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Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to

an 11th list of substances for food contact materials

Question N°EFSA-Q-2003-217, EFSA-Q-2005-227, EFSA-Q-2003-215

Adopted on 24 January 2006

SUMMARY

Within the general task of evaluating substances intended for use in materials in contact with food according to the Regulation (EC) No.1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with foodstuffs, the AFC Panel evaluated the following substances:

Ref. No.:	21970
Name of the substance:	N-Methylolmethacrylamide
CAS number:	00923-02-4
Classified in list:	3
Restriction:	0.05 mg/kg food

Ref. No.:	62020
Name of the substance:	12-Hydroxystearic acid, lithium salt
CAS number:	7620-77-1
Classified in list:	3
Restriction:	In accordance with other lithium compounds this will be subject to a group SML of 0.6 mg Li/kg food

Ref. No.:	79920
Name of the substance:	Poly(ethylene propylene) glycol
CAS number:	009003-11-6 and 106392-12-5
Classified in list:	3
Restriction:	None

KEY WORDS

Food Contact Materials, Plastics, Monomers, Additives, REF. No 21970, CAS No 00923-02-4, N-Methylolmethacrylamide, REF. No 62020, CAS No 7620-77-1, 12-Hydroxystearic acid, lithium salt, REF. No 79920, CAS No 009003-11-6 and 106392-12-5, Poly(ethylene propylene) glycol

BACKGROUND

Before a substance is authorised to be used in food contact materials and is included in a positive list EFSA´s opinion on its safety is required. This procedure has been established in Articles 8 and 9 of the Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food[1].

TERMS OF REFERENCE

The EFSA is required by Article 10 of Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food to carry out risk assessments on the risks originating from the migration of substances from food contact materials into food and deliver a scientific opinion on:

1. new substances intended to be used in food contact materials before their authorisation and inclusion in a positive list;
2. substances which are already authorised in the framework of Regulation (EC) No. 1935/2004 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) evaluated the following substances used in food contact materials. The substances examined are listed in ascending order of their Reference Number (REF No.), with their chemical name, Chemical Abstract Number (CAS No.) and classification according to the "SCF list". (Since in the past the evaluation of substances used in food contact materials was undertaken by the Scientific Committee on Food (SCF), the same system of classification into a "SCF list" is retained for uniformity purposes). The definitions of the various SCF lists and the abbreviations used are given in the appendix.

[1] This Regulation replaces Directive 89/109/EEC of 21 December 1988, OJ L 40, 11.2.1989, P.38

Ref. No.:	**21970**
Name of the substance:	**N-Methylolmethacrylamide**

CAS number: 00923-02-4
Document reference: SDS EFSA/AFC/FCM 550-Rev.IVA/21970 of November 2005

General information: According to the petitioner, N-methylolmethacrylamide is requested as a co-monomer in polymer dispersions used for the surface coating of packaging materials for sausage and cheese, filters, etc. at a maximum use level of 4%.

Previous evaluations (by SCF or AFC): The substance was first evaluated by the SCF in 1999 (SCF, 1999) on the basis of the following data: hydrolysis data, calculation of worst case migration assuming 100% migration of the residual N-methylolmethacrylamide, gene mutation assay in bacteria (negative), chromosomal aberration assay in cultured mammalian cells (positive), gene mutation assay in cultured mammalian cells (negative).
The substance was classified in SCF List 7 with the request for the following data: data on the estimation of the residual N-methylolmethacrylamide, assay for chromosomal damage in rodent bone marrow.
The substance was re-evaluated by the SCF in 2002 (SCF, 2002) on the basis of an assay for chromosomal damage in rodent bone marrow and analytical data on the residual content of the substance. It was concluded that the substance does not express a genotoxic potential *in vivo*. The substance was classified in List 7 with the request of data on analytical proof of the residual content.

Available data used for this evaluation:

Non-toxicity data:
- Analytical method for the determination of residual N-methylolmethacrylamide in dispersions

Toxicity data
- This aspect was evaluated by the SCF in 1999 and 2002

Evaluation: An analytical method, properly described and in-house validated, for the determination of the residual content in a dispersion was provided. The method was applied to a series of commercial products. From the residual levels of N-methylolmethacrylamide in dispersions the worst case migration, assuming a use level of 0.8g of polymeric dispersion /dm^2 of packaging material and 100% migration of the residual amount of N-methylolmethacrylamide from the coated product, was calculated to be <0.024 mg/6 dm^2 or <0.024 mg/kg food.

