SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 27 September 2018

doi: 10.2903/j.efsa.2018.5448

Safety assessment of the active substance polyacrylic acid, sodium salt, cross-linked, for use in active food contact materials

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Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) assessed the safety of polyacrylic acid, sodium salt, cross-linked, FCM substance No 1015, which is intended to be used as a liquid absorber in the packaging of fresh or frozen foods such as meat, poultry and seafood as well as fresh fruits and vegetables. Specific migration tests were not performed due to the high absorption of liquids by the substance. The Panel noted that if polyacrylic acid, sodium salt, cross-linked is used not in direct contact with food and placed in a pad under conditions where its absorption capacity is not exceeded, then no migration is to be expected and therefore no exposure from the consumption of the packed food is expected. The Panel also considered that the non-cross-linked polymer and the cross-linkers do not raise a concern for genotoxicity. The CEP Panel concluded that the use of this polyacrylic acid, sodium salt, cross-linked, does not raise a safety concern when used in absorbent pads in the packaging of fresh or frozen foods. The absorbent pads must be used only under conditions in which the absorption capacity of the active substance is not exceeded and direct contact with food is excluded.

Keywords: FCM substance No 1015, food contact materials, active and intelligent materials, liquid absorber, polyacrylic acid sodium salt cross-linked

Requestor: Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany

Question number: EFSA-Q-2018-00003

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Acknowledgements: The Panel wishes to thank the Working Group on Food Contact Materials of the former EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) for the preparatory work on this scientific output. The Panel wishes to thank the EFSA staff members Ellen Van Haver and Katharina Volk for the support provided to this scientific output.

Note: The full opinion will be published in accordance with Article 10(6) of Regulation (EC) No 1935/2004 once the decision on confidentiality, in line with Article 20(3) of the Regulation, will be received from the European Commission. The names of the cross-linkers, initiators and additives have been provided under confidentiality and they are redacted awaiting the decision of the Commission.

Suggested citation: EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP), Silano V, Barat Baviera JM, Bolognesi C, Brüschweiler BJ, Chesson A, Cocconcelli PS, Crebelli R, Gott DM, Grob K, Lampi E, Mortensen A, Riviere G, Steffensen I-L, Tlustos C, Van Loveren H, Vernis L, Zorn H, Kolf-Clauw M, Cravedi J-P, Franz R, Milana MR, Pfaff K, Tavares Poças MF, Svensson K, Wölfle D, Lioupis A and Castle L, 2018. Scientific Opinion on the safety assessment of the active substance polyacrylic acid, sodium salt, cross-linked, for use in active food contact materials. EFSA Journal 2018;16(11):5448, 7 pp. https://doi.org/10.2903/j.efsa.2018.5448

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 450/2009[1] of the Commission of European Communities is a specific measure that lays down specific rules for active and intelligent materials and articles intended for contact with foodstuffs in addition to the general requirements established in Regulation (EC) No 1935/2004[2] of the European Parliament and of the Council on materials and articles intended to come into contact with food. Active materials and articles are intended to extend the shelf life or to maintain or improve the condition of packaged food; they are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food.

The substance(s) responsible for the active and/or intelligent function of the material should be included in a positive list by the Commission following a safety evaluation by the European Food Safety Authority (EFSA) according to the procedure described in the above-mentioned regulations.

According to this procedure, the industry submits applications to the Member States competent authorities which transmit the applications to EFSA for their evaluation. The application is supported by a technical dossier submitted by the industry following the EFSA 'Guidelines on submission of a dossier for safety evaluation by EFSA of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food' (EFSA CEF Panel, 2009).

In this case, EFSA received an application from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, requesting the evaluation of the active substance polyacrylic acid, sodium salt, cross-linked, with the food contact material (FCM) substance No 1015. The dossier was submitted by Evonik Nutrition & Care GmbH.

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, EFSA is asked to carry out an assessment of the risks related to the intended use of the substance and to deliver a scientific opinion.

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier in support of their application for the authorisation of polyacrylic acid, sodium salt, cross-linked with mixtures of [redacted] crosslinker 1 [redacted] crosslinker 2 [redacted] cross-linker 3 and [redacted] cross-linker 4 to be used in active food contact materials (FCM).

Data submitted and used for the evaluation are:

Non-toxicological data and information

- Chemical identity
- Description of manufacturing process of substance/FCM
- Physical and chemical properties
- Intended use
- Existing authorisation(s).

Toxicological data

- Bacterial gene mutation test
- *In vitro* mammalian cell gene mutation test
- *In vivo* mouse bone marrow micronucleus test.

2.2. Methodologies

In the context of the safety evaluation by EFSA of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food (EFSA CEF Panel, 2009),

[1] Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food. OJ L 135, 30.5.2009, p. 3–11.

[2] 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.

the safety evaluation is conducted using the general methodological framework established for monomers and additives used to make plastics and published as the guidelines of the Scientific Committee on Food (SCF) (European Commission, 2001).

The assessment was conducted in line with the principles laid down in Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. This Regulation underlines that applicants may consult the guidelines of the SCF for the presentation of an application for safety assessment of a substance to be used in FCMs prior to its authorisation (European Commission, 2001), including the corresponding data requirements. The dossier that the applicant submitted for evaluation was in line with the SCF guidelines (European Commission, 2001).

