



TECHNICAL DESCRIPTION

BROMELAIN REGULAR BULK DENSITY
POWDER 2500 GDU/GM
IBROM11-001



Ananas comosus

Helen Eyre Pickett












TECHNICAL DESCRIPTION

Bromelain Regular Bulk density Powder 2500
GDU/gm

IBROM11-001

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PRODUCT SUBMISSION WARRANT

Date: 02/12/2022 B2I commits to deliver a product matching with all requirements mentioned in this file.

Customer: _____ - By approving the sample and/or associated technical description, the customer commits to accept batches compliant with requirements listed in this technical description.

Sample number (if applicable): _____ -

Sign and stamp:

Customer

B2I

CHRISTELLE CHANE-LAW
Quality manager

TECHNICAL SPECIFICATION DATA SHEET



Product Name: Bromelain Regular Bulk density Powder 2500 GDU/gm

Botanical origin: Ananas comosus

Code: IBROM11-001

Plant part: Stem

Origin: India

Extraction Solvent: Not applicable

Additives - carrier: Maltodextrin (25 to 50%)

	ANALYSIS	SPECIFICATION	ANALYSIS METHOD
PHYSICOCHEMICAL PROPERTIES	Appearance: White to Off-white Colour free flowing hygroscopic powder		Internal method
	Odor: Characteristic		Internal method
FOOD SAFETY PROPERTIES	Particle size: 100% pass through 40 mesh		Internal method
	Foreign matters: ≤1% of foreign bodies		Internal method
	Loss on drying: ≤10%		USP <731>
	Solubility: Almost soluble in water		Internal method
	pH: 5-8		Paper pH test
	Bulk density: 0,20 - 0,80 g/cc		Internal method
	ASSAY: Bromelain ≥ 2500 GDU/g		Titration: Internal method
	Identification: Positive for proteolytic activity		Titration: Internal method
	Residual solvent: Comply with European regulation (2009/32/EC)		GC-Hphase
	Lead: ≤3 ppm*		USP <251>
	Cadmium: ≤1 ppm*		USP <251>
	Mercury: ≤0,1 ppm*		USP <251>
Arsenic: ≤1 ppm*		USP <251>	
Pesticides: ≤MRLs defined in European Regulation in Force (Code 0163080)*		GC-LC-MS: Internal method	
Benzo(a)pyrene: ≤10 ppb*		GC-MS: Internal method	
4 PAH's: ≤50 ppb*		GC-MS: Internal method	
Aflatoxins B1: ≤5 ppb*		-	
Sums of aflatoxins: ≤10 ppb*		-	
Total plate count: ≤ 10 000 CFU/g**/*		USP	
Yeast & Moulds: ≤ 100 CFU/g**/*		USP	
Escherichia Coli: Absence / g*		USP	
Salmonella: Absence / g*		USP	
Regulatory information:	French Decree: Ananas comosus listed. Substance to monitor: Bromelain. Substances: Bromelain listed as substances for nutritional or physiological purposes eligible to be an ingredient of food supplement.		
Uses:	<p>Cosmetics: Facial cleansers and bath preparations. <i>Leung, A.Y., Foster, S. Encyclopedia of Common Natural Ingredients Used in Food, Drugs, and Cosmetics. New York, NY: John Wiley & Sons, Inc. 1996, p. 102</i></p> <p>Food - Food supplements: Anti-inflammatory, wound healing, digestive aid. Bromelain is promoted as a dietary supplement for reducing pain and swelling, especially of the nose and sinuses, gums, and other body parts after surgery or injury. It is also promoted for osteoarthritis, cancer, digestive problems, and muscle soreness. Topical bromelain is promoted for burns. O'Neil, M.J. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. 13th Edition, Whitehouse Station, NJ: Merck and Co., Inc., 2001, p. 232 Ullmann's Encyclopedia of Industrial Chemistry. 6th ed.Vol 1: Federal Republic of Germany. Wiley-VCH Verlag GmbH & Co. 2003 to Present, p. V12 165 (2003) https://www.nccih.nih.gov/health/bromelain</p>		
Storage advise:	Store in air-tight poly bags, in a cool & dry place (Hyroscopic Material), Below 10°C preferred.		
Shelf life:	2 years from the date of manufacturing in the original packed condition.		

