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SCIENTIFIC OPINION

Scientific Opinion on the safety evaluation of the active substances, iron, polyethyleneglycol, disodium pyrophosphate, monosodium phosphate and sodium chloride for use in food contact materials[1]

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 an iron based oxygen absorber, comprising polyethyleneglycol, disodium pyrophosphate, monosodium phosphate and sodium chloride. This mixture is incorporated in polyethylene (PE) or polypropylene (PP) articles intended to be in contact with foodstuffs for hot fill/pasteurisation and/or long term storage at room temperature. For dried and fatty foods, direct contact with the materials is envisaged whereas other food types will be separated from the active material by a layer that does not contain the active components. All the substances constituting the oxygen absorber system have been evaluated and authorised for use as plastic food contact materials, as food additives or as food supplements. Based on migration results, the specific migration limits for iron, polyethyleneglycol, pyrophosphoric acid salts, phosphoric acid salts and sodium chloride, and the tolerable intake of phosphorus (phosphate) are not expected to be exceeded when the oxygen absorber system is used under the intended conditions of use, notably behind a layer not containing the active substance for contact with aqueous or acidic foods. Therefore, the CEF Panel concluded that the use of the substances, iron, polyethyleneglycol, disodium pyrophosphate, monosodium phosphate and sodium chloride do not raise a safety concern when used as oxygen absorbers incorporated in polyethylene and in polypropylene articles used for long time storage and/or hot fill up to 95 °C for several minutes in i) direct contact with dry and fatty foods and ii) indirect contact with aqueous or acidic foods, separated from the active material by a layer of at least 10 µm polyethylene or polypropylene that does not contain the oxygen absorber formulation.

[1] On request from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, Question No EFSA-Q-2011-00191, adopted on 15 May 2013.

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

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KEY WORDS

Iron; Polyethyleneglycol, Disodium pyrophosphate; Monosodium phosphate; Sodium chloride; Active Food Contact Materials; Safety evaluation.

SUMMARY

According to the 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 the 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, Germany, the Panel on Food Contact Materials, Enzymes and Processing aids (CEF) was asked to deliver an opinion on two mixtures comprising iron (CAS No 7439-89-6, FCM Substance No 983), polyethyleneglycol (CAS No 25322-68-3, FCM Substance No 638), disodium pyrophosphate (CAS No 7758-16-9, FCM Substance No 01026), monosodium phosphate (CAS No 7558-80-7, FCM Substance No 01027) and sodium chloride (CAS No 7647-14-5 and FCM Substance No 985), for use as oxygen absorbers in polyethylene (PE) and polypropylene (PP) articles intended for contact with various types of oxygen sensitive foods, for long term storage at room temperature and hot fill/pasteurisation at temperatures at or below 95 °C for several minutes. For dried and fatty foods, direct contact with the materials is envisaged (monolayer) whereas for other food types the foods will be separated from the active material by a layer of PE or PP that does not contain the active components and has a thickness of at least 10 µm (multilayer). The dossier was submitted on behalf of the applicant, Albis Plastic GmbH, Germany.

The main active ingredient of the oxygen absorber system is iron which reacts with oxygen in presence of water, thereby removing oxygen from the primary packaging. The other chemicals are used to provide a media to facilitate the iron oxidation.

All the substances constituting the oxygen absorber systems have been evaluated and authorised for use as additives in plastic materials and articles in contact with foods, as food additives or as food supplements.

Specific migration of iron from PE and PP multilayers into 3 % acetic acid was 16.8 mg/kg and 13.2 mg/kg food, respectively. From a non-coated PP monolayer, migration of iron was up to 27.6 mg/kg into 3 % acetic acid. Iron was not detected at the detection limit of 6 mg/kg into 95 % ethanol and isooctane.

Overall migration from PE and PP multilayer materials was up to 61.8 mg/kg for the multilayer PP in contact with 3 % acetic acid. It was up to 238 mg/kg into 3% acetic acid for a non-coated PP film. Overall migration from the non-coated PP monolayer tested with 95 % ethanol and with isooctane was 15.2 mg/kg and 71 mg/kg respectively.

Based on migration results, the specific migration limits (SML) for iron, polyethyleneglycol, pyrophosphoric acid salts, phosphoric acid salts and sodium chloride, and also the tolerable phosphorus (phosphate) intake are not expected to be exceeded when the oxygen absorber system is used under the intended conditions of use, notably behind a layer not containing the active substance for contact with aqueous or acidic foods.

Potential by-products linked to the use of the oxygen absorber system were investigated. Two volatile substances were identified as impurities of the polyethylene glycol used to formulate the PE active system. The Panel noted that they do not bear structural alerts for genotoxicity and are predicted to be metabolized to innocuous products. Therefore no safety concern is raised at their estimated migration levels.

The CEF Panel, after having considered the above mentioned data, concluded that the use of the substances iron, polyethyleneglycol, disodium pyrophosphate, monosodium phosphate and sodium chloride do not raise a safety concern when used in oxygen absorbers incorporated in polyethylene and in polypropylene articles used for long time storage and/or hot fill up to 95°C for several minutes in:

i) direct contact with dry and fatty foods,

ii) indirect contact with aqueous or acidic foods, separated from the active material by a layer of at least 10 µm polyethylene or polypropylene that does not contain the oxygen absorber formulation.

