



**PRODUCT DECLARATION**

**Product name:** Empty vegetable CONI-SNAP capsules  
**Stock code:** 1127, 2235, 2414, 2849, 3080, 3088, 3083, 3084, 3085, 3193  
**Starting material:** Not applicable  
**Manufactured via:** Not applicable

**INGREDIENTS:** Refer to Medisca Certificate of Analysis.

**SOURCE OF HYPROMELLOSE:** Hypromellose is a cellulose material derived from softwood trees, mainly pine and spruce trees, which are grown and harvested from plantations in Western Europe and North America. The HPMC suppliers confirmed that only wood pulp obtained from FSC (Forest Stewardship Council) and/or PEFC (Programme for the Endorsement of Forest Certification) certified sources is being used, thereby assuring that the trees originate from sustainable forestry. The Hypromellose complies with the compendial requirements as listed in the harmonized USP, Ph. Eur., and JP monographs. It also meets the criteria for use as defined by 21 CFR 172.874 Hydroxypropyl Methylcellulose for food-related applications in the United States. Furthermore, it complies with the purity criteria for E464 (HPMC) as defined in Commission Regulation 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.

**BSE/TSE:** No components containing or derived from animal products are used in the production of unprinted Capsugel® empty DRcaps®, Enprotect®, Vcaps®, and Vcaps® Plus capsules. Consequently, and taking into account today’s supplier information, we herewith confirm that empty, unprinted DRcaps®, and Enprotect®, Vcaps®, and Vcaps® Plus capsules are not subject to any TSE/BSE regulations.

**GMO:** Capsugel® empty capsules do not contain and are not produced from or by genetically modified organisms (GMO) within the meaning of the Directive 2001/18/EC and subsequent amendments and 7 CFR 66 National Bioengineered Food Disclosure Standard of the USA. Consequently, they are not impacted by Regulation (EC) N° 1829/2003 on genetically modified food and feed, Regulation (EC) N° 1830/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products from GMOs, amending Directive 2001/18/EC, or the labeling requirements of 7 CFR 66 National Bioengineered Food Disclosure Standard.

**VEGAN:** Suitable

**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.

<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 checked="" type="checkbox"/> Preservatives
<input checked="" type="checkbox"/> Sulfites >10ppm
<input checked="" type="checkbox"/> Artificial Colors and Flavors (Can be present depending on the color formulation used. Please verify COFA)
<input checked="" type="checkbox"/> Beef/Chicken/Pork derivatives



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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**