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Use of *Yarrowia lipolytica* Selenium-enriched Yeast Biomass as a Novel Food and a Novel Food Ingredient
(Summary of the Dossier)

The subject-matter of this application is the use of selenium-enriched biomass of yeast *Yarrowia lipolytica* strain A-101 as a component of dietary supplements in the form of yeast cells, dried and deprived of metabolic activity, as an exceptionally rich source of selenium. Selenium-enriched *Yarrowia lipolytica* yeast biomass is classified in the category 'Food consisting of, isolated or produced from microorganisms, fungi or algae'.

Yarrowia lipolytica A-101 selenium-enriched yeast biomass is unique source of organic selenium at level 240µg Se/g dry matter of yeast, which at the suggested portion of 0.5-1 gramme (i.e. 1 or 2 capsules, 500 mg each) provides 120-240µg Se, while making up 218-436% of the NRV (Nutrient Reference Value) for selenium. Selenium contained in selenium-enriched biomass of yeast *Yarrowia lipolytica* is present in organic combinations with cellular structures, mainly selenomethionine and selenocysteine. Moreover, regardless of the application proposed in this application, yeast *Yarrowia lipolytica* A-101 is characterized by very good nutritional values, including high content of: protein (about 45-50%), beta-glucan, vitamins of group B (such as B1, B2, B3, B4, B5, B7, B9 and B12), E vitamin and a high proportion of unsaturated fats (over 90% of the total fat content), and wealth of micro and macroelements (including calcium, phosphorus, sodium, iron, copper, magnesium, potassium, manganese, zinc & iodine).

Selenium-enriched biomass of yeast *Yarrowia lipolytica* used as a Novel Food and a Novel Food Ingredient is intended for the population in general, but still the main consumer group will be adult men and women (with particular regard to the specific nutritional requirements of vegans and vegetarians). For the estimated dosage, including destination and age groups, see Table 15 (and also below).

Table 15. Recommended intake taking into account age groups and food categories

Type of consumer category	Intake as a component of dietary supplements (code 18 and A03RQ)
Adults: Men and women over 18 YO	0.5 - 1 g/day (1 g/day max.)
Youth between 10 and 17 YO	0.5 - 1 g/day (1 g/day max.)
Children from 36 months to 9 YO	0.1 – 0.2 g/day (0.2 g/day max.)

The main purpose of the reported Novel Food is to use it as a component of dietary supplements with specific functionalities, in the form of soft or hard capsules, tablets or loose powder (according to the FoodEx system classification in Group 18 – Products special nutritional use with all subgroups and A03RQ – “Products for non standard diets, food imitates and food supplements or fortifying agents”).

Due to the use of *Y.lipolytica* selenium-enriched yeast biomass mainly as a component of food supplements, the requirements for maximum permissible levels of heavy metals were adopted in accordance with Regulation (EC) no. 629/2008. The microbiological requirements adopted for *Y.lipolytica* selenium-enriched yeast biomass were prepared on the basis of Pharmacopoeia 7.0 for non-sterile products. Storage stability tests of the produced selenium-enriched biomass of yeast *Yarrowia lipolytica* showed its stability for a minimum of 12 months. In order to confirm the safety of use, analysis of heavy metals present in selenium-enriched biomass of *Yarrowia lipolytica* was performed (including application and intake), using the expertise of the National Institute of Public Health – National Institute of Hygiene in Warsaw on the consumption of heavy metals and the microbiological parameters found in the basic, non-enriched biomass of *Yarrowia lipolytica*. Results of other analyses described in details in par 2.4 prove that there are no other undesirable and harmful substances contained in selenium-enriched biomass of yeast *Yarrowia lipolytica* that could be consumed by humans.

Due to its unique and valuable properties, *Yarrowia lipolytica* yeast is increasingly used in biotechnology, the US Food and Drug Administration (FDA) has granted GRAS (Generally Recognized As Safe) status to many commercial scale processes performed with its involvement. The *Yarrowia lipolytica* is considered a classic in Biosafety Class 1 (no toxicity), and is listed as one of the most common and extremely important in dairy products, sausages and maturing hams [EFSA 2007; 587] and is included in the list of species with QPS status (Qualified Presumption of Safety) [EFSA 2018; 16(7):5315]. Consumption safety is also confirmed by the acute oral toxicity study for *Yarrowia lipolytica* selenium-enriched yeast biomass and by studies carried out in the 1970's by BP at the independent Centraal Instituut voor Voedingsonderzoek (CIVO) institute for basic non-enriched *Yarrowia lipolytica* yeast biomass. The study on basic non-enriched *Y.lipolytica* yeast biomass were conducted on a variety of animal species (mice, rats, chickens, and even quails) that were administered *Y.lipolytica* yeast biomass (up to 30% of diet), showing no negative effects of ingestion nor toxicity, genotoxic, carcinogenic or reproductive and developmental effects.

Due to fact that application was submitted on 10th November 2017 the scientific and research unit that maintained preliminary review for *Yarrowia lipolytica* selenium-enriched yeast biomass as a novel food and a novel food ingredient was Instytut Żywności i Żywienia im. prof. dr med. Aleksandra Szczygła in Warsaw (Prof. Aleksander Szczygiel, Ph.D, Memorial Institute of Food and Nutrition).