

# Safety Assessment of Isomaltulose Syrup (dried)

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**Novel Food Classification:** *Article 1.2 (c)*

## Introduction

An application for the authorisation of isomaltulose syrup (dried) was submitted to the Food Safety Authority of Ireland (FSAI) by Evonik Creavis GmbH of Germany in accordance with *Article 4* of the novel food Regulation (EC) No. 258/97. The application was accepted by the FSAI on June 28<sup>th</sup> 2017. Initial discussions with the applicant explored the possibility of achieving a substantial equivalence opinion with isomaltulose already authorised as novel food by Commission Decisions 2005/457/EC and 2005/581/EC. However, the previous novel food applications categorised isomaltulose in accordance with *Article 1.2(c)* of the novel food Regulation (EC) No 258/97 which makes it ineligible for the simplified procedure.

Isomaltulose is a disaccharide consisting of one glucose and one fructose molecule linked by an  $\alpha$ -1,6-glycosidic bond. The novel ingredient is intended for use as a sucrose substitute in various food categories including solid, semi-solid and liquid foods. Isomaltulose with a purity of  $\geq 98\%$  (dry matter) was authorised as a novel food by Commission Decisions 2005/457/EC and 2005/581/EC. Both the authorised and novel isomaltulose products are produced by the isomerisation of sucrose using *Protaminobacter rubrum* as a source of sucrose isomerase. Some minor differences in the production process are noted, such as the use of immobilised non-viable *P. rubrum* cells for the Evonik product compared to the use of formaldehyde inactivated *P. rubrum* cells by another manufacturer.

The applicant considers the novel ingredient to fall within *Article 1.2(c)* of the novel food Regulation (EC) No. 258/97: “foods and food ingredients with a new or intentionally modified primary molecular structure” in line with previous applications.

## I. Specification of the novel food

Isomaltulose, an isomer of sucrose, is a reducing disaccharide composed of a glucose and fructose molecule joined by an  $\alpha$ -1,6-glycosidic bond. The novel isomaltulose syrup (dried) is a water soluble, white or colourless, crystalline powder comprising  $\geq 80\%$  isomaltulose on a dry weight basis. The remaining  $\leq 20\%$  consists of some unreacted sucrose (2 - 3%),

trehalulose (8 - 9%), glucose and fructose (4.9 - 5.2%), as well as small amounts of isomelezitose (1.2 - 1.3%). Traces of unspecified oligosaccharides may also be present.

Parameter	(%Dry weight)
Isomaltulose	≥80
Trehalulose	≤12
Glucose	≤3
Fructose	≤4
Saccharose	≤4
Isomelezitose/oligosaccharides	≤2
Protein	≤1 mg/kg
Water	≤7
Ash	≤0.5
Lead	<0.1 mg/kg

## II. Effect of the production process applied to the novel food

The production process involves isomerisation of sucrose (from sugar beet or sugar cane) by the enzyme sucrose isomerase from *P. rubrum* cells (strain CBS 574.77) that are rendered non-viable when immobilized on a sterilised matrix of calcium alginate. This process is similar to that of the existing isomaltulose authorised by Commission Decision 2005/581/EC. The isomerised solution is heat sterilised and subsequently purified by ion-exchange chromatography at 70 °C before the demineralised isomaltulose solution is dried to a powder.

## III. History of the organism used for the novel food

Sucrose derived from both sugar beet and sugar cane is an established and safe ingredient used in the EU food industry and a globally traded commodity in line with the Codex standard for sugar (Codex Standard 212-1999).

## IV. Anticipated intake/extent of use of the novel food

The applicant proposes that the novel isomaltulose syrup (dried) will be used as a sucrose substitute in non-specified foods and beverages for the general population, similar to existing isomaltulose. The applicant provides two approaches to anticipate intake: i) by quoting estimated daily intake as contained in a dossier for an already approved, isomaltulose; ii) by

assuming that 100% of added sugars consumed are isomaltulose using data collected from US national food consumption surveys. Isomaltulose intakes in the dossier for the already approved isomaltulose were derived from intakes of specified beverages, cereals and cereal products, candy and chocolate bars and energy tablets. Details of the data sources, the population and total daily intakes are not provided, however, details of the highest users are listed as ‘children consuming dilutable soft drinks, with mean and 97.5th percentile intakes of 0.9 and 2.9 g/kg body weight/day respectively. Using the second approach, assuming that isomaltulose replaces intakes of all other dietary ‘added sugars’ in the US population, the potential highest intakes were reported for 2-5 year old children on a body weight basis of approximately 1 g/kg bw/day. NOAEL provided later in the document are reported as 3.2 g/kg bw/day (dry matter). The conservative nature of this second approach is noted as it used an unrealistic scenario where 100% of dietary added sugar would come from isomaltulose. Both data sources used to estimate intakes are relatively dated, being 10-14 years old. Therefore, it is possible that added sugar/isomaltulose may be obtained from food categories other than those factored here, and at different levels. In addition, current trends to reformulate and reduce the added sugar content of many key food categories (e.g. beverages) means that these intake estimates may be overly conservative.

