

Fish Gelatin Allergen Statement

There have been a number of inquiries as to the allergenic nature of gelatin made from fish. Unfortunately, to date there has not been a great deal of research into this. We are aware of a commissioned study at the University of Milan, Italy, but it is still ongoing, and the results have not yet been published.

The FDA government website located at: www.cfsan.fda.gov/~dms/a#22BF1D has recently published a document that includes references to the allergenic nature of fish gelatin. Review of this paper shows conflicting statements made from two published papers:

1. Sakaguchi, M., Toda, M., Ebihara, T., Irie, S., Hori, H., Imai, A., Yanagida, M., Miyazawa, H., Ohsuna, H., Ikezawa, Z., Inouye, S. (2000) IgE antibody to **fish gelatin** (type I collagen) in patients with fish allergy. *J Allergy Clin Immunol*, 106(3):579-584.
2. Hansen, T. K., Poulsen, L. K., Stahl Skov, P., Hefle, S. L., Hlywka, J. J., Taylor, S. L., Bindslev-Jensen, U., Bindslev-Jensen, C. (2004). A randomized, double-blinded, placebo-controlled oral challenge study to evaluate the allergenicity of commercial, food-grade **fish gelatin**. *Food Chem Toxicol*, 42(12):2037-2044.

The following statement is made regarding the first paper; *“A study of 10 fish allergic patients and 15 atopic individuals with eczema revealed that 3 and 5 individuals respectively had specific IgE to **fish gelatin**, suggesting the presence of allergenic protein (Sakaguchi et al., 2000).”*

The following statement is made regarding the second paper; *“However, in a recent double-blind placebo-controlled food challenge (DBPCFC) study, all 30 fish allergic subjects in the study **showed no response to a cumulative dose of 3.61 g of fish gelatin** (Hansen et al., 2004).”*

Vyse Gelatin Company is committed to sharing the most reliable information concerning the allergenic nature of its fish gelatins. However, due to conflicting and incomplete information, we cannot comment on whether your application will be suitable for people with sensitivity towards fish.