

SCIENTIFIC OPINION

Scientific Opinion on safety assessment of the active substance, iron (0) modified bentonite as oxygen absorber, for use 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 the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids deals with the safety assessment of iron (0) modified bentonite intended to be incorporated in monolayer or multilayer packages or in sachets for absorbing oxygen from the food environment. All starting substances have been evaluated and approved for use as additives in plastic FCM or as food additives. From a toxicological point of view, migration of iron, boron and aluminium ions from bentonite is of interest. Based on migration results, specific migration limits of iron and boron are not expected to be exceeded under the intended conditions of use. Migration of aluminium is expected to occur at levels corresponding to less than 1 % of the TWI set in 2008. The CEF Panel concluded that the use of iron (0) modified bentonite does not raise a safety concern when used as oxygen absorber incorporated without compatibilisers in polyolefin articles used for long term of storage at room temperature or refrigeration i) at level up to 3 % w/w incorporated in a polyolefin layer in direct contact with all types of food including beverages, or ii) at higher levels, when the food is separated from the active material by a layer of polyolefin that does not contain the oxygen absorber formulation and offering a barrier to diffusion against inorganic species at least equivalent to 10 µm polypropylene. The substance equally does not raise a safety concern when it is used in sachets, placed in the headspace of the packaging, that prevent the physical release of their contents into the food and are not in direct contact with liquid foods, exudates, or foods with external aqueous liquid phase. The Panel stressed that the final article should comply with specific migration limits applicable for plastic materials.

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KEY WORDS

Iron (0) modified bentonite; Boron; Aluminium; 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 Agencia Española de Seguridad Alimentaria y Nutrición, Spain, the EFSA Panel on Food Contact Materials, Enzymes and Processing aids (CEF) was asked to deliver an opinion on the safety of iron (0) modified bentonite (FCM Substance No 01036), made from the starting substances iron (III) chloride anhydrous (CAS No 7705-08-0), bentonite (CAS No 1302-78-9, FCM Substance No 393) and sodium borohydride (CAS No 16940-66-2, FCM substance No 981), for use as oxygen absorber. The substance is intended to be incorporated in monolayer or multilayer packages or in sachets for absorbing oxygen from the food environment. Dossier were submitted by the applicant, NanoBioMatters Industries, S.L., Spain.

The main active ingredient of the oxygen absorber system is iron which reacts with oxygen in the presence of water. The oxygen absorber is intended to be incorporated at level up to 3 % w/w in a polyolefin in contact with any type of foods for long term of storage at room temperature or refrigeration. It may also be used in sachets made of HDPE, which are intended to be placed in the headspace of the primary packaging or in contact with solid foodstuffs, but should not be in contact with liquid foods, or foods with external aqueous liquid phase.

All starting substances have been evaluated and approved for use as additives in plastic food contact materials or as food additives. The iron (0) modified bentonite is intended and expected to be present in the final article as non-nanoform.

From a toxicological point of view, migration of iron (incorporated), aluminium from bentonite (naturally present) and boron produced in the modification process of the natural clay, is of interest.

Based on migration tests carried out with high density polyethylene in direct contact with food simulants, it is expected that migration of iron and boron are lower than the SML values of set in Regulation EU No 10/2011, respectively 48 mg/kg and 6 mg/kg food, when the oxygen absorber is used at levels up to 3 % w/w into polyolefin layer in direct contact with acidic foods. Under these conditions of use, migration of aluminium was estimated to be up to 0.045 mg/kg in 3 % acetic acid solution, corresponding to less than 1 % of the Tolerable Weekly Intake set by the AFC Panel in 2008. The overall migration of 10 mg/dm² food set for plastics is also not expected to be exceeded.

The Panel noted that the SML of iron is based on the PMTDI of 0.8 mg/kg bw established by the Joint FAO/WHO Expert Committee on Food Additives in 1983 and agreed by the SCF in 1990. However in 2004, the EFSA NDA Panel concluded that the data available are insufficient to establish a tolerable upper intake level for iron. For boron, the CEF Panel noted the tolerable upper intake level (UL) of 10 mg boron/person per day set by the EFSA NDA Panel in 2004 and that, considering the various sources of exposure to boron, other than food contact materials, the Commission may wish to take note of other sources of exposure if setting a restriction for boron.