#### **IX. Information from previous human exposure to the novel food or its source**

Sucrose from sugar beet and sugar cane is a globally traded food commodity (Codex Standard 212-1999). Isomaltulose has been authorised for the EU market for more than a decade, but studies cited in the dossier do not identify any significant concerns related to its consumption.

#### **X. Nutritional information on the novel food**

The novel ingredient in the dried state ( $\leq 7\%$  moisture) consists of  $\geq 80\%$  isomaltulose, with the remaining  $\leq 20\%$  consisting of mono- and di-saccharides and minimal amounts of protein. Ingested isomaltulose is broken down to fructose and glucose in a similar manner to sucrose, albeit at a different rate. There is some evidence of a more protracted digestion of isomaltulose compared to sucrose which may be of nutritional interest to certain population sub-groups. There are no nutritional concerns regarding the known di- or tri-saccharides present in the novel isomaltulose syrup (dried). The relatively small proportion of uncharacterised oligosaccharides are also likely to be present in the EU-authorised

isomaltulose, as well as other foods, and would either be metabolised in the digestive tract or fermented by gut bacteria.

## **XI. Microbiological information on the novel food**

The safety of *Protaminobacter rubrum* (strain CBS 574.77) has already been assessed as part of a novel food application which was authorised in 2005 and is not considered a risk to humans or the environment. The novel isomaltulose syrup (dried) is produced in a similar manner to one of the EU-authorised isomaltulose products from the same raw material (food-grade sucrose). Considering the low water content of the final isomaltulose product, the microbiological quality is not considered a significant concern once good manufacturing processes are maintained. This, along with the heat treatments carried out during the production process should ensure a microbiologically safe product. In addition, the applicant has provided data demonstrating the absence of yeasts & moulds, *B. cereus*, *S. aureus*, *C. perfringens*, *E. coli* and *Salmonella*.

## **XII. Toxicological information on the novel food**

### ***Toxicological Studies***

Since the authorisation of isomaltulose as a novel food in the EU and Australia/NZ, additional studies on isomaltulose ingestion by animals and humans have been examined, with no adverse reactions reported. The chemical structure and metabolic utilization of glucose, fructose, trehalulose as well as small amounts ( $\leq 2\%$ ) of isomelezitose and oligosaccharides do not raise toxicological concern.

### ***Human Safety Data***

Sucrose and isomaltulose are hydrolysed in the small intestine by the same digestive enzyme, (sucrase-isomaltulase) which is located on the brush border membrane. Since ingested isomaltulose is rapidly hydrolysed and absorbed as glucose and fructose, several high doses could be consumed in the course of a day without risk of intestinal side-effects. Thus, daily doses of 1.0 – 1.3 g/kg bw/d are expected to be as well tolerated as corresponding doses of sucrose in adults and children.

### ***Undesirable substances***

The applicant has provided data on undesirable substances such as heavy metals (lead, arsenic, cadmium, mercury and nickel). However, the applicant contends that the sucrose used in the production of the novel ingredient is subject to internationally accepted Codex

standards (Codex Standard 212-1999) must comply with relevant EU legislation related to potential contaminants, and so batch testing of the novel ingredient for pesticide residues or environmental contaminants such as PCBs and dioxins is not warranted.

## **Conclusions**

Initial discussions with the applicant about this novel ingredient focused on the possibility of achieving an FSAI opinion on its substantial equivalence to EU-authorized isomaltulose products. However, such an approach was not feasible due to the novel food categorisation which meant it was not eligible for the simplified procedure.

Isomaltulose is an EU-authorized novel food, the consumption of which has not been associated with any health concerns. The novel ingredient is intended as a potential replacement for existing isomaltulose in certain food products. The applicant contends that the novel isomaltulose product is very similar to the EU-approved equivalent, as well as to its sucrose isomer, and therefore it does not pose a risk to human safety. As a result, much of the safety information is based on a direct comparison with EU-authorized isomaltulose rather than original safety data.

To be consistent with the isomaltulose products already authorized in the EU by Commission Decisions 2005/457/EC and 2005/581/EC, the novel ingredient should be designated as 'isomaltulose' on the labelling of the product as such, or in the list of ingredients of foods containing it. In addition, a prominently displayed footnote (typeface of at least the same size as the list of ingredients) related to the isomaltulose designation should explain that 'isomaltulose is a source of glucose and fructose'.

## **Recommendation**

The Food Safety Authority of Ireland has not identified any safety concerns associated with the consumption of the novel isomaltulose syrup (dried) produced by Evonik Creavis GmbH of Germany. Therefore the FSAI is of the opinion that it meets the criteria for novel food set out in *Article 3.1.* of the novel food Regulation (EC) No 258/97.