

Summary of the dossier

Applicant: Glucan Corporation, 25-15, Worasan-ro 950beon-gil, Munsan-eup, Jinju-si, Gyeongsangnam-do, 52840, South Korea

Name of the novel food: Black yeast beta-glucan

Black yeast beta-glucan (Polycan®) consists of complex, high molecular mass (around 100 kDa) polysaccharides extracellularly produced by *Aureobasidium pullulans* SM-2001. 'Black yeast beta-glucan' is similar with 'Yeast beta-glucans' derived from the cell wall of baker's yeast *Saccharomyces cerevisiae*, but differs from their cereal counterparts (such as beta-glucan derived from oats and wheats) in that they contain β -1,3- and 1,6-glucohydric bonds, compared to the cereal derivatives which contain β -1,3- and 1,4-glucohydric bonds. Black yeast beta-glucan produced by *Aureobasidium pullulans* SM2001 has a similar structure with beta-glucan present in cell walls of yeasts and filamentous fungi, as well as in mushrooms (*Agaricus* sp., *Ganoderma lucidum*, etc.). However it is extracellularly produced and water-soluble gel-like polysaccharide. The characterization, specification and production process do not give reasons for concern.

The source, *Aureobasidium pullulans*, has been used for the production of pullulan and does not give reason for concern since it has a long history of use in and outside Europe.

The applicant intends to market 'black yeast beta-glucan (Polycan®)' in food supplements at dose ranging from 120 to 150 mg per serving (one serving per day). The maximum doses of the novel food proposed by the applicant are 1 g/day thereafter (i.e. adolescents and adults). In addition, the applicant intends to market 'black yeast beta-glucan (Polycan®)' in a variety of foods including beverages for the general population. Based on these proposed uses, the applicant has provided an intake estimate for 'black yeast beta-glucan (Polycan®)' for different population groups, using data from U.S. by population group. Using the United States Department of Agriculture (USDA) 1994-1996 Continuing Survey of Food Intakes by Individuals (USDA CSFII 1994-1996) survey (USDA, 2000), under the conditions of intended use, the total population all-user mean intake of black yeast beta-glucan (Polycan®), an estimated heavy consumer (90th percentile) all-user intake of black yeast beta-glucan (Polycan®), the greatest mean and percentile all-user intakes of black yeast beta-glucan (Polycan®) on an absolute basis, and the greatest mean and 90th percentile all-user intakes of black yeast beta-glucan (Polycan®) on a body weight basis are 338.7 mg/person/day, 678.4 mg/person/day, 476.4 and 972.9 mg/person/day, 22.9 and 44.2 mg/kg body weight/day in infants, respectively. Furthermore, black yeast beta-glucan (Polycan®) is not intended directly to market for infant and toddler foods, resulting in limiting infants and toddlers to consume black yeast beta-glucan (Polycan®).

The safety of black yeast beta-glucan (Polycan®) is very similar to the Yeast beta-glucan safety, because both beta-glucans have the same chemical nature ((1,3)- β -linked backbone with small numbers of (1,6)- β -linked side chains).