

Product Technical Data Sheet
Product name: Bromelain 5000 GDU
AC code: I4U04026a

1. Technical Data Sheet		
Botanical Name	Ananas comosus	
Plant Used Part	Fruit	
CAS number	37189-34-7	
Molecular weight	33000	
EINECS Number	232-572-4	
Item	Standard	Analysis Method
Appearance & Solubility		
Appearance	The product is white crystal or crystalline powder, odorless	
Typical Analysis		
Description	White to Cream White Powder with Characteristic Odor	Organoleptic
Bromelain Activity	≥ 5000 GDU/g	In-house standard
Loss on Drying	≤ 6.0% w/w	USP <731>
Bulk Density	0.3g/ml ~ 0.7g/ml	USP <616>
Tapped Density	0.5g/ml ~ 1.0g/ml	USP <616>
Particle Size	100% pass through 60 mesh	USP <786>
Heavy metals		
Total Heavy Metals	≤ 20 ppm	ICP-MASS
Lead	≤ 3.0 ppm	ICP-MASS
Arsenic	≤ 1.0 ppm	ICP-MASS
Cadmium	≤ 1.0 ppm	ICP-MASS
Mercury	≤ 0.1 ppm	ICP-MASS
Microorganism		
Total Plate Count	≤10,000 cfu/g	USP <2021>
Total Molds & Yeasts	≤1,000 cfu/g	USP <2021>

E.Coli	Negative/10g	USP <2021>
Salmonella	Negative/25g	USP <2021>
Storage & Shelf Life		
Package	25kgs/drum	
Shelf life	The shelf life for the product is 24 months from date of production. Use it as soon as possible once it is opened.	
Storage	Store in unopened original package under clean and dry condition, away from sunlight	

2.Origin & Ingredient

Country of origin of the product: India

Origin statement: available

This product is a pure material <input checked="" type="checkbox"/>		This product is a compound material <input type="checkbox"/>	
Animal origin	<input type="checkbox"/> bovine	Specific Source: /	
	<input type="checkbox"/> porcine	Specific Source: /	
	<input type="checkbox"/> avian	Specific Source: /	
	<input type="checkbox"/> Others:	Specific Source: /	
Synthetic	<input type="checkbox"/>	Starting material:	origin: China
Biotechnological processing	<input type="checkbox"/> Catalysis By Enzymes	Name Of Enzyme: /	
		Sources Of Enzymes: /	
	<input type="checkbox"/> Fermentation	Source Of Medium: /	
		Strain: Bacteria:	
Botanical Origin	Botanical Name:	Ananas Comosus	
	Part:	Fruit	
	Wild Or Cultivated:	/	
	Country Of Origin:	/	
	Solvent Used:	/	

3.Nutrition Data		
Nutritional Composition	<input checked="" type="checkbox"/> Per 100g	<input type="checkbox"/> Per Serving
<input type="checkbox"/> Energy(Kj) <input checked="" type="checkbox"/> Energy(Kcal)	0kcal	
Fat(G)	0	
Carbohydrates(G)	0	
Protein(G)	0	
Sodium (Mg)	0	
Remarks: Nutrition Data Are Obtained By 3 rd Party Lab; Tested On A Yearly Basis		

4. GMO declaration	YES	NO (Means Not Contain)
The product does not contain or consist of GMO	<input type="checkbox"/>	<input checked="" type="checkbox"/>
The product is not produced from GMO or not contain ingredients produced from GMO (irrespective of whether there is NDA or protein of GM origin in the final production)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
This product is not produced by means of GM microorganism including precursor substances, e.g. with GMOs or Genetically Modified microorganisms processing aids(bacteria, yeast,..)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
This product is not produced with the help of enzymes, which were obtained from GMOs	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the product contain any ingredients from animal?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, are genetically modified crops contained in the feed for the animal?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
We confirm that this product complies with regulations EC/1829/2003 and EC1830/2003 and keep NON-GMO statement available		<input checked="" type="checkbox"/>

