



GONMISOL
FINE INGREDIENTS

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Productos Químicos Gonmisol S.A.
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Camí de la Verneda 47-49
Sant Adrià de Besòs 08930
Barcelona - Spain (EU)

Technical package

Dossier Técnico
24/04/2023

BROMELAIN 2'500 GDU

PRODUCT SPECIFICATION

Product Name	INCI Name	EINECS Number	CAS Code
BROMELAIN 2'500 GDU	N/A	N/A	

Description	Off white to white colour hygroscopic powder
Activity	2500 GDU/g
Odor	Characteristic
Loss on drying	Not more than 5.0%
Bulk Density	0.4 to 0.7g/cc
Heavy Metals	No more than 08ppm
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 0.1 mg/kg
Residual solvents	To comply as per USP
Residual pesticide	To comply as per USP
Particle Size	90% 80 Mesh
Microbiological Test	
Total Plate count	10000 CFU/g Max
Mold & Yeast	NMT 100 CFU/g
E.coli	Negative/10g
Salmonella	Negative/10g
Staphylococcus aureus	Negative/10g
Enterobacteriaceae	Absent in 1gm

Excipients Used: Maltodextrin



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GENERAL PRODUCT INFORMATION

Mesh of the product	90% 80 Mesh
Tapped density	0.5 to 0.7g/ml
Bulk density	0.4 to 0.7
Water solubility	Soluble in water. 0.5g/10ml
Type of Manufacturing process (Synthesis, Fermentation, Extraction, etc.)	Extraction
Specific Origin of the product (Animal, Vegetal, etc.)	From Pineapple Stem (Ananas comosus)
Is the product FREE of GLUTEN?	Yes
Approximate Extraction Range of the Product	100:1
Solvents used during the extraction process and their %	Water 100%
Is the product suitable for vegans?	Yes
Is the product suitable for vegetarians?	Yes
Is the product free of fructose?	Yes
Is this product suitable for food?	Yes
Can the product be used in baby food (according to Regulation (EU) N° 609/2013, Commission Delegated Regulation (EU) 2016/127, Commission Delegated Regulation (EU) 2021/572 and amendments)?	Yes
Pharmacopoeias that the product meets	USP
Drug indication	--
Melting point	NA
Country of origin of the raw material/s of the product	India
Storage conditions (in the warehouse)	Dry and cold place
Storage conditions (during the transport/short term)	Under 25°C



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TECHNICAL PRODUCT INFORMATION

IUPAC name	NA
ATC Code	NA
Molecular Formula	NA
Chemical Structure	NA
Stereochemistry	NA
Molecular mass	NA
Country of the factory (Manufacturing site)	India
Raw materials used for the manufacture of this product and their function	Pineapple stem only used to extract the Bromelain enzyme
Frequency of analysis of each contaminant?	Every Batch
Frequency of analysis of microbiology?	Every 3 Months
Frequency of analysis of each heavy metal?	Every batch



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FOREIGN MATERIAL

Explanation of actions taken during the manufacturing process of this product to reduce the risk of appearance of foreign material:

Metal detector	No
Sieve	Yes 90% 80 Mesh
Filter	Yes 0.2 micron filters are used during after the extraction of the enzyme to remove the foreign particles
X-Ray	No
Other	No



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INGREDIENTS

In accordance with the EU Regulation 1169/2011, amending EU Regulation 1924/2006 and EU Regulation 1925/2006, the following ones are the ingredients and their content (in %) in this product.

Bromelain	75-80%
Maltodextrin	20-25%



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BSE/TSE

This product does not contain and is not derived from Specified Risk Material as defined in European Commission Directive (and its amendments) and is therefore conform with the EU legislation relating to the risk of Transmission of Spongiform Encephalopathy (TSE).

GMO

The following EU regulations have been published in the Official Journal of the European Union in this subject:

- Regulation (EC) No.1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed.

- Regulation (EC) No.1830/2003 of the European Parliament and the Council of 22 September 2003 concerning tractability and labeling on genetically modified organisms and tractability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

This product has not been genetically modified so there is no obligation of GMO labeling as defined by the above mentioned regulations.

NON IRRADIATION/NON IONIZED

According to directives 1992/2/EC and 1999/3/EC, we confirm that this product is not made from irradiated/ionized raw materials and that this product was not irradiated/ionized.



