

Soy

Allergy prevalence and risk

Approximately 0.4 percent of children are allergic to soy. Research indicates that an allergy to soy generally occurs early in childhood and is often outgrown by age three with the majority of children outgrowing the allergy by the age of ten.¹

Notably, even the most sensitive individuals would theoretically need to consume a minimum 50 grams of highly refined soy oil to experience subjective symptoms,² an amount that far exceeds potential consumption based on the recommended dosage of any Klaire Labs™ product.

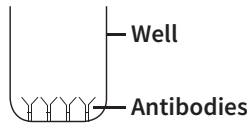
From a regulatory perspective, the FDA exempts highly refined soybean oil from being labeled as an allergen.³ This exemption is substantiated by studies that show most individuals with a soy allergy can safely eat highly refined soy oil (not cold-pressed, expeller-pressed, or extruded soybean oil).⁴

Allergen Testing

Klaire Labs™ products are routinely analyzed by a third-party laboratory for the presence of soy allergen using the Neogen® Veratox® enzyme-linked immunoassay. Results on final formulations consistently test below the limit of quantitation (BLQ) which equates to < 2.5 parts per million soy flour.

Veratox® ELISA

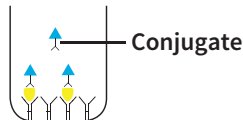
1. Microwells are coated with antibodies specific to target substance.



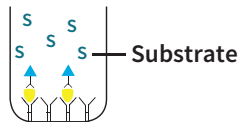
2. Samples and controls are added to their respective wells.



3. Conjugate is added, which binds to already bound target substance.



4. Substrate is added to produce a color change.



1. Savage JH, Kaeding AJ, Matsui EC, Wood RA. The natural history of soy allergy. *J Allergy Clin Immunol*, 2010;125:683-86.
 2. Rigby NM, Sancho AI, Salt LJ, et al. Quantification and partial characterization of the residual protein in fully and partially refined commercial soybean oils. *J Agric Food Chem*. 2011 Mar 9;59(5):1752-9. doi: 10.1021/jf103560h. Epub 2011 Jan 20.
 3. U.S. Food and Drug Administration. Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). Public Law 108-282, Title II. <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm> [Accessed 8/16/17]
 4. Rigby NM, Sancho AI, Salt LJ, et al. Quantification and partial characterization of the residual protein in fully and partially refined commercial soybean oils. *J Agric Food Chem*. 2011 Mar 9;59(5):1752-9. doi: 10.1021/jf103560h. Epub 2011 Jan 20.

†These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.