Ref. No.:	**21970**
Name of the substance:	**N-Methylolmethacrylamide**
Conclusion:	Based on the above-mentioned data the substance is classified:
SCF_List:	**3**
Restriction:	**0.05 mg/kg food**
Remark for Commission:	Only a method for the determination of the residual content in dispersions is available.
Needed data or information	None

References:

- Unpublished data submitted by the petitioner on 8 June 2001, 11 August 2004, 5 October 2004 and 18 August 2005
- Opinion of the Scientific Committee on Food on an additional list of monomers and additives for food contact materials, expressed on 17/6/1999

http://europa.eu.int/comm/food/fs/sc/scf/out37_en.pdf

- Opinion of the Scientific Committee on Food on an 18th additional list of monomers and additives for food contact materials, expressed on 24/9/2002

http://europa.eu.int/comm/food/fs/sc/scf/out140_en.pdf

Ref. No.:	**62020**
Name of the substance:	**12-Hydroxystearic acid, lithium salt**
CAS number:	7620-77-1
Document reference:	SDS EFSA/AFC/FCM 551-Rev.0A/62020 of November 2005

General information: According to the petitioner 12-hydroxystearic acid, lithium salt is intended to be used as a dispersion agent in polymers, mainly polyolefins. The lithium salt is prepared from 12-hydroxystearic acid derived from castor oil. The maximum amount added to the polymer is 0.15% w/w.

Previous evaluations (by SCF or AFC): None

Available data used for this evaluation:

Non-toxicity data:

- Data on identity
- Data on physical/chemical properties
- Data on use
- Data on authorisation
- Data on migration
- Data on residual content of substance

Ref. No.:	62020
Name of the substance:	12-Hydroxystearic acid, lithium salt

Toxicity data: None

Evaluation:

A polyolefin sample containing 0.15% w/w 12-hydroxystearic acid, lithium salt was submitted to migration testing with 3% acetic acid, 10% ethanol and olive oil (10 d at 40°C and 2h at 120°C). Migration of lithium was determined by atomic absorption spectrometry (AAS). Specific migration of lithium was found to be <0.020 mg/kg into the 3% acetic acid and 10% ethanol and <0.011 mg/kg into olive oil for both time-temperature conditions.

Both components of 12-hydroxystearic acid, lithium salt, namely 12-hydroxystearic acid as well as the cation lithium, are already listed in Directive 2002/72/EC. The 12-hydroxystearic acid is listed without a specific migration limit (SML). Lithium salts are listed with a group SML of 0.6 mg/kg food.

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

SCF_List: **3**

Restriction: **In accordance with other lithium compounds this will be subject to a group SML of 0.6 mg Li/kg food**

Remark for Commission: None

Needed data or information: None

References:

- Unpublished data submitted by the petitioner on 1 September 2005
- Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs

http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72_en.pdf

Ref. No.:	79920
Name of the substance:	Poly(ethylene propylene) glycol

CAS number: 009003-11-6 and 106392-12-5

Document reference: *EFSA/AFC/FCM/126-Rev.IA/79920 of November 2005*

General information:

According to the petitioner, poly(ethylene propylene) glycols are a family of polymeric additives intended for use as plasticizers and internal lubricants in all kinds of plastics in amounts up to 2%, for all type of foodstuffs and with no restrictions with respect to time.

Ref. No.:	79920
Name of the substance:	Poly(ethylene propylene) glycol

and temperature conditions.