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PESTICIDES

To our actual knowledge of the production process, of the raw materials and of the equipment used, the potential pesticide residues in this product comply with the European legislation on pesticide residues (esp. Regulation (EC) No. 396/2005 and amendments). However, we do not test for pesticide residues on a routine basis.

RESIDUAL SOLVENTS

The product meets with:

- DIRECTIVE 2009/32/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients
- DIRECTIVE 2010/59/EU of 26 August 2010 amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

CONTAMINANTS

The product is in accordance and meets with the Commission Regulation (EU) No. 2023/915 setting maximum levels for certain contaminants in foodstuffs.

PCBS AND MELAMINE

This product is in accordance and meets with the Commission Regulation (EU) No. 2023/915 as regards the maximum levels of the contaminants Ochratoxin A, non-dioxin-like PCBS and melamine in foodstuffs.

ANTI-DOPING

As per the list of 2023 of the World Anti-Doping Agency (WADA), this product is not a doping substance or a combination of doping substances. This product is not manufactured from a doping substance.

NANOMATERIALS

According to the definition of 'Nanomaterials' of the UE Regulation No 1169/2011 of the European Parliament and of the Council of 25th of October 2011 (amending Commission Regulation (EC) 1924/2006 and Commission Regulation (EC) 1925/2006) on the provision of food information to consumers, we hereby attest that no nanomaterials are used in the manufacture, in the formulation nor in the packaging materials of this product.



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PACKING

We confirm that the packing used for this product is in compliance with:

- Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27th of October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
- Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

ETHYLENE OXIDE (ETO) & 2-CHLORO-ETHANOL

Ethylene Oxide (& 2-Chloroethanol) is not used in any phases of the process of manufacture or storage of this product. This product does not enter in contact with Ethylene Oxide (& 2-Chloroethanol) in any phases of the process of manufacture or of storage. Therefore, this product is compliant with the limit established in Commission Regulation (EC) No. 396/2005.



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ALLERGENS

In accordance with Regulation (EU) No. 1169/2011, amending Commission Regulation (EC) No. 1924/2006 and Commission Regulation (EC) No. 1925/2006, we confirm the following information:

Does this product contain or is derived from or could be cross-contaminated by any of the following allergens?

Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof	No
Crustaceans and products thereof	No
Eggs and products thereof	No
Fish and products thereof	No
Peanuts and products thereof	No
Soybeans and products thereof (with exceptions established in Annex II)	No
Milk and products thereof (including lactose) (with exceptions established in Annex II)	No
Nuts (i.e. almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut, macadamia nut and Queensland nut) and products thereof (with exceptions established in Annex II)	No
Celery and products thereof	No
Mustard and products thereof	No
Sesame seeds and products thereof	No
Sulphur dioxide and sulphite at concentrations of more than 10 mg/kg or 10 mg/l expressed as SO ₂	No
Lupine and products thereof	No
Molluscs and products thereof	No



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ALBA LIST (ALLERGENS)

Note: 'Yes' means that there is contamination from

- 1) recipe contents,
- 2) other products handled on the same production line or
- 3) other products handled at same side.

	Cross contamination (mg/kg)?	Where?
Cow milk protein	No	-
Lactose	No	-
Chicken egg	No	-
Soya protein	No	-
Soya oil	No	-
Gluten	No	-
Wheat	No	-
Rye	No	-
Cattle	No	-
Pork	No	-
Chicken	No	-
Fish	No	-
Shellfish and Crustaceae	No	-
Corn	Yes	1
Cocoa	No	-
Leguminous plants	No	-
Nuts	No	-
Nut oil	No	-
Peanut	No	-
Peanut oil	No	-
Sesame	No	-
Sesame oil	No	-
Glutamate	No	-
Sulphide (E220 to E228)	No	-
Coriander	No	-
Celery	No	-
Carrot	No	-
Lupines	No	-

Part or total information is provided as received from our supplier. The data outlined and the Statements made are intended only as a source of information. No warranties, expressed or implied, are made. On the basis of this information it is suggested that you analyze the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.



