



**NANOTRITION
NORD**

PRODUCT TECHNICAL DOCUMENTATION

ENZYPURE®

**BROMELAIN-12P
ENZYME POWDWER**

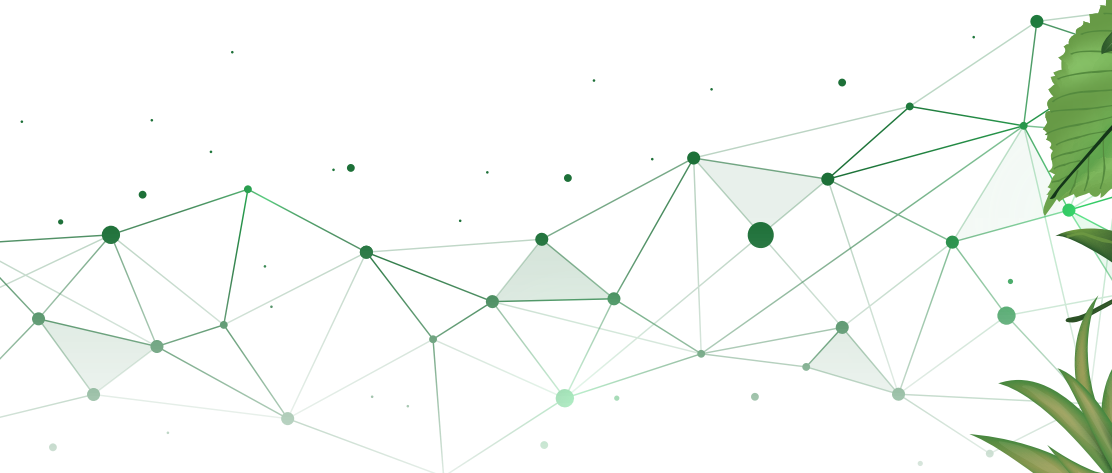


Table of Contents

- Certificate of analysis (COA)
- Material safety data sheet (MSDS)
- Source Statement
- Elemental impurities statement



CAT No.:EG-RM-BRO-1-25K
 Batch No. 15-JUN-BRO-23
 Manufacturing Date: 07/06/2023
 Retest Date:06/12/2024
 Revision No: 3.01

Certificate of Analysis

ENZYPURE® Bromaline-12P Powder

Off-white to brown free flowing, dry powder, consisting of spherical particles of bromaline extract. We recommend a quantitative analysis of contents in the final product for reconfirmation.

Test	Reference	Specification	Result
Assay	In-house- MOA-BRM-4	1090-1320GDU\g	Conforms
Loss on Drying at 105°C	In-house- MOA-LOD-20	NMT 5%	Conforms
Lead	In-house- MOA-HMD-06	NMT 3 ppm	0.15 ppm
Cadmium	In-house- MOA-HMD-07	NMT 1ppm	0.05 ppm
Arsenic	In-house- MOA-HMD-08	NMT 1ppm	ND
Appearance	In-house-Visual MOA-OLV-21	Powder	Conforms
Taste	In-house - MOA-OLS-23	Characteristic	Conforms
Odor	In-house - MOA-OLS-23	Characteristic	Conforms
Granulometry at mesh 60	In-house - MOA-MS-2	NLT 95%	Conforms
Color	In-house - Visual MOA-OLV-22	Off-white to brown	Conforms
Flavor	In-house- Sensory MOA-OLS-23	Characteristic	Conforms
Microbiology Test	Reference	Specification	Result
Total Plate Count	In-house-MOA-MA-01	<1000 CFU/g	100 CFU/g
Total Yeast and Mold	In-house-MOA-MA-02	<100 CFU/g	Absent
Escherichia coli	In-house-MOA-MA-03	Absent	Absent
Staphylococcus aureus	In-house-MOA-MA-04	Absent	Absent
Enterobacteriaceae	In-house-MOA-MA-05	Absent	Absent

CAUTION:

For manufacturing, processing, or repackaging No Class 1, 2, 3 or other solvents are used or produced in the manufacturing or purification of the product.

