. In the absence of the final report of a chromosomal aberration test in mammalian cells, it is not possible to reach a conclusion on the mutagenicity of this substance. The results of a 2-week palatability study indicated that the test substance can be administered via the diet and by gavage.</p> <p>In a 13-week sub-chronic toxicity study in SD rats involving administration by gavage of the test compound at doses of 3, 8.5 and 20 ml/kg bw/day a number of significant changes in biological parameters (food consumption, haematology, clinical chemistry, organ weights and histopathology) were reported. However, the administration of corn oil to the control group resulted in a number of biological changes, which presented difficulties in interpreting the outcome of the 13-week toxicity study. In particular, it was not possible to determine whether the changes were as a result of treatment with the test compound or if they were due to the use of corn oil as vehicle. Further analysis (by cross-comparison with control data from other studies and historical controls) of the data was presented but this did not allow the derivation of a NOAEL for the test substance.</p> <p><u>Conclusion</u> Based on the above-mentioned data the substance is classified: SCF_List: 7</p> <p><u>Needed data or information:</u> Because of the high migration, the full core set of toxicity data (unless it can be shown that the substance is metabolised to constituents which occur normally in the diet)</p> <p><u>References:</u> Unpublished data submitted by the petitioner.</p>
<p><u>Ref. No.:</u> 34240</p> <p><u>Name of the substance:</u> Alkyl (C10-C20) sulfonic acid, esters with phenol</p> <p><u>CAS number</u></p>	<p style="text-align: right;">SDS CS/PM/313-Rev.IIC/34240 of 13 November 2002</p> <p><u>General information</u></p> <p>According to the petitioner, The test article (alkyl(C10-C20)sulfonic acid, esters with phenol) is a mixture of mono-, di- and trialkylsulfonic phenylesters based on n-paraffin and it is used as a plasticizer in PVC articles</p> <p>This substance was temporarily authorised until 1st January 2002, taking into account an evaluation of 1990, and now is no longer authorised.</p> <p><u>Previous evaluations (by SCF)</u> The test substance was previously evaluated in 1990 (SCF, 1995). The maximum migration in food simulants was 69.0 ± 17.4 mg/6dm². Acute toxicity data indicated that the substance was moderately to slightly toxic. The NOAEL in the 90-day feeding study in rats was 55.4 mg/kg b.w. per day. Dose-dependent accumulation of the compound in fatty tissues was observed, while no accumulation was seen in liver. The substance was not mutagenic in the Ames test. On this basis, the SCF allocated a t-TDI of 0.1 mg/kg b.w.</p> <p>Two further mutagenicity studies (gene mutation and chromosomal aberrations in mammalian cells in vitro) were requested to complete the toxicity data.</p> <p><u>Available data:</u> <u>Non-toxicity data</u> Information concerning identity, physical chemical data, use, authorisation, migration and content.</p> <p><u>Toxicity data</u></p> <ul style="list-style-type: none"> - data on distribution and bioaccumulation - acute and subchronic toxicity - effects on reproduction (an old multigenerational study) - reverse mutation test in bacteria (negative)

