

SCIENTIFIC OPINION

Scientific Opinion on the safety evaluation of the active substances citric acid (E330) and sodium hydrogen carbonate (E500ii), used as carbon dioxide generators, together with liquid absorbers cellulose and polyacrylic acid sodium salt crosslinked, in active 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 evaluation of the mixture of the active substances citric acid (E330, CAS No 77-92-9, FCM Substance No 139) and sodium hydrogen carbonate (E500ii, CAS No 144-55-8, FCM Substance No 21), which is intended to be used as a carbon dioxide generator in liquid absorbent pads in the packaging of fresh or frozen meat, poultry, fish, fruits and vegetables. Depending on absorption capacity needed, pure cellulose or a mixture of cellulose and polyacrylic acid sodium salt crosslinked may be used as absorber. The Panel noted that if the active substances are used not in direct contact with food, but are 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. Therefore the CEF Panel concluded that the use of the mixture of the active substances citric acid (E330) and sodium hydrogen carbonate (E500ii), as carbon dioxide generator in liquid absorbent pads in the packaging of food such as fresh or frozen meat, poultry, fish, fruits and vegetables, does not raise a safety concern. The absorbent pads should 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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KEY WORDS

Citric acid (E330, CAS No 77-92-9, FCM Substance No 139); sodium hydrogen carbonate (E500ii, CAS No 144-55-8, FCM Substance No 21); Food contact materials; Active and intelligent materials; Safety assessment; Evaluation.

SUMMARY

According to the Commission Regulation (EC) No 450/2009⁴ 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 1935/2004⁵ 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 cellulose, citric acid (E330), sodium hydrogen carbonate (E500ii) and polyacrylic acid sodium salt crosslinked for use as a liquid absorber and carbon dioxide generator in the packaging of fresh or frozen meat, poultry, fish, fruits and vegetables. The application was submitted by McAirmaid's Vliesstoffe GmbH & Co KG.

The active component containing a mixture of citric acid (E330) and sodium hydrogen carbonate (E 500ii) of food grade quality is incorporated in a liquid absorbent pad. Depending on the absorption capacity needed, pure cellulose or a mixture of cellulose and polyacrylic acid sodium salt crosslinked may be used. The pads absorb liquid released from the foods (e.g. meat, fish, fruits) and start generating carbon dioxide.

EFSA has already evaluated the polyacrylic acid sodium salt crosslinked used in this application. Pads composed of 100 % cellulose do not fall under the definition of active materials and articles of the Commission Regulation (EC) No 450/2009 (European Commission, 2011). Therefore the safety evaluation is focused on citric acid (E330) and sodium hydrogen carbonate (E500ii).

Since the substance is incorporated into the inner layer of pads, there is no direct contact possible between the active mixture and the food. Moreover the substances used in the active article are not volatile and they will not migrate via the vapour phase. Therefore provided that the absorption capacity of the absorbent pads is not exceeded, the Panel considered that no migration is to be expected.

The CEF Panel, after having considered the above mentioned information, concluded that the use of the mixture of the active substances, citric acid (E330) and sodium hydrogen carbonate (E500ii), as carbon dioxide generator in liquid absorbent pads in the packaging of food such as fresh or frozen meat, poultry, fish, fruits and vegetables does not raise a safety concern. The absorbent pads should be used only under conditions in which the absorption capacity is not exceeded and direct contact between the substances and the food is excluded.

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.

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BACKGROUND AS PROVIDED BY THE LEGISLATION

Commission Regulation (EC) No 450/2009 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 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 abovementioned 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 the 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, requesting the evaluation of cellulose, citric acid (E330), sodium hydrogen carbonate (E500ii) and polyacrylic acid sodium salt crosslinked.

TERMS OF REFERENCE AS PROVIDED BY THE APPLICANT

EFSA is required to carry out an assessment on the risks originating from the migration into food of the substances cellulose, citric acid (E330), sodium hydrogen carbonate (E500ii) and polyacrylic acid sodium salt crosslinked used as liquid absorber and carbon dioxide generator in food contact materials and deliver a scientific opinion, according to the Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food.

In this evaluation EFSA will focus on citric acid (E330) and sodium hydrogen carbonate (E500ii) only because:

EFSA has already evaluated the polyacrylic acid sodium salt crosslinked used in this application (EFSA Scientific Panel on food contact materials, enzymes, flavourings and processing aids (CEF), 2013) what was not known by the applicant at the time of submission and;

materials and articles functioning on the basis of the natural constituents only, such as pads composed of 100 % cellulose, are not designed to deliberately incorporate components that would release or absorb substances hence do not fall under the definition of active materials and articles of the Regulation (EC) No 450/2009 (European Commission, 2011).

The opinion of EFSA will be considered by the Commission for adoption of a Community list of authorised substances where according to the Regulation (EC) No 450/2009 there will be specified:

- (a) the identity of the substance(s);
- (b) the function of the substance(s);
- (c) the reference number;

- (d) if necessary, the conditions of use of the substance(s) or component;
- (e) if necessary, restrictions and/or specifications of use of the substance(s);
- (f) if necessary, conditions of use of the material or article to which the substance or component is added or into which it is incorporated.

