

## **20<sup>th</sup> list of substances for food contact materials<sup>1</sup>**

### **Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF)**

#### **Question N°**

**EFSA-Q-2008-030, EFSA-Q-2006-183, EFSA-Q-2006-171,  
EFSA-Q-2007-013, EFSA-Q-2006-139, EFSA-Q-2007-019**

**Adopted on 25 September 2008**

*This scientific output, published on 9 June, 2017 replaces the earlier version published on 9 October 2008<sup>2</sup>*

#### **PANEL MEMBERS\***

Arturo Anadón, David Bell, Mona-Lise Binderup, Wilfried Bursch, Laurence Castle, Riccardo Crebelli, Karl-Heinz Engel, Roland Franz, Nathalie Gontard, Thomas Haertlé, Trine Husøy, Klaus-Dieter Jany, Catherine Leclercq, Jean-Claude Lhuguenot, Wim Mennes, Maria Rosaria Milana, Karla Pfaff, Kettil Svensson, Fidel Toldrá, Rosemary Waring, Detlef Wölfle.

#### **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 CEF Panel evaluated the following substances:

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<sup>1</sup> For citation purposes: Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF) on a 20<sup>th</sup> list of substances for food contact materials. *The EFSA Journal* (2008) 816-821, 1-20.

<sup>2</sup> The CAS number allocated to the substance “poly(3-nonyl-1,1-dioxo-1-thiopropene-1,3-diyl)-block-poly(x-oley1-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x=1 and/ or 5, neutralised with dodecylbenzenesulfonic acid” with the Ref. No. 80510 was deleted in the “Summary”, “Keywords” and “Assessment” as it is incorrect. No CAS number is available for this substance.

EFSA Question Number: EFSA-Q-2008-030  
Ref. No.: 30607  
Name of the substance: Acids, C2-C24, aliphatic, linear, monocarboxylic, from natural oils and fats, lithium salt  
CAS number: -  
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

EFSA Question Number: EFSA-Q-2006-183  
Ref. No.: 33105  
Name of the substance: Alcohols, C12-14 secondary, beta-(2-hydroxyethoxy), ethoxylated  
CAS number: 146340-15-0  
SCF\_List: 3  
Restriction: 5 mg/kg food  
Remark for Commission: The restriction may be exceeded in polyolephines

EFSA Question Number: EFSA-Q-2006-171  
Ref. No.: 33535  
Name of the substance: alpha-Alkenes(C20-C24) maleic anhydride-4-amino-2,2,6,6-tetramethylpiperidine, polymer  
CAS number: 152261-33-1  
SCF\_List: 3  
Restriction: Not for contact with fatty or alcoholic foods  
Remark for Commission: No method for specific migration – only a method for determination of the content in polymer and a method for determination of the starting substances in food simulants are available.

EFSA Question Number: EFSA-Q-2007-013  
Ref. No.: 80510  
Name of the substance: Poly(3-nonyl-1,1-dioxo-1-thiopropene-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x=1 and/ or 5, neutralised with dodecylbenzenesulfonic acid  
CAS number: -  
SCF\_List: 3  
Restriction: Only to be used as a polymerization production aid in PE, PP and PS  
Remark for Commission: None

EFSA Question Number: EFSA-Q-2006-139  
Ref. No.: 81870  
Name of the substance: N,N''-1,3-propanediylbis(N'-octadecylurea)  
CAS number: 35674-65-8  
SCF\_List: 3  
Restriction: 0.05 mg/kg food

Remark for Commission: None

EFSA Question Number: EFSA-Q-2007-019

Ref. No.: 93450

Name of the substance: Titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt]

CAS number: 5283-66-9 for octyltrichlorosilane, 2235-43-0 for aminotris(methylenephosphonic acid), penta sodium salt and 13463-67-7 for titanium dioxide

SCF\_List: 3

Restriction: Specification: Content of the surface treatment copolymer of the coated titanium dioxide less than 1% w/w

Remark for Commission: None

## KEYWORDS

Food Contact Materials, Plastics, Additives, Ref. No. 30607, Acids, C2-C24, aliphatic, linear, monocarboxylic, from natural oils and fats, lithium salt; Ref. No. 33105, CAS number 146340-15-0, Alcohols, C12-14 secondary, beta-(2-hydroxyethoxy), ethoxylated; Ref. No. 33535, CAS number 152261-33-1, alpha-Alkenes(C20-C24) maleic anhydride-4-amino-2,2,6,6-tetramethylpiperidine, polymer; Ref. No. 80510, Poly(3-nonyl-1,1-dioxo-1-thiopropene-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x=1 and/ or 5, neutralised with dodecylbenzenesulfonic acid; Ref. No. 81870, CAS number 35674-65-8, N,N'-1,3-propanediylbis(N'-octadecylurea); Ref. No. 93450, CAS number 5283-66-9 for octyltrichlorosilane, CAS number 2235-43-0 for aminotris(methylenephosphonic acid), penta sodium salt, CAS number 13463-67-7 for titanium dioxide, Titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt].

