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SCIENTIFIC OPINION

Scientific Opinion on safety assessment of the active substance, polyacrylic acid, sodium salt, crosslinked, for use in active food contact materials[1]

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

This scientific output, published on 13 May 2014, replaces the earlier version published on 6 May 2014*.

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 name of the crosslinker has been provided under confidentiality and it is deleted awaiting the decision of the Commission.

ABSTRACT

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids deals with the safety assessment of the polyacrylic acid, sodium salt, crosslinked, 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, crosslinked, is used not in direct contact with food 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 non-crosslinked polymer and the crosslinker do not raise a concern for genotoxicity. The CEF Panel concluded that the use of the substance polyacrylic acid, sodium salt, crosslinked, does not raise a safety concern when used in absorbent pads in the packaging of fresh or frozen meat foods poultry, and seafood as well as fresh fruits and vegetables. 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.

[1] On request from the Bundesamt für Verbraucherschultz und Lebensmittelsicherheit, Germany, Question No EFSA-Q-2011-00066, adopted on 09 April 2014.

[2] Panel members: Ulla Beckman Sundh, Mona-Lise Binderup, Claudia Bolognesi, Leon Brimer, Laurence Castle, Alessandro Di Domenico, Karl-Heinz Engel, Roland Franz, Nathalie Gontard, Rainer Gürtler, Trine Husøy, Klaus-Dieter Jany, Martine Kolf-Clauw, Catherine Leclercq (until July 2013), Jean-Claude Lhuguenot (until November 2012), Wim Mennes, Maria Rosaria Milana, Maria de Fátima Poças, Iona Pratt †, Kettil Svensson, Fidel Toldrá and Detlef Wölfle. One member of the Panel did not participate in the discussion on the subject referred to above because of potential conflicts of interest identified in accordance with the EFSA policy on declarations of interests. Correspondence: cef@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Food Contact Materials: Mona-Lise Binderup, Laurence Castle, Riccardo Crebelli, Alessandro Di Domenico, Roland Franz, Nathalie Gontard, Ragna Bogen Hetland, Martine Kolf-Clauw, Eugenia Lampi, Maria Rosaria Milana, Maria de Fátima Poças, Philippe Saillard, Kettil Svensson and Detlef Wölfle for the preparatory work on this scientific opinion.

† Deceased

* A minor change of an editorial nature was made. The change does not affect the contents of this report. To avoid confusion, the original version of the opinion has been removed from the website, but is available on request, as a version showing all the changes made.

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KEY WORDS

polyacrylic acid sodium salt crosslinked, FCM substance No 1015, food contact materials, active and intelligent materials, safety assessment, evaluation

SUMMARY

According to Commission Regulation (EC) No 450/2009 of the Commission of European Communities of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food, substances responsible for the active or intelligent function need first to be evaluated by EFSA before their inclusion into a positive Community list. The procedure of the evaluation and the tasks of EFSA are described in 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.

In the context of this evaluation procedure following a request from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL), Germany, the Panel on Food Contact Materials, Enzymes, Flavourings and Processing aids (CEF) was asked to deliver an opinion on polyacrylic acid, sodium salt, crosslinked, as a liquid absorber in absorbent pads used in the packaging of fresh or frozen food such as meat, poultry, and seafood as well as fresh fruits and vegetables. The application was submitted by Evonik Industries AG, Germany.

The non-crosslinked polymer is authorised as an additive for plastic materials and articles in contact with food (Commission Regulation (EU) No 10/2011) with a group SML of 6 mg/kg food, expressed as acrylic acid (polyacrylic acid, salts, FCM Substance No 70). The crosslinker is also authorised as a monomer or other starting substance in Annex I of Commission Regulation (EU) No 10/2011.

Specific migration tests were not performed on the absorbent pads due to the high absorption of liquids by the substance. Since the substance is incorporated into the inner layer of the pads, there is no direct contact possible between the substance and the food. Provided that the absorption capacity of the absorbent pads is not exceeded, the Panel concluded that no migration of the substance itself into the food is expected, therefore no exposure from the consumption of the packed food is expected. Based on the residual content of monomeric acrylic acid, sodium salt, the worst case migration calculated for total mass transfer is well below the SML. Based on an estimation of the residual content of the unreacted crosslinker, the worst case migration calculated for total mass transfer is 0.002 mg/kg food.