* According to a control plan

** Acceptable 5 times the criterion

BOTANICAL INFORMATION



Bromelain Regular Bulk density Powder 2500 GDU/gm

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GENERAL INFORMATION

Botanical name: Ananas comosus Aspect: Other, precise Not available -
 Synonym: <http://www.theplantlist.org/tpl1.1/record/kew-218669>
 Common name: Ananas comosus
 Harvest Country - Area: India - Karnataka
 Part used: Stem
 CITES Applicable: No CITES & Reg. 338/97 regarding the protection of species of wild fauna and flora

CULTURE INFORMATION

Growing method: Cultivated Lifecycle: Annual
 Irrigation: Yes Natural
 Seed origin: India - Karnataka
 Type of soil: Red Soil Gravel
 Soil's fertilization: -

CROP INFORMATION

Harvest period: June to September
 Vegetative state: Not available
 Crop: Manual Precise equipment (if applicable): -
 Weed control description: Manual
 GAP respect: Yes But not certified

PHYTOSANITARY TREATMENT

TYPE	USED?	DURING HARVEST		POST HARVEST		OTHER, PRECISE:
		NAME	QTY (kh/ha)	NAME	QTY (kh/ha)	
WEEDKILLERS	Not available	-	-	-	-	-
INSECTICIDES	Not available	-	-	-	-	-
FUNGICIDES	Not available	-	-	-	-	-
CONSERVATION	Not available	-	-	-	-	-

AFTER HARVEST TREATMENT

WASHING: Yes Specify, method used: -
 SORTING: Yes
 DRYING: No Precise: Not natural
 Temperature: -
 Duration: -
 Drying ratio: -
 PHYSICAL TREATMENTS: Separation Stone removing Dust removing Crushing
 Sifting Metal removing Cut Pulverisation Not available
 SANITARY TREATMENTS: None
Specify, method/product used: -
 OTHER TREATMENTS: -

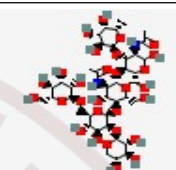
ACTIVE SUBSTANCE INFORMATION

Bromelain Regular Bulk density Powder 2500 GDU/gm

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GENERAL INFORMATION

Commercial name:	Bromelain				
Origin:	India				
Manufactured country:	India				
Substance nomenclature:	CAS NUMBER	EINECS	RTECS	CODE ATC	OTHER, precise:
	9001-00-7	232-572-4	-	,	,
Molecular structure:	MOLECULAR formula	STRUCTURAL Formula	MOLAR MASS	MOLECULAR geometry	STEREOCHEMISTRY
	C39H66N2O29	alpha-L-Fucp-(1->3)-[alpha-D-Manp-(1->6)-[beta-D-Xylp-(1->2)]-beta-D-Manp-(1->4)-beta-D-GlcpNAc-(1->4)]-D-GlcpNAc	1026.9		,

PHYSICO-CHEMICAL PROPERTIES

PHYSICAL	Appearance:	White to Off-white Colour free flowing hygroscopic powder	Method & Reference:	Internal method
	Odor:	Characteristic	Method & Reference:	Internal method
	Particle Size:	100% pass through 40 mesh	Method & Reference:	Internal method
	Loss on drying:	≤10%	Method & Reference:	USP <731>
	Ashes:	≤	Method & Reference:	-
	Bulk density:	0.20 - 0.80 g/cc	Precise type:	Internal method
Melting point:	Not available			
Boiling point:	Not available			
Solubility in water:	Partially			
CHEMICAL	Active substance content:	Bromelain ≥ 2500 GDU/g	Method & Reference:	Titration: Internal method
	Additional analysis:	-	Method & Reference:	-

PROCESS INFORMATION

PROCESS						
Type	Name	Einecs Number	Content (if applicable)	Origin	Function	
x	Raw material(s)	Ananas comosus stem	-	Botanical	Raw material	
x	Other inputs, precise:	Maltodextrin	232-940-4	50-75%	Botanical	Carrier

