

Statement on Allergens

Capsugel® empty capsule products

When exposed to certain substances, individuals can develop allergic reactions or intolerances. As the only way to manage these conditions is to avoid being exposed, it is relevant that information about ingredients potentially causing allergies and/or intolerances is available throughout the complete supply chain of a product, ensuring compliant labelling of finished products in the market. Indeed, in many regions there is a clear regulatory framework mandating this kind of information to be presented on the label (see statement on “*Labelling considerations*”).

To support your company in following allergen requirements on labelling and in order to provide clear and accurate information to customers, we pass you following information on Capsugel® empty capsules:

SUBSTANCE	Reference	Contained as an ingredient YES/NO	Potential for trace amounts* YES/NO	Present in the production plant YES/NO
Gluten and cereals containing gluten, namely: wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof	[1], [2], [3], [7]	NO	NO	NO
Crustaceans and products thereof	[1], [2], [7]	NO	NO	NO
Eggs and products thereof	[1], [2], [7]	NO	NO	NO
Fish and products thereof <i>¹Except for the Fish gelatin capsules (= OceanCaps™) for which fish derived gelatin is the main ingredient.</i> <i>²Except for plants producing Fish gelatin capsules (= OceanCaps™)</i>	[1], [2], [7]	NO ¹	NO ¹	NO ²
Peanuts and products thereof	[1], [2], [3], [7]	NO	NO	NO
Soya, soybeans and products thereof	[1], [2], [3], [7]	NO	NO	NO
Milk and products thereof	[1], [2], [7]	NO	NO	NO
Tree nuts and products thereof	[1], [2], [7]	NO	NO	NO
Celery and products thereof	[1]	NO	NO	NO
Mustard and products thereof	[1]	NO	NO	NO
Sesame seeds and products thereof	[1], [6], [7]	NO	NO	NO

SUBSTANCE	Reference	Contained as an ingredient YES/NO	Potential for trace amounts* YES/NO	Present in the production plant YES/NO
Sulphur dioxide and sulphites (at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO ₂ ^[1])	[1], [3], [7]	NO	NO	NO
Lupin and products thereof	[1]	NO	NO	NO
Molluscs and products thereof	[1], [7]	NO	NO	NO
Sugars including: Glucose Lactose Galactose Fructose Sugar alcohols Monosaccharides and disaccharides sugars ³ Except for empty capsules containing spirulina, radish or turmeric concentrate as a colorant. See also 'Nutritional Value statement'	[1], [3], [7]	NO	NO ³	NO
Artificial sweeteners including: Aspartame Saccharin Sucralose	[7]	NO	NO	NO
Particular colouring agents: e.g., E102 Tartrazine E104 Quinoline Yellow E110 Sunset Yellow FCF/FD&C Yellow No.5 E122 Azorubine, carmoisine E123 Amarant E124 Ponceau 4R red, cochineal red A E129 Allura red E151 Brilliant Black BN	[3], [4], [5], [7]	Can be present depending on the color formulation used. Please check the product specification sheet for the product in scope.		YES
Latex	[3]	NO	Unlikely	YES

SUBSTANCE	Reference	Contained as an ingredient YES/NO	Potential for trace amounts* YES/NO	Present in the production plant YES/NO
Antibiotics	[7]	NO	NO	NO
Benzoates, Hydroxybenzoic acid esters		Can be added upon explicit customer's request. Please check the product specification sheet for the product in scope.		NO
Ethanol <i>⁴Ethanol can be used in the manufacturing process of imprinted capsules. The alcohols present in the imprinting ink are consistently being removed during the drying phase.</i>		NO ⁴	Unlikely ⁴	YES
Phenylalanine <i>⁵Although no phenylalanine is deliberately added during the manufacturing of empty gelatin capsules, empty hard gelatin capsules may contain traces of the amino acid 'phenylalanine' due to the nature of gelatin which is a protein</i>		NO ⁵	Unlikely ⁵	NO
Pollen, propolis, royal jelly		NO	NO	NO
Potassium and sodium salts <i>⁶Except for Vcaps® Plus for which potassium acetate is used as a processing aid (max. 0.5%) and Plantcaps® for which potassium chloride is used as a processing aid (max 2.0%). For all other capsules, potassium and sodium salts are not used but may be present in limited quantities originating from some of the raw materials and/or the water used during manufacturing. Please check 'Nutritional Value' statements. ⁷Except for plants producing Vcaps® Plus and Plantcaps®.</i>		NO ⁶	Unlikely ⁶	NO ⁷
Sorbates		NO	NO	NO

* The potential presence of a substance as a trace amount was determined based upon theoretical considerations. If a substance is not deliberately used in the empty capsule production process, not present in the manufacturing areas and not related in its nature to any of the raw materials used for empty capsule manufacturing, it is not likely to be present as trace amounts in the empty capsule. No analytical testing has been conducted to support this assumption.

References:

- [1] Annex II of food Regulation (EU) 1169/2011 and current amendments on the provision of food information to consumers.
- [2] FDA Food Allergen Labelling and Consumer Protection Act of 2004 (FALCPA).
- [3] Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (EMA/CHMP/302620/2017 Rev. 1).
- [4] USA Code of Federal Regulations 21 CFR Part 74 'Listing of color additives subject to certification'.
- [5] Annex V of food Regulation (EU) 1333/2008 and current amendments on food additives.
- [6] FASTER (Food Allergy Safety, Treatment, Education, and Research) Act (S. 578).
- [7] Therapeutic Goods Order No. 91 'Standard for labels of prescription and related medicines' and Therapeutic Goods Order No. 92 'Standard for labels of non-prescription medicines'.

The information contained herein corresponds to Lonza's knowledge on the subject at the date of publication and is, to the best of our knowledge, accurate. However, Lonza refuses any liability for the application and use of further processed material containing our products. Solely the manufacturer of the final product is responsible according to the relevant regulations.

For further information, please contact your Account Solutions Representative.

**Last update:
October, 2024**

10, Rue Timken
FR-68027 Colmar Cedex
T +33 3 89 20 57 09
F +33 3 89 41 48 11

Rijksweg 11
BE-2880 Bornem
T +32 3 890 05 11
F +32 3 889 26 22

535 North Emerald Road
SC-29646 Greenwood USA
T (888) 783 6361
F (888) 783 6360

Boulevard 18 de Noviembre
1030A
Puebla 72270, México
T +52 (222) 372 1545