The Panel noted that the substances used for the manufacture of the active substance have already been evaluated and authorized as substances to be used for plastic materials and articles in contact with food (Commission Regulation (EU) No 10/2011). The Panel also noted that the crosslinker was tested in a recent *in vivo* comet assay in rat stomach and liver. This study confirmed the lack of genotoxicity *in vivo* of the crosslinker.

The CEF Panel, having considered the above mentioned information, concluded that the use of the substance polyacrylic acid, sodium salt, crosslinked, does not raise a safety concern when used in absorbent pads in the packaging of fresh or frozen meat, poultry, and seafood as well as fresh fruits and vegetables. 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.

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BACKGROUND AS PROVIDED BY THE LEGISLATION

Regulation (EC) No 450/2009[4] 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[5] 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 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, 2009).

In this case, EFSA received an application from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, submitted by Evonik Industries AG, Germany, requesting the evaluation of polyacrylic acid, sodium salt, crosslinked.

TERMS OF REFERENCE AS PROVIDED BY THE LEGISLATION

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.

[4] 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

[5] 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

EFSA was asked by the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany to evaluate the safety of polyacrylic acid, sodium salt, crosslinked (FCM substance No 1015), which is used as a liquid absorber in absorbent pads. The request has been registered in the EFSA's register of questions under the number EFSA-Q-2011-00066. The dossier was submitted by the applicant Evonik Industries AG, Germany.

2. General information

According to the applicant, the active substance, polyacrylic acid, sodium salt, crosslinked, is intended to be used in absorbent pads as a liquid absorbent medium in the packaging of fresh or frozen foods such as meat, poultry and seafood, fruits and vegetables. The pads are intended to come into contact with foods for approximately up to 14 days under refrigerated conditions in case of fresh food and for longer time for frozen food.

The absorbent pads have three layers:

- an upper inert plastic or nonwoven layer which is in contact with food.
- a bottom nonwoven-based or micro-perforated film layer which is in contact with the bottom of the food tray where the liquids are present.
- an inner layer composed of a blend of a compressed cellulosic fluff pulp and the active substance in granular form.

The inner layer is confined between the upper and lower layer of the pad, which is sealed on the 4 sides to prevent leakage of the active substance.

According to the applicant, liquids are absorbed and retained in the absorbent core, even under pressure by the formation of a hydrogel.

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

However, polyacrylic acid, sodium salt is authorized as an additive for plastic materials and articles in contact with food (Commission Regulation (EU) No 10/2011[6]) with a group SML of 6 mg/kg food, expressed as acrylic acid (polyacrylic acid, salts, FCM Substance No 70).

The crosslinker is also authorized as a monomer or other starting substance in Annex I of Commission Regulation (EU) No 10/2011.

3. Data available in the dossier used for this evaluation

The studies submitted for evaluation followed the EFSA guidelines on submission of a dossier for safety evaluation by the EFSA of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food (EFSA, 2009).

Non-toxicity data:

- Data on identity
- Data on physical and chemical properties
- Data on manufacturing process

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

- Data on function, intended use and authorisation

Toxicity data:

- *In vivo* comet assay on the crosslinker

4. Evaluation

4.1. Non-toxicological data

The active substance is stable under the conditions of processing and use. It is a high molecular weight polymer. The low molecular weight fraction in the polymer is soluble in water.

The retention capacity of the substance was determined with 0.9 % and 0.2 % saline solution and was 24 g and 40 g of fluid per g of substance, respectively. The amount of the active substance required for the absorption of fluids released from various food types was estimated by applicant to be up to 2.5 g per kg of food, depending of the exuding nature of the food.

Specific migration tests were not performed on the absorbent pads due to the high absorption of liquids by the substance. Since the substance is incorporated into the inner layer of the pads, there is no direct contact possible between the substance and the food.

Provided that the absorption capacity of the absorbent pads is not exceeded, the Panel concluded that no migration of the high molecular weight active substance is to be expected and therefore no exposure from the consumption of the packed food is expected. Considering the conditions of the manufacturing process, the Panel concluded that volatile substances are not present in the final active material, therefore no exposure is expected.

Based on the residual content of monomeric acrylic acid, sodium salt, the worst case migration calculated for total mass transfer was well below the SML. Based on an estimation of the residual content of the unreacted crosslinker, the worst case migration calculated for total mass transfer is 0.002 mg/kg food.

