Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to

a 1st list of substances for food contact materials

(Opinion adopted on 1 October 2003)

SUMMARY

Within the general task of evaluating substances intended for use in food contact materials according to Council Directive 89/109/EEC of 21 December 1988 relating to materials and articles intended to come into contact with foodstuffs the AFC Panel evaluated following four substances.

Ref. No. 31542; Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-C18 alkyl esters; CAS No 174254-23-0
Classified in list 7: Further information requested before acceptance.

Ref. No 33105; Alcohols C12-C14 Secondary. beta.-(2-hydroxyethyoxy)-ethoxylated; CAS No 146340-15-0
Classified in list 7: Further information requested before acceptance.

Ref. No 48960; 9,10-dihydroxy stearic acid CAS No 000120-87-6
Classified in list 7: Further information requested before acceptance.

Ref. No 69160; Oleic acid, cobalt salt; CAS No 014666-94-5
Classified in list 3: Accepted with migration restriction 0.05 mg/kg food for cobalt and in list 0: Accepted with no restriction for oleic acid.

BACKGROUND

According to Article 3(3) of the Council Directive 89/109/EEC of 21 December 1988 it is necessary to consult the European Food Safety Authority (EFSA) on the risks connected with the migration of substances into food from food contact materials in which they are used. The opinion of the EFSA is required before a substance is authorised to be used in food contact materials and be included in a positive list when this is established in the relevant legislation.

TERMS OF REFERENCE

The Commission asks EFSA to carry out risk assessments on:

1. all new substances used in food contact materials before their authorisation and inclusion in a positive list;

2. substances which are already authorised in the framework of Council Directive 89/109/EEC but need to be re-evaluated.

ASSESSMENT

Within this general task the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) (re)evaluated four substances used as additives in food contact materials. The substances examined are listed in alphabetical order with their Reference Number (REF No.), Chemical Abstract Number (CAS No.) and classification according to the "SCF list". Previously the evaluation of substances used in food contact materials was undertaken by the Scientific Committee on Food (SCF). The definitions of the various SCF lists is given in the appendix.

Ref. No.:	**31542**
Name of the substance:	**Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-C18 alkyl esters**
CAS number:	174254-23-0
Document reference:	SDS CS/PM/4061-Rev.0C/31542 of February 2003
General information:	According to the petitioner acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-C18 alkyl esters is intended for use as co-stabiliser and/or dispersant for fillers, pigments, stabilisers, nucleating agents, and chemical blowing agents in plastics, particularly in polyolefins
Previous evaluations (by SCF or AFC):	None (New substance)
Available data used for this evaluation:	
Non-toxicity data:	Data on specification Data on use Data on specific migration from polypropylene, high density polyethylene and low density polyethylene into 10 % and 95 % ethanol
Toxicity data	Gene mutation in bacteria with a low molecular weight fraction
Evaluation:	2-Propenoic acid, methyl ester, telomer with 1-dodecanethiol, C16-18-alkyl esters is requested as a co-stabiliser and/or dispersant for additives (fillers, pigments, stabilisers, nucleating agents, and chemical blowing

Ref. No.:	31542
Name of the substance:	**Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-C18 alkyl esters**

agents). The substance would be used in amounts up to 0.5 % in polymers, particularly in polyolefins. No restrictions of use of the final articles are foreseen by the petitioner.
The requested substance is a polymeric additive having a molecular weight of >10000 D, the fraction <1000 D is 1.35 %.
Based on the assumption that 0.5 % of the substance is present in the final article, the worst case migration is calculated to be 1 mg/6dm².
Taking into account the maximum concentration of 30 ppm of dodecyl mercaptane in the polymeric additive, the worst case migration of dodecyl mercaptane is 2.25 µg/6dm² of food contact material or per kg of food.
The migration of the polymeric additive into 10 % and 95 % ethanol was tested from PP, HDPE, and LDPE containing 0.53, 0.31 and 0.21 % respectively of the additive at conditions representing hot fill and long term storage. The highest migration was determined in 95 % ethanol from low density polyethylene (LDPE) (containing only 0.21 % instead of 0.5 %) at 1.25 mg/kg food simulant.
A method should be provided for the determination of the requested substance in polymers.
Although for polymeric additives with average molecular weight > 10000 D no toxicological data are requested according to the SCF Guidelines, the petitioner provided a test for gene mutations in bacteria with a low molecular weight fraction. This test showed no induction of gene mutations.
For the starting substances methyl acrylate [PM Ref.N. 11710, L 2, Group t-TDI = 0,1 mg/kg b.w. (as acrylic acid)], cetyl alcohol and stearyl alcohol (PM Ref.N. 33120, L 3 without restriction) no further data are needed.
Dodecyl mercaptane is a chain stopper, a category which is not specifically regulated yet. Taking this into account and the low potential migration, no further toxicity data are requested.

