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Safety assessment of the substance isobutane, for use in 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, Alexandros Lioupis and Laurence Castle

Abstract

The substance isobutane is intended to be used as a foaming agent at max 4.5% to produce expanded polystyrene (EPS) to be used for packaging foods, such as fruits, vegetables, meat, fish and cheese, at room temperature or lower. Isobutane is approved in Europe as a food additive (E 943b) to be used *quantum satis* as a gas propellant only in vegetable oil pan spray (for professional use only) and water-based emulsion spray according to Regulation (EC) No 1333/2008. The purity requirements for the use of isobutane as a food additive are described in Commission Regulation (EU) No 231/2012. The substance is a gas at room temperature. It is a saturated hydrocarbon, obtained with a high level of purity, and is not expected to react under the processing conditions used to make foamed polystyrene materials and articles. Data on migration of isobutane from trays at 20°C for 10 days ranged from 0.2 to 0.4 mg/kg food. Considering the intended applications, estimated exposure is extremely low based on migration data. In the absence of genotoxicity alerts and given the very low toxicity following repeated exposure with no observed adverse effect concentration (NOAEC) of several thousands of mg/m³ by inhalation, it was considered that the use of isobutane as a foaming agent, at the expected exposure from food, does not raise a safety concern.

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Correspondence: fip@efsa.europa.eu

Panel members: Claudia Bolognesi, Laurence Castle, 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, Vittorio Silano, Jannavi Srinivasan, Maria de Fátima Tavares Poças, Christina Tlustos, Detlef Wölfle and Holger Zorn.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Before a substance is authorised to be used in food contact materials (FCM) and is included in a positive list EFSA's opinion on its safety is required. This procedure has been established in Articles 8, 9 and 10 of Regulation (EC) No 1935/2004¹ of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States' competent authorities which transmit the applications to EFSA for their evaluation.

In this case, EFSA received an application from the Ministerio de Sanidad, Servicios Sociales e Igualdad, Spain, requesting the evaluation of the substance isobutane, with the CAS number 75-28-5, the FCM substance No 1069 and the Food Additive E number 943b (propellant gas) for use as foaming agent.

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 isobutane to be used in 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
- Residual content of the substance
- Identification and quantification of reaction products and impurities.

Toxicological data

None.

2.2. Methodologies

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 Scientific Committee on Food (SCF) for the presentation of an application for safety assessment of a substance to be used in FCM 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 substance that is 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.

¹ 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.

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:

- In case of high migration (i.e. 5–60 mg/kg food), an extensive data set is needed.
- In case of migration between 0.05 and 5 mg/kg food, a reduced data set may suffice.
- 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, 2009) and considering the relevant guidance from the EFSA Scientific Committee.

3. Assessment

The substance isobutane is used as a foaming agent at up to 4.5% to produce expanded polystyrene (EPS). The EPS articles are intended to be used for foods such as fruits, vegetables, meat, fish and cheese, at room temperature or lower.

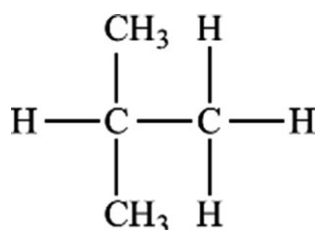
Isobutane is not listed in Commission Regulation (EC) No 10/2011² but *n*-butane (CAS 106-97-8) is listed in that regulation as a plastic additive without restrictions.

Isobutane is approved in Europe as a food additive (E 943b) to be used *quantum satis* as a gas propellant in vegetable oil pan spray (for professional use only) and water-based emulsion spray, according to Regulation (EC) No 1333/2008³. The purity requirements for the use of isobutane as a food additive are described in Commission Regulation (EU) No 231/2012⁴.

3.1. Non-toxicological data

Chemical formula: C₄H₁₀

Chemical structure:



CAS number: 75-28-5

With a boiling point of –11.7°C, the substance is a gas at room temperature. Isobutane is soluble in organic solvents such as ethanol, diethylether and chloroform. It is sparingly soluble in water (e.g. 49 mg/L at 25°C). It has a partition coefficient log K_{o/w} value of 2.76. The substance is a saturated hydrocarbon that is not expected to react under the processing conditions used to make foamed polystyrene materials and articles.

