

SCIENTIFIC OPINION

Scientific Opinion on the safety assessment of the substance, polyglycerol, CAS No 25618-55-7, for use in food contact materials¹

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)^{2, 3}

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ABSTRACT

This scientific opinion of EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids deals with the safety assessment of the additive polyglycerol with the CAS No 25618-55-7, the FCM substance No 01017 for use as plasticizer at a maximum use level of 6.5 % w/w in polymer blends of aliphatic-aromatic polyesters. Final articles are intended to be used in contact with all type of foods for any time at room temperature. Specific migration from a material containing the maximum requested concentration for polyglycerol was calculated by migration modelling to be up to 50 mg/kg food under contact conditions of 10 days at 40 °C. Polyglycerol esters were evaluated by JECFA who established an ADI of 0-25 mg/kg bw, and are listed as a food additive (E 475) at levels between 500 and 10 000 mg/kg in certain foods. Up to 7 % of free glycerol/polyglycerol is allowed in E 475 (i.e. 700 mg/kg). No accumulation of polyglycerol in body tissue was observed in an ADME study. The Panel considered that impurities and glycerol which is authorised as a food contact material substance in Regulation (EU) No 10/2011 without a specific migration limit do not raise a safety concern. The CEF Panel concluded that the substance polyglycerol does not raise a safety concern for the consumer if the substance is only to be used as plasticizer at a maximum use level of 6.5 % w/w in polymer blends of aliphatic-aromatic polyesters in contact with all type of foods for any time at room temperature and below.

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KEY WORDS

polyglycerol; polyglycerine; CAS No 25618-55-7; FCM substance No 01017; 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 the Food Standards Agency, United Kingdom, for safety evaluation of polyglycerol, following an application from Spiga Nord S.p.A. and Novamont S.p.A.

The safety assessment of polyglycerol with the CAS No 25618-55-7 and the FCM substance No 01017, was requested for use as plasticizer at a maximum use level of 6.5 % w/w in polymer blends of aliphatic-aromatic polyesters. Final articles are intended to be used in contact with all type of foods, for any time at room temperature.

The substance is a mixture of mainly linear polyols (n=1-5) with cyclic polyols as minor components. It is stable up to 275 °C which is higher than the maximum processing temperature of the intended polyesters and therefore no decomposition is expected.

Specific migration from a material containing the maximum requested concentration for polyglycerol was calculated by migration modelling to be up to 50 mg/kg food under contact conditions of 10 days at 40 °C.

JECFA evaluated in 1974 polyglycerol esters with an ADI of 0-25 mg/kg bw which are listed as a food additive (E 475) at levels between 500 and 10 000 mg/kg in certain foods. Up to 7 % of free glycerol and polyglycerol is allowed in E 475 (i.e. 700 mg/kg). In addition, no accumulation of polyglycerol in body tissue was observed in an ADME study.

The Panel considered that impurities and glycerol which is authorised as a food contact material substance in Regulation (EU) No 10/2011 without a specific migration limit do not raise a safety concern.

The CEF Panel concluded that the substance polyglycerol does not raise a safety concern for the consumer if the substance is only to be used as plasticizer at a maximum use level of 6.5 % w/w in polymer blends of aliphatic-aromatic polyesters in contact with all type of foods for any time at room temperature and below.

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BACKGROUND AS PROVIDED BY THE LEGISLATION

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 1935/2004⁴ of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure the industry submits applications to the Member States competent Authorities which in their turn transmit the applications to 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, EFSA received an application from the Food Standard Agency, United Kingdom, requesting the evaluation of the additive polyglycerol with the CAS No 25618-55-7, and the FCM substance No 01017.

TERMS OF REFERENCE AS PROVIDED BY THE LEGISLATION

EFSA is required to carry out assessment on the risks originating from the migration into food of the additive polyglycerol, intended to be used as plasticizer in polymer blends of aliphatic-aromatic polyesters, and to deliver a scientific opinion according to Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food.

⁴ 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 and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4-17.

ASSESSMENT

1. Introduction

The European Food Safety Authority was asked by the Food Standards Agency, United Kingdom, to evaluate the safety of polyglycerol with a CAS No 25618-55-7 and FCM substance No 01017. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2013-00175. The dossier was submitted on behalf of the applicants Spiga Nord S.p.A. and Novamont S.p.A.