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

SCF_List: 7

Remark for Commission: Fat (consumption) Reduction Factor could apply

Needed data or information: Data to demonstrate the actual content of the substance in polymers at the intended level of addition.
A method for the determination of the requested substance in polymers according to guidelines.

References: Unpublished data submitted by the petitioner

Ref. No.:	33105
Name of the substance:	**Alcohols C12-C14 Secondary. beta.-(2-hydroxyethyoxy)-ethoxylated**

CAS number: 146340-15-0

Document reference: SDS CS/PM/4117-Rev.0B/33105 of September 2003

General information: According to the petitioner Alcohols C12-C14 Secondary.beta.-(2-hydroxyethoxy)-ethoxylated is a polymeric additive which is intended for use as an emulsifier in all types of packaging materials.

Ref. No.:	**33105**
Name of the substance:	**Alcohols C12-C14 Secondary. beta.-(2-hydroxyethyoxy)-ethoxylated**

Previous evaluations (by SCF or AFC): None (New substance)

Available data used for this evaluation:

Non-toxicity data: Inadequate data on identity.
Inadequate data on specific migration.
No data on actual content in the polymer.

Toxicity data: In vitro gene mutation assays in bacteria and in mammalian cells.
In vivo micronucleus assay in bone marrow.
90-day study in rats (oral).
Additional data on acute toxicity, sensitisation, eye and skin irritation.

Evaluation: Specific migration of Alcohols C12-C14 Secondary.beta.-(2-hydroxyethoxy)-ethoxylated from PVC plates in water, 50% ethanol and heptane was found to be 6 – 9 µg/dm². Data on recovery of the substance, including the migration period have not been provided.
Simulation of the migration by mathematic modelling demonstrates that migration of the substance from LDPE is the worst case, resulting in 157 mg/kg after 10 days at 40°C, while from PVC migration is calculated to be 0.1 mg/kg.
The substance had no mutagenic activity in bacteria. The results from a mammalian mutation assay using V79 cells were equivocal. A chromosomal aberration test with mammalian cells was not available.
Based on negative results from an in vivo micronucleus assay, the substance is considered to have no clastogenic potential.
In a 90-day oral rat study, a lowest-observed-effect-level (LOEL) of 30 mg/kg bodyweight/day was derived from observed effects on the forestomach..

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

SCF list: 7

Needed data or information: Spectra of Alcohols C12-C14 Secondary.beta.-(2-hydroxyethyoxy).ethoxylated
Information on impurities
Recovery of Alcohols C12-C14 Secondary.beta.-(2-hydroxyethyoxy) from food simulants, including the migration period
Detailed supporting information on the statement concerning the actual content of the substance in the test sample.
Confirmation that the substance is intended to be used in all types of plastics, given the high calculated migration in LDPE
in vitro gene mutation assay in mouse lymphoma cells.

Remark for Commission: Based on solubility data the fat (consumption) reduction factor is not applicable.
Mathematic modelling predicts high migration of subject substance from LDPE.

References: Unpublished data submitted by the petitioner

Ref. No.:	**48960**
Name of the substance:	**9,10-dihydroxy stearic acid oligomers**
CAS number:	000120-87-6
Document reference::	SDS CS/PM/4091-Rev.0B/48960 of September 2003

General information: According to the petitioner 9,10-dihydroxystearic acid is a defined mixture of monomer, dimer, trimer and tetramer of 9,10-dihydroxystearic acid. It is used as an emulsifier in PVC.

Previous evaluations (by SCF or AFC): None (New Substance)

Available data used for this evaluation:

Non-toxicity data: Migration data.
Residual amount of 9,10-dihydroxystearic acid in PVC.

Toxicity data: Gene mutation assay in bacteria.
Gene mutation assay in mammalian cells.
Chromosomal aberration assay in cultured mammalian cells (incomplete, data only with S9).
90-day oral toxicity study with reversibility in rats.