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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. 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 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 in their turn transmit the applications to the 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).

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. Intelligent materials and articles monitor the condition of packaged food or the environment surrounding the food.

In this case, the EFSA received an application from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, requesting the evaluation of mixtures comprising iron, polyethyleneglycol, disodium pyrophosphate, monosodium phosphate and sodium chloride for use as oxygen absorbers.

TERMS OF REFERENCE AS PROVIDED BY THE APPLICANT

The EFSA is required to carry out a risk assessment on the risks originating from the migration into food of the substances, iron, polyethyleneglycol, disodium pyrophosphate, monosodium phosphate and sodium chloride, used in oxygen absorbing components 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. The opinion of the 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.

[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

The European Food Safety Authority was asked by the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, to evaluate the safety of iron based oxygen absorber systems for food packaging. These absorbers are composed of iron (CAS No 7439-89-6, FCM Substance No 983), polyethyleneglycol (CAS No 25322-68-3, FCM Substance No 638), disodium pyrophosphate (CAS No 7758-16-9, FCM Substance No 01026), monosodium phosphate (CAS No 7558-80-7, FCM Substance No 01027) and sodium chloride (CAS No 7647-14-5 and FCM Substance No 985). The request has been registered in the EFSA's register of received questions under EFSA-Q-2011-00191. The dossier was submitted on behalf of the applicant, Albis Plastic GmbH, Germany.

2. General information

According to the applicant, the oxygen absorber system is prepared by mixing together iron, polyethyleneglycol, disodium pyrophosphate, monosodium phosphate and sodium chloride. The oxygen absorbing principle is based on iron oxidation in the presence of water. The active mixture is incorporated into polyethylene (PE) or polypropylene (PP) articles. Final food contact materials are PE or PP films of up to 100 µm thickness and PP trays with a thickness from 300 to 1000 µm.

These oxygen absorbers materials are intended to be used in contact with various foods which are oxygen sensitive, such as convenience food (e.g. pasta with sauce), meat paste or salads (e.g. tuna salad, various salads), sliced meat and sausage-based snacks. The contact conditions include long term storage at room temperature and hot fill/pasteurisation at temperatures at or below 95°C for several minutes.

For dried and fatty foods, direct contact with the materials is envisaged whereas for other food types the foods will be separated from the active material by a layer of PE or PP that does not contain the active components and has a thickness of at least 10 µm.

The mixture as such has not been evaluated by the SCF or EFSA in the past. However, all the substances constituting the oxygen absorber systems are authorized as additives in plastic materials and articles in contact with foods (Regulation (EU) No 10/2011[6]), as food additives (Regulation (EC) No 1333/2008[7]) or as food supplements (Regulation (EC) No 1925/20068) as follows:

- Iron powder is authorised as additive for plastic materials and articles in contact with foods with a specific restriction of 48 mg iron/kg food based on a Provisional Maximum TDI (PMTDI) of 0.8 /kg bw set by JECFA/WHO (1983) and agreed by the SCF (1990) (FCM Substance No 983);
- Polyethyleneglycol is authorised as additive for plastic materials and articles in contact with foods, with no specific restriction (FCM Substance No 638);
- Pyrophosphoric acid salts is authorised as additive for plastic materials and articles in contact with foods, with no specific restriction (FCM Substance No 445);
- Phosphoric acid salts is authorised as additive for plastic materials and articles in contact with foods, with no specific restriction (FCM Substance No 509);

[6] 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.
[7] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, OJ L354, p.16-33.
[8] Regulation (EC) No 1925/2006 of the European Parliament and the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods, , OJ L404, p.26-38.

- Monosodium phosphate is authorised as food additive (E 339) with maximum levels permitted from 1000 mg/kg (expressed as P_2O_5) to *quantum satis*;
- In addition, the EFSA NDA Panel concluded in 2005 that, although the available data were not sufficient to establish a tolerable upper level of phosphorus, normal health individuals can tolerate phosphorus (phosphate) intakes of up to at least 3000 mg/per day without adverse systemic effects (EFSA NDA Panel, 2005);
- Sodium chloride is covered by sodium salt of hydrochloric acid authorised as additive for plastic materials and articles in contact with foods, with no specific restriction (FCM Substance No 507). In addition, sodium chloride (common salt) may be used as an ingredient in the preparation of food Regulation (EC) No 1925/2006).

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 (EC, 2009).

Non-toxicity data:

- Data on identity
- Data on physical and chemical properties
- Data on manufacturing process
- Data on function, intended use and authorization
- Data on overall and specific migration
- Data on residual content and screening on by-products

Toxicity data:

- None

4. Evaluation

4.1. Non-toxicological data

The oxygen scavenging principle is based on iron oxidation. The oxidation of iron is an electrochemical process occurring in the presence of water and other chemicals used to provide a medium to facilitate the oxidation reaction.

