

Certificate

Allergens diaphragm codes 17, 19, 54 and 5M

We hereby confirm that the products listed above are free of the following substances:

- **Peanut** (arachis hypogaea)/peanut oil
- **Tree nuts**⁸ (almond oil, Juglans nigra, macadamia nut oil, Macadamia ternifolia, almond (prunus dulcis), walnut)
- **Sesame seeds** (sesamun indicum)/sesame oil
- **Lactose**
- **Galactose**
- **Sucralose**
- **Milk** (Casein hydrolysed milk protein nonfat dry milk whey powder whole dry milk)
- **Eggs**/products manufactured in eggs (dried egg yolk, egg lecithin, influenza vaccine)
- **Fish**¹ (cod, cod liver oil, halibut, tuna)
- **Crustaceans**² (crab, lobster, white shrimp)
- **Soybeans**³ (glycine max) (soya bean, soya oil)
- **Gluten**⁴ or derived from gluten-containing grain
 - where gluten is present in a concentration of 20 parts per million or more.
 - (Wheat, Barley, Rye, Oats, Spelt, Kamut)
- **Sulfites and/or Sulfur dioxide**⁵ (potassium metabisulfite, sodium bisulfite, sodium metabisulfite, sodium sulfite)
- **Sugars**⁶ – monosachharides & disaccharides (fructose, glucose, honey, invert sugar, lactose, maltose, sucrose)
 - where total sugar content exceeds 100 mg per maximum recommended daily dose.
- **Saccharin** (saccharin calcium, saccharin sodium)
- **Ethanol** – where present in a concentration of 3 % v/v or more
- **Sugar alcohols** (eythritol, isomalt, lactitol, maltitol, mannitol, polydextrose, sorbitol, xylitol)
 - where total sugar alcohol content of the formulation > 2 g per maximum recommended daily dose.
- **Aspartame**
- **Antibiotics** – when the antibiotic is not an active ingredient and is present only as a residual impurity
- **Benzoates** (benzoic acid, sodium benzoate)
- **Hydroxybenzoic acid esters** (ethyl hydroxybenzoate, methyl hydroxybenzoate propyl hydroxybenzoate, sodium ethyl hydroxybenzoate, sodium methyl hydroxybenzoate, sodium propyl hydroxybenzoate)
- **Phenylalanine**⁹
- **Tartrazine**
- **Pollen**
- **Propolis**
- **Royal jelly**
- **Sodium salts** (sodium bicarbonate, sodium choride)
 - where total sodium content of the maximum recommended daily dose is >120 mg elemental sodium per dose
- **Potassium salts** (potassium bicarbonate, potassium chloride)
 - where total potassium content of the maximum recommended daily dose is >39 mg (1 mmol) elemental potassium per dose
- **Sorbates** (potassium sorbate, sorbic acid)

- **Latex** (Include: natural rubber latex on packaging components e.g. vial stoppers)

¹ **Fish** – includes freshwater fish, diadromous fish and marine fish, including shark

² **Crustacea** – include aquatic animals with an inedible chitinous outer shell (e.g. crab, crayfish, lobster, prawn & shrimp etc.)

³ **EXCLUDES** soya oil that is fully refined; d-alpha tocopheryl acetate, d-alpha tocopheryl acid succinate, mixed (high-alpha type) tocopherols concentrate, or mixed (low-alpha type) tocopherols concentrate when derived from soybean sources; vegetable oils derived phytosterols and phytosterol esters from soybean sources; plant stanol ester produced from vegetable oil sterols from soybean sources.

⁴ **Gluten** – some formulations may contain gluten that is present naturally as a constituent of an ingredient such as wheat starch.

⁵ **Sulfur dioxide** – some formulations may contain sulfur dioxide as a residue, for example, gelatin, but must be identified.

⁶ **Sugars** – monosaccharides and disaccharides – Lactose forms part of total sugars for the purposes of determining if the sugars will have a significant glycaemic effect and for calculating the total daily dose.

⁸ **Tree nuts** are the seeds of a variety of trees and shrubs, characterised by a hard inedible shell enclosing an oily seed. Tree nuts include almond, Brazil, cashew, chestnut, and walnut. Coconut is the fruit of the palm (*Cocos nucifera*) and is not considered to be a tree nut.

⁹ **Phenylalanine** – For medicines containing ingredients such as Spirulina, legumes, nuts or soy products that are naturally high in phenylalanine.

– Where processing of an ingredient, prior to inclusion in a pharmaceutical dosage form, results in enrichment of the phenylalanine content.

i.V. Maximilian Barghoorn

Head of Global Technics

Ingelfingen 04-11-2021

This document is valid without signature.