GENERAL STATEMENT

Yeast derivates for oenological use
Maxaferm range, Natuferm Range, Extraferm range, Oenophonia range

Food Ingredient Fit for Human Consumption

We hereby confirm that raw materials/ ingredients used in the production of aforementioned products have a high purity level. The aforementioned products do not contain components or admixtures injurious to the health of the consumers. They meet applicable standards for food for human consumption as recommended by the Codex Alimentarius.
Under these manufacturing conditions these products are safe for their intended use.

Food Safety / Food Defence

These products have been processed in a manner consistent with current Good Manufacturing Practices, HACCP method and general principles of food safety and food hygiene applicable in the US (21 CFR § 117 including measures to control physical, chemical, and microbiological hazards), Canada (Safe Food for Canadians Act (S.C. 2012, c.24), and the EU (Regulation 852/2004 as amended on the hygiene of foodstuffs).

Practices include traceability, non-conformance, and recall. The facilities have written, implemented, recorded, and reviewed plans for manufacturing, processing, packaging, and holding food items.
Risk assessments have been done to identify potential food fraud or adulteration acts. Procedures are in place to manage potential emergencies, accidents and other acts that can affect food safety. Additionally, each production and storage facility have a plan specific to their building to address facility security and food security.

Namely, our production facilities all have implemented Quality Management Systems and obtained GFSI (Global Food Safety Initiative) certification such as BRC, IFS or FSSC22000. Some of the facilities also have an ISO 9001 Quality Management Systems.

Microbiological Origin

We hereby certify that the products are completely derived from plant and microbiological sources. Our yeast strains are microorganisms which can be found in nature, and they are not chemically synthesized substances. Our yeasts are produced on a variety of sugar-containing substrates.

Food Allergens

The product(s) sold have been produced without the foods or their derivatives that account for most human food allergic reactions as listed in EU Regulation 1169/2011 as amended, US Food Allergen Labelling and Consumer Protection Act of 2004, ANZ Food Standards Code – Standard 1.2.3 about information requirements and Japan Specifications and Standards for Foods, Food Additives under the Food Sanitation Act (2010).

These products are considered free of the following:

- Cereals containing GLUTEN and products thereof.
- Crustaceans and products thereof.
- Eggs and products thereof.
- Fish and products thereof.
- Peanuts and products thereof.
- Soy and products thereof.
- Milk (including lactose) and products thereof.
- Tree Nuts and products thereof.
- Celery and products thereof.
- Mustard and products thereof.
- Sesame seeds and products thereof.
- Lupine and products thereof.
- Molluscs and product thereof.
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/Kg or 10 mg/L expressed as SO_2.

OIV (International Organisation of Vine and Wine)

The products we market for use in oenology are listed in the OIV Code as allowed in wine production. These products are in conformance with the current oenological OIV Codex regulations.

European Regulation

The aforementioned products are allowed in oenological practices and processing aid according to Regulation (EU) 2019/934 and its amendments, supplementing Regulation (EU) 1308/2013 and its amendments.

Food Contact Packaging

Based on our packaging suppliers' statements, we hereby confirm that the packaging materials of these products are suitable for the packaging of food.
The product contact packaging is consistent with EC 1935/2004, EU 10/2011 as amended, EU 2020/1245 as amended and meet the requirements of EC 2023/2006.
According to the information we have received from our supplier, the product complies with the requirements of the Japan's Ministry of Health, Labour, and Welfare (MHLW) Notification No. 196 of April 28th, 2020 (promulgated pursuant to Japan's Food Sanitation Act) positive list system for food container and packaging materials.
All primary packaging materials which are in direct contact with the product are food grade and meet the requirements of the Canadian Food and Drug Regulations on food packaging materials (C.R.C., c. 870, B.23).
The components used in the primary packaging materials of the aforementioned products meet FDA requirements for indirect food additives as described in 21 CFR § 175, 176 and 177 for adhesives, papers and polymers where applicable.

In addition, phthalates, or its derivatives [bis-phenol A, and poly brominated substances (PBBs & PBDEs)] are not added or are not present in any package or packaging component during the manufacturing process.
Also, per- and polyfluoroalkyl substances (PFASs) are not intentionally added or used as additives in packaging materials we bought from our suppliers.
These substances are not used in the production of micro-organisms or in the manufacture of ingredients used in the final products.