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NUTRITIONAL INFORMATION

Approximative Nutritional Information of this product is as follows:

Energy: 250K Calories (1046KJ)

Parameters Value/100gms

Total Protein 15gms

Total Carbohydrates 85gms

Total Fat 0

(Saturated

Polyunsaturated

Monounsaturated

Trans

Cholesterol)

Total cholesterol 0

Sodium 0.002

Potassium 0

Fibre 0

Calcium 0.002

Iron 0

Vitamin A 0

Vitamin C 0



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RESIDUE LIMITS (GELATIN, COLLAGEN)

We herewith certify that this product in compliance with: Commission Regulation (EU) No. 2016/355 of 11st of March 2016, amending Annex III to Commission Regulation (EC) No. 853/2004 of the European Parliament and of the Council as regards the specific requirements for gelatine, collagen and highly refined products of animal origin intended for human consumption.

HYGIENE OF FOODSTUFFS

We herewith certify that this product complies with Commission Regulation (EC) No. 852/2004 of the European Parliament on the hygiene of foodstuffs and all its amendments.

FULL TRACEABILITY

This product complies with the full traceability criteria as mentioned in Commission Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28th of January 2002, laying down the general principles and requirements of food law, establishing the European food safety authority and laying down procedures in matters of food safety.



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FACTORY ACCREDITATIONS/CERTIFICATIONS

ISO 9001	Yes
ISO 22000	No
HACCP	Yes
GMP	Yes
FAMI QS	No
BRC	No
Other accreditations/certifications	Halal



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NON ANIMAL TESTING

We certify that the product has not been tested on animals.



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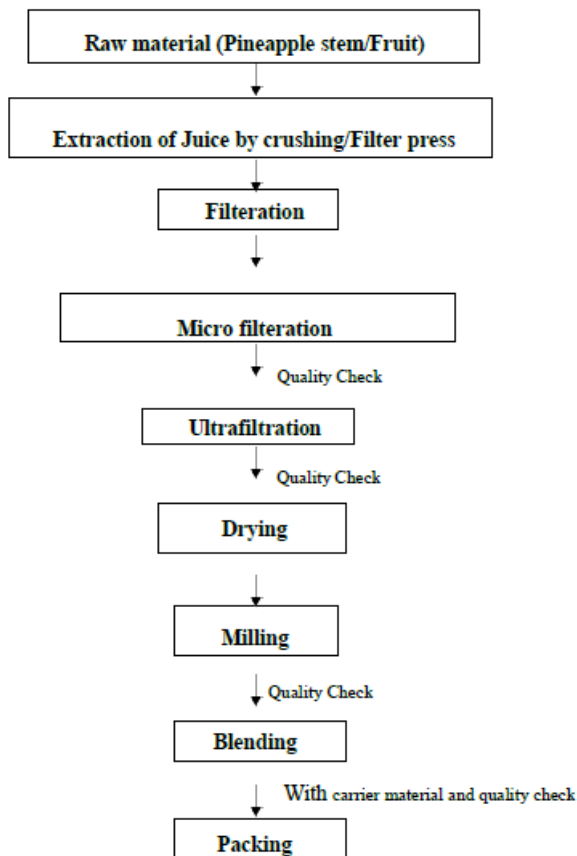
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Flow Chart





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**Material Safety Data
Sheet**

**Documento MSDS
09/01/2023**

BROMELAIN 2'500 GDU

MSDS (Material Safety Data Sheet)

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND COMPANY

Product Name: BROMELAIN 2'500 GDU

CAS Number:

Supplier Information:

Productos Químicos Gonmisol S.A.

Camino de la Verneda 47-49

08930 - San Adrian del Besos

Barcelona - Spain

Phone +34 933136118

Fax +34 933147427

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2. COMPOSITION / INFORMATION ON INGREDIENTS

Component name: Bromelain

CAS No. : 9001-00-7

Conc. (% w/w): 100%

3. HAZARD IDENTIFICATION

POTENTIAL HEALTH EFFECTS: EMERGENCY OVERVIEW

Human: Non hazardous

Eyes: Irritant

Skin: Irritant

Ingestion: Slightly hazardous

Inhalation: Lung irritant

Ecological: Not Applicable

4. FIRST AID MEASURES

Skin: In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

5. FIRE FIGHTING MEASURES

Flash point: Not Applicable

Extinguishing media: Not Applicable

Special exposure hazards: Not Applicable



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MSDS (Material Safety Data Sheet)

Protective equipment for fire-fighting: Not Applicable

Fire fighting guidance: SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Environmental precautions: Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Spillage: NA

Note: NA

7. HANDLING AND STORAGE

Handling: Keep away from sources of ignition. Ground all equipment containing material.

