

## **EXECUTIVE SUMMARY:**

IFF Health & Biosciences (IFF) is seeking approval for a “lysophospholipase (EC 3.1.1.5)” enzyme for use as processing aid for starch hydrolysis for the production of glucose syrup and other starch hydrolysates. The enzyme is designated as “Lysophospholipase” throughout the dossier.

The enzyme Lysophospholipase is derived from a selected non-pathogenic, non-toxicogenic strain of *Trichoderma reesei* which is genetically modified to express the lysophospholipase gene from *Aspergillus niger*.

The enzyme is intended for use in carbohydrate processing to produce liquid glucose and other starch hydrolysates. Lysophospholipase performs its technological function during the liquefaction and/or saccharification phase to improve filtration efficiency and enhance syrup clarity.

In all of these applications, Lysophospholipase will be used as a processing aid where the enzyme is either not present in the final food or present in insignificant quantities having no function or technical effect in the final food.

To assess the safety of the Lysophospholipase for use in these applications, IFF have vigorously applied the criteria identified in the guidelines as laid down by Food Standards Australia New Zealand (FSANZ) and U.S. Food and Drug Administration (FDA) utilising enzyme toxicology/safety data, the safe history of use of enzyme preparations from *T. reesei* and of other lysophospholipase enzymes in food, the history of safe use of the *T. reesei* production organism for the production of enzymes used in food, an allergenicity evaluation, and a comprehensive survey of the scientific literature.

In addition, different endpoints of toxicity were investigated, and the results are evaluated and assessed in this document. In genotoxicity studies, Lysophospholipase is not mutagenic, clastogenic or aneugenic. Daily oral administration of Lysophospholipase up to and including a dose level of 1000 mg TOS/kg bw/day does not result in any manifestation of systemic, hematologic, or histopathologic adverse effects.

Based on a worst-case scenario that a person is consuming Lysophospholipase from in liquid glucose and other hydrolysed starch applications, the calculated Theoretical Maximum Daily Intake (TMDI) will be 0.087 mg TOS/kg body weight/day. This still offers a 11494-fold margin of safety.

Based on the results of safety studies and other evidence, Lysophospholipase has been demonstrated as safe for its intended applications and at the proposed usage levels. Approval of this application would provide manufacturers and/or consumers with benefits of facilitating the superior product quality and advantageous production efficiencies.