

PRODUCT DECLARATION

Product name: Cellulose, NF/EP (Microcrystalline) (Flocel® 101)

Stock code: 0567

Starting material: Cellulose pulp obtained from wood. A number of tree varieties are utilized in the production of high purity cellulose pulp used for manufacturing microcrystalline cellulose for the pharmaceutical and nutraceutical industries. The timber resources used to make wood pulp are referred to as pulpwood. Wood pulp comes from softwood trees such as spruce, pine, fir, larch and hemlock, and hardwoods such as eucalyptus, aspen and birch. Some pulping processes use the entire tree, while others use parts of the tree that cannot be used to make lumber. The trees are harvested in accordance with best practices, chipped, aged, and processed to make high-purity alpha-cellulose pulp. The manufacture selects the appropriate pulp for the production of microcrystalline cellulose. The pulp goes through several processing steps to make the finished product. As such, the finished product, microcrystalline cellulose, is a highly refined and purified cellulose product, meeting pharmaceutical standards.

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 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 checked="" type="checkbox"/> Beef/Chicken/Pork derivatives

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

Version: 04

Issued Date: 02/12/2025