STABILITY DATA

PROTOCOL:	TYPE	STORAGE CONDITION	FREQUENCY	ATTRIBUTES TESTED						
Give brief description:	X Long-term	15°C+/-2°C	Not available	X	Physical : Appearance, solubility and moisture					
				X	Chemical : Enzyme Activity (GDU/G)					
					Microbiological : -					
CONCLUSION: Item stable under recommend condition										
Test parameters	Specification	Initial	Months							
			3	6	9	12	18	24		
Description	Off white colour hygroscopic powder	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	
Solubility	Partially in water	Complies	Complies	Complies	Complies	Complies	Complies	Complies	Complies	
Moisture	8%	3,91%	3,88%	4,20%	4,33%	4,10%	3,97%	4,15%		
Enzyme activity (GDU/g)	2500	2630	2611	2605	2623	2591	2575	2542		
Date of analysis	-	12/04/2014	14/07/2014	13/10/2014	12/01/2015	15/04/2015	16/10/2015	15/04/2016		
Remarks	-	Satisfactory	Satisfactory	Satisfactory	Satisfactory	Satisfactory	Satisfactory	Satisfactory		

FINAL PRODUCT INFORMATION



Bromelain Regular Bulk density Powder 2500 GDU/gm

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GENERAL INFORMATION

Botanical name: Ananas comosus
 Synonym: http://www.theplantlist.org/tpl1.1/record/kew-219669
 Common name: Ananas comosus
 Manufactured country: India - Karnataka
 Part used: Stem
 CITES Applicable: No CITES & Reg. 338/97 regarding the protection of species of wild fauna and flora

EXTRACTION INFORMATION

Process: Cut Grinding Pressing Heat treatment, precise:
 Sieving Sifting Spray drying Purification, precise:
 Ionization Fumigation Others, precise: See flow chart

Description: Type of extraction: Not applicable
 Solvent: Not applicable Precise percentage in case of mixture:
 DER (drug/extracting ratio): Not available

Composition: Additives: Flavouring Colour additives Sweeteners Preservatives
Specify, Einescs N° and content:
 Carrier: yes Precise type and percentage: Maltodextrin (25 to 50%)

ANALYTICAL DATA

TYPE	TEST	SPECIFICATION	METHODS	REFERENCE	FREQUENCY	COMMENTS
BOTANICAL	Macroscopic:	White to Off-white Colour free flowing hygroscopic powder	Visual	Internal	Systematic	-
	Organoleptic:	Characteristic	Olfactive	Internal	Systematic	-
CHEMICAL	Identification:	Positive for proteolytic activity	Titration: Internal method	Internal	Systematic	-
	Assay:	Bromelain ≥ 2500 GDU/g	Titration: Internal method	Internal	Systematic	-
	Residual solvent:	Comply with European regulation (2009/32/EC)	GC-Hphase	Internal	Control plan	-
PHYSICAL	Loss on drying:	≤10%	USP <731>	Internal	Systematic	-
CONTAMINANTS	Lead:	≤3 ppm*	USP <251>	ER 1881/2006 & amdts	Control plan	-
	Cadmium:	≤1 ppm*	USP <251>	ER 1881/2006 & amdts	Control plan	-
	Mercury:	≤0,1 ppm*	USP <251>	ER 1881/2006 & amdts	Control plan	-
	Arsenic:	≤1 ppm*	USP <251>	ER 1881/2006 & amdts	Control plan	-
	Pesticides:	≤MRLs defined in European Regulation in Force (Code 0163080)*	GC-LC-MS: Internal method	ER 396/2005 & amdts	Control plan	-
	Benzo(a)pyrene - sum of PAHs	Refers to TDS	GC-MS: Internal method	ER 1881/2006 & amdts	Control plan	-
	Aflatoxins B1, Sum of aflatoxins	Refers to TDS	GC-MS: Internal method	ER 1881/2006 & amdts	Control plan	-
MICROBIOLOGICAL	Total plate count:	≤ 10 000 CFU/g**/*	USP	European pharmacopea	Systematic	-
	Yeast & Moulds:	≤ 100 CFU/g**/*	USP	European pharmacopea	Systematic	-
	Escherichia Coli:	Absence / g*	USP	European pharmacopea	Systematic	-
	Salmonella:	Absence / g*	USP	European pharmacopea	Systematic	-

PROCESS FLOW CHART



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INPUT	PROCESS STEP	OUTPUT	CONTROL
Raw material (pineapple stem)	Raw material reception		Quality control
	Extraction of Juice by crushing/filter press		
	Filtration		
	Micro filtration using 0,25 μ filter		Quality control
	Ultrafiltration		Quality control
	Lyophilization		
	Milling		Quality control
Carrier	Blending		Quality control
Big Bag	Packaging		
	Expedition		

METHODE OF ANALYSIS



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1. SCOPE - DESCRIPTION

This method is used to determinate the enzymatic activity.