## **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<sup>3</sup>.

## **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.

## **ACKNOWLEDGEMENTS\***

The European Food Safety Authority wishes to thank Herman Autrup, Mona-Lise Binderup, Laurence Castle, Riccardo Crebelli, Wolfgang Dekant, Roland Franz, Nathalie Gontard, Sander Koster, Eugenia Lampi, Jean-Claude Lhuguenot, François Xavier Malcata, Maria Rosaria Milana, Karla Pfaff, Tjoena Siere, Linda Stolker, Paul Tobback, Detlef Wölfle and Esther Zondervan for their contribution to the draft opinion.

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\* Sander Koster and Esther Zondervan declared an interest for the substances Ref. No. 91530, 91815 as their Institute had submitted the petition on behalf of the industry. This was considered as a conflict of interest. They left the room during the discussion. Linda Stolker declared an interest for the substances Ref. No. 81870 as her Institute had filed the dossier on behalf of industry. This was considered as a conflict of interest. She left the room during the discussion.

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<sup>3</sup> This Regulation replaces Directive 89/109/EEC of 21 December 1988, OJ L 40, 11.2.1989, P.38

## 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.

The studies submitted for evaluation followed the SCF guidelines for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation ([http://ec.europa.eu/food/fs/sc/scf/out82\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out82_en.pdf)).

<b>EFSA Question Number:</b>	<b>EFSA-Q-2008-030</b>
<b>Ref. No.:</b>	<b>30607</b>
<b>Name of the substance:</b>	<b>Acids, C2-C24, aliphatic, linear, monocarboxylic, from natural oils and fats, lithium salt</b>

CAS number:

-

Document reference:

SDS EFSA/CEF/FCM/1239-Rev.0B/30607 of September 2008

**General information:**

According to the petitioner, acids, C2-C24, aliphatic, linear, monocarboxylic, from natural oils and fats, lithium salt is used as dispersion agent in all types of polymers mainly polyolefins in amounts up to 0.15%. These polymers are intended for contact with any type of food for short time at high temperatures and for long time storage at and below room temperature.

**Previous evaluations (by SCF or CEF):**

None (new substance)

**Available data**

**used for this evaluation:**

Non-toxicity data:

- Data on identity
- Data on physical and chemical properties
- Data on intended use and authorisation of the substance
- Data on migration
- Data on residual content of the substance
- Data on analytical method for the specific migration and residual

<b>EFSA Question Number:</b>	<b>EFSA-Q-2008-030</b>
<b>Ref. No.:</b>	<b>30607</b>
<b>Name of the substance:</b>	<b>Acids, C2-C24, aliphatic, linear, monocarboxylic, from natural oils and fats, lithium salt</b>

content

**Toxicity data:** None on the substance as such. However the cation lithium and the acids C2-C24 aliphatic, linear, monocarboxylic from natural oils and fats are already authorised for the manufacture of plastics in contact with food (EC, 2002).

**Evaluation:** Migration of lithium into 3% acetic acid, 10% ethanol and olive oil was tested with a random polypropylene copolymer containing the maximum intended concentration of the substance at 100°C for 2 hours and at 40°C for 10 days. In all test conditions migration was below the limit of quantification < 9.7 µg/6 dm<sup>2</sup> in aqueous simulants and < 3.8 µg/6 dm<sup>2</sup> in olive oil.

Both components of the substance namely acids, C2-C24, aliphatic, linear, monocarboxylic, from natural oils and fats (Ref N° 30610) as well as the cation lithium (Ref N° 24886, 38000, 42400, 62020, 64320, 67896, 73040, 85760, 85840, 85920, 95725) are already authorized and listed in Directive 2002/72/EC (EC, 2002).