	<ul style="list-style-type: none"> - forward mutation assay in mammalian cells (negative) - chromosomal aberrations assay in vitro (equivocal). <p><u>Evaluation</u> The requested mutagenicity studies were provided. The data indicate that the test article is not mutagenic in the gene mutation assay in mammalian cells, while equivocal results were obtained in a chromosomal aberration study, with increases in the number of aberrant cells not related to the dose and not reproducible in parallel cultures. For an adequate evaluation of genotoxicity, the repetition of the in vitro chromosomal aberration assay is necessary. Furthermore, in view of the need to set a restriction for substances for which a provisional t-TDI was established in the past on the basis of limited toxicity data, the petitioner should provide an assessment of the risk of accumulation of migrants, in consideration of the evidence of accumulation in fatty tissue obtained in the feeding study.</p> <p><u>Conclusion</u> Based on the above-mentioned data the substance is classified: SCF_List: 7</p> <p><u>Needed data or information:</u> Chromosomal aberration assay in vitro according to prevailing guidelines, controlling the effects of test article on pH and osmolality of the medium, and providing historical data on spontaneous aberration frequencies in the test system. Data to demonstrate the absence of potential for accumulation in man.</p> <p><u>References:</u> SCF (1995): Report of the Scientific Committee for Food. 33rd series. First report of the Scientific Committee for Food on certain additives used in the manufacture of plastic materials intended to come into contact with foodstuffs. Opinion expressed until 3 May 1992. Directorate General for Industry 1995.</p> <p>Unpublished data submitted by the petitioner.</p>
<p><u>Ref. No.:</u> 34650</p> <p><u>Name of the substance:</u> Aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert. butylphenyl) phosphate</p> <p><u>CAS number:</u> 151841-65-5</p>	<p style="text-align: right;">SDS CS/PM/3792-Rev.IC/34650 of November 2002</p> <p><u>General information</u> According to the petitioner aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert. butylphenyl) phosphate is used as a clarifying and nucleating agent in polypropylene and its copolymers to improve transparency, crystallisation temperature and impact strength of the polymer.</p> <p><u>Previous evaluations (by SCF)</u> The substance was first evaluated in 2000 (SCF, 2001) and classified in SCF_List 7. Needed: a) clarification of the observed large difference in extraction into 95% ethanol (60 µg/dm²), into 10% ethanol (41 µg/dm²) and into isooctane (5.6 µg/dm²) and olive oil (17.2 µg/dm²), which are essentially similar lipophilic solvents. b) explanation of the contradictory statements on the solubility in the solvents used for carrying out the mutagenicity studies and the doses used. c) evidence for the absence of a potential for bioaccumulation because only a reduced core set of toxicological data was available for the safety evaluation of the extent of migration into the packaged food.</p> <p><u>Available data:</u> <u>Non-toxicity data</u> Migration data in aqueous food simulants, 95% ethanol and iso-octane</p> <p><u>Toxicity data</u></p> <ul style="list-style-type: none"> - Gene mutation assay in bacteria (negative) - Chromosomal aberration assay in cultured mammalian cells (negative) - Gene mutation assay in cultured mammalian cells (negative) - 28-day oral gavage toxicity study (with recovery) in rats - 90-day oral gavage toxicity study in rats -

	<p><u>Evaluation</u> Petitioner has identified the reason for unexpected migration results in iso-octane and 95% ethanol. Presence of sodium stearate influences the migration in iso-octane due to reaction of the stearate with the substance. In 95% ethanol the association product of the aluminium component and the stearate is dissociated and stearate being soluble in ethanol contributes to the migration. As stearate is insoluble in isooctane, it cannot appear as a migrant, only the aluminium component actually migrates into isooctane. The concentration of the test substance needed in the bacterial gene mutation assay was 50 mg/ml DMSO, which is about the limit for the solubility of the subject substance. For the gene mutation test in cultured mammalian cells a concentration of 500 mg/ml DMSO would be required. This exceeds by far the solubility in DSMO. Therefore a suspension in culture medium, with only 1% DMSO present, was used for treating the cultured mammalian cells. Similar reasons, namely toxicity to the cultured cells of high concentrations of DMSO, prevented the use of DMSO as a solvent and therefore a dispersion in water in the presence of methylcellulose was chosen as solvent system. This explanation clarifies the use of different solvents in the relevant genotoxicity assays. The substance was shown not to be genotoxic in the three required assays. The 28-day gavage study showed some biochemical and histological evidence of hepatotoxicity and yielded a NOEL of 80 mg/kg bw/day. The 90-day gavage study did not show any biologically significant treatment or dose-related changes, but yielded no clear NOEL A bioaccumulation test using carp showed absence of a potential for bioaccumulation.</p> <p><u>Conclusion</u> Based on the above-mentioned data the substance is classified: SCF_List: 3 Restriction: 5 mg/kg of food. Based on the reduced core set of toxicological data according to the migration level. Remark for Commission: None</p> <p><u>Needed data or information:</u> None</p> <p><u>References:</u> Unpublished data submitted by the petitioner.</p> <p>SCF (2001): Opinion of the Scientific Committee on Food on the 13th additional list of monomers and additives for food contact materials (adopted at the 127th meeting, 30 May 2001) http://europa.eu.int/comm/food/fs/sc/scf/out86_en.pdf</p>
<p><u>Ref. No.:</u> 34895</p> <p><u>Name of the substance:</u> 2-Amino-benzamide</p> <p><u>CAS number:</u> 000088-68-6</p>	<p style="text-align: right;">SDS CS/PM/3881-Rev.IB/34895 of November 2002</p> <p><u>General information</u> According to the petitioner 2-aminobenzamide is used as an additive in the production of PET polymers.</p> <p><u>Previous evaluations (by SCF)</u> The substance was evaluated in 2001 (SCF, 2001). Based on inadequate migration data and incomplete genotoxicity assays, the substance was classified in List 7.</p> <p><u>Available data:</u> <u>Non-toxicity data</u> Information concerning identity, physical chemical data, use, authorisation, migration and content in PET.</p> <ul style="list-style-type: none"> - Adequate migration data of subject substance in aqueous food simulants - Migration data of the reaction product of acetaldehyde and subject substance in aqueous food simulants <p><u>Toxicity data</u></p> <ul style="list-style-type: none"> - gene mutation assay in bacteria (negative) - gene mutation assay in cultured mammalian cells (negative)

