

PRODUCT DECLARATION

Product name: USODIOL, USP/EP

Stock code: 1987

Starting material: Bile

Manufactured via: Chemical Synthesis

BSE/TSE: URSODIOL is manufactured using Cholic Acid purchased from qualified suppliers, in possession of currently valid Certificates of Suitability issued by the European directorate for the Quality of Medicines. Cholic Acid which is produced from bovine bile deriving from animals bred in countries free of risk of contamination from BSE/TSE without the use of fodder containing meat meal. Therefore, the product is free of contamination due to BSE/TSE in compliance with European note one “guidance EMEA/410/01 rev3 regarding minimizing the risk of transmitting Animal Spongiform Encephalopathy”.

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 checked="" 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 (source of bile)

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