

TO WHOM IT MAY CONCERN

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Statement - Allergens

Fourteen (14) allergens are listed in Annex II of Regulation (EU) 1169/2011. They are cereals containing gluten (wheat (such as spelt and Khorasan wheat), rye, barley, oats or their hybridized strains), crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame, sulfur dioxide and sulfites at concentrations above 10 mg/kg, lupin, molluscs and products derived thereof.

Food Allergen Labeling Consumer Protection Act (FALCPA) identifies the following foods or food groups as the major food allergens.: milk, eggs, fish (e.g., bass, flounder, cod), Crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, walnuts, pecans), peanuts, wheat, sesame and soybeans.

We, the undersigned, hereby state that the food grade and the pharmaceutical grade gelatine produced by:

- Tessengerlo Group NV, division PB Leiner in Vilvoorde Belgium,
- PB Gelatins GmbH in Nienburg, Germany,
- PB Gelatins UK Ltd. in Treforest, United Kingdom,
- PB Leiner S.A. in Santa Fe, Argentina,
- PB Leiner USA in Davenport, USA,
- PB Brasil Industriae E Comercio de Gelatinas Ltda in Acorizal, Brazil and/or
- PB Gelatins Heilongjiang Co., Ltd. in Nehe city, P.R. China,

do not contain any substances listed as allergen in Annex II of Regulation 1169/2011 and in the FALCPA, with the exception of sulphur dioxide, which is generally present at levels lower than 40 mg/kg.

As a result of the harmonisation, the European Pharmacopeia, the US Pharmacopeia and the Japanese Pharmacopeia last editions specify a limit of 50 mg Sulphur dioxide/kg gelatine. The same limit is specified in Annex III of Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin as last amended.

The abovementioned companies produce exclusively gelatine on the gelatine production lines. All the gelatines are handled and transported in a manner in order to prevent subsequent contamination of the product.



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