	<ul style="list-style-type: none"> - chromosomal aberration assay in vitro (negative) - mouse bone marrow micronucleus assay (negative) - gene mutation assay in bacteria on the reaction product of test article with acetaldehyde (negative) <p><u>Evaluation</u> Specific migration of 2-aminobenzamide from PET bottles, containing 500 ppm of the substance, in water, 3% acetic acid and 10% ethanol was found to be maximum 0.04 mg/kg in 10% ethanol, after 30 days at 40°C. The test substance anthranilamide was inactive in gene mutation assays in bacteria and in mammalian cells, in a chromosomal aberration assay in vitro, and in the mouse bone marrow micronucleus test. Negative results were also obtained in a bacterial mutation assay with the reaction product of anthranilamide with acetaldehyde</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><u>Remark for Commission:</u> only requested in contact with water and beverages. Substance may be reactive with fat components, therefore authorisation should be restricted to requested application “PET for water and beverages”.</p> <p><u>Needed data or information:</u> None</p> <p><u>References:</u> Unpublished data submitted by the petitioner.</p> <p>SCF (2001). Opinion of the Scientific Committee on Food on a 16th 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/out115_en.pdf</p>
<p><u>Ref. No.:</u> 67896</p> <p><u>Name of the substance:</u> Myristic acid, lithium salt</p> <p><u>CAS number:</u> 020336-96-3</p>	<p style="text-align: right;">SDS CS /PM/3939-Rev0A/67896 of November 2002</p> <p><u>General information</u> According to the petitioner myristic acid, lithium salt, is used as a colour and heat stabiliser additive during manufacturing of articles made from polypropylene polymers and copolymers.</p> <p><u>Previous evaluations (by SCF)</u> None (new substance). Other substances, related to lithium myristate such as palmitic acid, lithium salt (PM/REF No. 70820) and stearic acid, lithium salt (PM/REF No. 90260) for application in coatings, have already been evaluated by the SCF. For these substances the fatty acid moiety was listed in SCF_List 1 (ADI not specified) and lithium in SCF_List 2 with a group-TDI of 0.01 mg/kg bw. (as Li) (SCF 1995) Myristic acid (PM/REF No. 67891), for application in both plastics and coatings, is listed in SCF_List 1 (SCF 1995) with reference to the ADI not specified previously allocated (SCF 1991).</p> <p><u>Available data:</u> <u>Non-toxicity data</u> Specific migration data for a worst-case specimen tested using simulants under the worst-case conditions.</p> <p><u>Toxicity data</u> No new data</p> <p><u>Evaluation</u> A random polypropylene copolymer with low crystallinity and containing 0.15% of the substance, was tested as a worst-case for migration, in 3% acetic acid, 15% ethanol and olive, at 100°C for 2 hr followed by 10 days at 40°C. There was no detectable migration of</p>

