05/2018

# PhytoSpherix™ Safety

**INCI Name:** Glycogen
**CAS #:** 9005-79-2
**EINECS #:** 232-683-8

## Glycogen Safety

Glycogen has been used as an additive in cosmetic and food products for many years without any reported adverse effects.
Glycogen is a natural component of a wide variety of tissues as it provides structural integrity and strength. In addition, glycogen is constantly being produced and broken down by the liver to control sugar levels in the body. Most importantly, extensive toxicity testing has been done on pure glycogen by specialized testing labs and have found no toxicity issues related to glycogen.

PhytoSpherix™ is manufactured by extraction of glycogen from sweet corn by microfiltration and ultrafiltration which protects the integrity of the molecular structure of the extracted, naturally-occurring phytoglycogen.

PhytoSpherix™ complies with CAS number 9005-79-2, assigned to the generic entity glycogen:

- Health Hazard: not hazardous
- Physical Hazards: not harzardous
- Carcinogenic effects: none
- Mutagenic effects: none
- Acute toxicity: none

The common chemical identifier number (CAS number) is the same for both glycogen and phytoglycogen. This indicates that the materials are essentially interchangeable. The chemical compositions of both materials are the same (glucose) and all the other key physical parameters are similar.

There are only a few studies which have specifically tested the safety of glycogen, since it is an endogenous polysaccharide found in many plants and animals. In an acute toxicity rat-feeding study, Tafazoli (Tafazoli, S, et al. 2010. Safety evaluation of an enzymatically-synthesized glycogen. Regulatory Toxicology and Pharmacology. 57 (2010) 210-219) concluded that isolated glycogen is safe as a food ingredient for human consumption.
A lethal dose test to 5000 mg/kg, which is the standard upper level to demonstrate non-toxicity, was conducted as a rat-feeding trial. Adhering to the protocol of a 50% “up and down procedure”, the results indicate that, should a lethal dose for phytoglycogen exist, that it is greater than 5000 mg/kg, or, greater than 5000 ppm.

Nutrient analysis revealed PhytoSpherix™ to be minimum 93% polysaccharide and is free from food allergens. In the growing, harvesting and manufacture of PhytoSpherix, there is no contact with fish/crustacean/shellfish allergens and with sulfites.
The intended use of PhytoSpherixTM in the food manufacturing sector, is as a food ingredient, to be added to processed foods at levels as low as 5% to as high as 25%. The intended food system functions are as a stabilizer, thickener and/or texturizer.

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PhytoSpherix™ complies with the standard microbiological, mineral and heavy metal limitations.

To support literature findings, some initial safety assessments have been conducted by University of Guelph on PhytoSpherix™ directly. For example, the effect of PhytoSpherix™ on cultured living cells (known as an in vitro test) was tested. In a series of experiments, isolated animal liver cells (known as Hep2 cells) were periodically exposed to PhytoSpherix™ at increasing concentrations from 0% (no material, control group) to 1% in the media bathing the cells. For comparison, these cells were also exposed to different concentrations of poly(lactic acid-co-glycolic acid) (PLGA) nanoparticles. PLGA is an FDA approved polymer for drug delivery mechanisms due to its high biocompatibility and biodegradability. All tested doses of PhytoSpherix™ showed similar responses to that of the PLGA materials. In fact, PhytoSpherix™ is arguably even safer than PLGA as equivalent cellular responses were observed when using 10-100 times more PhytoSpherix™ than the selected PLGA concentrations

In 2015, cutaneous tolerance and sensitization has been conducted (HRIPT) and showed PhytoSpherix™ (at 2% in an emulsion) is not an irritant/sensitizer and is hypo-allergenic.

**PhytoSpherix™ as"Nanoparticles"**

Since PhytoSpherix™ is composed of small phytoglycogen particles with nanoscale dimensions, they may be referred to as "nanoparticles". Although some concerns have been raised in public forums about the safety of nanoparticles, it is our view that based on existing scientific literature and in vitro safety tests conducted by Mirexus that the use of PhytoSpherix™ should not pose any significant human health risks. In addition, public concerns raised about nanoparticle safety generally refer to material classes that would not include PhytoSpherix™. For example, most nanomaterial safety discussions are focused on "engineered" or synthetic nanomaterials. PhytoSpherix™ is a natural nanomaterial, composed of simple sugars, and is certainly not engineered. In addition, the majority of safety concerns related to nanoparticles involve exposure to the lungs via inhalation. Consumer products containing PhytoSpherix™ particles will not be sold in the form of dry particles that can be inhaled directly and thus will pose no danger for inhalation risk when used as directed.

**Conclusion**

PhytoSpherix™ is a glycogen product isolated directly from corn in its natural particle form. Humans have been eating corn, and therefore phytoglycogen, for ages without any adverse health effects. This material is chemically identical to the glycogen produced and actively used in our own bodies. The scientific literature is replete with studies involving glycogen, none of which allude to any specific safety concerns. Furthermore, safety studies run by Mirexus and other independent parties have indicated no safety concerns. Based on this data, and subject to the assumptions and limitations identified with this document, we do not anticipate that PhytoSpherix™ will cause any significant safety or toxicity issues when formulated and used properly in a commercial product.

The above information supports the safety of PhytoSpherix™ in cosmetic applications at use levels as recommended.
No further testing is required at this time.