The substance acids, C2-C24, aliphatic, linear, monocarboxylic, from natural oils and fats is listed without any specific migration limit (SML). Lithium salts are listed with a group SML of 0.6 mg/kg food (expressed as lithium).

**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 in November 2007
- EC (European Commission), 2002. Commission Directive 2002/72/EC, 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](http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72_en.pdf)

<b>EFSA Question Number:</b>	<b>EFSA-Q-2006-183</b>
<b>Ref. No.:</b>	<b>33105</b>
<b>Name of the substance:</b>	<b>Alcohols, C12-14 secondary, beta-(2-hydroxyethoxy), ethoxylated</b>

CAS number: 146340-15-0

Document reference: SDS EFSA/CEF/FCM/1140-Rev.IC/33105 of September 2008

**General information:** According to the petitioner alcohols, C12-14 secondary, beta-(2-hydroxyethoxy), ethoxylated are intended to be used as emulsifiers in emulsion polymerisation reactions.

The use of the substance may result in concentrations of up to 3% for PVC and 0.1% w/w for other polymers. The materials and articles made from these polymers are intended to come into contact with all types of foods.

**Previous evaluations (by SCF or AFC):** The substance was evaluated by the EFSA on 1<sup>st</sup> October 2003 and was classified in List 7 with the request for further information (EFSA, 2003).

**Available data used for this evaluation:**

- Non-toxicity data:
- Data on identity
  - Data on physical and chemical properties
  - Data on intended use and authorisation
  - Data on migration
  - Data on residual content of the substance

- Toxicity data:
- Gene mutation in bacteria test
  - *In vitro* mammalian cells gene mutations test
  - *In vivo* mouse bone marrow micronucleus test
  - 90-day oral toxicity study in rats

<b>EFSA Question Number:</b>	<b>EFSA-Q-2006-183</b>
<b>Ref. No.:</b>	<b>33105</b>
<b>Name of the substance:</b>	<b>Alcohols, C12-14 secondary, beta-(2-hydroxyethoxy), ethoxylated</b>

**Evaluation:**

The substance consists of a mixture of alcohols, C12-14 secondary, beta-(2-hydroxyethoxy), ethoxylated and their corresponding dimers. The number average and weight average molecular weight values are 625 and 675 Da respectively. The mass fraction of the substance with a molecular weight below 1000 Da is 90%.

The substance is stable thermally in the intended conditions of PVC production (up to 200°C).

Specific migration was tested from rigid PVC plates, containing 1% of the substance. Migration was 0.08 mg/kg into water (24hr, 90°C), 0.15 mg/kg in 50% ethanol (24hr, 49°C) and 0.1 mg/kg into heptane (24 hr, 49°C). Mathematical modeling predicted a migration at a similar level of 0.1 mg/kg, which was in agreement with experimental data.

Mathematical modeling was then applied to low density polyethylene (LDPE) containing 0.1% of the substance. A migration of 12.3 mg substance /kg food was predicted (10 days at 40°C).

The substance had no mutagenic activity in bacteria. The results from a mammalian mutation assay using Chinese Hamster V79 cells were negative with metabolic activation and equivocal without metabolic activation. In a limited mouse lymphoma cell assay without extended treatment time without S9, the test substance had no mutagenic effects. In an *in vivo* micronucleus assay, the substance had no clastogenic or aneugenic effects. Based on the weight of the experimental evidence the substance is considered as non-genotoxic.

In a 90-day oral rat study, a lowest-observed-effect-level (LOEL) of 30 mg/kg bw/day was derived from reversible histopathological effects on the forestomach (hyperkeratosis, epithelial infiltrates and ulcerations) in males only.

Due to the high solubility in water, accumulation in man is not expected.

**Conclusion:**

Based on the above-mentioned data the substance is classified

**SCF list:** 3

**Restriction:** 5 mg/kg food

Needed data or information

None

**Remark for Commission:**

The restriction may be exceeded in polyolephines

<b>EFSA Question Number:</b>	<b>EFSA-Q-2006-183</b>
<b>Ref. No.:</b>	<b>33105</b>
<b>Name of the substance:</b>	<b>Alcohols, C12-14 secondary, beta-(2-hydroxyethoxy), ethoxylated</b>