A glycoprotein which is a highly active thiol proteinase (non-specific cysteine protease), which splits glycine esters but not lysine esters; it is also a proteindigesting and milk-clotting enzyme. It is found in the leaves and stems of the pineapple plant. Substrates susceptible to bromelain include all of the common protein materials such as gelatin, casein, gluten, collagen, elastin, globulins and muscle fiber protein.

2. DEFINITION

Unit Definition (Gelatin Digestion Unit - GDU): One unit will hydrolyze 1.0 mg of amino nitrogen from gelatin in 20 minutes at pH 4.5 at 45°C.

2. REAGENTS

1. Gelatin Substrate (5.0%):

To 25.00 g of Gelatin (high-test-275 bloom) in an 800 ml beaker, add 400 ml of boiling deionized water. Add one drop of antifoam and stir. Maintain the temperature of the gelatin solution at 85°C to 86°C in a water bath with occasional stirring. Cool to 45°C and immediately adjust to pH 4.5 with 2N NaOH. Dilute to 500 ml with deionized water. This substrate should be made fresh daily.

2. Buffer Solution:

Add 5.7 ml Glacial Acetic Acid and 150 g Sodium Chloride to 700 ml deionized water and adjust to pH 4.5 with 50% NaOH. Dilute to one liter.

3. Sodium Hydroxide, 0.05N:

Dissolve 2 g of NaOH in deionized water. Transfer to a 1000 ml volumetric flask and dilute to volume with deionized water.

3. METHODE

Standard solution:

Weigh exactly 100mg of Bromelain in a 50 ml beaker and add 20 ml buffer solution. Stir until the bromelain is well dispersed. Transfer to a 100 ml volumetric flask, wash down the beaker and make up to volume with deionized water. This solution must be tested within 30 minutes of the time the buffer solution is added.

Sample preparation:

1. Pipette 25 mL of substance into a 100 ml beaker.
2. Add 1.0 mL of enzyme solution, start timing and stir briefly.
3. After exactly 20 min of digestion, add 1.0 ml of 3% hydrogen peroxide solution and stir briefly.
4. Remove from water bath, adjust to pH 6.0 with NaOH and add 10 ml of 37% formaldehyde.
5. Titrate to pH 7.8 with 0.05N NaOH. This is the sample titer, T.
6. For the blank, pipette 25 ml of substrate into a 100 ml beaker as above, add 0.1ml of 3% Hydrogen Peroxide, hold at 45°C for exactly 20.0 minutes.
7. Remove from water bath, adjust to pH 6.0 with NaOH and add 10 ml of 37% formaldehyde.
8. Titrate to pH 7.8 with 0.05N NaOH. This is the blank titer, B.

5. CALCULATION

$$\text{GDU/g} = \frac{(T - B) \times 700}{\text{Weight of Enzyme used for titration assay in mg}}$$

700 x 14 x 0,05 x 1 000
14= Constant factor (nitrogen Eq. Weight)
0,05= Normality of NaOH
1000 = mg to gm conversion

Weight of the enzyme used for assay (in mg) = 2 mg
(100 mg in 100 ml; Hence, 1 ml used for Titration would contain 2 mg of Bromelain)

Testing Parameters:

Prepare a solution containing 2.0-4.0 units/ml Bromelain in 4.5 pH Buffer Enzyme preparations are diluted to a concentration of approximately 0.001 g/ml