5.Allergen declaration

We have carefully reviewed this product according to EU Regulation 1169/2011 and modifications and confirm the following:

	Direct incorporation as a base raw material or in a derivative form (don't forget the carriers, the additives and the processing aids)		CROSS CONTAMINATION					
			Presence on the production line		Presence on the production workshop		Presence on the production factory	
	Yes (precise nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No	Yes (precise the nature)	No
Cereals containing gluten(1) and products thereof		N		N		N		N
Crustaceans and products thereof		N		N		N		N
Eggs and products thereof		N		N		N		N
Fish and products thereof (2)		N		N		N		N
Peanuts and products thereof		N		N		N		N
Soybeans and products thereof (3)		N		N		N		N
Milk and products thereof (including lactose)(4)		N		N		N		N
Nuts (5) or products thereof		N		N		N		N
Celery and products thereof		N		N		N		N
Mustard and products thereof		N		N		N		N
Sesame seeds and product thereof		N		N		N		N
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/l expressed as SO ₂		N		N		N		N
Lupines and products thereof		N		N		N		N
Mollusc and product thereof		N		N		N		N

(1) Cereals which contain gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) except: wheat-based glucose syrups including dextrose, wheat-based maltodextrins, glucose syrups based on barley, cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

(2) Except: fish gelatine used as carrier for vitamin or carotenoid preparations, fish gelatine or Isinglass used as fining agent in beer and wine;

(3) Except fully refined soybean oil and fat, natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources; vegetable oils derived phytosterols and phytosterol esters from soybean sources; plant stanol ester produced from vegetable oil sterols from soybean sources;

- (4) Except when used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages, lactitol;
- (5) almond (*Amygdalus communis* L.) hazelnuts (*Corylus avellana*), walnut (*Juglans regia*), cashew (*Anacardium occidentale*), pecan nuts (*Carya illinoensis*), brazil nut (*Bertholletia excelsa*), pistachio nut (*Pistacia vera*), macadamia nut and queensland nut (*Macadamia terniflora*) and products thereof, except nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

6. NON IRRADIATION		
(According to EU directive 1999/2/EC & 1999/3/EC)		
This product has not been treated with ionising radiation	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO, not treated
None of the raw materials we used for this product have been treated with ionising radiation.	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO, not treated
We confirm above Non-Irradiation statement is available	<input checked="" type="checkbox"/>	

7. NANOMATERIAL		
(according to EU Regulation (EU) No. 1169/2011)		
This product does not contain any nanomaterials as defined in EU food legislation	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO, does not contain
This product has not been made with nanotechnology	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO, is not made with nanotechnology
We confirm above Non-Nanomaterial statement is available	<input checked="" type="checkbox"/>	

8. Residual solvents		
(according to UE Directive 2009/32 modified by (UE)2010/59; EP5.4; USP476; ICH Q3C(R7))		
For this product following solvents are used during production process:		
Solvent A: Ethanol max residual level: 0.5%	<input checked="" type="checkbox"/> solvent used <input type="checkbox"/> solvent not used	
	<input checked="" type="checkbox"/> EP 7.0	

We confirm solvent residual of this product complies with:	<input checked="" type="checkbox"/> USP <476> <input checked="" type="checkbox"/> EC2009/32 <input checked="" type="checkbox"/> Directive 2010/59/EU <input checked="" type="checkbox"/> NA
We confirm Solvent residual statement is available	<input checked="" type="checkbox"/>

9.Pesticide residual	
(according to EC 396/2005; EP07; USP <561>)	
This product is of vegetable origin	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
We confirm pesticide residual of this product complies with:	<input checked="" type="checkbox"/> EC 396/2005 <input checked="" type="checkbox"/> EP 07/2008 <input checked="" type="checkbox"/> USP<561> <input type="checkbox"/> N/A
Pesticide residual statement available	<input checked="" type="checkbox"/>