METALLIC RESIDUES:

No metal catalysts or metal reagents, as defined by EMA Guideline EMEA/CHMP/SWP/4446/2000, are used in the production of this material.

TRANSPORTATION CONDITIONS:

Ingredients don't need refrigeration during transportation for 24 hours with avoidance of direct sunlight.

STORAGE:

This product should be stored between 15-30°C, in an area where it is not exposed to extreme temperatures. Shelf life of this product is influenced by many conditions of which temperature, exposure to light / air and general good storage are the major factors. Material stored in adverse conditions may deteriorate much faster.

PACKAGING:

- Plastic bags in aluminum bags (10, 15kg package)
- Plastic bags in multi-layer Kraft-plastic bags (10, 15, 25 kg package)

NOTE:

It is the responsibility of the user to check before use that the products are suitable for the intended purposes. The users are also obliged to ensure that all legal requirements for the use of the products are being complied with, - this also includes the legality of the use of the product itself. This document, or any answers or information provided herein by Nanotrution Nord, does not constitute a legally binding obligation of Nanotrution Nord.

Submitted by:	Approved by:
Rahaf Elmeligy	Asmaa Yehia
Quality Assurance Executive	Senior Technical Operations Executive

MSDS

EnzyPure®

Bromelain-12P

POWDER

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name:	EnzyPure®
Formula Name:	Powder
Molecular Weight:	N/A
Manufacturer:	NanoTriton NORD, Egypt under license from NanoTriton NORD, Norway.

2. COMPOSITION/ INFORMATION ON INGREDIENTS

2.1 Substances

- Bromelain activity.

3. HAZARDS IDENTIFICATION

3.1 Classification of the substance or mixture

According to Regulation (EC) No. 1272/2008 [CLP]
No need for classification according to GHS criteria for this product.

3.2 Label Elements

Globally Harmonized System, EU (GHS)
The product does not require a hazard-warning label in accordance with GHS criteria.



4. FIRST AID MEASURES

4.1 Description of first aid measures

Remove contaminated clothing.

-If inhaled: keep patient calm, move to fresh air.

-On skin contact: wash thoroughly with soap and water.

-On contact with eyes: wash affected eyes for at least 15minutes under running water with eyelids held open.

-On ingestion: rinse mouth and then drink plenty of water.

4.2 Most important symptoms and effects, both acute and delayed.

Symptoms: No significant symptoms are expected due to the non-classification of the product.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Symptomatic treatment (decontamination, viral function)



5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: water spray, foam, dry powder, carbon dioxide.

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture.

Burning produces harmful and toxic fumes.

5.3 Advice for firefighters

Special protective equipment: wear self-contained breathing apparatus.

Further information

Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

Cool endangered containers with water spray.



6. ACCIDENTAL RELEASE MEASURES

Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Avoid the formation and build-up of dust – danger of dust explosion.

6.1 Personal precautions, protective equipment, and emergency procedures

Information regarding personal protective measures see section 8.

6.2 Environmental precautions:

Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up:

For large amounts: Sweep/shovel up. Dispose of contaminated material as prescribed.

For residues: Sweep/shovel up. Dispose of contaminated material as prescribed.

Avoid raising dust.

6.4 Reference to other sections:

Information regarding exposure controls/personal protection and disposal considerations can be found in section 8 and 13.



7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling

Handle in accordance with good industrial hygiene and safety practice.

Protection against fire and explosion: take precautionary measures against static discharges. Avoid all sources of ignition, heat, sparks, open flame.

7.2 Conditions for safe storage, including any incompatibilities.

This product should be stored between 15-25°C, in an area where it is not exposed to extreme temperatures.

Shelf life of this product is influenced by many conditions of which temperature, exposure to light / air and general good storage are the major factors. Material stored in adverse conditions may deteriorate much faster.



