

**PRODUCT DECLARATION**

**Product name:** VENUCEANE™

**Stock code:** 2823

**Starting material:** Biotechnological and Plant Origin

**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:**

**Fragrance allergens according to Annexes II and III of the Regulation (EC) No 1223/2009 and its amendments:**

Raw vegetables, derivatives and end products used as raw material in the manufacturing products are monitored for the presence of fragrance allergens according to a risk assessment approach based on materials, processes, analytical availabilities and relevance. The above stated product contains ingredients obtained from vegetable derivatives but, based on knowledge of the raw materials and of the manufacturing process of the product, the presence of fragrance allergens residues is not expected. The product itself does not require fragrance allergens residues monitoring. The above stated product can contain raw materials derived from wheat, barley and/or rye. Nevertheless, according to the manufacturing process, the presence of gluten is not expected in the product.

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.

| <b>The product is unlikely to contain the following -</b>                              |
|--|
| <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 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,



## **PRODUCT DECLARATION**

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.

**Animal testing:** The above stated product has not been tested on animals to fulfil the requirements of the European Cosmetics Regulation (EC) No 1223/2009 and its amendments, by or on behalf of the manufacturer. Since 1998 the manufacturer has decided not to perform any animal testing on its products (except for other specific regulatory purposes).

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**