ALLERGEN STATUS

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SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES	Presence in product		Cross contamination		Notes
	Yes	No	Yes	No	
1. Cereals containing gluten, namely: wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof, except:					
(a) wheat based glucose syrups including dextrose ⁽¹⁾ ;					
(b) wheat based maltodextrins ⁽¹⁾ ;		X		X	
(c) glucose syrups based on barley;					
(d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin;					
2. Crustaceans and products thereof;		X		X	
3. Eggs and products thereof;		X		X	
4. Fish and products thereof, except:					
(a) fish gelatine used as carrier for vitamin or carotenoid preparations;		X		X	
(b) fish gelatine or Isinglass used as fining agent in beer and wine;					
5. Peanuts and products thereof;		X		X	
6. Soybeans and products thereof, except:					
(a) fully refined soybean oil and fat ⁽¹⁾ ;					
(b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources;		X		X	
(c) vegetable oils derived phytosterols and phytosterol esters from soybean sources;					
(d) plant stanol ester produced from vegetable oil sterols from soybean sources;					
7. Milk and products thereof (including lactose), except:					
(a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin;		X		X	
(b) lactitol;					
8. Nuts, namely: almonds (<i>Amygdalus communis</i> L.), hazelnuts (<i>Corylus avellana</i>), walnuts (<i>Juglans regia</i>), cashews (<i>Anacardium occidentale</i>), pecan nuts (<i>Carya illinoensis</i> (Wangenh.) K. Koch), Brazil nuts (<i>Bertholletia excelsa</i>), pistachio nuts (<i>Pistacia vera</i>), macadamia or Queensland nuts (<i>Macadamia ternifolia</i>), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin;		X		X	
9. Celery and products thereof;		X		X	
10. Mustard and products thereof;		X		X	
11. Sesame seeds and products thereof;		X		X	
12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO ₂ which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers;		X		X	
13. Lupin and products thereof;		X		X	
14. Molluscs and products thereof.		X		X	

CONCLUSION:

No allergen declaration to be made

PACKAGE OF STATEMENTS



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SUBJECT	SETTLEMENT	REGULATIONS REFERENCE	STATEMENT	COMMENTS
FOOD GRADE	Conform	Regulation 178/2002/EC Regulation 852/2004/EC And amendments	Based on the mentioned regulation, We confirm that the product is food grade and respects all requirements listed on the regulation commonly known as Food laws.	-
FOREIGN BODY	Confirmed		We confirm that the product does not contain any foreign body with more than 1cm diameter.	-
WADA	Not concerned	Link : https://www.wada-ama.org/fr	We confirm that this product is not composed by any doping substance as defined in World Anti-Doping Agency last list in force.	-
VEGAN - VEGETARIAN	Suitable	-	We confirm that the product is suitable for vegan & vegetarian consumption. It doesn't contain any animal products or produced by them.	-
ANIMALS TESTING	Not concerned	-	We declare that the above product was not tested on any animals.	-
TSE - BSE	Not concerned	Regulation 999/2001/EC And amendments	We confirm that the product does not contain any product of animal origin and therefore are free from Specified Risk materia , laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSE).	-
GMO	Not concerned	Directives 2001/18/EC Regulation 1829/2003/EC Regulation 1830/2003/EC And amendments	Based on the mentioned law texts, We confirm that the product above is not composed, consisted of or produced from GMOs (as defined in Article 2.2 of Directive 2001/18/EC). No label mentioning the presence of GMO is mandatory.	-
NOVEL FOOD	Not concerned	Regulation 258/97/EC Regulation 2015/2283/EC And amendments	We confirm that the product is not a novel food as defined in mentioned European regulation.	-
RESIDUAL SOLVENT COMPLIANCE	Compliance	Directive 2009/32/EC Directive 2010/59/EU And amendments	We confirm that the extraction solvent is complying with requirements listed in mentioned regulations.	-
IONIZATION	Not concerned	Directives 1999/2/EC Directives 1999/3/EC And amendments	We confirm that the above product is not subject to any ionizing treatment throughout the production chain in accordance with European regulations.	-
NANOMATERIAL	Not concerned	Recommendation 2011/696/EU Regulation 1169/2011/EC And amendments	We confirm that the above product does not contain nanomaterials as defined in both mentionned regulation. No label mentioning the presence of [NANO] is mandatory.	-
CMR	Not concerned	Regulation 2018/1480/EU	We confirm that the above product does not contain any CMR substance. There is no hazard label required.	-
SDS	Not mandatory	Directives 67/548/CE Directives 1999/45/CE Regulation 1907/2006/CE Regulation 1272/2008/CE	We confirm that the above product is not classified and classifiable as dangerous product. It is not mandatory to provide SDS according to european regulation.	-
PRIMARY PACKAGING		Regulation 10/2011/EC Regulation 1935/2004/EC Directives 80/590/EEC Directives 89/109/EEC And amendments	We confirm that the packaging of above product is fully compliant with mentioned regulations in force.	-
ETHYLENE OXIDE		Regulation 396/2005/EC Regulation 540/2011/CE and amendments	The ethylene oxide is not used during all the process from the plant harvest to the final delivery to our customer.	-
		Date: 02/12/2022	<p>CHRISTELLE CHENE-LAW Quality manager</p>	

