



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

Review date:

05.01.2023

Version:

5.0

93885-LACTOSE MONOHYDRATE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1 Identification of the substance or preparation

Name: Lactose monohydrate

Bulk code: 93885

Internal code: 405999

1.2 Synonyms

No information available.

2. DESCRIPTION

Appearance: Crystalline powder

Colour: White

Origin: Obtained from bovine milk/sweet whey

Geographical origin: Germany, Austria and Italy

3. COMPOSITION/INFORMATION ON COMPONENTS

CAS: 10039-26-6

Formula: $C_{11}H_{22}O_{11} \cdot H_2O$

Molecular weight: 360 g/mol

Components: 100% lactose

Method of production: The product has been treated at least 72°C for 15 s during the production process. It is produced with microbial rennet.

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: Slowly soluble in water and practically insoluble in alcohol, chloroform and ether.

5. PROPERTIES/USES

Excipient for pharmaceutical use.

Food use.

The product can be used for human consumption and does not have any genotoxic impurities.



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The above-mentioned factories in which the products are manufactured are under official veterinary supervision and have been produced in accordance with food hygiene standards:

- EU 852/2004 (food hygiene)
- EU 853/2004 (specific hygiene rules for food of animal origin)
- EU 854/2004 (specific rules for the organisation of official controls on products of animal origin intended for human consumption)
- EU 2017/625 (official controls to ensure the implementation of food and feed law and rules for animal health and welfare)
- EU 2073/2005 (microbiological criteria for food products)

6. DOSAGE

No information available.

7. REMARKS

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

STORAGE:

Store in a cool, dry place protected from sunlight in a hermetically sealed container, away from heat and moisture.

The documentation available related to the product's regulatory compliance is included below.

BSE/TSE:

The milk used to manufacture the product comes from healthy animals collected under the same conditions as milk intended for human consumption. This is a regulatory requirement required by the European Union hygiene directives with Regulations (EEC): 178/2002, 852/2004, 853/2004 and 2073/2005. Production plants and products are under current veterinary supervision.

There is no well-founded scientific knowledge, in Spain or elsewhere, for transmissibility of BSE in milk (EMEA/410/01 rev. 03). The EU has excluded milk and milk products from BSE risk material. With this current decision established in Regulation (EC) 1326/2001, milk and milk products are considered safe.

Milk is unlikely to present any risk of TSE contamination in light of current scientific knowledge, irrespective of its geographical origin (EMEA/410/01 rev 3). Milk and dairy



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products are considered safe according to WHO publication (<http://www.who.int/bloodproducts/tablestissueinfectivity.pdf?ua=1>) and according to Regulation (EC) 2011/C73/01.

GMOs:

Lactose monohydrate is not genetically modified, nor does it contain any ingredients derived from genetic engineering. Therefore, it is not subject to GMO requirements.

NANOMATERIALS:

The product is derived from milk and therefore does not contain nanoparticles that must be declared in accordance with Regulation (EU) 1169/2011.

RADIATION:

The product has not undergone irradiation and is filled without gassing.

PRESERVATIVES/ADDITIVES:

No additives or preservatives are used in the manufacturing process.

RESIDUAL SOLVENTS:

No solvents are used in the manufacturing process.

The product does not contain residual solvents as defined and classified in USP (467), ICH Guideline (Q3C(R6) 2016) and Annexes I and II to CPMP/ICH/283/95 and CVMP/VICH/502/99 and the current edition of the European Pharmacopoeia (Chapter 5.4).

CONTAMINANTS:

The product is compliant with the relevant German and EU legislation for the maximum residue limit according to EU Regulation (EC) 1881/2006, 37/2010 and 396/2005.

Residues and contaminants are controlled in a risk assessment and inspection programme by the Government of Bavaria. According to existing EU regulations, there is a RASFF (Rapid Alert System for Food and Feed) programme within the EU with a daily national alert and a crisis report.

As a result of these monitoring programmes and the control by the manufacturer (such as aflatoxin M1, polychlorinated biphenyl, toxic heavy metals or pesticides), it is possible to ensure compliance with the legislation.

In addition, the product is free of antibiotics. Only milk tested with a negative result is accepted and used for production.

The activity of the radionuclides Cesium 134 and Cesium 137 in the product is below 10 Bq/kg. The product is suitable for human consumption with regard to radiochemical analysis.



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IMPURITIES:

The product is not expected to contain elemental impurities according to ICHQ3D. In addition, these are not added in the manufacturing process.

The product does not contain:

- Ethylene oxide/2-chloroethanol: There is no risk of cross-contamination with ethylene oxide/2-chloroethanol, nor are these used in any manufacturing area or in pest control.
- Latex.
- Nitrites, nitrates, nitrosating agents: These are not used at any stage of the manufacturing process, nor are they generated as impurities derived therefrom.
- Antibiotics.

HEAVY METALS:

These are not intentionally added during the manufacturing process, so they are not expected to be present beyond technically unavoidable trace levels.

ALLERGENS:

- **Food allergens:** The products mentioned above are derived from milk and therefore contain or may contain milk, milk protein, whey protein, lactose and/or other potential allergens that could be found in milk. The products do not contain any other allergens. According to Regulation (EU) 1169/2011, the term milk and milk products (including lactose) could be used as a possible description in the list of ingredients. It does not contain any allergens other than milk and milk products according to Annex II of Regulation (EU) 1169/2011.

HALAL:

The product is Halal certified.

KOSHER:

The product is Kosher certified.

NUTRITIONAL COMPOSITION:

Nutritional values per 100 g of product:

Energy: 399 kcal/1667 kJ

Total fat: 0 g

Saturated fat: 0 g

Total carbohydrates: 99.7 g

Sugar: 99.7 g

Protein: 0 g

Salt: 0 g

Carbohydrate exchange unit 8.3 BE



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These values are average values, as there may be a possible fluctuation due to seasonal and feed variation.

WADA:

The product is not listed on the World Anti-Doping Agency's (WADA) list of prohibited substances.

Due to the manufacturing process and the raw materials used, the product is not expected to contain any traces of the chemicals mentioned in the anti-doping lists (anabolics, hormones, beta-2 antagonists, anti-oestrogenic agents, diuretics and other masking agents, stimulants, narcotics, cannabinoids, glucocorticoids, alcohol and any other substance on this list).

REACH:

Exempt from registration.

TARIFF ITEM NUMBER:

1702.11.00.00