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

The substance may also be used in sachets, placed in the headspace of the packaging. Such sachets must prevent the physical release of their contents into the food and should not be in direct contact with liquid foods, exudates, or foods with external aqueous liquid phase. Under these conditions of use, migration of iron, boron and aluminium is not expected.

Therefore, the CEF Panel concluded that the use of the substance iron (0) modified bentonite does not raise a safety concern when used as oxygen absorber incorporated without compatibilizers in polyolefin articles used for long term of storage at room temperature or refrigeration:

- i) At level up to 3 % w/w incorporated in a polyolefin layer in direct contact with all types of food including beverages;
- ii) At higher levels, when the food is separated from the active material by a layer of polyolefin that does not contain the oxygen absorber formulation and offering a barrier to diffusion against inorganic species at least equivalent to 10 µm polypropylene.

The substance equally does not raise a safety concern when it is used in sachets, placed in the headspace of the packaging, that prevent the physical release of their contents into the food and are not in direct contact with liquid foods, exudates, or foods with external aqueous liquid phase.

The Panel stressed that the final article should comply with specific migration limits applicable for plastic materials.

TABLE OF CONTENTS

Abstract	1
Key words	2
Summary	3
Table of contents	5
Background as provided by the Legislation	6
Terms of reference as provided by the Applicant	6
Assessment	7
1. Introduction	7
2. General information.....	7
3. Data available in the dossier used for this evaluation.....	8
4. Evaluation.....	8
4.1. Non-toxicological data.....	8
4.2. Toxicological data.....	9
Documentation provided to EFSA	10
References	10
Glossary and abbreviations	12

BACKGROUND AS PROVIDED BY THE LEGISLATION

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 above mentioned regulations.

According to this procedure the industry submits applications to the Member States competent Authorities which transmit the applications to EFSA for 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 context, EFSA received an application from the Agencia Española de Seguridad Alimentaria y Nutrición, Spain, requesting the evaluation of the substance iron (0) modified bentonite for use as oxygen scavenger.

TERMS OF REFERENCE AS PROVIDED BY THE APPLICANT

EFSA is required to carry out a risk assessment on the risks originating from the migration into food of the substance iron (0) modified bentonite, made from the starting substances iron (III) chloride anhydrous, bentonite and sodium borohydride, 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 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

The European Food Safety Authority was asked by the Agencia Española de Seguridad Alimentaria y Nutrición to evaluate the safety of the oxygen scavenger iron (0) modified bentonite (FCM Substance No 01036), made from the starting substances iron (III) chloride anhydrous (CAS No 7705-08-0), bentonite (CAS No 1302-78-9, FCM Substance No 393) and sodium borohydride (CAS No 16940-66-2, FCM Substance No 981). The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2011-000197. The dossier was submitted by the applicant, NanoBioMatters Industries S.p.a.

2. General information

According to the applicant, the active oxygen absorber is iron (0) modified bentonite. The natural bentonite clay is surface modified by cation exchange between sodium and added iron which has oxygen scavenging properties. The active substance is intended to be incorporated up to 3 % w/w in a polyolefin layer in direct or indirect contact with any type of foods including beverages under conditions of long term of storage at room temperature or refrigeration. It may also be used in sachets made of HDPE, placed in the headspace of the primary packaging or in contact with solid foodstuffs, but should not be in contact with liquid foods (i.e. dressings, soups, beverages) or foods with external aqueous liquid phase (i.e. sliced fruits, fresh meat and poultry).

The iron (0) modified bentonite has not been evaluated by EFSA in the past. However, non-modified bentonite and iron powder are listed in Regulation (EU) 10/2011⁶. The by-products formed during the process are boric acid and sodium chloride.

- Bentonite is authorised as additive for plastic materials and articles in contact with foods (Regulation (EU) No 10/2011) with no specific restriction (FCM Substance No 393).
- 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 (JECFA, (1983) and agreed by the SCF (1990) (FCM Substance No 983).

Iron (II) has also been evaluated for use in oxygen scavenger mixtures incorporated in polyolefin layers (EFSA CEF Panel, 2012a; EFSA CEF Panel, 2013). The CEF Panel concluded that the active substances do not raise a safety concern a) when incorporated without compatibilisers in polyolefin layers of food packages up to 15 % w/w (EFSA CEF Panel, 2012 a and b) when 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 (EFSA CEF Panel, 2013).

