

APPLICATION FOR THE APPROVAL OF CHINOVA'S FIBRE EXTRACTED FROM WHITE BUTTON MUSHROOMS (*AGARICUS BISPORUS*) UNDER THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE – STANDARD 1.3.1 – FOOD ADDITIVES

Executive Summary

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EXECUTIVE SUMMARY

This application is being submitted to Food Standards Australia New Zealand (FSANZ) to seek approval for the use of Chinova's fibre extracted from white button mushrooms (*Agaricus bisporus*) as a food additive with the technical purpose for use as a preservative. Chinova's fibre extracted from white button mushrooms (*A. bisporus*) is a mixture of chitosan and *beta*-1,3-D-glucans and is sold under the trade name Chiber™. Chitosan is the main component, representing approximately 95% of the total volume; chitosan is a soluble polymer derived from the cell walls of a non-genetically modified white button mushroom (*A. bisporus*) biomass.

Chitosan, the main component of Chinova's fibre extracted from white button mushrooms (*A. bisporus*), is not currently listed in *Schedule 15 – Substances that may be used as food additives* or *Schedule 16 – Types of substances that may be used as food additives* of the Code. Chinova's fibre extracted from white button mushrooms (*A. bisporus*) is proposed for use in Australia and New Zealand at levels consistent with current Good Manufacturing Practice (cGMP). This food additive is intended for use as a preservative in food and beverage products at the minimum levels required to achieve the desired technical effect in accordance with cGMP, with maximum levels ranging from 0.01 to 0.150 g/100 g (equivalent to 100 to 1,500 ppm). The proposed food uses of Chinova's fibre extracted from white button mushrooms (*A. bisporus*) are similar to those that have been recently approved in Canada and are Generally Recognized as Safe (GRAS) in the United States (U.S.), as well as those currently under evaluation by the relevant authorities in the European Union (EU) and the United Kingdom (UK). As such, the purpose of this application is to amend *Schedule 16 – Types of substances that may be used as food additives, "Additives permitted at GMP"* (S16—2) to include Chinova's fibre extracted from white button mushrooms (*Agaricus bisporus*) (FSANZ, 2019b).

Chinova's fibre extracted from white button mushrooms (*A. bisporus*) is manufactured in accordance with cGMP with a Hazard Analysis and Critical Control Points (HACCP) plan in place. The manufacturing process includes controls to ensure the quality of the final product prior to its release. The ingredient is produced by extraction of chitosan from white button mushrooms (*A. bisporus*) using a deacetylation process. Purification processes results in the final ingredient.

Chinova's fibre extracted from white button mushrooms (*A. bisporus*) is specified to contain an average molecular weight (MW) of 10 to 400 kDa, with a degree of acetylation (DDA) greater than 80%. Analysis of 3 production batches of the ingredient demonstrates the average MW to be approximately 100 kDa and the DDA to be 90 to 94%. Chinova has established product specifications for the fibre extracted from white button mushrooms (*A. bisporus*) consistent with the *Food Chemicals Codex* monograph for chitosan derived from crustacean sources. As well, Chinova's fibre extracted from white button mushrooms (*A. bisporus*) is compositionally equivalent to crustacean-derived chitosan as confirmed by Fourier-transform infrared spectroscopy (FTIR) and proton nuclear magnetic resonance (¹H-NMR) spectroscopy. Batch analysis of 5 non-consecutive lots of Chinova's fibre extracted from white button mushrooms (*A. bisporus*) verified that the manufacturing process produces a consistent product that meets the defined specifications.

Crustacean-derived chitosan has a long history of safe use in the global food supply. Regarding fungal sources, in the EU, chitosan extract from fungi (*Agaricus bisporus*; *Aspergillus niger*) are authorised for use in food supplements as defined in Directive 2002/46/EC¹ on the approximation of the laws of the Member States relating to food supplements at levels "in line with normal use in food supplements of chitosan from crustacean sources." Chinova's fibre extracted from white button mushrooms (*A. bisporus*) is GRAS in the U.S. for use in a variety of foods and beverages similar to those described

¹ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57. Available online: <https://eur-lex.europa.eu/eli/dir/2002/46/oj> (current consolidated version: 06/02/2024).

herein. This GRAS status was notified to the U.S. Food and Drug Administration (FDA) as “*Chitosan and beta-1,3-glucans from white button mushrooms (Agaricus bisporus)*” (GRAS Notice [GRN] 997), and on 28 February 2022, the U.S. FDA issued a “no questions” letter in response to this Notice (U.S. FDA, 2022). In Canada, Chinova’s fibre extracted from white button mushrooms (*A. bisporus*) is authorised for use under the same proposed food uses and maximum use levels as described herein; thus, it is included on Health Canada’s List of Permitted Food additives as an antibacterial (Class 2) and antifungal (Class 3) preservative (Health Canada, 2024).

The safety assessment of Chinova’s fibre extracted from white button mushrooms (*A. bisporus*) was conducted through an evaluation of the metabolic profile of the substance and the available animal toxicology and human studies on chitosan, as well as studies conducted regarding the safety of *beta*-glucan. Based on the totality of scientific data, the proposed uses of Chinova’s fibre derived from white button mushrooms (*A. bisporus*) is not expected to be associated with any adverse outcomes and no safety concerns are anticipated.

The sum of the data and information provided in this application support the safe use of Chinova’s fibre extracted from white button mushrooms (*A. bisporus*) as a preservative in food and beverages intended for human consumption in Australia and New Zealand.