SCIENTIFIC OPINION

Scientific Opinion on the safety evaluation of the substance, alkyl(C10-C21)sulphonic acid, esters with phenol, CAS No. 91082-17-6, for use in food contact materials[1]

EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF)[2,3]

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ABSTRACT

This scientific opinion of EFSA deals with the risk assessment of the additive alkyl(C10-C21)sulphonic acid, esters with phenol, CAS No. 91082-17-6, REF. No. 34240 for which the CEF Panel concluded that there is no safety concern for the consumer if the substance is not used in articles for contact with fatty foods and its migration is up to 0.05 mg/kg food.

KEY WORDS

Alkyl(C10-C21)sulphonic acid, esters with phenol; CAS number 91082-17-6; Ref. No. 34240; Food contact materials; Safety assessment; Evaluation.

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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 received a request from a competent Member State Authority for safety evaluation of a substance following a corresponding application from the industry.

The request received and the outcome of the safety evaluation is summarised below:

The Food Standards Agency, United Kingdom, requested the evaluation of the additive alkyl(C10-C21)sulphonic acid, esters with phenol with the CAS number 91082-17-6 and the European Commission reference number (REF. No.) 34240, for use as plasticizer up to 46% (w/w) in poly(vinyl chloride) (PVC) intended to be in contact with dry and aqueous foods at room temperature including long term storage and excluding fatty food contact. The dossier was submitted by the applicant, Lanxess Deutschland GmbH.

The CEF Panel concluded that there is no safety concern for the consumer if the substance is not used in articles for contact with fatty foods and its migration is up to 0.05 mg/kg food.

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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[4].

According to this procedure the industry submits applications to the Member States competent Authorities which in their turn transmit the applications to the EFSA for their evaluation. The application is supported by a technical dossier submitted by the industry following 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" (EC, 2001).

In this case, the EFSA received an application from the Food Standards Agency, United Kingdom, requesting the evaluation of the additive alkyl(C_{10}-C_{21})sulphonic acid, esters with phenol with CAS number 91082-17-6 and REF. No. 34240.

TERMS OF REFERENCE AS PROVIDED BY THE LEGISLATION

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.

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

ASSESSMENT

1. Introduction

The European Food Safety Authority was asked by the Food Standards Agency, United Kingdom, to evaluate the safety of the alkyl(C10-C21)sulphonic acid, esters with phenol with CAS number 91082-17-6 and REF. No. 34240. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2009-00733. The dossier was submitted by the applicant, Lanxess Deutschland GmbH.

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 A.

2. General information

According to the applicant, the substance is a mixture consisting mainly of mono-, di- and tri-esters, intended to be used as plasticiser up to 46 % w/w in poly(vinyl chloride) (PVC). The finished articles are intended for use in contact with dry and aqueous foods at room temperature including long term storage. Contact with fatty food is excluded.

The substance has been evaluated by the SCF in the past (EC, 1995; EC, 2003) on the basis of an application including intended use in contact with fatty food. In its last evaluation, it was classified in SCF_List 7 with the request of the following data:

- 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.

3. Data available in the dossier used for this evaluation

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 (EC, 2001).

Non-toxicity data:

- Data on identity
- Data on physical and chemical properties
- Data on intended use and authorization
- Data on migration of the substance and its impurities
- Data on worst case migration of residual content
- Data on residual content of the substance

Toxicity data:

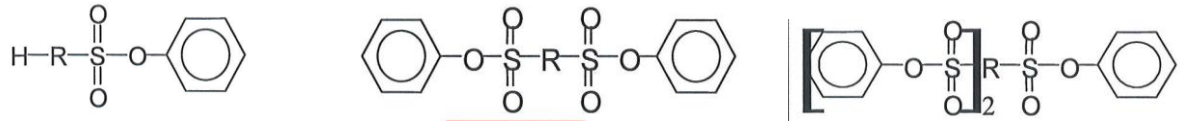
- Bacterial gene mutation test
- *In vitro* mammalian cell gene mutation test
- Two *in vitro* mammalian chromosome aberration tests
- 90-day oral toxicity study in rats
- Developmental toxicity study in rats
- One-generation study in rats
- Study on distribution in fatty and liver tissues in rats

4. Evaluation

4.1. Non-toxicological data

Molecular and structural formulae:

$C_{16}H_{26}O_3S$-$C_{27}H_{48}O_3S$ $C_{22}H_{30}O_6S_2$-$C_{33}H_{52}O_6S_2$ $C_{28}H_{34}O_9S_3$-$C_{39}H_{56}O_9S_3$



mono-ester di-ester tri-ester

The substance is a mixture in which the main components are alkyl (C10-C21)sulphonic acid, mono-, di-and tri-esters with phenol whose the molecular and structural formulae are given above. It contains also alkyl (C10-C21)sulphonic acid, tetra-ester with phenol as a minor component (< 1%). Phenol, alkanes and chloroalkanes are present as impurities.

The substance is lipophilic and stable under manufacturing and intended use conditions. Log Po/w depends on the degree of esterification and the alkyl chain length (C10-C21). It ranges from 4 to 11 for the mono-, di- and tri-alkylsulphonic esters.

The specific migration of the substance into 10 % ethanol was tested after contact up to 10 days at 40°C. Actual content of the plasticiser in migration test samples was found to be at the added maximum percentage. Migration was not detectable by HPLC-MS/MS at a detection limit corresponding to 30 µg/kg food.