8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

- **Occupational exposure limits:**
 - **Exposure limit values:** No exposure limits value known.

8.2 Exposure controls

- **Individual protection measures**
 - **Hand protection:** chemical resistant protective gloves
 - **Eye/face protection:** safety glasses with side-shields (frame goggles).
 - **Body protection:** must be chosen depending on activity and possible exposure, e.g., apron, protective boots, chemical protection suit (according to EN 14605 in case of splashes or EN ISO 13982 in case of dust).
 - **Respiratory protection:** Breathing protection if dust is formed. Particle filter with low efficiency for solid particles.
- **General safety and hygiene measures**

Your hands and/or face should be washed before breaks and at the end of the shift.
- **Environmental exposure controls**

For information regarding environmental exposure controls, see section 6.



9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- **Appearance**

- **Physical state:** Powder
- **Color:** Off white to brown
- **Odor:** Faint
- **Odor threshold:** Not available.
- **Melting point/freezing point:** Not available.
- **Initial boiling point and boiling range:** the product is a non-volatile solid.
- **Flash point:** Not applicable, the product is a solid.
- **Evaporation rate:** the product is a non-volatile solid.
- **Flammability:** Not flammable.
- **Upper/lower flammability or explosive limit:** for solids not relevant for classification and labelling.
- **Vapor pressure:** Negligible.
- **Vapor density:** Not relevant.
- **Partition coefficient:** Not applicable.
- **Viscosity:** Not applicable, the product is solid.
- **Self-ignition:** not self-igniting.
- **Explosion hazard:** product is not explosive.
- **Fire promoting properties:** not fire-propagating.



10. STABILITY AND REACTIVITY

10.1 Reactivity: No hazardous reactions if stored and handled as indicated.

10.2 Chemical stability: The product is stable if stored and handled as indicated.

10.3 Possibility of hazardous reactions: The product is stable if stored and handled as indicated.

10.4 Conditions to avoid: Avoid dust formation, avoid all sources of ignition.

10.5 Incompatible materials: Do not mix with oxidizing agents.

10.6 Hazardous decomposition products: No hazardous decomposition if stored and handled as indicated.



11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

- **Sensitization:** No known effect according to our database
- **Mutagenicity:** No known effect according to our database
- **Carcinogenicity:** No known effect according to our database
- **Reproductive toxicity:** No known effect according to our database
- **Teratogenicity:** No known effect according to our database
- **Specific target organ toxicity (single exposure):** No known effect according to our database
- **Specific target organ toxicity (repeated exposure):** No known effect according to our database
- **Aspiration hazard:** No known effect according to our database
- **Symptoms related to physical, chemical, and toxicological characteristics.**
 - **Eye contact:** No specific data.
 - **Inhalation:** No specific data.
 - **Skin contact:** No specific data.
 - **Ingestion:** No specific data.
- **Delayed and immediate effects and also chronic effects from short- and long-term exposure**
 - **Short term exposure**
 - **Potential immediate effects:** Not available,
 - **Potential delayed effects:** Not available.
 - **Long term exposure**
 - **Potential immediate effects:** Not available,
 - **Potential delayed effects:** Not available.
- **Potential chronic health effects:** Not available.



12. ECOLOGICAL INFORMATION

12.1 Toxicity

There is a high probability that the product is not acutely harmful to aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations. The product has not been tested. The statement has been derived from the properties of the individual components.

12.2 Persistence and degradability:

Assessment biodegradation and elimination (H₂O): Biodegradable.

12.3 Bio accumulative potential: No known effect according to our database.

12.4 Mobility in soil

Assessment transport between environmental compartments: No data available.

12.5 Results of PBT and vPvB assessment: according to Annex XIII of Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH): the product does not contain a substance fulfilling the PBT criteria or the vPvB.

12.6 Other adverse effects: the product does not contain substances that are listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

12.7 Additional information

Other ecotoxicological advice: At the present state of knowledge, no negative ecological effects are expected.



