

PhosChol®

Soy Allergen Statement

No specific toxicological or allergenicity studies have been carried out for PhosChol. This is due to the fact that only non-toxic ingredients are being used in the manufacturing process based on physical methods.

PhosChol contains one major component, i.e. highly purified lecithin (purified polyenylphosphatidylcholine (PPC)) from soybeans.

This major component has been confirmed to be “generally recognized as safe” (GRAS) by the US Food and Drug Administration.

All minor components of PhosChol, i.e. safflower oil, mono-diglycerides, soya fatty acids, medium chain triglycerides, and ethanol are commonly used in food products.

Standard Soy lecithin (10-15% PC) is not a known allergen. However, during the process of manufacturing lecithin, it is possible that trace amounts of potentially allergenic soy protein remains in lecithin. This protein carries over during a processing step when soybean oil is extracted from the soybeans. Lecithin producers indirectly measure a residual protein by utilizing the toluene-insoluble or hexane-insoluble methodology.

The soy lecithin used in the production of PhosChol is further purified by means of ethanolic extraction and chromatographic purification. These purification steps substantially limit the potential for any trace amounts of protein.

In reviewing opinions of threshold values required to initiate an allergenic response, a general consensus of food allergy experts believes it to be in the range of 0.5-1.0 mg. This conservatively estimated threshold range is based on other allergens and therefore theoretical. An exact amount is difficult to assess considering that individuals vary greatly in their sensitivity to allergens.

Using a theoretical example, if we selected a lecithin sample containing a relatively high amount of soy protein (50 mg/kg for example) a person would have to consume roughly 10 grams of lecithin to reach the lower threshold value.

The actual protein content in PhosChol has been analyzed, and is below 0.5 ppm, which is the detection limit of the ELISA method for the quantification of proteins. **Residual proteins in PhosChol are actually “not-detected”.**

It is very difficult to provide a precisely calculated allergic response factor induced by soy lecithin as it is used for the production of PhosChol. However, based upon the information provided, one can easily deduce that oral products with typical inclusion rates of standard lecithin (fractions) do not pose a risk of eliciting an allergic response.