- 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 6mg/kg (expressed as boron) (FCM Substance No 584). Sodium borohydride was also evaluated as active FCM substance (EFSA CEF Panel, 2012b). In that case, the CEF Panel concluded that there is no safety concern for the consumer when the sodium borohydride is only used behind a plastic layer to prevent direct contact with the packaged food.

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.

Sodium chloride is covered by the sodium salt of hydrochloric acid authorised as an 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). Sodium chloride has also been evaluated for use in oxygen scavenger mixtures incorporated in polyolefin layers (EFSA CEF Panel, 2013; EFSA CEF Panel, 2013) with the same conclusion as quoted above for iron.

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 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:

- Identity of the active system
- Physical/chemical characteristics of the active system, including particle size distribution and morphology studies
- Manufacturing process of the active system
- Intended use of the active system
- Existing authorisations
- Migration data (specific migration of iron, aluminium and boron, and overall migration).

Toxicity data:

- None

4. Evaluation

4.1. Non-toxicological data

The active substance is iron (0) modified bentonite, produced from the starting substances iron (III) chloride anhydrous (53 %), bentonite (32 %), sodium borohydride (15 %) and water as solvent. Aluminium is naturally present in bentonite clay. The natural clay is surface modified with the attachment of iron which has oxygen scavenging properties and the process for bentonite modification is a physical blending with iron (III), following reduction to iron (0) at a maximum temperature of 80 °C. Boric acid and sodium chloride are formed in the process. The soluble inorganic products are mainly washed off with the process water. However, analysis by ICP-MS showed that the final clay contained approx. 5% total boron.

Iron (0) modified bentonite is incorporated in a polyolefin layer intended for direct or indirect (multilayer) contact with any type of foods. The incorporation of modified iron (0) bentonite into the passive polyolefin matrix involves physical blending and moulding by conventional plastics processing operations, at maximum temperature of 250 °C. Decomposition or degradation of the active substance is not expected at the production and use conditions. The active mixture can also be used in sachets made from HDPE. The iron (0) modified bentonite is insoluble in water and organic solvents.

Particle size distribution of iron (0) modified bentonite showed values in the micron range: higher than 3 µm for more than 90 % of the particles and with an average particle size (50th percentile) of 9 µm. The specific surface area is lower than 1 m²/g. Morphology studies of the clay incorporated in the passive material do not indicate exfoliation of the clay particles. Given the non-polar nature of the polymers (polyolefins) and the processing conditions without compatibiliser addition, the iron (0) modified bentonite is intended and expected to be present in the final article as non-nanoform. Analyses of simulants from the migration experiments, targeting the evaluation of nanoparticles, gave

negative results. However, the formation of nanoparticles due to exfoliation cannot be excluded if the substance were to be incorporated in non-polar polymers with compatibilisers, or in polar polymers without such additives.

Specific migration of iron, boron and aluminium were measured for a HDPE layer containing 10 % w/w iron (0) modified bentonite in direct contact with the food simulants. Long term contact at room temperature was simulated by testing with water, acetic acid 3 % and ethanol 10 % for 10 days at 40 °C. Migration was also conducted into isooctane for 2 days at 20 °C. Migration of iron, boron and aluminium was found to be up to 28 mg/kg, 13 mg/kg and 0.15 mg/kg in 3 % acetic acid, respectively.

Using the maximum amount of active substance foreseen (3 % w/w), maximum migration of iron, boron and aluminium from an HDPE layer in direct contact with acidic foods can be estimated to be lower than the measured one by a factor 3.33, i.e. 8.4, 3.9 and 0.045 mg/kg foodstuffs.

When the layer containing the active formulation is used in multilayer food contact materials, i.e. indirect contact with foods, no significant migration of any of the inorganic active components is likely to occur through a polyolefin barrier layer and the specific migration limits for iron and boron are not expected to be exceeded.

The overall migration limit tested in the same conditions as used for specific migrations testing was up to 20 mg/dm² food into 3 % acetic acid. When used at levels up to 3 % w/w into polyolefin layer in direct contact with acidic foods, the overall migration of 10 mg/dm² food set for plastics is not expected to be exceeded.

The substance may also be used in sachets, placed in the headspace of the packaging. Such sachets must prevent the physical release of their contents into the food and should not be in direct contact with liquid foods, exudates, or foods with external aqueous liquid phase. Under these conditions of use, migration of iron, boron and aluminium is not expected.