13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods Product:

Observe national and local legal requirements.



14. TRANSPORT INFORMATION

- This preparation is not classified as a dangerous good according to international transport regulations (ADR/RID, IMDG or ICAO/IATA).
- For long distance transport ingredients do not need refrigeration during transportation for 24 hours with avoidance of direct sunlight.



15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture: If other regulatory information applies that is not already provided elsewhere in this safety data sheet, then it is described in this subsection.

Source Statement

The above-mentioned catalog item is manufactured by chemical synthesis. No animal products are used in the manufacturing process.

BSE\TSE statement

The above-mentioned catalog item does not contain nor is manufactured using any animal-derived products and is, therefore, BSE\TSE free.

Allergen Statement

The above-mentioned catalog item does not contain any of the following

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Peanuts
- Cereals containing Gluten
- Celery
- Sesame Seed
- latex
- Sulfites >10 ppm

EU Fragrance Allergen Statement

The above-mentioned Catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 76-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above-mentioned catalog item is manufactured without the use of genetically modified organisms and is, therefore, GMO-free.

Melamine Statement

The above-mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine free.



Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in the material.

Organic compliance statement

The above-mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO), or sewage sludge.

Shelf-life statement

The above-mentioned catalog item is typically assigned a shelf life of 18 months from the date of manufacture. the actually assigned shelf life of any specific lot should be referenced on the certificate of analysis.

Submitted by:	Approved by:
Rahaf Elmeligy	Asmaa Yehia
Document Controller Executive	Senior Technical Operations Executive

Heavy Metals Elemental impurities-

To whom it may concern:

Thank you for your interest in Nanotrution Nord.
The above-mentioned material complies with the Egyptian NFSA guidelines for heavy metals. These substances are not used in the production process, are not intentionally added, or are known to be present in the above-mentioned material above the required limits as mentioned below.

ITEM	LIMIT
Lead	NMT 3ppm
Cadmium	NMT 1ppm
Arsenic	NMT 1ppm

The information is subject to change and is intended for risk assessment only. It is the responsibility of the end user to evaluate the suitability of any chemicals for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective certificate of analysis. If you have any future questions, please contact us by telephone at (01069529529) option 2, or by E-mail at info@nanotrution.tech

Sincerely,

Document controller department
Nanotrution Nord.

This document has been produced electronically and is valid without a signature.

RE: Batch No. description:

Dear Valued Customer,

This letter is to inform you of Nanotrirtion Products' batch Numbering System. The system is based on an alpha-numerical sequence that provides the month, year, an abbreviation of the product.

The batch numbering system is a sequence of **four characters**, a number followed by three characteristics. The first number represents the order ID number. The second letter represents the month. The third one represents the abbreviation of the product and the fourth represents the year of production.

Example: 02-AUG-LGT-22= The LGT material produced in Egypt in August 2022

- (02) represents the order ID number.
- (AUG) represents the month.
- (LGT) represents Liposomal Glutathione
- (22) represents the year of production.

Thank you for your interest in Nanotrirtion products. Please feel free to contact us at (01069529529) via email (info@nanotrirtion.tech) if we may be of further assistance.

Sincerely,
Document controller department

RE: IQC description:

Dear Valued Customer,

This letter is to inform you of Nanotrirtion Products IQC Numbering System. The system is based on a numerical sequence that provides the ID number of orders, number of lots, and lot number.

The IQC numbering system is a structure of **Seven numbers**. The first number represents the order ID number, the second number represents the total lots number and the third number represents the lot ID number.

Example: 3905001

- (39) represents the order ID number
- (50) represents the total lots number
- (1) represents the lot ID number

Thank you for your interest in Nanotrirtion products. Please feel free to contact us at (01069529529) via email (info@nanotrirtion.tech) if we may be of further assistance.

Sincerely,
Document controller department



Not appropriate for regulatory submission. Please visit www.nanotrution.tech or contact Tech Services for the most up-to-date information contained in this information package.

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