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SCIENTIFIC OPINION

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Safety assessment of the active substances carboxymethylcellulose, acetylated distarch phosphate, bentonite, boric acid and aluminium sulfate, for use in active food contact materials

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), Vittorio Silano, Claudia Bolognesi, Kevin Chipman, Jean-Pierre Cravedi, Karl-Heinz Engel, Paul Fowler, Roland Franz, Konrad Grob, Rainer Gürtler, Trine Husøy, Sirpa Kärenlampi, Wim Mennes, Maria Rosaria Milana, Karla Pfaff, Gilles Riviere, Jannavi Srinivasan, Maria de Fátima Tavares Poças, Christina Tlustos, Detlef Wölfle, Holger Zorn, Martine Kolf-Clauw, Eugenia Lampi, Kettil Svensson, Ellen Van Haver and Laurence Castle

Abstract

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) deals with the safety evaluation of the active substances carboxymethylcellulose, acetylated distarch phosphate (FCM substance No 1071), bentonite, boric acid and aluminium sulfate (FCM substance No 1072). The mixture is intended to be used as a liquid absorber in the packaging of perishable foods to extend their shelf-life. All substances have been evaluated and approved for use as additives in plastic food contact materials and/or as food additives. Migration of boron into foods was up to 0.7 mg/kg food. Migration of aluminium was not detected (limit of detection (LOD) of 0.001 mg/kg). The CEF Panel concludes that the substances carboxymethylcellulose, acetylated distarch phosphate, bentonite, boric acid and aluminium sulfate are not of safety concern for the consumer when used as active components in moisture and liquid absorbers. The absorbent pads must be used under conditions in which direct contact between the active mixture and the food is avoided and the fluid absorption capacity of the absorber is not exceeded.

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Keywords: carboxymethylcellulose, acetylated distarch phosphate, bentonite, boric acid and aluminium sulfate, FCM substance Nos 1071 and 1072, food contact materials, active and intelligent materials, safety assessment

Requestor: Ministero della Salute, Italy

Question number: EFSA-Q-2017-00054

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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, 2009).

In this case, EFSA received an application from the Ministero della Salute, Italy, requesting the evaluation of the substances carboxymethylcellulose (CAS number 9000-11-7, FCM substance No 542), acetylated distarch phosphate (CAS number 68130-14-3, FCM substance No 1071), bentonite (CAS number 7647-14-5, FCM substance No 393), boric acid (CAS number 10043-35-3, FCM substance No 584) and aluminium sulfate (CAS number 10043-01-3, FCM substance No 1072). The dossier was submitted by the applicant Magic Srl, Italy.

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 carboxymethylcellulose, acetylated distarch phosphate, bentonite, boric acid and aluminium sulfate 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)
- Migration of the substance
- Identification, quantification and migration of reaction products and impurities.

Toxicological data

- None.

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 substances that are 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 Scientific Committee, 2009) and considering the relevant guidance from the EFSA Scientific Committee.

3. Assessment

According to the applicant, the active mixture, consisting of carboxymethylcellulose, acetylated distarch phosphate, bentonite, boric acid and aluminium sulfate, increases the water/liquid/exudate absorption capacity of packaging materials and devices in order to extend the shelf life of perishable foods, such as meat, poultry, fish, fruit and vegetables. The active mixture in the form of granules is made into a non-woven fabric by mixing with fibrous materials (e.g. cellulosic fluff-pulp, viscose, plastic fibres like polypropylene (PP), polyethylene (PE) or polyethylene terephthalate) which the granules become entangled with during the manufacturing process. Addition of binders and the use of thermally bondable fibres and calendering, contribute to bind the active mixture into a non-woven structure. The non-woven fabric containing the mixture is covered, either on one or on both sides, with plastic film of PE or PP (perforated or not) or other non-woven layers not containing the mixture in order to avoid direct contact with the food.

3.1. Non-toxicological data

Chemical formula: It is a mixture consisting of carboxymethylcellulose, acetylated distarch phosphate, bentonite, boric acid and aluminium sulfate.

Bentonite is authorised as an additive for plastic materials and articles in contact with foods (Regulation (EU) No 10/2011[3]) with no specific restrictions (FCM substance No 393).

Sodium carboxymethylcellulose is authorised as an additive for plastic materials and articles in contact with foods (Regulation (EU) No 10/2011) with no specific restrictions (FCM substance No 542).