Specific migration of iron was measured for multilayers and monolayer materials. Multilayers materials comprise a 500 µm inner layer containing the maximum intended use level of iron covered on both sides with a 10 µm layer of PE or PP not containing the active ingredients. Monolayers are non-coated PP films of 1000 µm containing the maximum intended use level of iron.

Migration of iron from PE and the PP multilayers into 3 % acetic acid for 4 hour at 100°C was 16.8 mg/kg and 13.2 mg/kg food, respectively. From a non-coated PP monolayer, migration was up to 27.6 mg/kg into 3 % acetic acid (4 hours at 100°C) and 11.6 mg/kg in orange juice (4 hours at reflux temperature). Iron was not detected at the detection limit of 6 mg/kg into 95 % ethanol (4 hours at reflux temperature) and isooctane (24 hours at 40°C).

All other ingredients of the active mixture, polyethyleneglycol, disodium pyrophosphate, monosodium phosphate and sodium chloride, are highly polar and soluble in aqueous media. As those components

are not restricted by any specific migration limit, their migration was assessed by overall migration testing both for the multilayer covered with a layer not containing the active ingredients and the monolayer PP film described above.

Overall migration from the PE and PP multilayer materials (520 µm) tested with 3 % acetic acid and 10 % ethanol for 4h at 100°C was up to 61.8 mg/kg for the multilayer PP in contact with 3 % acetic acid. Overall migration from a non-coated 1000 µm PP film measured under same testing conditions was up to 238 mg/kg into 3 % acetic acid and 123 mg/kg into 10 % ethanol.

Overall migration from the non-coated PP monolayer was also tested with 95 % ethanol for 4 hours at 100°C and with isooctane for 24 hours at 40°C. The overall migration was 15.2 mg/kg into 95 % ethanol and 71 mg/kg into isooctane. Given the aggressiveness of isooctane against polyolefines under the applied conditions of test, overall migration into fatty foods under the intended conditions of use is expected to be less than 60 mg/kg food.

Potential by-products linked to the use of the oxygen scavenging system were investigated. Except for two volatile substances identified as impurities in the polyethyleneglycol used to formulate the PE active system, no other by-products were seen in either polymer type.

4.2. Toxicological data

All substances present in the oxygen absorber formulations, iron, polyethyleneglycol, disodium pyrophosphate, monosodium phosphate and sodium chloride, have been evaluated and authorised for use as additives in plastic food contact materials, as food additives or as food supplements. Therefore no toxicity data are required.

All these ingredients are expected to be stable in normal storage and handling conditions. Moreover, based on above migration results, specific migration limits (SML) of 48 mg/kg food for iron, of 60 mg/kg food (overall migration limit) for polyethyleneglycol, pyrophosphoric acid salts, phosphoric acid salts and sodium chloride, and the tolerable phosphorus (phosphate) intake up to at least 3000 mg/day, are not expected to be exceeded when the oxygen absorber systems are used under the intended conditions of use notably behind a layer not containing the active substance for contact with aqueous or acidic foods. In addition, the Panel noted that highest overall migration measured from a multilayer PE or PP in contact with aqueous food contact simulant and from a non-coated monolayer in contact with fatty food simulant was up to 61.8 and 71 mg/kg, respectively. This is in line with overall migration limit applied to plastics which is 10 mg/dm² (equivalent to 60 mg/kg considering 6 dm² in contact with 1 kg food) (Regulation (EU) No 10/2011).

Regarding the two volatile NIAS identified, the Panel noted that they do not have structural alerts for genotoxicity (as assessed with *ToxTree* 2.5.0 software) and are predicted to be metabolized to innocuous products (WHO, 1977). Therefore no safety concern is raised at the observed migration levels.

CONCLUSIONS

The CEF Panel, after having considered the above mentioned data, concluded that the use of the substances iron, polyethyleneglycol, disodium pyrophosphate, monosodium phosphate and sodium chloride do not raise a safety concern when used in oxygen absorbers incorporated in polyethylene and in polypropylene articles used for long time storage and/or hot fill up to 95 °C for several minutes in:

i) direct contact with dry and fatty foods,

ii) indirect contact with aqueous or acidic foods, separated from the active material by a layer of at least 10 µm polyethylene or polypropylene that does not contain the oxygen absorber formulation.

DOCUMENTATION PROVIDED TO EFSA

1. EFSA/CEF/FCM/2156. February 2011. Submitted on behalf Albis Plastic GmbH, Germany.

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GLOSSARY AND ABBREVIATIONS

bw	body weight
EC	European Commission
FCM	Food Contact Materials
FEEDAP	Additives and Products or Substances used in Animal Feed
JECFA/WHO	The Joint FAO/WHO Committee on Food Additives
LMWF	Low molecular weight fraction
LOAEL	Low observed adverse effect level
Mn	Number average molecular weight
Mw	Weight average molecular weight
NDA	Dietetic Products, Nutrition and Allergies
PET	Poly(ethylene terephthalate)
PMTDI	Provisional Maximum Tolerable Daily Intake
REF No	Reference Number
SCF	Scientific committee on food
SML	Specific Migration Limit
w/w	Weight by weight