10.BSE/TSE information	
(according to EU legislation 999/2001; EP general chapter 5.2.8)	
<p>Cattle, sheep, goats and animals that are naturally susceptible to infect with transmissible spongiform encephalopathy agents or susceptible to infection through the oral route other than humans and non-human primates are defined as "ESE-relevant animal species</p> <p>Pigs ad birds are not naturally susceptible to infection via the oral route; therefore, they are not TSE-relevant animal species. Dogs, rabbits and fish are not TES-relevant animal species."</p>	
the product contains no ingredients of ruminant origin and no materials derived from, or exposed to ruminants affected by or under quarantine for Transmitting Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE)	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> NA
In the manufacturing of this product, there is no any raw or source material	<input type="checkbox"/> YES

and /or reagent used that is of animal origin i.e. bovine, serum-albumin, enzymes, culture broths including those used to prepare working or master cell tanks	<input checked="" type="checkbox"/> NO
Equipment/systems/tools use for processing or storage of the material do not come into contact at any time with materials of animal origin (e.g., components of media filler used to check such system)	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
The material is not purified by using solvents, chromatographic media or buffers that contain components of animal origin	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
We confirm this product complies with:	<input checked="" type="checkbox"/> EU legislation 999/2001 & <input checked="" type="checkbox"/> EP general chapter 5.2.8
We confirm BSE/TSE statement is available	<input checked="" type="checkbox"/> YES

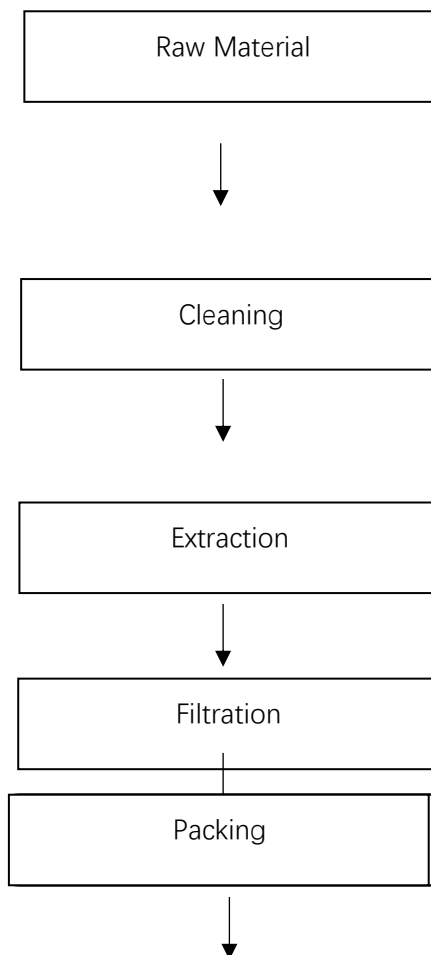
11. Contaminants information	
(according to EU Regulation No 915/2023 and NO.629/2008 as regards maximum levels for certain contaminants in foodstuff)	
<ul style="list-style-type: none"> ●Aflatoxin B1 <5ppb ●Aflatoxins B1 + B2 + G1 + G2 <10ppb ●Ochratoxin A <15ppb 	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
●Melamine	<input checked="" type="checkbox"/> YES
For polycyclic aromatic hydrocarbons, in cocoa fibre, banana chips, food supplements and their preparations, dried herbs <i>and dried spices</i> : <ul style="list-style-type: none"> ●Maximum level of 10 µg/kg of benzo(a)pyrene ●50 µg/kg for the sum of PAH4 (PAH4; benzo[a]pyrene, chrysene, benz[a]anthracene and benzo[b]fluoranthene) in food supplements 	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
We confirm this product complies with NO.1881/2006 and NO.629/2008 and keep compliance statement available	<input checked="" type="checkbox"/> YES

12. Others

We confirm we could meet with the requirement on hygiene of foodstuffs according to Reg 852/2004.