References

- Unpublished data submitted by the petitioner in 2002, 2006 and 2007
- EFSA, (European Food safety Authority), 2003. 1<sup>st</sup> list of substances for food contact materials - Scientific Opinion of the Panel on food additives, flavourings, processing aids and materials in contact with food (AFC); *the EFSA Journal* (2003) 3, 1-9; [http://www.efsa.europa.eu/cs/BlobServer/Scientific\\_Opinion/opinion\\_afc\\_01\\_en1.pdf?ssbinary=true](http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/opinion_afc_01_en1.pdf?ssbinary=true)

<b>EFSA Question Number:</b>	<b>EFSA-Q-2006-171</b>
<b>Ref. No.:</b>	<b>33535</b>
<b>Name of the substance:</b>	<b>alpha-Alkenes(C20-C24) maleic anhydride-4-amino-2,2,6,6-tetramethylpiperidine, polymer</b>

CAS number: 152261-33-1  
Document reference: EFSA/CEF/FCM/853-Rev.IC/33535 of September 2008

**General information:** According to the petitioner alpha-alkenes(C20-C24) maleic anhydride-4-amino-2,2,6,6-tetramethylpiperidine, polymer is intended to be used as a UV light stabilizer in plastics intended to come into contact with all types of aqueous foodstuffs. Maximum percentage in formulation is 0.3%.

**Previous evaluations (by SCF or CEF):** None (new substance)

**Available data**

**used for this evaluation:**

Non-toxicity data:

- Data on identity
- Data on physical and chemical properties
- Data on intended use and authorisation
- Data on migration of the two starting substances
- Data on residual content of the substance

Toxicity data: alpha-Alkenes(C20-C24)maleicanhydride-4-amino-2,2,6,6-tetramethylpiperidine, polymer

- Gene mutation in bacteria test
- *In vitro* mammalian cells gene mutations test
- *In vitro* chromosomal aberrations in cultured mammalian cells test
- *In vivo* micronucleus test in mice
- 90-days oral toxicity test in rats

4-Amino-2,2,6,6-tetramethylpiperidine (unintentional contaminant)

<b>EFSA Question Number:</b>	<b>EFSA-Q-2006-171</b>
<b>Ref. No.:</b>	<b>33535</b>
<b>Name of the substance:</b>	<b>alpha-Alkenes(C20-C24) maleic anhydride-4-amino-2,2,6,6-tetramethylpiperidine, polymer</b>

from the synthesis)

- Gene mutation in bacteria test
- *In vitro* mammalian cells gene mutations test
- *In vitro* chromosomal aberrations in cultured mammalian cells test
- 90-days oral toxicity test in rats

**Evaluation:**

alpha-Alkenes(C20-C24) maleic anhydride-4-amino-2,2,6,6-tetramethylpiperidine has a weight average molecular weight ( $M_w$ ) of 16000 Da and a number average molecular weight ( $M_n$ ) of 2000 Da and the fraction with molecular weight below 1000 Da is approximately 5.7%. This low molecular weight fraction mainly consists of residual starting substances  $\alpha$ -alkenes (C20-C24) and 4-amino-2,2,6,6-tetramethylpiperidine.

Specific migration of the high molecular weight substance was not determined experimentally as this was considered not relevant taking into account the high molecular weight and the poor solubility in aqueous foods.

Migration of the low molecular weight oligomeric fraction of the substance from a sample of Low Density Polyethylene (LDPE) containing 0.3% was estimated to be less than 0.001 mg/kg into 10% ethanol and water by using migration modeling.

Migration of the two chemicals used to make the substance and present as impurities, was measured from the same LDPE sample in 3% acetic acid and 10% ethanol. There was no detectable migration of alpha-alkenes (C20-C24), at a detection limit of 0.025 mg/kg.

The migration of 4-amino-2,2,6,6-tetramethylpiperidin in 3% acetic acid was not detectable at a detection limit of 0.01 mg/kg; its migration in 10% ethanol (10 days; 40<sup>0</sup> C) was up to 0.85 mg/kg with continuous increasing of migration until the 10<sup>th</sup> day of the test which may indicate instability of the parent substance when the material is in contact with alcoholic media.

alpha-Alkenes(C20-C24)maleic anhydride-4-amino-2,2,6,6-tetramethyl-piperidine, polymer did not show mutagenic potential in bacteria and in mammalian cells *in vitro*. In the *in vitro* chromosome aberration test in V79 Chinese hamster cells a positive effect on chromosome aberrations was reported at the highest concentration tested with S9 mix. However in an *in vivo* micronucleus test, no clastogenic or aneugenic potential of the substance could be observed. Therefore the substance is considered as non-genotoxic.

