

PRODUCT DECLARATION

Product name: Empty Hard Gelatin Capsules

Stock code: 3270, 3271, 3272, 3273, 3274, 3157, 3158, 3159, 3160, 3161, 3162

INGREDIENTS: Refer to Medisca Certificate of Analysis.

ARTIFICIAL COLORS: Where applicable refer to Medisca Certificate of Analysis.

BSE/TSE: Considering the below conditions, as well as the present scientific knowledge about Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE), the US and European experts from respectively the US Food and Drug Administration and the European Food Safety Authority have declared bovine gelatin and bovine collagen peptides safe end products regarding BSE/TSE risk. The manufacturer ensures that bovine gelatin, used for manufacturing of "Hard Gelatin Capsule Shells" conforms to Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) regulations as applicable to the country of use:

1. Regulation (EC) No 999/2001 & amendment thereof
2. Regulation (EC) No 853/2004
3. USFDA Sept 1997, Guidance to Industry for the sourcing & processing of gelatin to reduce the potential risk posed by BSE in FDA regulated products.
4. USFDA 21 CFR parts 189,589,700 pertaining to prohibited cattle materials in human food, drugs & cosmetic & animal feeds.
5. USFDA 9 CFR Part 94.23 Importation of gelatin from bovines
6. Commission directive 2003/63/EC and Ph. Eur -1483 evidenced by the Certificate of Suitability. The gelatin corresponding to one or more of the following CEP is used SR. No Gelatin Vendors Cep Numbers: R1-CEP 2003-172; R1-CEP 2001-332; R1-CEP 2002-115; R1-CEP 2006-086.

GMO: Empty Gelatin capsules are GMO free and no GMO derived components involved.

VEGAN: Empty Gelatin capsules do not comply with a vegan or vegetarian diet.

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 type="checkbox"/> Sulfites >10ppm
<input checked="" type="checkbox"/> Chicken/Pork derivatives (Capsules are made from bovine gelatin, see above)

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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