Previous evaluations (by SCF or AFC): None

Available data used for this evaluation:

Non-toxicity data:
- Data on identity, physical and chemical properties, intended use and authorization of the substance
- Data on molecular weight distribution of reference substances
- Data on migration
- Analytical method to determine the content in polymers

Toxicity data:
- several studies with a variety of poly(ethylene propylene)glycols on gene mutation in bacteria;
- *in vitro* mammalian gene mutation tests;
- *in vitro* mammalian chromosome aberration tests;
- *in vivo* micronucleus test;
- *in vivo* sister chromatoid exchange (SCE) test ;
- germ cell mutation test in *Drosophila melanogaster* ;
- a subchronic oral rat study for a Poly(ethylene propylene)glycol with a weight averaged molecular weight of 11500 D.
- toxicokinetic studies in rats and dogs;

Evaluation:

Two reference substances were used by the petitioner:

A. Poly(ethylenepropylene) glycol (ca 20 % Ethylene glycol) with a weight averaged molecular weight (MW) of 2980 D and a Low Molecular Weight fraction (<1000 D) of 5.9% and

B. Poly(ethylene propylene) glycol (ca 80 % Ethylene glycol) with a weight averaged molecular weight (MW) of 8073 D and a Low Molecular Weight fraction (<1000 D) of 0.11%.

The migration of the low molecular weight fraction for 10d at 40°C was estimated by migration modelling to be 18.1 mg/kg food for a sample of LDPE containing 2% w/w of the reference substance A.

Two analytical methods were provided, one for the determination of the migration of the substance in food simulants and the other to determine the content in the polymer.

Data on numerous genotoxicity studies were provided. The studies on poly(ethylene propylene)glycols with a MW 3000 D - 5000 D showed an equivocal potential for the induction of gene mutations in bacteria and in mammalian cells *in vitro*, but no clastogenic potential was observed under the used *in vitro* test conditions. Two *in vivo* genotoxicity tests gave negative results (*Drosophila*

Ref. No.:	79920
Name of the substance:	Poly(ethylene propylene) glycol

melanogaster germ cell mutation assay and SCE assay in Chinese hamster bone marrow cells). In an additional study in mice, a poly(ethylene propylene)glycol with a MW of 2400 D had no clastogenic activity, but the study was performed without concomitant positive controls. A poly(ethylene propylene) glycol considered as worst case substance for the toxicity studies (with 10 % ethylene glycol, a MW of 1730 D and a low molecular weight fraction 26.8% <1000 D) was not mutagenic in bacteria or mammalian cells and was not clastogenic in mammalian cells. Based on these three adequately performed *in vitro* genotoxicity tests it is concluded that poly(ethylene propylene) glycols have no genotoxic potential.

A subchronic drinking water study with a high molecular weight poly(ethylene propylene) glycol (MW 11500 D; 70% ethylene glycol) gave no treatment-related effects in rats. The NOAEL in this study was 15000 ppm corresponding to about 1140 mg/kg bw/d in male and 1560 mg/kg bw/d in female rats. Toxicokinetic data for the reference substance A (MW 2980) in dogs indicate that a substantial portion of the substance was absorbed from the digestive tract and excreted via urine.

The substance is a block co-polymer of ethylene- and propylene-glycol. Polyethyleneglycol (REF No 23590) and polypropyleneglycol (REF No 23651) have been evaluated by the SCF (SCF, 1999) for use in food contact materials and classified in List 2, with a TDI of 5 mg/kg bw and List 3, as "toxicologically acceptable" respectively.

Conclusion: Based on the above-mentioned data and on the existing evaluation of the homopolymers the substance is classified:

SCF_List: **3**

Restriction: **None**

Remark for Commission: None

Needed data or information: None

References:

- Unpublished data submitted by the petitioner dated July 2003 and August 2005
- M.L Wilcox et al. (1978) A study of labeled Pluronic F-68 after intravenous injection into the dog. J. Surg. Res., 349-356
- SCF report, 42nd series, compilation of the evaluations of the Scientific Committee for Food on certain monomers and other starting substances to be used in the manufacture of plastic materials and articles intended to come into contact with

Ref. No.:	**79920**
Name of the substance:	**Poly(ethylene propylene) glycol**

foodstuffs until 21 March 1997, 1999.
http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_42.pdf

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List of abbreviations:

AAS	Atomic Absorption Spectrometry
bw	Body weight
D	Dalton
MW	Molecular weight
NOAEL	No observed adverse effect level
SML	Specific migration limit
TDI	Tolerable daily intake

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.

Depending on the available toxicological studies a restriction of migration into food of 0.05 mg/kg of food (3 mutagenicity studies only) or 5 mg/kg of food (3 mutagenicity studies plus 90-day oral toxicity study and data to demonstrate the absence of potential for bio-accumulation in man) may be allocated.

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.