An oral 90-day toxicity study in rats has been performed. The dietary levels used were up to 15000 mg/kg diet. No treatment related changes

<b>EFSA Question Number:</b>	<b>EFSA-Q-2006-171</b>
<b>Ref. No.:</b>	<b>33535</b>
<b>Name of the substance:</b>	<b>alpha-Alkenes(C20-C24) maleic anhydride-4-amino-2,2,6,6-tetramethylpiperidine, polymer</b>

were seen at clinical examinations and in haematological, clinical biochemical and urine analysis parameters; and no adverse effects were observed on necropsy and histopathological examinations. The no observed adverse effect level (NOAEL) was considered to be 15000 mg/kg diet, the highest dose tested, equivalent to 1060 mg/kg bw/day in males and 1214 mg/kg bw/day in females.

4-Amino-2,2,6,6-tetramethylpiperidine did not show mutagenic activity in bacteria and in mammalian cells *in vitro*, and did not induced chromosome aberrations in mammalian cells *in vitro*. In an oral 90-day toxicity study in rats using dietary levels up to 5000 mg/kg diet, the no observed adverse effect level (NOAEL) was 500 mg/kg diet equal to 36 mg/kg bw/day in males and 42 mg/kg bw/day in females.

The Panel recognised that due to steric hindrance effects, N-nitrosation at the ring nitrogen atom of 4-amino-2,2,6,6-tetramethylpiperidine is inhibited and thus not of concern.

**Conclusion:** Based on the above-mentioned data the substance is classified:  
**SCF\_List:** 3  
**Restriction:** **Not for contact with fatty or alcoholic foods**  
**Remark for Commission:** No method for specific migration – only a method for determination of the content in polymer and a method for determination of the starting substances in food simulants are available.  
**Needed data or information:** None

**References:**

- Unpublished data submitted by petitioner in September 2006 and October 2007
- González-Mancebo, S., Calle, E., Garcí'a-Santos, M.-P. and Casado, J. 1997. Inhibition of Nitrosation by Steric Hindrance. *Journal of agricultural Food Chemistry* 1997, 45, 334-336.

<b>EFSA Question Number:</b>	<b>EFSA-Q-2007-013</b>
<b>Ref. No.:</b>	<b>80510</b>
<b>Name of the substance:</b>	<b>Poly(3-nonyl-1,1-dioxo-1-thiopropene-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x=1 and/ or 5, neutralised with dodecylbenzenesulfonic acid</b>

CAS number: -

Document reference: SDS EFSA/CEF/FCM/1091-Rev.IB/80510 of September 2008

**General information:** According to the petitioner, Poly(3-nonyl-1,1-dioxo-1-thiopropene-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x=1 and/ or 5, neutralised with dodecylbenzenesulfonic acid is used as an antistatic agent into the polymerisation process to produce food contact plastics (polystyrene (PS), polypropylene (PP) and polyethylene (PE)). It improves the yield of the process and throughput rates. The substance has no technical function in the final food contact material. Its use may give rise to a maximum concentration level of 4.5 mg/kg plastic. The finished materials are intended to be used in contact with all types of foods in any condition of time-temperature.

**Previous evaluations (by SCF or AFC):** None (new substance)

**Available data**

**used for this evaluation:**

- Non-toxicity data:
- Data on identity
  - Data on physical and chemical properties
  - Data on intended use and authorisation
  - Data on worst case migration
  - Data on actual content

- Toxicity data: For oleyl propylene diamine:
- Gene mutation in bacteria test
  - *In vitro* mammalian cells gene mutation test
  - *In vitro* chromosomal aberrations in cultured mammalian cells

<b>EFSA Question Number:</b>	<b>EFSA-Q-2007-013</b>
<b>Ref. No.:</b>	<b>80510</b>
<b>Name of the substance:</b>	<b>Poly(3-nonyl-1,1-dioxo-1-thiopropane-1,3-diyl)-block-poly(x-oley-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x=1 and/ or 5, neutralised with dodecylbenzenesulfonic acid</b>

**SCF\_List:** 3

**Restriction:** Only to be used as a polymerization production aid in PE, PP and PS

Remark for Commission: None

Needed data or information: None

- References:**
- Unpublished data submitted by the petitioner in January 2007 and in March 2008
  - EC (European Commission), 2002. Commission Directive 2002/72/EC, relating to plastic materials and articles intended to come into contact with foodstuffs  
[http://www.itc.gov.hk/en/quality/psis/doc/psis/app/app\\_0206.pdf](http://www.itc.gov.hk/en/quality/psis/doc/psis/app/app_0206.pdf)

