

Summary of the application: Nicotinamide Riboside Chloride

Applicant: Elysium Health Inc., 434 Broadway, 2nd floor, New York, NY 10013

Nicotinamide riboside chloride is obtained by chemical synthesis and has a minimum purity of 95% by weight. It is intended for use as a source of niacin in food supplement products at a maximum level of 300 mg/day for the general adult population and 230 mg/day for pregnant and lactating women as recommended by the manufacturer.

Available ADME data in mice, rats, dogs and humans indicate that nicotinamide riboside chloride is expected to hydrolyse readily in the gastrointestinal tract and to be absorbed primarily as nicotinamide. The available data in animals demonstrate that nicotinamide riboside chloride contributes to the nicotinamide pool in the body, acting as a precursor to NAD⁺ in cells.

A NOAEL for nicotinamide riboside chloride of 500 mg/kg body weight/day in male rats and 1,200 mg/kg body weight/day in female rats was derived from the findings of a 90-day repeated dose oral toxicity study conducted by Elysium Health Inc. On a body weight basis, the maximum use level of 300 mg/day for the general adult population corresponds to an intake of 4.3 mg/kg body weight/day for a 70 kg individual. The margin of exposure between the proposed use level and the NOAEL of 500 mg/kg body weight/day for male rats is 116.

The proposed maximum use level of 230 mg/kg body weight/day for pregnant and lactating women corresponds to 3.3 mg/kg body weight/day for a 70 kg individual. The margin of exposure between the proposed use level and the NOAEL of 1,200 mg/kg body weight/day for female rats is 364.

The available toxicological information taken together with the findings of human clinical trials using nicotinamide riboside chloride support the safety of nicotinamide riboside chloride under the conditions of intended use.