The methodology is based on the characterisation of the substance that is the subject of the request for safety assessment prior to authorisation, its impurities and reaction and degradation products, the evaluation of the exposure to those substances through migration, and the definition of minimum sets of toxicity data required for safety assessment.

To establish the safety from ingestion of migrating substances, the toxicological data indicating the potential hazard and the likely human exposure data need to be combined. Exposure is estimated from studies on migration into food or food simulants and considering that a person may consume daily up to 1 kg of food in contact with the relevant FCM.

As a general rule, the greater the exposure through migration, the more toxicological data is required for the safety assessment of a substance. Currently, there are three tiers with different thresholds triggering the need for more toxicological information as follows:

a) In case of high migration (i.e. 5–60 mg/kg food), an extensive data set is needed.
b) In case of migration between 0.05 and 5 mg/kg food, a reduced data set may suffice.
c) In case of low migration (i.e. < 0.05 mg/kg food), only a limited data set is needed.

More detailed information on the required data is available in the SCF guidelines (European Commission, 2001).

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and considering the relevant guidance from the EFSA Scientific Committee.

3. Assessment

According to the applicant, the substance polyacrylic acid, sodium salt, cross-linked, is intended to be used in absorbent pads in the packaging of fresh and frozen meat, fish and poultry, and fresh fruits and vegetables, in order to absorb liquids released from the food.

The pads are intended for use at room temperature or lower. The pads are made of two layers sealed in the edges and an absorption core. The upper layer is a plastic in contact with the food and the bottom layer is a perforated plastic material, for example polyethylene, allowing for absorption of the liquids. The absorption core consists of the active substance mixed with virgin fluff pulp (cellulose). Liquids are absorbed and retained in the absorbent core, even under pressure, by the formation of a hydrogel.

3.1. Non-toxicological data

Chemical formula: $(C_3H_4O_2)_x$.xNa (polyacrylic acid, sodium salt) (Figure 1).

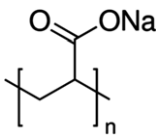

Figure 1: Chemical structure of polyacrylic acid (sodium salt)

The active substance is polyacrylic acid, sodium salt, cross-linked with a mixture of four cross-linkers. Polyacrylic acid, sodium salt is authorised as an additive for plastic materials and articles in contact with food under Regulation (EU) No 10/2011[3] with a group specific migration limit (SML) of 6 mg/kg, expressed as acrylic acid (polyacrylic acid, salts, FCM Substance No 70).

[3] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.1.2011, p. 1–89.

The substance cross-linked polyacrylic acid, sodium salt, has been evaluated by EFSA in the past. The cross-linkers used in the present application correspond to cross-linkers 1, 2, 3 and 4 of the EFSA CEF Panel (2014) opinion (EFSA-Q-2013-00639, -00725 and -00726). Cross-linkers 3 and 4 were also used in the EFSA CEF Panel (2016) opinion (EFSA-Q-2015-00612).

The following additional substances are used, which are authorised under Regulation (EU) 10/2011 or are food additives: [redacted]. Two of these substances, [redacted] and [redacted], have not been used in previous petitions of the applicant for CEF Panel evaluation of the active substance polyacrylic acid, sodium salt, cross-linked.

The substance and the additives are stable under the conditions of processing and use. The absorption capacity of the substance, measured with saline solutions of 0.2% and 0.9%, is 45 g/g and 25 g/g, respectively. The amount of active substance required for the absorption of fluids released from various foods was estimated by the applicant to be up 0.9–2.4 g/kg of food, depending of the exuding nature of the food.

The substance is not intended to make direct contact with the food. Migration of the substance and additives and its residual ingredients and impurities is not to be expected, when the substance is used in the foreseen conditions and provided the absorption capacity of the pad is not exceeded. Considering the conditions of the manufacturing process, the Panel concluded that volatile substances are not present in the final active material and no migration and therefore no exposure is expected.

3.2. Toxicological data

The substance is a cross-linked polymer manufactured using acrylic acid which is an authorised monomer and sodium hydroxide which is an authorised additive/polymer production aid. The non-cross-linked polymer is an authorised additive. The cross-linkers have been evaluated by EFSA in the past.

The cross-linkers 1, 2 and 3 were previously evaluated by the Panel and no concern for genotoxicity was reported (EFSA CEF Panel, 2014).

Cross-linker 4 has been re-evaluated by EFSA ([redacted]) and is authorised as a monomer in Regulation (EU) No 10/2011 with a specific migration limit. Any migration from this application will be well below this SML.

Considering the nature of the active substance and that, due to the intended use of the active component, no migration of the substance itself and of the additives into the food is expected, the Panel considers that the use of the active substance is not of safety concern.

4. Conclusions

The CEP Panel, based on the above-mentioned data, concluded that the substance polyacrylic acid, sodium salt, cross-linked, is not of safety concern for the consumer if the substance is only to be used in liquid absorbent pads, in the packaging of fresh meat, fish, fruits and vegetables, at room temperature or lower. The absorbent pads must be used only under conditions in which the liquid absorption capacity is not exceeded and direct contact between the substance and the food is excluded.

Documentation provided to EFSA

1) Dossier FAVOR PAC 600 Series. December 2017. Submitted by Evonik Nutrition & Care GmbH.

[redacted]

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[redacted]

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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 to its authorisation. Available online: http://ec.europa.eu/food/fs/sc/scf/out82_en.pdf

Abbreviations

CEF EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
FCM food contact materials
SCF Scientific Committee on Food
SML specific migration limit