4.2. Toxicological data

In a previous evaluation (SCF, 1999) the crosslinker was considered to be clastogenic *in vitro* in a cytogenetic assay on human lymphocytes in the presence of metabolic activation, where it induced mainly chromatid deletions. Negative results were obtained in gene mutation assays in bacteria and in mouse lymphoma cells and in a micronucleus test in mouse bone marrow, with limited evidence of target cells exposure. Based on these results the SCF concluded that genotoxicity of the crosslinker could not be ruled out. Therefore the substance has been included in Annex I of Commission Regulation (EU) No 10/2011 but under restrictions for use taking account of the possible genotoxic nature.

The crosslinker was tested in an *in vivo* comet assay in rats. The substance was administered twice by oral intubation to male rats (4 and 24 hours before sacrifice). As the top dose 100 mg/kg bw was selected, two lower doses (50 and 25 mg/kg bw) were also tested. Positive controls received methylmethansulfonate. DNA damage was evaluated by alkaline comet assay in cells from glandular stomach and liver of each animal. The % DNA in the tail, measured by an image analysis program was used as parameter of DNA damage. Administration of the test item was associated with clinical signs (reduced spontaneous activity, eyelid closure, ruffled fur) at all doses. For both tissue preparations, the incidence of dead cells (necrotic and apoptotic) was negligible (≤ 5 %).

Compared to the corresponding vehicle controls, no increase in DNA damage was observed in stomach cells at any dose (% tail intensities of medians ± SD were 3.83 ± 1.69, 3.59 ± 2.28, 1.66 ±

0.82, 3.17 ± 2.17 in control, low, medium and high dose, respectively). Positive control elicited a clear increase in DNA damage.

In liver cells, an increase in DNA damage compared to negative control was observed at the intermediate and high doses (% tail intensities were 1.28 ± 0.69, 0.86 ± 0.39, 2.87 ± 1.26, 2.11 ± 1.10 in control, low, medium and high dose, respectively). All data were within the historical control range reported by the performing laboratory for this parameter (3.82±2.02, mean ± SD). Thus the observed increase in % tail intensity at the mid dose in liver cells is considered not biologically significant. The tail intensity in the positive control was clearly increased.

Additionally, a inspection of supplementary data in tail length and tail moment values in vehicle and substance-treated animals showed no significant differences. The absence of a reduction of DNA damage in treated cells compared to control values indicates that the substance had no DNA crosslinking effect. Overall, the crosslinker is considered non-genotoxic in this *in vivo* assay.

Considering the nature of the substance and that, due to the intended use of the active component, no migration of the substance itself into the food is expected, migration of the acrylic acid, sodium salt would be well below SML, and migration of the crosslinker would be no more than 0.002 mg/kg food, the Panel considers that the use of the active substance is toxicologically acceptable.

CONCLUSIONS

The CEF Panel, having considered the above mentioned information, concluded that the use of the substance polyacrylic acid, sodium salt, crosslinked, does not raise a safety concern when used in absorbent pads in the packaging of fresh or frozen meat, poultry, and seafood as well as fresh fruits and vegetables. 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. Polyacrylic acid, sodium salt, crosslinked. February 2011. Submitted by Evonik Industries AG.

2. Additional data for dossier “Polyacrylic acid, sodium salt, crosslinked”. January 2012. Submitted by Evonik Industries AG.

3. Additional data for dossier “Polyacrylic acid, sodium salt, crosslinked”. October 2013. Submitted by Evonik Industries AG.

4. Additional data for dossier “Polyacrylic acid, sodium salt, crosslinked”. January 2014. Submitted by Evonik Industries AG.

REFERENCES

EFSA (European Food Safety Authority), 2009. Guidelines on submission of a dossier for safety evaluation by the EFSA of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food. The EFSA Journal 2009, 1208, 10-1.

SCF (Scientific Committee for Food), 1999. Reports of the Scientific Committee for Food (42nd Series) Compilation of the evaluation of the scientific committee for food on certain monomers and additives used in the manufacture of plastics materials intended to come into contact with foodstuffs until 21 March 1997. http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_42.pdf

ABBREVIATIONS

BVL Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
CEF Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
DNA Deoxyribonucleic acid
EC European Commission
FCM Food Contact Materials
EFSA European Food Safety Authority
EU European Union
SCF Scientific Committee on Food
SD Standard deviation
SML Specific Migration Level