SAFETY DATA SHEET



Bromelain Regular Bulk density Powder 2500 GDU/gm

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I. COMPANY AND SUBSTANCES (OR PREPARATION) IDENTIFICATION

I.1 Supplier's Safety Data Sheet details

SUPPLIER DETAILS

Company name: BOTANICALS TO INGREDIENTS
 Address : 50 Bd Stalingrad Bureau 3 - 06300 NICE, France
 Phone: +33 (0)6 85 71 40 75
 Contact Name: Christelle CHANE-LAW
 Email: quality@b-2i.com

EMERGENCY INFORMATION

Urgency contact: ORFILA number (based on INRS Data)
 Phone: + 33 (0)1 45 42 59 59
 Website: <http://www.centres-antipoison.net>
 Opening hours: 24hours/24 - 7days/7

These details will put you in contact with the nearest poison French center which will be able to provide you with free medical assistance.

I.2 Product Identification

 Available registration number

Substance NAME or Commercial Name	International Chemical ID	Index No	EC No	CAS No	UICPA Name	Other:
Bromelain		-	232-572-4	9001-00-7	Bromelain Bromelain, juice Bromelains	-

 Absence of registration number:

- Recovered substance meeting the criteria of Article 2(7)(d) of REACH (free from registration requirements).
 Transitional period for this substance registration under Article 23 of REACH has not yet expired.
 Free from registration in accordance with the provisions of Article 2(7)(a) and Annex IV of REACH.

I.3 Product Identified uses

Relevant identified use: Food (human consumption) Feed (animal consumption) Cosmetics
 Not recommended for use: Not available

II. COMPOSITION - INGREDIENTS IDENTIFICATION

Dénomination d'identification	Numéro d'identification	Type d'identificateur de produit	Teneur en % en masse (en gramme)	Numéro CE
Bromelain	9001-00-7	CAS NUMBER	25-50%	232-572-4
Maltodextrin	9050-36-6	CAS NUMBER	50-75%	232-940-4

III. HAZARDS CLASSIFICATION

III.1 Classification

 The product is not classified as dangerous under current legislation. No labeling is required for this product.

 The product is classified as below:

Code	Pictogram	Signal word	Hazard class	Category
H315		Warning	Skin corrosion/irritation	Category 2
H319		Warning	Serious eye damage/eye irritation	Category 2A
H335		Warning	Specific target organ toxicity, single exposure; Respiratory tract irritation	Category 3
H334		Danger	Sensitization, respiratory	Category 1, 1A, 1B

III.2 Labelling

Hazard	Code	Statement
<input checked="" type="checkbox"/>	H315	Causes skin irritation
	H319	Causes serious eye irritation
	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
	H335	May cause respiratory irritation
Prevention	Code	Statement
<input checked="" type="checkbox"/>	- P261	Avoid breathing (dust/fume/gas/mist/vapors/spray).
	- P264	Wash (hands) thoroughly after handling.
	- P280	Wear (protective gloves/protective clothing/eye protection/face protection).
	- P284	Wear respiratory protection.
	- P302+P352	IF ON SKIN: Wash with plenty of soap and water;
	- 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.
	- P312	Call a POISON CENTER or doctor/physician if you feel unwell.
	- P332+P313	If skin irritation occurs, get medical advice/attention.
	- P337+P313	If eye irritation persists, get medical advice/attention.
- P342+P311	If experiencing respiratory symptoms call a POISON CENTER or doctor/physician.	
- P362+P364	Take off contaminated clothing and wash it before reuse.	

IV. FIRST AID MEASURES

In general, in case of doubt or if symptoms persist, always call a doctor. Never give anything by mouth to an unconscious person. Dust may irritate eyes and respiratory system.

EYE CONTACT

Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

SKIN CONTACT

Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse

INGESTION

Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

INHALATION

Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

SAFETY DATA SHEET



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V. FIRE FIGHTING MEASURES

Flammable No-Flammable No data available

V.1 Extinguishing

Suitable extinguishing: Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.
Extinguishing to avoid: A solid water stream may be inefficient.

V.2 Typical hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to these fumes can be dangerous to health. Do not breathe fumes.

