

**PGX<sup>®</sup> (PolyGlycopleX<sup>®</sup>) is a unique high-viscosity functional fibre complex that has been proven non-mutagenic in genotoxicity studies.**

Genotoxicity Studies of PolyGlycopleX<sup>®</sup> (PGX<sup>®</sup>): A Novel Dietary Fibre

Marone PA, Lyon M, Gahler R, Donath C, Hofman-Hüther H, Wood S. Genotoxicity Studies of PolyGlycopleX (PGX)<sup>®</sup>: A Novel Dietary Fiber. *International Journal of Toxicology* 2009;28:318-331.

Consumption of dietary fibre is associated with protective effects against disease. The type and viscosity of dietary fibre greatly affects both its action and potential use. Highly viscous fibres have previously been reported to reduce blood glucose levels after meals, induce satiety by providing bulk, reduce body weight, improve laxation and modify blood lipids. The beneficial effects on colon health and coronary heart disease may be directly related to the viscosity of the fibre. PolyGlycopleX<sup>®</sup> ( $\alpha$ -D-glucurono- $\alpha$ -D-manno- $\beta$ -D-manno- $\beta$ -D-glucosyl- $\beta$ -D-mannurono), ( $\alpha$ -L-gulurono- $\beta$ -D-mannurono),  $\beta$ -D-glucosyl- $\beta$ -D-mannan; (PGX<sup>®</sup>); Inovobiologic Inc, Calgary, Canada) is a novel functional fibre complex manufactured by a proprietary process (EnviroSimplex<sup>®</sup>) from three dietary fibres to form a highly viscous polysaccharide with high water-holding and gel-forming properties. The proprietary process causes strong interactions between these three fibres to produce a polysaccharide complex with a level of viscosity that is higher than any currently known individual polysaccharide and is 3 to 7 times higher than common fibres, such as psyllium gums. PGX<sup>®</sup> has been found effective in managing elevated blood glucose levels, cholesterol, appetite cravings and weight and colon health. A previous toxicological study for PGX<sup>®</sup> found that the “no observable adverse effect level” (NOAEL) in rats was 5% of the diet with no significant physical or pathological changes reported. The present study, conducted in Germany, examines the genotoxic (capable of damaging genetic material such as DNA, causing mutations or possibly cancer) potential of PGX<sup>®</sup> to promote a mutagenic response in the bacterial reverse mutation assay (Ames test) and a clastogenic (causing disruptions or breakages, such as in chromosomes) and/or aneugenic (a chromosome change characterized by loss or gain of whole chromosomes) response in the mammalian erythrocyte micronucleus (MMA) test. The Ames test is a commonly used assay to determine the mutagenic potential of a product. A positive test result indicates that the product might act as a carcinogen. The MMA test detects chromosomal damage and is recognized as a reliable assay for carcinogens. A micronucleus is the erratic or third nucleus that can be formed during cell growth or division, which is associated with genetic damage. The Ames test was performed using the highest possible concentration of PGX<sup>®</sup>. The results showed that PGX<sup>®</sup> did not induce any gene mutations. The MMA test assessed the potential of PGX<sup>®</sup> to induce micronuclei in red blood cells in the bone marrow of the mouse. PGX<sup>®</sup> did not induce chromosomal damage or increase the number of micronuclei. This genotoxicity study shows PGX<sup>®</sup> to be non-mutagenic in both the bacterial reverse mutation assay (Ames test) and the mammalian erythrocyte micronucleus (MMA) test. The authors concluded that based on these studies, the results for PGX<sup>®</sup> were considered within normal range for use in the food industry.