ASSESSMENT

1. Introduction

EFSA was asked by the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany to evaluate the safety of the active substances cellulose, citric acid (E330, CAS No 77-92-9, FCM Substance No 139), sodium hydrogen carbonate (E500ii, CAS No 144-55-8, FCM Substance No 21), polyacrylic acid sodium salt crosslinked (FCM Substance No 1015). The request has been registered in the EFSA's register of questions under the number EFSA-Q-2011-00219. The dossier was submitted by the applicant, McAirLaid's Vliesstoffe GmbH & Co KG.

2. General information

According to the applicant, the active substances citric acid and sodium hydrogen carbonate are intended to be used in absorbent pads for packaging of fresh or frozen meat, poultry, fish, fruits and vegetables, for long term storage at room temperature or below. The pads absorb liquid released from the food (e.g. meat, fish, and fruits) and start generating carbon dioxide. Depending on absorption capacity needed, pure cellulose or a mixture of cellulose and polyacrylic acid sodium salt crosslinked may be used.

The pads are made of:

- a core layer which is composed of a liquid absorber in which citric acid and sodium hydrogen carbonate are incorporated. This layer is covered on both sides by cellulosic tissue layers.
- a perforated polyethylene film surrounding the core welded at all 4 sides in order to avoid direct contact with food. The film is designed to let fluids in and carbon dioxide out.

The mixture as such has not been evaluated by the SCF or EFSA in the past.

However,

Citric acid is authorised as additive and monomer for plastic materials and articles in contact with food (Commission Regulation (EU) 10/2011⁶) with no specific restriction (FCM Substance No 139). The substance is also approved as food additive (Commission Regulation (EU) 1129/2011⁷). It may be added to a series of food following quantum satis principle, except for cocoa and chocolate products (as covered by Directive 2000/36/EC) for which the limit of use is 5000 mg/kg, for nectars (as defined by Directive 2001/112/EC) for which the limit of use is 5000 mg/l and for fruit and vegetable juices (as defined by Directive 2001/112/EC) for which the limit of use is 3000 mg/l.

Sodium hydrogen carbonate is authorised as additive for plastic materials and articles in contact with food (Commission Regulation (EU) No 10/2011) with no specific restriction (FCM Substance No 21). It is also approved as food additive (Commission Regulation (EU) 1129/2011) It may be added to a series of food following *quantum satis* principle.

Considering the absorbent components:

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.

⁷ Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives Text with EEA relevance. OJ L 295, 12.11.2011, p. 1–177.

Cellulose is authorised as monomer and additive for plastic material and articles in contact with food (Commission Regulation (EU) No 10/2011) with no specific restriction (FCM Substance No 553).

The polyacrylic acid sodium salt crosslinked used in this application, used as a liquid absorber in active food contact materials has already been evaluated by EFSA (EFSA Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2013). It was concluded that there is no safety concern for the consumer if the substance is used in absorbent pads under conditions in which the liquid absorption capacity of the pads is not exceeded and direct contact between the substance and the food is excluded.

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 manufacturing process
- Data on function, intended use and authorisation

4. Evaluation

4.1. Non-toxicological data

The active component contains a mixture of citric acid (E 330) and sodium hydrogen carbonate (E 500ii) of food grade quality, incorporated in a liquid absorbent pad. In the presence of moisture the active substances react, form sodium citrate, water and release carbon dioxide.

Specific migration tests were not performed on the absorbent pads due to the high absorption of liquids by the substance. The retention capacity of the substance was measured with deionised water and with a 0.9 % saline solution and was 221 g and 37 g of fluid per g of substance, respectively (EFSA Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2013).

Since the substance is incorporated into the inner layer of pads, there is no direct contact possible between the active mixture and the food. Moreover the substances used in the active article are not volatile and they will not migrate via the vapour phase.

The Panel concluded therefore that, provided that there is no direct contact between the food and the substances and provided that the absorption capacity of the absorbent pads is not exceeded, no migration and consequently no exposure from the consumption of the packed food is to be expected.

4.2. Toxicological data

The Panel noted that citric acid and sodium hydrogen carbonate have already been evaluated and authorised as substances to be used for plastic materials and articles in contact with food (Commission Regulation (EU) No 10/2011) and as food additives (Commission Regulation (EU) No 1129/2011).

In addition, considering the nature of the substances and the reaction product, carbon dioxide, released and the intended use of the active component, the Panel considered that the use of these substances would not give rise to safety concerns.

CONCLUSIONS

The CEF Panel, after having considered the above mentioned information, concluded that the use of the mixture of the active substances, citric acid (E330) and sodium hydrogen carbonate (E500ii), as carbon dioxide generator in liquid absorbent pads in the packaging of food such as fresh or frozen meat, poultry, fish, fruits and vegetables does not raise a safety concern. The absorbent pads should be used only under conditions in which the absorption capacity is not exceeded and direct contact between the substances and the food is excluded.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier referenced: EFSA/CEF/FCM/2191. March 2011. Submitted by McAirmaid's Vliesstoffe GmbH & Co KG.

REFERENCES

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GLOSSARY AND ABBREVIATIONS

BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
CAS	Chemical Abstracts 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
SCF	Scientific Committee on Food