2. General information

According to the applicants, the substance polyglycerol is intended to be used as plasticizer blends of aliphatic-aromatic polyesters at a maximum content of 6.5 % w/w. Final articles are intended to be used in contact with all food types at room temperature for a long period.

The substance has not been evaluated by the SCF or EFSA in the past.

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 authorisation
- Migration modeling of the substance

Toxicity data:

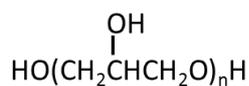
- ADME study in rats (D. Howes *et al.*, 1998)

4. Evaluation

4.1. Non-toxicological data

Chemical formulae: Mixture of substances with general formula $C_{3n}H_{6n+2}O_{2n+1}$

Chemical structure: Mixture of substances with a general structure for the linear form, shown below:



The substance is a mixture of mainly linear polyols with cyclic polyols as minor components. It has a molecular weight in the range of 92 to 758 Da. The main constituents are glycerol $\leq 10\%$, diglycerol $\geq 50\%$, triglycerol $\leq 25\%$, tetraglycerol $\leq 20\%$ and the remainder being pentaglycerol and higher oligomers. Purity is higher than 99.9%. The impurities of polyglycerol are free fatty acids and their esters linked to the production of glycerol. Glycerol is authorised as a food contact material substance in Regulation (EU) No 10/2011⁵ without a specific migration limit and as food additive E 422 (Regulation (EU) No 231/2012).⁶

The substance is freely soluble in water, ethanol and methanol and has a $\log P_{o/w}$ of -3.3. The substance is stable up to 275 °C which is higher than the maximum processing temperature of the intended polyesters and therefore no decomposition is expected.

Migration modelling was used to calculate the specific migration from a material containing the maximum requested concentration for polyglycerol of 6.5% w/w. Using worst case assumption, specific migration was calculated to be up to 50 mg/kg food under contact conditions of 10 days at 40 °C.

4.2. Toxicological data

Given that esters of polyglycerol are listed as a food additive (E 475) at levels between 500 and 10 000 mg/kg in certain foods and that up to 7% of free glycerol/polyglycerol is allowed in E 475 (i.e. 700 mg/kg), no further toxicological data are needed for polyglycerol. JECFA (1974) has evaluated polyglycerol esters with an ADI of 0-25 mg/kg bw. It is noted that polyglycerol esters are hydrolysed in the gastrointestinal tract. It has been reported that the mono-, di- and triglycerols are extensively absorbed from the intestinal tract and rapidly excreted mainly in the urine unchanged. The penta-, hexa- and higher polyglycerols are essentially not absorbed and excreted in the faeces unchanged. Based on an ADME study in rats (D. Howes *et al.*, 1998), no accumulation of polyglycerol in body tissue was observed.

Glycerol is authorised as a food contact material substance in Regulation (EU) No 10/2011 without a specific migration limit and as food additive E 422 (Regulation (EU) No 231/2012).

The Panel noted that the impurities, free fatty acids and their esters, have simple chemical structure and no structural alert for the genotoxicity. Therefore the Panel considered that the impurities do not raise a safety concern.

⁵ Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

⁶ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

CONCLUSIONS

Having considered the above-mentioned data, the CEF Panel concluded that the substance polyglycerol does not raise a safety concern for the consumer if the substance is only to be used as plasticizer at a maximum use level of 6.5 % w/w in polymer blends of aliphatic-aromatic polyesters in contact with all type of foods for any time at room temperature and below.

DOCUMENTATION PROVIDED TO EFSA

Dossier referenced: SP09632.02 and NO13320.04. Dated: January 2013. Submitted by Spiga Nord S.p.A. and Novamont S.p.A.

REFERENCES

- EC (European Commission), 2001. Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior its authorisation, 6 pp.
- JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1974. Toxicological evaluation of certain food additives with a review of general principles and of specifications, WHO Technical Report Series no 539, 42 pp.
- Howes D, Wilson R and James C T, 1998. The fate of ingested glycerine esters of condensed castor oil fatty acids [Polyglycerol polyricinoleate (PGPR)] in the rat. Food and Chemical Toxicology, 36, 719-738.

ABBREVIATIONS

ADI	Acceptable Daily Intake
ADME	Absorption, Distribution, Metabolism and Excretion
CAS	Chemical Abstract Service
CEF	Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FCM	Food Contact Materials
JECFA	Joint FAO/WHO Expert Committee on Food Additives
Po/w	Partition Coefficient octanol-water
SCF	Scientific Committee on Food
SML	Specific Migration Limit