	<p>lithium (limit of detection: 0,032 mg/kg) and so it is concluded that the migration of lithium myristate is less than 1,1 mg/kg.</p> <p>No new toxicology data are provided by the petitioner. However, given the previous evaluations of lithium containing substances, lithium myristate can be added to the list of additives for the application in plastics.</p> <p><u>Conclusion</u> Based on the above-mentioned data the substance is classified: SCF_List: L1 for myristic acid (ADI: Not specified). L2 for lithium (Group-TDI = 0.01 mg/kg bw. (as Li))</p> <p>Remark for Commission: None</p> <p><u>Needed data or information:</u> None</p> <p><u>References:</u> Unpublished data submitted by the petitioner.</p> <p>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</p> <p>SCF (1995): Report of the Scientific Committee for Food. 33rd series. First report of the Scientific Committee for Food on certain additives used in the manufacture of plastic materials intended to come into contact with foodstuffs. Opinion expressed until 3 May 1992. Directorate General for Industry 1995</p>
<p><u>Ref. No.:</u> 72081/10</p> <p><u>Name of the substance:</u> Petroleum hydrocarbon resins (hydrogenated)</p> <p><u>CAS number:</u> 088526-47-0</p>	<p style="text-align: right;">SDS CS/PM/3082-Rev.IVB/72081/10 of November 2002</p> <p><u>General information</u> According to the petitioner the hydrogenated hydrocarbon resins (Arkon-P) is used as a polymeric additive in polyethylene and polypropylene to improve processability, gas/vapour permeability, transparency and stiffness</p> <p><u>Previous evaluations (by SCF)</u> The substance was first evaluated in 1998 (SCF 2000) on the basis of three mutagenicity studies (performed with the hydrogenated hydrocarbon resin) but was classified in SCF_List 7 on the basis of inadequate migration data. (Needed: In first instance, migration data on the polymeric additive; explanation why the residual amount of the hydrogenated monomers and unpolymerisable components are rather high (in the product), more information on specification, i.e. information on hydrogenation, purification and viscosity of final product.) The substance was again evaluated in 2000 (SCF 2000). Because of the high migration to be expected in fatty food the substance was again classified in SCF_List 7, requesting in first instance reduction of the residues of the hydrogenated monomers and non-polymerisable components (by technical processing). Additional information concerning the residual content of non-hydrogenated and hydrogenated monomers in Arkon P-100 and also information on the Mw distribution of Arkon P-100 has now been provided.</p> <p><u>Available data:</u> <u>Non-toxicity data</u></p> <ul style="list-style-type: none"> - molecular weights and molecular weight distribution curves - residual amounts of monomers, hydrogenated monomers and catalysts of some types of resin - data on global migration <p><u>Toxicity data</u></p> <ul style="list-style-type: none"> - gene mutation assay in bacteria (negative; performed with the hydrogenated hydrocarbon resin (Arkon M-90)) - chromosomal aberration assay in cultured mammalian cells (negative; performed with the hydrogenated hydrocarbon resin (Arkon M-90))

- gene mutation assay in cultured mammalian cell (negative; performed with the hydrogenated hydrocarbon resin (Arkon M-90)
- 90-day oral rat study including an in utero phase (performed with Arkon M-90)
- 90-day inhalation study with decalin, one of the hydrocarbon impurities of Arkon M-90, in dogs, rats and mice (Gaworsky et. al)

Evaluation

Resin with the lowest molecular weight and mean distribution was examined for residual content of non-hydrogenated and hydrogenated monomers. Residual non-hydrogenated and hydrogenated monomers are not detectable at a quantification limit of 2 and 50 mg/kg respectively.

Overall migration of the resin was determined from PP films containing 10 or 15% resin and from a PE film containing 5% resin. Overall migration was determined in aqueous food simulants (15% ethanol and 3% acetic acid) under conditions of 10 days at 40°C and 1 h at reflux temperature. In addition migration in olive oil and 95% ethanol (10 d-40°C) was determined. Migration of resin into aqueous simulant under any condition was close to 1 mg/kg. Migration into olive oil and 95% ethanol from a PP with 10% resin was 51 mg/kg and 11.6 mg/kg respectively

Arkon M-90 was tested negative in assays for the induction of gene mutations in bacteria and mammalian cells and in a chromosomal aberration assay in CHO cells. With respect to the polymeric nature of the test substance the result of the chromosomal aberration assay could be accepted, even if the test protocol was not in full accordance with the guidelines.

From a 90-day oral rat study including an *in utero* exposure phase with Arkon M-90 a NOAEL of 36000 ppm in the diet could be established.

A 90-day inhalation study with decalin, one of the hydrocarbon impurities of Arkon M-90, in dogs, rats and mice has also been provided. Besides nephrotoxicity in male rats other treatment-related effects were observed even at a concentration of 5 ppm. However, an inhalation study is of limited value for the evaluation of the oral intake of decalin

Taking into account the general discussion about hydrogenated hydrocarbon resins (PM Ref. n. 47520//66950//66960//72081/10 //76680) the final evaluation of Arkon P-100 will be possible only after solving the problem of possible accumulation in man of hydrogenated hydrocarbon resins tested with a worst-case sample out of the group.

Conclusion

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

SCF_List: 7

Needed data or information:

Data to demonstrate the absence of potential for accumulation in man of hydrogenated hydrocarbon resins tested with a worst-case sample out of the group.

References:

Unpublished data submitted by the petitioner.

C.L. Gaworski et al. (1985). A 90-day vapor inhalation toxicity study of decalin, *Fundamental and Applied Toxicology* **5**: 785-793.

SCF (2000): Opinion of the Scientific Committee on Food on the 11th additional list of monomers and additives for food contact materials (expressed on 19 October 2000)

http://europa.eu.int/comm/food/fs/sc/scf/out76_en.pdf

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 December 2002)

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”)

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)

- 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.