Migration of the impurities alkanes and chloroalkanes was given at the same level with this of the substance itself, determined however with a high degree of uncertainty. Nevertheless, based on their low solubility in aqueous media, and the very low concentration compared to the parent substances, their migration can be expected to be lower than this of the parent substances.

Migration of phenol (Ref No 22960) which is authorised as a monomer in plastics without a restriction (EC, 2002) was less than 0.5 mg/kg food.

4.2. Toxicological data

The test substance was not mutagenic in bacteria or mammalian cells. A previous chromosome aberration study showed equivocal increases in aberrant cells in some treated cultures. However, based on results of a new, well performed, *in vitro* study, the substance did not induce chromosomal aberrations in mammalian cells. The latter results overrule the equivocal data from the previous study. Therefore, the substance was considered to be non-genotoxic.

In a previously evaluated 90-day feeding study in rats, a NOAEL of 55 mg/kg bw/day was derived based on increases in liver weights along with increased lactate dehydrogenase activities at higher doses in both sexes (EC, 1995; EC, 2003). This value is supported by a new one-generation study in rats. Based on effects in the F1 generation, i.e. reduced body weights which were associated with absolute and/or relative increases in liver and kidney weights and prolonged developmental milestones (balano-preputial separation, vaginal opening), the NOAEL in this study was approximately 68 mg/kg bw/day (based on the intake of F0 females).

In a developmental toxicity study, no teratogenic potential of the test substance was observed.

Based on limited data from a study on the distribution of the substance in fatty and liver tissues in the rat, the substance may express a potential to accumulate in man. However, considering the expected low migration level, a potential for accumulation of the substance or the migrants in man does not raise a safety concern.

Taking into account the low migration level and the opinion of the Scientific Committee on Health and Environmental Risks concluding that alkanes with 14 to 17 carbon atoms and different degrees of chlorination (medium-chained chlorinated paraffin) are non-genotoxic (EC, 2008), the Panel considered that chloroalkanes impurities do not raise safety concern.

CONCLUSIONS

The CEF Panel after having considered the above-mentioned data proposes that the substance alkyl(C10-C21)sulphonic acid, esters with phenol be classified in the SCF_List 3 with a restriction of 0.05 mg/kg food and not to be used in articles for contact with fatty foods.

DOCUMENTATION PROVIDED TO EFSA

Dossier referenced: LA13373.01. Dated: July 2009. Submitted by Lanxess Deutschland GmbH, Germany.

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APPENDICES

1. APPENDIX A

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 CEF 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.

2. APPENDIX B

TERMS USED RELEVANT TO MIGRATION:

Overall migration: 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

ABBREVIATIONS

AFC	Scientific Panel on additives, flavourings, processing aids and materials in contact with food
ADI	Acceptable daily intake
ADME	Absorption, distribution, metabolism, and excretion
BFDGE	Bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ether
BfR	German federal institute for risk assessment
BMDL	Benchmark dose lower confidence limit
bw	body weight
cSt	centistokes
CAS	Chemical abstracts service
CEF	Scientific Panel on food contact materials, enzymes, flavourings and processing aids
CHO	Chinese hamster ovary
Da	Dalton
DHB	3,4-dihydroxy-1-butene
DNA	Deoxyribonucleic acid
DEHT	Terephtalic acid, bis(2-ethylhexyl) ester
EC	European Commission
EFSA	European food safery authority
EHAc	Ethylhexanoic acid
EN	European Number
EO	Ethylene Oxide
EVOH	Ethylene vinyl alcohol
FAO	Food and Agriculture Organization of the United Nations
FCM	Food Contact Material(s)
FTIR	Fourier transform infrared spectroscopy
GC-MS	Gas chromatography coupled to high resolution mass spectrometry
GLP	Good laboratory practice
HIPS	High impact polystyrene
HPV	High production volume Challenge Program
ICP/MS spectrometry	Inductively Coupled Plasma coupled to high resolution mass
JECFA	Joint Expert Committee on Food Additives

HPLC-MS	Liquid chromatography high pressure with mass detection
LCA	Long chain alcohols
LDPE	Low density polyethylene
Li	Lithium
LLDPE	Linear low density polyethylene
LOAEL	Lowest observed adverse effect level
LOEL	Lowest observed effect level
MCH	Mean corpuscular volume
MCV	Mean corpuscular haemoglobin
Mn	Number average molecular weight
MPD	3-Methyl-1,5-pentanediol
MTDI	Maximum tolerable daily intake
MW	Molecular weight
Mw	Weight average molecular weight
NDA	Dietetic products, nutrition and allergies
NOAEL	No observed adverse effect level
OECD	Organisation for economic co-operation and development
PA	Polyamide
PAO	Polyalphaolephine
PE	Polyethylene
PET	Poly(ethylene terephthalate)
PGA	Polyglycolic acid
PMTDI	Provisional maximum tolerable daily intake
Po/w	Octanol/water partition coefficient
PP	Polypropylene
PVA	Polyvinyl alcohol
PVC	Poly(vinyl chloride)
PS	Polystyrene
REF No	Reference Number
SCCNFP	Scientific Committee for Cosmetics and Non-Food Products
SCF	Scientific Committee on food
SEC-ELSD detection	Size exclusion chromatography with evaporative light scattering
SML	Specific migration limit
TiN	Titanium Nitride

TiO_2	Titanium dioxide
TDI	Tolerable daily intake
UDS	Unscheduled DNA synthesis
US EPA	United State Environmental Protection Agency
UV	Ultra-violet
WHO	World health organisation
w/w	Weight by weight