V.3 Advice for firefighters

Procedures against fire: Prevent the formation of a cloud of dust.
Special protective equipment: Firefighters should use standard protective equipment including flame retardant coat, face mask with helmet, gloves, boots, and in enclosed spaces, self-contained breathing apparatus.

VI. ACCIDENTAL RELEASE MEASURES

VI.1 Personal precautions, protective equipment and emergency procedures

Refers to sections V, VII and VIII.

VI.2 Precautions for environmental protection

Dangerous for the environment Precaution: The product is not dangerous for the environment, however, prevent entry into sewers or waterways.
 Not dangerous for the environment

VI.3 Materials and methods for containment and storage

Get the dry product by mechanical means (sweeping / vacuuming). Do not generate dust. For waste disposal refer to section XIII.

VII. HANDLING & STORAGE

Precautions for safe handling: Refers to Section Vi and VIII.
Recommendations: No smoking in premises where the substance is used.
Avoid the formation or spread of dust in the atmosphere.
Provide adequate ventilation.
Hygiene Prevention: Handle product in accordance with good industrial hygiene and safety practice.
Conditions for safe storage: Store in a dry and well sealed. Store in a sealed package in plastic.
Incompatibilities storage: No data available

VIII. EXPOSURE CONTROL & PERSONAL PROTECTION

Parameters:	Exposure route	Acute local effects	Acute systemic effects
	Oral	No data available	No data available
	Inhalation	No data available	No data available
	Dermal	No data available	No data available

Individual protective equipment: Use personal protective equipment and properly maintained.
Store personal protective equipment in a clean place, away from the work area.
When using, do not eat, drink or smoke. Remove and wash contaminated clothing before reuse.
Ensure adequate ventilation, especially in confined areas.
Eye / face protection: Avoid contact with eyes. Wear goggles adjusted if dusts.
Hand protection: Wear suitable protective gloves if prolonged or repeated contact with skin.
Body protection: Wear regularly laundered. After contact with the product, all parts of the body should be washed.
Respiratory protection: Avoid contact with eyes. Wear goggles adjusted if dusts



IX. PHYSICAL & CHEMICAL PROPERTIES

Refers to technical data sheet

X. STABILITY & REACTIVITY

Chemical stability: This product is stable at the handling and storage conditions recommended in section VII.
Refers to stability data analysis if available.

Condition to avoid: Refers to section VII.

Hazardous decomposition product: No data available

XI. TOXICOLOGICAL INFORMATION

The toxicological effects of this product have not been thoroughly studied.

XII. ECOLOGICAL INFORMATION

Toxicity: Avoid release into the environment. Runoff from fire control or dilution water may cause pollution
Persistence and degradability: No data available
PBT and vPvB: No data available

SAFETY DATA SHEET



Bromelain Regular Bulk density Powder 2500 GDU/gm

IBROM11-001

XIII. DISPOSAL INFORMATION

Appropriate management of wastes from the product and / or its container must be determined in accordance with the 2008/98/EC directives. Do not discharge into drains or rivers.

Waste: Waste management is done without endangering human health, harming the environment or any risks to water, soil, plants or animals.

Recycle or dispose waste in accordance with the legislation in force (preferably by a collector or an approved company)

Do not contaminate the ground or water. Do not dispose them in the environment.

Contaminated packaging: Empty container. Do not remove the label. Send to an approved disposal contractor.

XIV. TRANSPORT INFORMATION

The product is not covered by international regulation on the transport of dangerous goods (IMDG, ICAO / IATA, ADR / RID). Not transport requirements to follow.

The product is covered by international regulation on the transport of dangerous goods (IMDG, ICAO / IATA, ADR / RID). Below are the requirements to respect:

Abbreviations:

ADR: Accord européen au transport international de marchandises Dangereuses par la Route. RID: Regulations concerning the International carriage of Dangerous goods by rail. IMDG: International Maritime Dangerous Goods. OACI: Organisation de l'Aviation Civile Internationale. IATA: International Air Transport Association.

XV. REGULATORY INFORMATION

No data available

XVI. OTHER INFORMATION

The user's working conditions are outside the supplier. The information given on this safety data sheet is based on the state of our knowledge and on national and community regulations.

It is always the user's responsibility to take the necessary steps to meet the requirements of local laws and regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to this product and not as a guarantee of the properties thereof.