4.2. Toxicological data

The substances used for the manufacture of the iron (0) modified bentonite, iron (III) chloride, sodium borohydride and bentonite, have been evaluated and approved for use as additives in plastic food contact materials or as food additives. Boric acid and sodium chloride are formed in the process as by-products. Iron and sodium chloride have also been evaluated for use in oxygen scavenger mixtures incorporated in polyolefin layers.

From a toxicological point of view, migration of iron (incorporated), aluminium (naturally present) from bentonite and boron (used in the process) is of interest.

From the migration results, it is expected that migration of iron and migration of boron into foods are lower than the SML values of set in Regulation EU No 10/2011, respectively 48 mg/kg and 6 mg/kg food, if the oxygen absorber is used under the intended conditions of use.

The Panel noted that the SML of iron is based on the PMTDI of 0.8 mg/kg bw established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1983) and agreed by the SCF (SCF, 1990). However in 2004, the EFSA NDA Panel concluded that the data available are insufficient to establish a tolerable upper intake level for iron (EFSA, 2004).

Substances containing boron (boric acid, barium tetraborate, sodium tetraborate and boron nitride) are authorised additives and listed in the Regulation (EU) No 10/2011, with a combined specific migration limit (SML) of 6 mg/kg (expressed as boron). Nevertheless, based on results from repeated dose studies on reproduction and development and on boron toxicokinetic, the CEF Panel agreed in 2012 with the tolerable upper intake level (UL) of 10 mg boron/person per day which was set by the EFSA NDA Panel (EFSA, 2004) (EFSA CEF Panel, 2012b). Considering the various sources of exposure to boron, other than food contact materials, such as foodstuffs, mineral water, food supplements and a

wide range of consumer products, e.g. medicinal products, cosmetics, toys, detergents and adhesives (EFSA, 2004 and 2005; ECHA, 2008), the Commission may wish to take note of these other sources of exposure if setting a restriction for boron.

Migration of aluminium can be estimated to be up to 0.045 mg/kg in 3 % acetic acid solution. The Panel took note of the opinion of the AFC Panel (EFSA, 2008) setting a TWI of 1 mg/kg bw/week for aluminium. Based on a conservative scenario of consumption of 1 kg of acidic food per day containing aluminium migrated at the level of 0.045 mg/kg, an adult of 60 kg bodyweight in one week time would be exposed to 0.00525 mg Al/kg bw/week corresponding to less than 1 % of the TWI set in 2008.

Therefore, the Panel considered that under the intended conditions of use, the oxygen absorber is toxicologically acceptable.

CONCLUSIONS

The CEF Panel concluded that the use of the substance iron (0) modified bentonite does not raise a safety concern when used as oxygen absorber incorporated without compatibilizers in polyolefin articles used for long term of storage at room temperature or refrigeration:

- i) At level up to 3 % w/w incorporated in a polyolefin layer in direct contact with all types of food including beverages;
- ii) At higher levels, when the food is separated from the active material by a layer of polyolefin that does not contain the oxygen absorber formulation and offering a barrier to diffusion against inorganic species at least equivalent to 10 µm polypropylene.

The substance equally does not raise a safety concern when it is used in sachets, placed in the headspace of the packaging, that prevent the physical release of their contents into the food and are not in direct contact with liquid foods, exudates, or foods with external aqueous liquid phase.

The Panel stressed that the final article should comply with specific migration limits applicable for plastic materials.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier referenced: iron based oxygen scavenger, dated: 8 February 2011. Submitted by NanoBioMatters Industries, S.L.

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GLOSSARY AND ABBREVIATIONS

Overall migration: The sum of the amounts of volatile and non volatile substances, except water, released from a food contact material or article into food or food simulant

Specific migration: The amount of a specific substance released from a food contact material or article into food or food stimulant

AFC	Food additives, Flavourings, processing aids and materials in Contact with food
bw	body weight
CAS No	Chemical Abstract Service Number
CEF	Food Contact Materials Enzymes, Flavourings and Processing Aids
EC	European Commission
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization
FCM	Food Contact Materials
HDPE	High Density Polyethylene
JECFA	The Joint FAO/WHO Committee on Food Additives
ICP-MS	Inductively coupled plasma-mass spectroscopy
NDA	Dietetic Products, Nutrition and Allergies
PMTDI	Provisional Maximum Tolerable Daily Intake
SCF	Scientific committee on food
SML	Specific Migration Limit
TDI	Tolarable daily Intake
TWI	Tolerable Weekly Intake
w/w	Weight by weight