

**PGX<sup>®</sup> (PolyGlycopleX<sup>®</sup>) is a unique high-viscosity functional fibre complex that has been proven safe without risk of toxicity in a rodent study.**

Matulka RA, Lyon MR, Wood S, Marone PA, Merkel DJ, Burdock GA. The safety of PolyGlycopleX<sup>®</sup> (PGX<sup>®</sup>) as shown in a 90-day rodent feeding study. *Nutrition Journal* 2009,8:1.

The safety of the unique fibre complex PGX<sup>®</sup> (PolyGlycopleX<sup>®</sup>) was assessed by feeding 4 groups of 20 rats levels of 0, 1.25, 2.5 or 5% PGX<sup>®</sup> for 90 days in an OECD study conducted in the USA. Detailed observations of health and records of food consumption were performed daily and weekly. Male (10) and female (10) animals consumed between 0 and 3799 mg/kg/day of PGX<sup>®</sup>. PolyGlycopleX<sup>®</sup> ( $\alpha$ -D-glucurono- $\alpha$ -D-manno- $\beta$ -D-manno- $\beta$ -D-gluco), ( $\alpha$ -L-gulurono- $\beta$ -D mannurono),  $\beta$ -D-gluco- $\beta$ -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. All animals appeared active and healthy during the study period. At the end of the study, rats were euthanized and examined in detail, including detailed pathology of organs, tissues and biochemical changes. While small differences occurred in liver enzyme and triglyceride levels, these changes did not correlate to any changes seen in tissues or organs and appear to be not clinically or toxicologically significant. Significant decreases in sodium, potassium and chloride concentrations were observed in female rats fed 5.0% PGX<sup>®</sup> and decreases in red blood cell count were noted in the male rats fed 5.0% PGX<sup>®</sup>. These effects may be the result of increased urinary volume in both male and female rats and decreases in specific gravity and protein concentration, which may be due to the diet being in powder form and the high oral viscosity of PGX<sup>®</sup> increasing water intake. The changes are, however, within values that are normally observed and are not considered adverse. Further, the observed effects have been reported in previous high-dose studies of similar substances in rats and may be the result of a predictable adaptive response to high levels of dietary fibre and/or increased urinary volume. The results indicate that 5.0% PGX<sup>®</sup> in the diet, corresponding to an average daily intake of 3219 and 3799 mg/kg of body weight per day in male and female rats respectively, is safe and considered to be its “no observed adverse effect level” (NOAEL).