Do not ingest. Do not breathe dust. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes. Keep away from incompatibles such as oxidizing agents.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area. Refrigerate

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering controls: Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Respiratory protection: Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent gloves.

Hand protection: Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Eye protection: Use Splash goggles.

Other: Not Applicable

9. PHYSICAL AND CHEMICAL PROPERTIES

For this information, please, refer directly to the Certificate of Analysis OR Specifications

10. STABILITY AND REACTIVITY

Stability: This product is stable

Materials to avoid: Not Applicable

11. TOXICOLOGICAL INFORMATION

Acute studies

Eye: Slightly irritant

Skin: Hazardous in case of skin contact (irritant),



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**Documento MSDS
09/01/2023**

BROMELAIN 2'500 GDU

MSDS (Material Safety Data Sheet)

Ingestion: Slightly hazardous in case of ingestion.
Inhalation: lung irritant, lung sensitizer
Long term studies: Not Applicable
Carcinogenicity: Not Applicable
Mutagenicity: Not Applicable
Reproductive toxicity: Not Applicable

12. ECOLOGICAL INFORMATION

Persistence in the environment: Not Applicable
Toxic effects on organisms: Not Applicable
Fish: Not Applicable
Daphnia magna: Not Applicable
Birds: Not Applicable

13. DISPOSAL CONSIDERATIONS

Product disposal: Waste must be disposed of in accordance with federal, state and local environmental control regulations.
Container disposal: Waste must be disposed of in accordance with federal, state and local environmental control regulations.

14. TRANSPORT INFORMATION

ADR/RID: 3316 IMDG: 3316 IATA: 3316

15. REGULATORY INFORMATION

This safety data sheet complies with the requirements of Regulation (EC) no 1907/2006
Imidacloprid Technical CAS No: Not Applicable
The following precautions appear in the 'PRECAUTIONS' section of label / leaflet: Not Applicable

16. OTHER INFORMATION

Substance name: Bromelain, 2500GDU/g
CAS: 9001-00-7
R-Phase: 36/37/38/42
S-Phase: 22-24-26-36/37
GHS Pictogram:





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**Documento MSDS
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MSDS (Material Safety Data Sheet)



Hazard Statement: H315-H319-H334-H335

Precautionary Statement: P261-P305+P351+P338-P342+P311

WKG: 1

Relevant R-phrase(s), S-phrase(s), GHS Pictogram(s), Hazard statement(s), and Precautionary statement(s)

Risk Phrase(s) R 22 : Harmful if swallowed R 36 : Irritating to the eyes R 36/37/38 : Irritating to eyes, respiratory system and skin

R 42 : May cause sensitization by inhalation R 42

Safety Phrase(s) S 22 : Do not breathe dust S 24 : Avoid contact with skin S 26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S 27 : Take off immediately all contaminated clothing S 36/37 : Wear suitable protective clothing and gloves S 36/37/39: Wear suitable protective clothing, gloves and eye/face protection

GHS Pictogram



: Eye Irrit.



: Acute Toxicity Eye Irrit. 2 STOT SE 3





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MSDS (Material Safety Data Sheet)

: Carcinogenicity 1A, 1B

Hazard statement(s) H315 : Causes skin irritation H317 : May cause an allergic skin reaction H319 : Causes serious eye irritation H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled H335 : May cause respiratory irritation
Precautionary statement(s) P261 : Avoid breathing dust/fume/gas/mist/vapours/ P304 + P340 : IF INHALED: Remove victim to fresh air and Keep at rest in a position comfortable for breathing.. P305 + P351 + P338 : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 : Immediately call a POISON CENTER or doctor/physician. P337 : If eye irritation persists, get medical advice/attention. P342 + P311 : IF experiencing respiratory symptoms: call a POISON CENTER or doctor/physician

Disclaimer

The above information is intended to give general health and safety guidance on the storage and transport of the substance or product to which it relates. The requirement or recommendation of any relevant site or working procedure, system or policy in force or arising from any risk assessment involving the substance or product shall take precedence over any of the guidance contained in this safety data sheet where there is a difference in the information given. The information provided in this safety data sheet is accurate at the date of publication, and will be updated as and when appropriate.