

General ISOMALT Quality Compliance

ISOMALT is a polyol (food additive E 953) produced from food-grade beet sugar (sucrose) by enzymatic conversion into isomaltulose and subsequent catalytic hydrogenation. The production site of ISOMALT (country of origin) is the Federal Republic of Germany, a Member State of the European Union. Origin of beet sugar is the European Union as well.

BENEO-Palatinit produces all food-grade products including ISOMALT in strict compliance with European Food Law with particular focus on hygiene and safety standards. Safety standards applied by BENEO-Palatinit are in accordance with the requirements of Regulation (EC) No 178/2002 *"laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety"*. Hygiene provisions follow Regulation (EC) No 852/2004 *"on the hygiene of foodstuffs"*.

Apart from the general requirements, the specific requirements for ISOMALT as defined in Commission Regulation (EC) No 231/2012 *"laying down specifications for food additives listed in Annexes II and III to Regulation (EU) No 1333/2008..."*, are ensured with the BENEO-Palatinit ISOMALT Product Sheet.

Compliance with EU-Regulations Nos 178/2002, 852/2004 and 231/2012 includes the absence of unacceptable levels of mycotoxins, heavy metals, pests, foreign bodies, microbiological agents, pesticides as well as other chemicals. This is ensured via preventive process control measures, raw material qualities, plant construction as well as installed hygienic personnel and environmental measures.

Particular substances at risk and with global attention such as melamine, 3-MCPD, isopropanol, acrylamide, dioxins, polychlorinated biphenyls, polycyclic aromatic hydrocarbons etc. are not used in the production of ISOMALT resp. their formation from a pure carbohydrate such as ISOMALT is not likely. In the absence of directly applicable provisions for ISOMALT in Regulation (EC) No 1881/2006 *"setting maximum levels for certain contaminants in foodstuffs"*, we can confirm that it would comply with the lowest ML laid down in said Regulation (current valid version) for plant-derived foods for the general (adult) population.

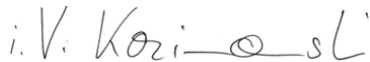
For pesticide residues, compliance with Regulation (EC) No 396/2005 *"on maximum residue levels of pesticides in or on food and feed of plant and animal origin..."* is the ensured benchmark; verification is carried done by monitoring of the raw material sucrose as well as ISOMALT.

ISOMALT from BENEО-Palatinit does not require allergen labelling under the provisions of Regulation (EU) No 1169/2011 "*on the provision of food information to consumers...*" (Annex II).

For the raw materials and processing aids used, ISOMALT from BENEО-Palatinit is not affected by mandatory labelling defined in Regulations (EC) No 1829/2003 and 1830/2003 that contain provisions regarding authorization, labelling and traceability of genetically modified foods.

This statement also covers galenIQ™, the excipient type of ISOMALT, unless the requirements for excipients are more stringent than the food ingredient requirements.

In summary, BENEО-Palatinit guarantees the delivery of ISOMALT worldwide in compliance with the applicable regulations with the inherent provisions for product safety and hygiene.



Dr. Gunhild Kozianowski
Corporate Product Safety/Specifications Management
BENEО GmbH

This statement is valid on the date of issue. The legally binding character automatically expires 3 years after date of issue.