Boric acid is authorised as a monomer and additive for plastic materials and articles in contact with foods (Regulation (EU) No 10/2011) with a combined specific migration limit (SML) with other substances containing boron of 6 mg/kg (expressed as boron) (FCM substance No 584).

[3] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. Available online: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32011R0010&from=EN

Aluminium sulfate is authorised by the general listing of 'aluminium salts of listed acids' of Regulation (EU) No 10/2011, i.e. sulfuric acid (FCM substance 511) in this case. Regulation (EU) 1416/2016[4] amending and correcting Regulation (EU) No 10/2011 established a SML for aluminium of 1 mg/kg that should apply from 14 September 2018.

Acetylated distarch phosphate is a food additive (E 1414).

The individual substances are mixed and converted to granules in the size range of several hundred micrometres. Up to 25% w/w granules are incorporated into the non-woven fabric. A plastic film (perforated or not) or other non-woven layer separates the mixture from the food.

During manufacturing, the mixture is heated for a few seconds. The substances are expected to be stable under these conditions.

Specific migration of aluminium and boric acid, and overall migration were determined by immersion of a pad (comprising a non-woven fabric made with the active mixture incorporated and with one face glued to a perforated PE layer) in 3% acetic acid, 50% ethanol and 95% ethanol for 10 days at 40°C and isooctane for 2 days at 20°C. The results obtained were < 0.001 mg/kg for aluminium and up to 0.7 mg/kg for boric acid. Overall migration testing gave the following results: 47 mg/dm^2 in 3% acetic, 52 mg/dm^2 in 50% ethanol, 14 mg/dm^2 in 95% ethanol and 14 mg/dm^2 in isooctane. The analytical methods and the method performance for the specific migration tests were poorly described. However, the Panel also noted that the conditions of these immersion tests do not reflect the intended use and give rise to unrealistically high migration.

To check for the possible formation of reaction products that may migrate, the absorbent pad was heated at 125°C for 30 min and a screening headspace gas chromatography/mass spectrometry (HS-GC/MS) analysis was applied. The only substances that were detected originated from the passive parts.

3.2. Toxicological data

The substances bentonite, sodium carboxymethylcellulose, boric acid, aluminium sulfate and acetylated distarch phosphate have been approved for use as additives in plastic FCMs and/or as food additives.

From a toxicological point of view, the potential for migration of aluminium and boron is of interest.

Based on the test results provided, it is expected that under the intended conditions of use, migration of boron into foods would be markedly lower than the SML value of 6 mg/kg food, as set by Regulation EU No 10/2011.

Migration of aluminium into 3% acetic acid solution was below 0.001 mg/kg. This migration is well below the SML of 1 mg/kg set for aluminium in Regulation (EU) 1416/2016 and that comes into effect from 14 September 2018. The Panel also took note of the opinion of the EFSA Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (EFSA AFC Panel, 2008), setting a tolerable weekly intake (TWI) of 1 mg/kg body weight (bw) for aluminium. Based on the usual assumption of a consumption of 1 kg of food per day containing aluminium at the maximum level of 0.001 mg/kg, an adult of 60 kg bw would be exposed to 0.000116 (1.16×10^{-4}) mg Al/kg bw per week, corresponding to clearly less than 0.02% of the TWI set in 2008.

Therefore, the Panel considers that under the intended conditions of use of the absorbent pad, the potential migration of aluminium and boron is of no toxicological concern.

4. Conclusions

The CEF Panel, after having considered the above-mentioned data, concludes that the substances carboxymethylcellulose, acetylated distarch phosphate, bentonite, boric acid and aluminium sulfate are not a safety concern for the consumer when used as active components in moisture and liquid absorbers. The absorbent pads must be used only under conditions in which direct contact between the active mixture and the food is avoided and the fluid absorption capacity of the absorber is not exceeded.

[4] Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. Available online: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2016.230.01.0022.01.ENG

Documentation provided to EFSA

1) Initial dossier. April 2017. Submitted by Magic Srl, Italy.
2) Additional data. September 2017. Submitted by Magic Srl, Italy.
3) Clarification during the pre-notification process on the pad structure used as sample for migration testing. January 2018. Submitted by Magic Srl, Italy.

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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.

Abbreviations

bw	body weight
CAS	Chemical Abstracts Service
CEF Panel	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
FCM	food contact materials
HS-GC/MS	headspace gas chromatography/mass spectrometry
LOD	limit of detection
PE	polyethylene
PP	polypropylene
SCF	Scientific Committee on Food
SML	specific migration limit
TWI	tolerable weekly intake