

**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 3rd list of substances for food contact materials**

adopted on 15 March 2004 by written procedure

SUMMARY

Within the general task of evaluating substances intended for use in materials in contact with food 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 the following substances.

Ref. No.: 80000
Name of the substance: Polyethylene wax
CAS number: 9002-88-4
Classified in list: 3
Restriction: None

Ref. No.: 81060
Name of the substance: Polypropylene wax
CAS number: 9003-07-0
Classified in list: 3
Restriction: None

Ref. No.: 93930
Name of the substance: 2,4,4'-Trichloro-2'-hydroxydiphenyl ether (triclosan)
CAS number: 3380-34-5
Classified in list: 3
Restriction: 5 mg/kg of food

KEY WORDS

Food Contact Materials, Plastics, Monomers, Additives, Polyethylene wax, REF. No 80000, CAS No 9002-88-4, Polypropylene wax, REF. No 81060, CAS No 9003-07-0, 2,4,4'-Trichloro-2'-hydroxydiphenyl ether (triclosan), REF. No 93930, CAS No 3380-34-5

BACKGROUND

According to Article 3(3) of the Council Directive 89/109/EEC of 21 December 1988 it is necessary to consult the Scientific Committee on Food (SCF) on the risks connected with the migration of substances into food from food contact materials in which they are used. This competence was transferred to the European Food Safety Authority (EFSA) by virtue of the Regulation (EC) 178/2002. 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 three substances used as additives 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". (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 and the abbreviations used are given in the appendix.

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| Ref. No.: | 80000 |
| Name of the substance: | Polyethylene wax |

CAS number: 9002-88-4

Document reference: SDS CS/PM/3787-Rev.IA/80000(76951) of February 2004

General information: According to the petitioner polyethylene wax is used as lubricant and pigment carrier in the manufacture of all kinds of plastics.

Previous evaluations (by SCF or AFC): The substance was evaluated by SCF in 2001 and classified in List 7 and data on the characterisation of the type of PE material used in the migration test and on migration into olive oil or any other suitable fatty food simulant were requested.

Available data**used for this evaluation:**

Non-toxicity data: - migration data of low molecular weight wax components
- reduction of maximum use amount to 2% w/w

Toxicity data: - evaluation of mineral and synthetic hydrocarbons (oils and waxes) as direct food additives by SCF (SCF 1995).

Evaluation: The maximum percentage of polyethylene wax (PE-wax) in polymers is

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| Ref. No.: | 80000 |
| Name of the substance: | Polyethylene wax |

now reduced to 2% w/w.

For 3 polyethylene waxes of different manufacturers the data of the molecular weight distribution curves had been used to derive the content of the low molecular weight fraction (LWF, MW <1000) in the wax. From this, the migration of LWF from Low Density Polyethylene containing 2% w/w of PE-wax (olive oil at 10 days /40 °C) was calculated by migration modelling to be 2.563 mg/dm² corresponding to 15.4 mg/kg of food; this result can be regarded as worst case.

From a chemical point of view polyethylene wax is similar to and complies with the specifications for mineral and synthetic hydrocarbon waxes with defined specifications. For these waxes SCF allocated a group ADI of 20 mg/kg b.w. (SCF 1995, "Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks") See also substance Ref No. 95859. From this analysis, the Panel, while not adding polyethylene wax to the group ADI for mineral and synthetic hydrocarbon waxes, is reassured that polyethylene wax can safely be used in plastic materials in contact with food.

Conclusion: Based on the above-mentioned data 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.
- Opinion of the Scientific Committee on Food on the 13th additional list on monomers and additives for food contact materials (adopted on 30 May 2001)
http://europa.eu.int/comm/food/fs/sc/scf/out86_en.pdf
- Opinion on mineral and synthetic hydrocarbons (expressed on 22 September 1995)
http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_37.pdf

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| Ref. No.: | 81060 |
| Name of the substance: | Polypropylene wax |

CAS number: 009003-07-0

Document reference: SDS CS/PM/3788-Rev.IIA/81060(80765) of January 2004

General information: According to the petitioner polypropylene wax is used as lubricant and pigment carrier in the manufacture of all kinds of plastics.

Previous evaluations (by SCF or AFC): The substance was evaluated by SCF in 2001 and classified in List 7 and data on the characterisation of the type of PE material used in the migration test and on migration into olive oil or any other suitable fatty

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| Ref. No.: | 81060 |
| Name of the substance: | Polypropylene wax |

food simulant were requested.

Available data

used for this evaluation:

Non-toxicity data: - migration data of low molecular weight wax components
- reduction of maximum use amount to 2% w/w

Toxicity data: - evaluation of mineral and synthetic hydrocarbons (oils and waxes) as direct food additives by SCF (SCF 1995).

Evaluation:

The maximum percentage of polypropylene wax (PP-wax) in polymers is now reduced to 2% w/w.

