



PRODUCT DECLARATION

Product name: LACTOSE, NF (Monohydrate) (Spray Dried)
Stock code: 0316
Starting material: All Natural (Bovine Milk)
Manufactured via: Extraction

BSE/TSE: Based on the ingredients, the product is in compliance with the note for the guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products.

GMO: Product does not contain any GMO material.

ALLERGEN: Please note that there may be several steps before the raw material is produced and access to data on manufacturing raw materials is not easily obtained for the starting materials and intermediates used in the production process. The following items are not used in the manufacturing process of the product, and although manufacturer does not specifically assay for the presence of the items below, it is unlikely that any traces of these items are present in the starting materials or in the final product.

The product is unlikely to contain the following -
<input checked="" type="checkbox"/> Cereals containing gluten and products thereof
<input checked="" type="checkbox"/> Corn and products thereof
<input checked="" type="checkbox"/> Celery and products thereof
<input checked="" type="checkbox"/> Soybeans and products thereof
<input checked="" type="checkbox"/> Yeast
<input checked="" type="checkbox"/> Fish and crustacean shellfish and products thereof
<input checked="" type="checkbox"/> Eggs and products thereof
<input type="checkbox"/> Dairy Products (Milk, Lactose, Caseinates, Whey)
<input checked="" type="checkbox"/> Peanuts and products thereof
<input checked="" type="checkbox"/> Tree nuts (oils) or derivatives
<input checked="" type="checkbox"/> Mustard and products thereof
<input checked="" type="checkbox"/> Sesame Oil
<input checked="" type="checkbox"/> Preservatives
<input checked="" type="checkbox"/> Sulfites >10ppm
<input checked="" type="checkbox"/> Artificial Colors and Flavors
<input type="checkbox"/> Beef/Chicken/Pork derivatives (Contains bovine-milk-derived raw materials)

This allergen statement is for the use of the product in pharmaceutical compounding and is provided for informational purposes only. It is based on information received from the manufacturer concerning the product contents and manufacturing process, and Medisca makes no representations, and takes no responsibility for the content thereof. No analytical testing has been performed by Medisca or by the manufacturer for these allergens, and representations concerning their presence in trace amounts are based on theoretical considerations. Accordingly, this statement should not be taken as a guarantee of the absence of the above-stated allergens.

This statement replaces all previous versions for the above-mentioned product.

We trust this information, which is made to the best of our knowledge in conformance with the foregoing, will be helpful to you.

With kind regards,
The MEDISCA Team

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The manufacturer confirms that the LACTOSE products are manufactured in compliance with CPMP Guideline “Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products”. EMEA/410/01-Rev.3, and Australian Government TGA “Transmissible Spongiform Encephalopathies (TSEs), April 2014. The manufacturer confirms that the bovine milk used in the production of Lactose is sourced from healthy animals in the same conditions as milk collected for human consumption. No other ruminant or animal materials are used during the process to obtain the NF Lactose products. Enzyme products used are microbially produced and are not derived from animal sources (i.e. calf rennet is not used). Therefore, the Lactose product is excluded from the scope of the above stated guidance and thus a Certificate of Suitability from the European Directorate for the Quality of Medicines (EDQM) is not required.