

Use of Allergenic Substances

This statement is an extract from Pall's Supplier Guidance on Disallowed and Controlled Substances (E962). This statement is intended to provide information regarding the use of allergenic substances in Pall Corporation disposable pharmaceutical-grade filters, tangential flow filtration (TFF) cassettes, and biotechnology single-use systems (SUS).

Pall is pleased to inform you that the following substances are not direct materials of construction or knowingly utilized in the manufacture of the above listed products:

- Celery (root, leaves, stalk, not seeds)
- Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridized strains)
- Crustaceans
- Eggs or egg products (whites, yolks, meringue, mayonnaise, etc.)
- Fish (cod, flounder, salmon, trout, tuna, etc.)
- Lupin
- Milk and milk (dairy) derivatives
- Mollusks
- Mustard
- Peanuts or peanut products (butter, oil, flour)
- Sesame seeds
- Soy bean or soy products (soy derived vegetable protein, tofu, etc.)
- Tree nuts (including almond, brazil, cashew, chestnut, filbert or hazelnut, hickory, macadamia, pecan, pine, pistachio, queensland or walnut)
- Sulfur dioxide and sulfites, at concentrations greater than 10 mg/kg or 10 mg/L expressed as SO₂.

While we do not expect any of these substances to be present, please be aware that the raw materials we purchase are not certified as "allergen free". Therefore, we cannot exclude the possibility that an allergenic substance may be present in trace quantities deriving from the raw material manufacturing processes. Pall does not test these products for these substances.

Furthermore, wetted components of these products are manufactured from primary construction materials which are synthetic in nature. Therefore, are not deemed to be packaged food items or foodstuffs so do not fall in scope of the U.S. Food and Drug Administration's "Food Allergen Labeling and Consumer Protection Act of 2004" or Annex IIIa of the European Labelling Directive 2003/89/EC.

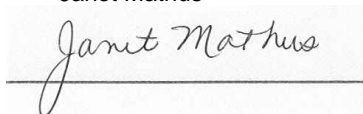
Please do not hesitate to contact dossieradmin@pall.com should you have any additional questions on this subject.

References:

Pall Corporate Quality page: Supplier Information – Controlled and Disallowed Substances; <https://www.pall.com/en/about-pall/quality.html>

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