<b>EFSA Question Number:</b>	<b>EFSA-Q-2006-139</b>
<b>Ref. No.:</b>	<b>81870</b>
<b>Name of the substance:</b>	<b>N,N''-1,3-propanediylbis(N'-octadecylurea)</b>

CAS number: 35674-65-8

Document reference: EFSA/CEF/FCM/849-Rev.IB/81870 of September 2008

**General information:** According to the petitioner, N,N''-1,3-propanediylbis(N'-octadecylurea) is a component of defoamer formulations. It is intended for water based coatings to be applied on metal substrates and for water based printing inks. Coatings may contain up to 0.003% (based on wet coating) equivalent to about 0.009% in the final dry coating. Coated metal substrates are intended for contact with any type of food. Typical applications are for beer and beverage cans, dairy products, chocolate... These foods are stored at temperatures ranging from -20°C to +35°C for very long times.

**Previous evaluations (by SCF or AFC):** None (new substance)

**Available data**

**used for this evaluation:**

- Non-toxicity data:
- Data on identity and purity
  - Data on physical and chemical properties
  - Data on the intended use and authorisation of the substance

<b>EFSA Question Number:</b>	<b>EFSA-Q-2006-139</b>
<b>Ref. No.:</b>	<b>81870</b>
<b>Name of the substance:</b>	<b>N,N''-1,3-propanediylbis(N'-octadecylurea)</b>

- Data on migration of the substance
- Data on residual content in finished coating

- Toxicity data:
- Gene mutation in bacteria test
  - *In vitro* chromosomal aberrations in cultured mammalian cells test
  - *In vitro* mammalian cells gene mutations test

**Evaluation:** The substance is highly lipophilic. It is insoluble in aqueous media and slightly soluble in olive oil.

For migration testing a typical coating containing 0.0018% of the substance was tested for 10 days at 40°C. The sample had a thickness of 3.6 µm and contained around 11 µg substance/6 dm<sup>2</sup>. Migration was found to be non-detectable in 3% acetic acid and 10% ethanol, and 0.7 µg/kg olive oil. From the data on this sample, it can be concluded that migration from a sample containing the substance at the maximum intended level will be less than 1.2 µg/kg food simulant.

N,N''-1,3-propanediylbis(N'-octadecylurea) did not induce mutagenicity in bacteria and mammalian cells and did not induce chromosome aberrations in mammalian cells. The substance is therefore considered as non-genotoxic.

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

**SCF\_List:** 3

**Restriction:** 0.05 mg/kg food

Remark for Commission: None

Needed data or information: None

**References:** Unpublished data submitted by petitioner in September 2006 and in October 2007

<b>EFSA Question Number:</b>	<b>EFSA-Q-2007-019</b>
<b>Ref. No.:</b>	<b>93450</b>
<b>Name of the substance:</b>	<b>Titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt]</b>

CAS number: 5283-66-9 for octyltrichlorosilane  
2235-43-0 for aminotris(methylenephosphonic acid), penta sodium salt  
13463-67-7 for titanium dioxide

Document reference: EFSA/CEF/FCM/1042-Rev.IB/93450 of September 2008

**General information:** According to the petitioner, the substance is intended to be used as filler and colorant in plastics intended to come into contact with all types of foodstuffs. The surface treatment results in better compatibility of the titanium dioxide with the plastic. Coated titanium dioxide contains a maximum of 1% w/w of surface treatment polymer. The maximum percentage of additive in plastics is 6%, so the maximum percentage of surface treatment polymer in plastics is 0.06% w/w.

**Previous evaluations (by SCF or AFC):** None (new substance)

**Available data used for this evaluation:**

- Non-toxicity data:
- Data on identity
  - Data on physical and chemical properties
  - Data on use and authorisation
  - Data on migration of the substance and its monomers
  - Data on residual content of the substance

- Toxicity data: For surface coated titanium dioxide covered by the application:
- Gene mutation in bacteria test
  - *In vitro* mammalian cells gene mutations test
  - *In vitro* chromosomal aberrations in cultured mammalian cells test
- For one of the starting compounds of the surface treatment copolymer (aminotris(methylenephosphonic acid), penta sodium salt)
- Gene mutation in bacteria test
  - *In vivo* mouse bone marrow micronucleus test

**Evaluation:** The surface treated titanium dioxide is made from titanium dioxide (TiO<sub>2</sub>) and two monomers octyltrichlorosilane and aminotris(methylenephosphonic acid), penta sodium salt. TiO<sub>2</sub> (Ref N° 93440) is already assessed, authorized and listed in Directive 2002/72/EC (EC, 2002).