We confirm we could meet with the requirement on general principles and requirements of food law according to REGULATION (EC) No 178/2002

Flow Chart



Material Safety Data Sheet (MSDS)

SECTION 1- PRODUCT AND COMPANY IDENTIFICATION

Common Name : Bromelain 3000 GDU

Manufacturer: Confidential

Product use: For dietary supplement purpose for anti-inflammatory effect.

SECTION 2 – HAZARD INFORMATION

Adverse Effects: Adverse effects may include nausea or other gastrointestinal upset. Possible allergic reaction to material inhaled ingested, or in contact with skin.

Overdose Effects: n/f

Acute: Possible eye, skin, gastrointestinal, and /or respiratory tract irritation.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material

Cross Sensitivity : n/f

Target organs: n/f

For additional information on toxicity, see Section 11

SECTION 3- COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Bromelain

Botanical Nae: Ananas comosus

CAS: 37189-34-7

Therapeutic Category: n/f

Composition: Pure Material

SECTION 4- FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air

Eye: May cause irritation. Flush with copious quantities of water

Skin: May cause irritation. Flush with copious quantities of water

Ingestion: May cause irritation. Flush out mouth with water

General First Aid Procedures: Remove from exposure. Remove from exposure. Remove contaminated clothing. Person developing serious hypersensitivity(anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: For current information about the treatment of overdose, consult a certified

Regional Poison Control Center by Calling the number Listed in your local telephone directory.

SECTION 5-FIREFIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical ,carbon dioxide, or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders,

it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area,Firefighters should

use self-contained breathing equipment and protective clothing.

SECTION 6 -ACCIDENTAL RELEASE MEASURES

Spill Response: Wear approved respiratory protection, chemically compatible gloves, and protective clothing. Wipe up spillage or collect spillage using a high –efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

SECTION 7 – HANDLING AND STORAGE

Handling: As a general rule, avoid all contact and inhalation of dust, mists, and /or vapors associated with the material. Wash thoroughly after handling.

Storage: Store in tight container . This material should be handled and stored per label instructions to ensure product integrity. Store in desiccator.

SECTION 8- EXPOSURE CONTROL/PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilate are recommended.

Respiratory Protection: Use a NIOSH-approved respirator, if it is determined to be necessary by

an industrial hygiene survey involving air monitoring. If a respirator is not required. An approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety glasses or goggles

Protective Clothing: Protect exposed skin

Exposure Limits: n/f

SECTION 9- PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general.

Appearance and Odor: Whitie –yellowish powder slightly characteristic odor.

Odor Threshold: n/f

Melting Point: n/f

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: n/f

Evaporation Rate: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Specific Gravity: n/f

Solubility in water: n/f

Fat solubility : n/f

Other solubility : n/f

Partition Coefficient: n-octanol/water: n/f

Percent Volatile: n/f

Reactivity in water: /f

Explosive Properties: n/f

Oxidizing Properties: n/f

Molecular Weight: n/f

SECTION 10 STABILITY AND REACTIVITY

Condition to Avoid: Avoid exposure to moisture

Incompatibilities: n/f

Decomposition Products: When heated to decomposition, material emits toxic fumes of Sox and

Na₂O. Emits toxic fumes under fire conditions.

Stable? Yes Hazardous Polymerization? NO

SECTION 11 TOXICOLOGICAL PROPERTIES

Oral Rat: LD₅₀:> 10 grams/kg

Oral Mouse: LD₅₀:> 10 grams/kg

Other Toxicity Data: n/f

Irritancy Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

Listed as Carcinogen by : NTP: No IARC No OSHA: No

Other Carcinogenicity Data: No

Mutagenicity Date: n/f

SECTION 12- ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13- DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable National, Provincial, and local laws

SECTION 14 TRANSPORT INFORMATION

Non-hazardous for air, sea and road freight.

Shipping name: Not regulated.

Transport Hazard Class: Not regulated

Packing Group: Not regulated

Environmental hazards: None. The substance is not subject to IMO IMDG Code.

SECTION 15- REGULATORY INFORMATION

China Regulatory Information: n/f

International al Regulatory Information: n/f