Evaluation:

Non toxicity data: Migration of 9,10-dihydroxystearic acid into food simulants water, 3% acetic acid, 15% ethanol and 100% ethanol from two PVC samples containing 0.03 and 0.07% of 9,10-dihydroxystearic acid was found to be less than 0.0015 mg/kg after a contact period of 10 days at 40°C. However the data should be reconfirmed.

Genotoxicity: The test substance did not cause mutations in the two requested gene mutation assays (in bacteria and in mammalian cells). The chromosomal aberration assay reported in the dossier was done only in the presence of metabolic activation (S9 mix). Data without S9 in a chromosomal aberration assay are needed in order to conclude about the genotoxic potential of the test substance.

Sub-chronic toxicity: An oral 90-day study with a reversibility period has been performed. The doses used were 0 (control), 60, 150, 300 and 1000 mg/kg b.w/day. Monitoring for toxic effects included clinical observations, body and organ weights, food and water consumption, hematology and serum chemistry evaluations, thyroid function assays, urinalysis, macroscopic and microscopic evaluations. These were not significantly modified by the treatment at any dose. A no-observed-effect-level (NOEL) greater than 1000 mg/kg bodyweight/day can be taken on the basis of this study.

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

SCF list: 7

Ref. No.:	**48960**
Name of the substance:	**9,10-dihydroxy stearic acid oligomers**
Needed data or information	Specification of the actual substance. Information on the actual substance used for the determination of the solubility. Confirmation whether iso-octanol or iso-octane is used in the determination of the solubility. Confirmation of the detection limit (μg/dm²) supported by convincing chromatograms to establish the detection limit. Data on the actual amount of 9,10-dihydroxystearic acid recovered from simulants to which the substance has been added at a relevant concentration and stored for 10 d at 40°C, in accordance with the Note for Guidance. Detailed data to evaluate the reliability of the migration results presented. A complete chromosomal aberration assay in mammalian cells including data without metabolic activation (S9)
Remark for Commission:	Fat (consumption) Reduction Factor should not apply to this substance
References:	Unpublished data submitted by the petitioner.

Ref. No.:	**69160**
Name of the substance:	**Oleic acid, cobalt salt**
CAS number:	014666-94-5
Document reference:	SDS CS/PM/3934-RevIB/69160 of September 2003
General information:	According to the petitioner, cobalt oleate is used as an additive along with a photo initiator, which activates an oxygen-scavenging polymer. Cobalt oleate is added together with a photo initiator to the finished polymer in the form of a masterbatch at the point of extrusion. The photo initiator, upon a brief activation with UV light in the presence of cobalt oleate, can trigger the selective and engineered oxidation of the polymer The polymer has been designed so that in its activated form it can be oxidised and thereby scavenge oxygen that may be present in the headspace of the package.
Previous evaluations (by SCF or AFC):	New substance, however, 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.
Available data used for this evaluation:	
Non-toxicity data:	Information concerning identity, physical chemical data, use, authorisation, migration, and data on the actual content of cobalt oleate in the masterbatch.
Toxicity data:	No new data submitted.
Evaluation:	The specific migration of cobalt in 3% acetic acid, 10% ethanol and 95% ethanol is < 50 μg/kg food. Given the previous evaluations of cobalt and oleic acid, no further toxicity data are required.

Ref. No.:	**69160**
Name of the substance:	**Oleic acid, cobalt salt**
Conclusion:	Based on the above-mentioned data the substance is classified:
SCF list:	SCF_List: 3 - Restriction : 0.05 mg/kg for cobalt SCF_List: 1 for oleic acid ; food additive "ADI not specified"
Needed data or information	None
Remark for Commission:	Intended to be used in active packaging
References:	Unpublished data submitted by the petitioner. 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 http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_25.pdf 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. http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_42.pdf

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APPENDIX

DEFINITION OF THE SCF LISTS

List 0 Substances, e.g. foods, which may be used in the production of plastic materials and articles, e.g. food ingredients and certain substances known from the intermediate metabolism in man and for which an ADI need not be established for this purpose.

List 1 Substances, e.g. food additives, for which an ADI (=Acceptable Daily Intake), a t-ADI (=temporary ADI), a MTDI (=Maximum Tolerable Daily Intake), a PMTDI (=Provisional Maximum Tolerable Daily Intake), a PTWI (=Provisional Tolerable Weekly Intake) or the classification "acceptable" has been established by this Committee or by JECFA.

List 2 Substances for which 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)**

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.

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.

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.

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.