Food Additives
No food additives, no preservatives, no artificial flavours, or colourings have been used in the production processes of the aforementioned products.

Genetic Modification
According to our knowledge, yeasts have not been modified through genetic engineering. They have been rigorously selected, checked, and analysed for identity and purity. Based on our suppliers' declarations, the raw materials used in their production processes do not contain GMO. In these conditions, those products do not contain GMO.
The products are considered to be GMO-free products and are exempt from GMO labelling and Bioengineered (BE) food disclosure.

Ingredients of Animal Origin
The manufacture and development of the aforementioned products and their ingredients do not involve the use of any animal product, by product or derivative. These products are therefore free of any risk from BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy).

Vegan and Non-Animal Testing
The manufacture and development of our products, and their associated ingredients and processing aids used in the manufacture of, do not and have not involved the use of any animal product, by product or derivative. They do not or have not involved testing of any sort on animals (this includes testing for efficacy, toxicity, safety, cosmetic purposes etc.) conducted at the initiative of the company or on its behalf, or by parties over whom the company has effective control. In these conditions, the aforementioned products are suitable for vegan. We understand the word "animal" to refer to the entire Animal Kingdom that is all vertebrates and all multi-cellular invertebrates.

Nanotechnologies
To the best of our knowledges and based on our raw material suppliers' statements, the aforementioned products have not been produced with the use of nanotechnology and therefore do not contain any nanomaterials or engineered nanoparticles as defined in Regulation (EU) 2015/2283.

Radioactivity and Ionization
The aforementioned products have not been ionized or irradiated and do not contain any ionized or irradiated components.

Sewage Sludge
Sewage sludge has not been used in the production of the aforementioned products.

Growth of Petrochemical Substrate
The aforementioned products have not been grown on petrochemical substrate or sulphate waste liquor.

Antibiotics
No antibiotics are used in the aforementioned products manufacturing process.

Dioxins and PCB

The manufacturing process of the aforementioned products is not susceptible of releasing dioxins. Additionally, the aforementioned products have not been manufactured near industrial or natural processes susceptible of releasing dioxins; nor were they manufactured using raw materials, processing aids or water resulting from such processes.
There are no maximum dioxin levels set out for yeast products according to European Commission Regulation (EU) 2023/915. Periodical dioxins spot-checks are performed on selected products based on risk assessment.

Solvents or Ethylene

No solvents or ethylene oxide (EtO) have been used in the aforementioned products production process. These components are part of our food safety program hence controlled through verification plan and risk assessment.

MOSH and MOAH

“Mineral Oil Saturated Hydrocarbons and Mineral Oil Aromatic Hydrocarbon” are not used during the manufacturing process of the aforementioned products. Moreover, mineral oil components are also part of our food safety program hence controlled through supplier verification plan and risk assessment.

Heavy Metals

The aforementioned products are produced from ingredients that are not considered as a risk of heavy metal content. The production processes themselves do not bring any risk of introducing heavy metals in these products. The products are in compliance with the OIV Codex.

Hazardous Substances

These products are not listed on the EU REACH CMR (Carcinogenic, Mutagenic, or toxic to Reproduction) and SVHC (Substances of Very High Concern), the US NTP (National Toxicology Program), and the WHO IARC monographs. The use of the aforementioned products does not represent a risk of exposure to the substances listed on California Proposition 65.

Safety and Handling

According to the Globally Harmonized System (GHS), REACH Regulation and to Regulation 1272/2008/CE (CLP), a safety data sheet is not required for these products under US, CAN, and EU regulation.
For the aforementioned products, Safety Data Sheets have been created on a voluntary basis to pass on safety information, they are available on request.

Although diligent care has been used to ensure that the information provided herein is accurate, nothing contained herein can be construed to imply any representation or warranty for which we assume legal responsibility, including without limitation any warranties as to the accuracy, currency, or completeness of this information or of non-infringement of third-party intellectual property rights. The content of this document is subject to change without further notice. Please contact us for the latest version of this document or for further information. Since the user’s product formulations, specific use applications and conditions of use are beyond our control, we make no warranty or representation regarding the results which may be obtained by the user. It shall be the responsibility of the user to determine the suitability of our products for the user’s specific purposes and the legal status for the user’s intended us of our products.