<b>EFSA Question Number:</b>	<b>EFSA-Q-2007-019</b>
<b>Ref. No.:</b>	<b>93450</b>
<b>Name of the substance:</b>	<b>Titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt]</b>

Based on the insolubility of the TiO<sub>2</sub> and the increased compatibility of the coated TiO<sub>2</sub> with the plastic matrix due to the surface treatment, the substance is not expected to migrate in foods. Therefore the evaluation is focused on the organic coating.

The fraction of the surface treatment polymer below weight average molecular weight (Mw) 1000 Da is 3.6 % w/w. The log Po/w is 4.97. The amount of oligomers with Mw<1000 Da was 8 mg/kg coated titanium dioxide.

No residual amount of the starting monomer, aminotris(methylenephosphonic acid), penta sodium salt, was found at the detection limit of 0.34 mg/kg treated TiO<sub>2</sub>. Assuming its presence at the limit of detection, the potential worst case migration of this monomer was calculated to be less than 0.3 µg/kg food.

The other starting monomer, n-octylchlorosilane was considered that it cannot survive in the conditions of the manufacturing process. However, assuming that the entire fraction of extractable <750 Da is n-octylchlorosilane, the worst case migration in foods would be 1.2 µg/kg.

Surface coated titanium dioxide was negative in the requested 3 *in vitro* genotoxicity tests and thus is considered as non-genotoxic. However, it was noted that the substance contained only 8 mg/kg of oligomers with molecular mass less than 1000 Da.

An *in vivo* micronucleus assay on one of the starting substances of the copolymer, aminotris(methylenephosphonic acid), penta sodium salt was negative. It did not induce mutations in bacteria in a recent bacterial mutagenicity test. Thus, this starting substance is considered as non-genotoxic.

Data on the other starting substance of the polymer, N-octyltrichlorosilane, were not available. However, they are not considered relevant since the substance is highly reactive polymerising to known octylsiloxanes and it is not expected to be present in the finished coating neither in food.

**Conclusion:**

Based on the above-mentioned data the substance is classified

**SCF\_List:** 3

**Restriction:** **Specification: Content of the surface treatment copolymer of the coated titanium dioxide less than 1% w/w**

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Remark for Commission: None

Needed data or

information

**References:**

- Unpublished data received from the petitioner in January 2007 and February 2008
- EC (European Commission), 2002. Commission Directive 2002/72/EC, 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](http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72_en.pdf)

## APPENDIX

### DEFINITION OF THE SCF LISTS

The classification into a SCF\_List is a tool used for tackling authorisation dossiers and do not prejudice the management decisions that will be taken on the basis of the scientific opinions of the AFC Panel and in the framework of the applicable legislation

- 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.

**Term used relevant to migration:**

Overall migration (OM): The sum of the amounts of volatile and non volatile substances, except water, released from a food contact material or article into food or food simulant

Specific migration: The amount of a specific substance released from a food contact material or article into food or food stimulant

**List of abbreviations:**

AFC	Scientific Panel on additives, flavourings, processing aids and materials in contact with food
ADI	Acceptable daily intake
bw	body weight
CAS	Chemical Abstracts Service
CEF	Scientific Panel on food contact materials, enzymes, flavourings and processing aids
Da	Dalton
EC	European Commission
EFSA	European Food Safety Authority
FCM	Food contact material(s)
LDPE	Low density polyethylene
Li	Lithium
LOEL	Lowest observed effect level
Mn	Number average molecular weight
MTDI	Maximum tolerable daily intake
Mw	Weight average molecular weight
NOAEL	No observed adverse effect level
PE	Polyethylene
PMTDI	Provisional maximum tolerable daily intake
PP	Polypropylene
PTWI	Provisional tolerable weekly intake
PVC	Polyvinyl chloride
PS	Polystyrene
REF N°	Reference Number
SCF	Scientific Committee on food
SML	Specific migration limit
TiO <sub>2</sub>	Titanium dioxide
TDI	Tolerable daily intake
UV	Ultra-violet
w/w	Weight by weight