The substance is obtained with a high purity (specifications > 95%) from a mixture of hydrocarbons by distillation followed by purification steps. Information on the impurities was provided and the main impurities were *n*-butane (specifications 4% max) and propane (2% max).

Being a C₄ hydrocarbon, a potential impurity of concern of isobutane would be 1,3-butadiene. 1,3-Butadiene is listed in Regulation (EC) No 10/2011 as a monomer, with Plastics Reference Number 13630. This regulation specifies that migration of butadiene should not be detectable and furthermore that any residual butadiene should be no more than 1 mg/kg in the final plastic. From the analytical results provided, no 1,3-butadiene was detected (< 2 mg/kg) in the isobutane used as a polystyrene foaming agent.

² 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.

³ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

⁴ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 1–295.

The isobutane meets the purity criteria for the use of isobutane as a propellant gas (see above) except for the content of methane for which no data is available. Considering that the substance is obtained by distillation and taking into account the very low levels of C2 hydrocarbons, the concentration of methane is expected to be far below the specification as a food additive.

Limited data on migration of isobutane was presented. Tests with EPS trays using the food simulant modified polyphenylene oxide (simulant E) at 20°C for 10 days, resulted in a migration equivalent to 0.2–0.4 mg/kg food. Considering the intended applications, fish and meat products are further processed in most cases, and fruits and vegetables are often whole and unpeeled. Therefore, the migration data presented can be considered as indicative of a low level of potential exposure to isobutane (0.005 mg/kg body weight (bw) per day as a gross overestimate, if 1 kg of food eaten per day and 60 kg bw are assumed).

3.2. Toxicological data

No toxicological data were provided. However, the Panel noted that the SCF did not have a toxicological concern about the use of water-based emulsion sprays and oil-based aerosol sprays for baking and frying purposes, which contain propane, butane or isobutane (SCF, 1999).

Isobutane has no structural alert for genotoxicity and was reported with negative results in a bacterial mutation assay (Kirwin and Thomas, 1980).

In a combined repeated exposure study with a reproduction/development toxicity screening test (OECD 422) conducted in rats by inhalation of isobutane (McKee et al., 2014), no systemic toxicity and no neurotoxicity potential were observed at concentrations up to 9,000 ppm (v/v) of isobutane. Based on a reduction of fertility, a NOAEC for reproductive toxicity was set at 3,000 ppm (7,125 mg/m³). Considering the very low toxicity by inhalation and the low expected human exposure from food for the intended application, the Panel concludes that no safety concern arises from the use of isobutane as foaming agent.

The Panel noted the existing migration restriction on 1,3-butadiene used for food contact plastics and therefore it is not necessary to place a specification on this potential impurity.

This application is for using isobutane as a foaming agent specifically to produce expanded polystyrene. The Panel is aware that other foamed plastics are made, such as foamed polyurethanes, using other foaming agents. Also, polystyrene can be made using a variety of co-monomers in addition to styrene itself. Given the low and largely self-limiting exposure to isobutane (since it is a gas) and given the very low toxicity of isobutane, the Panel did not consider it necessary to limit the use to polystyrene only.

4. Conclusions

The CEF Panel, after having considered the above-mentioned data, concluded that the substance isobutane does not raise a safety concern for the consumer if used as a foaming agent for plastics intended for food contact applications.

Documentation provided to EFSA

- 1) Dossier "Isobutane", January 2017. Submitted by RLESA (REPSOL LUBRICANTES Y ESPECIALIDADES, SA), Spain.
- 2) Additional information for the dossier "Isobutane", September 2017. Submitted by RLESA (REPSOL LUBRICANTES Y ESPECIALIDADES, SA), Spain.

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Abbreviations

bw	body weight
CAS	Chemical Abstracts Service
CEF Panel	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
EPS	expanded polystyrene
FCM	food contact materials
$K_{o/w}$	octanol/water partition coefficient
NOAEC	no observed adverse effect concentration
OECD	Organisation for Economic Co-operation and Development
SCF	Scientific Committee on Food
SML	specific migration limit