The migration of the low molecular weight fraction (MW < 1000) from Low Density Polyethylene containing 2% w/w of PP-wax (olive oil at 10d/40°C) was estimated by migration modelling to be 2.691 mg/dm² corresponding to 16.1 mg/kg of food; this result can be regarded as worst case.

From a chemical point of view polypropylene wax is similar to and complies with the specifications for mineral and synthetic hydrocarbon waxes with defined specifications. For these waxes SCF allocated a group ADI of 20 mg/kg b.w (SCF 1995, "Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks"). See also substance Ref No. 95859. From this analysis, the Panel, while not adding polypropylene wax to the group ADI for mineral and synthetic hydrocarbon waxes, is reassured that polypropylene wax can safely be used in plastic materials in contact with food.

Conclusion:

Based on the above-mentioned data 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.
- Opinion of the Scientific Committee on Food on the 13th additional list on monomers and additives for food contact materials (adopted on 30 May 2001)
http://europa.eu.int/comm/food/fs/sc/scf/out86_en.pdf
- Opinion on mineral and synthetic hydrocarbons (expressed on 22 September 1995)
http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_37.pdf

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| Ref. No.: | 93930 |
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| Name of the substance: | 2,4,4'-Trichloro-2'-hydroxydiphenyl ether (triclosan) |
| CAS number: | 3380-34-5 |
| Document reference: | SDS CS/PM/3194-Rev.VE/93930, January 2004 |
| General information: | According to the petitioner, 2,4,4'-Trichloro-2'-hydroxydiphenyl ether is intended to be used to improve hygienic conditions of plastic articles (made from e.g.: PP, HDPE, PVC) coming into contact with food during holding and transportation |
| Previous evaluations (by SCF or AFC): | The substance was evaluated in 2000 (SCF, 2000) and classified in SCF_List 3 with a restriction:5 mg/kg of food with the following remark for the Commission : <ul style="list-style-type: none"> - Migration could exceed 5 mg/kg of food. - The use of this compound should not lead to lowering of hygienic standards in food handling. |
| Available data used for this evaluation: | |
| Non-toxicity data: | This aspect was previously evaluated by the SCF (SCF, 2000) |
| Microbiological data: | Data have been provided demonstrating the absence of any effect of the active substance on foods placed in contact with the packaging material. |
| Toxicity data: | This aspect was previously evaluated by the SCF (SCF, 2000) |
| Evaluation: | The spectrum of microbiological activity of the active substance shows activity against most Gram-positive and Gram-negative bacteria while <i>Pseudomonas</i> species, major spoilage organisms, are resistant. In cultured media the minimum inhibitory concentration (MIC) ranges from 0.01-5.0 mg/L for most Gram-positive bacteria and from 0.1-0.5 mg/L for Gram-negative bacteria including many food-borne pathogens. No convincing evidence exists for a potential to induce antibacterial resistance under current conditions of use from studies of this substance in its more extensive non-food-contact applications (SSC, 2002). When used in chopping boards no selection for resistant bacteria over mesophilic aerobes was noted but the sensitive population was not inhibited. Concentrations of the substance up to 100 mg/L had no clear inhibitory effect on microorganisms in food matrices, thus there is no evidence of a preservative effect on the food. When tested against non-triclosan controls, triclosan-containing articles did show antimicrobial activity. Antimicrobial efficiency was little affected by cycles of repeated washing or freeze/thawing or by prolonged storage at 40°C. |
| Conclusion: | The above-mentioned data do not affect the result of the previous evaluations |
| SCF_List: | 3 |
| Restriction: | 5 mg/kg of food |
| Remark for Commission: | <ul style="list-style-type: none"> - Migration could exceed 5 mg/kg of food - The use of this substance should not lead to a lowering of hygienic |

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| Ref. No.: | 93930 |
| Name of the substance: | 2,4,4'-Trichloro-2'-hydroxydiphenyl ether (triclosan) |

standards in food handling

- The Fat(consumption) Reduction Factor is not applicable despite log $P_{o/w} = 4.8$, because migration in aqueous simulants may be higher than 10 % of the SML allocated to this substance, i.e. 5 ppm.
- Concerning efficacy, none of the data submitted demonstrated whether there is a significant effect on microbial numbers under in-use conditions of triclosan and to what extent the substance might contribute to reducing cross contamination.
- The Panel noted that no data were submitted to demonstrate activity against common food pathogens such as *Campylobacter* spp.

Needed data or information None

References:

- 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 22/6/2000)
http://europa.eu.int/comm/food/fs/sc/scf/out62_en.pdf
- Opinion of the Scientific Steering Committee on the triclosan resistance (adopted by the SSC on 27-28/6/2002)
http://europa.eu.int/comm/food/fs/sc/ssc/out269_en.pdf
- Unpublished data submitted by the petitioner

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List of abbreviations:

QMA = maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs

SM = Specific migration

SML = Specific migration limit

MIC = Minimum inhibitory concentration

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.