1712 - Papain ≥30000 USP-U/mg

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier: 1712 - Papain ≥30000 USP-U/mg

Papain

CAS: 9001-73-4

EC: 232-627-2

Index: 647-007-00-0

REACH: Not relevant

Other means of identification:

Not relevant

1.2 Relevant identified uses of the substance or mixture and uses advised against:

Relevant uses (Professional users): For use in laboratory and production. Not for human or animal use.
Relevant uses (Industrial user): For use in laboratory and production. Not for human or animal use.
For Professional users/Industrial user only.
Uses advised against: All uses not specified in this section or in section 7.3

1.3 Details of the supplier of the safety data sheet:

GERBU Biotechnik GmbH
69123 Heidelberg - Germany
Phone: +49 6221 7264167
safety@gerbu.de
www.gerbu.de

1.4 Emergency telephone number: Eire: 01809 2566

Emergency call (EU): 112

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

CLP Regulation (EC) No 1272/2008:

Classification of this product has been carried out in accordance with CLP Regulation (EC) No 1272/2008.

Eye Irrit. 2: Eye irritation, Category 2, H319
Resp. Sens. 1: Sensitisation, respiratory, Category 1, H334
Skin Irrit. 2: Skin irritation, Category 2, H315
STOT SE 3: Respiratory tract toxicity, single exposure, Category 3, H335

2.2 Label elements:

CLP Regulation (EC) No 1272/2008:

Labelling of packages where the contents do not exceed 125 ml:

Danger

Hazard statements:

Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements:

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
P501: Dispose of contents/container in accordance with regulations on hazardous waste or packaging and packaging waste respectively.

2.3 Other hazards:

Product does not meet PBT/vPvB criteria
Endocrine-disrupting properties: The product does not meet the criteria.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

Chemical description: Chemical substance

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification		Concentration
CAS: 9001-73-4 EC: 232-627-2 Index: 647-007-00-0 REACH: Not relevant	**Papain**	ATP CLP00	**75 - <100 %**
	Regulation 1272/2008	Eye Irrit. 2: H319; Resp. Sens. 1: H334; Skin Irrit. 2: H315; STOT SE 3: H335 - Danger	

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

3.2 Mixture:

Not relevant

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

Remove the person affected from the area of exposure, provide with fresh air and keep at rest. In serious cases such as cardiorespiratory failure, artificial resuscitation techniques will be necessary (mouth to mouth resuscitation, cardiac massage, oxygen supply,etc.) requiring immediate medical assistance.

By skin contact:

Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection.

By eye contact:

Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By ingestion/aspiration:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

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

Acute and delayed effects are indicated in sections 2 and 11.

4.3 Indication of any immediate medical attention and special treatment needed:

Not relevant

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

Unsuitable extinguishing media:

Non-applicable

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and Self Contained Breathing Apparatus. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...)

Additional provisions:

- CONTINUED ON NEXT PAGE -

SECTION 5: FIREFIGHTING MEASURES (continued)

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Preferably use aspiration for cleaning. Given the danger of the product by inhalation, any cleaning method that involves exposure to the product in this way (sweeping, etc.) is not recommended

For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Preferably use aspiration for cleaning. Given the danger of the product by inhalation, any cleaning method that involves exposure to the product in this way (sweeping, etc.) is not recommended

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Due to its non-inflammable nature, the product does not present a fire risk under normal conditions of storage, handling and use.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Specific storage requirements

Minimum Temp.: 8 ºC

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be assessed in the workplace:

Nuisance dust: Inhalable dust 10 mg/m3 // Respirable dust 4 mg/m3

DNEL (Workers):

- CONTINUED ON NEXT PAGE -

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Not relevant

DNEL (General population):

Not relevant

PNEC:

Not relevant

8.2 Exposure controls:

A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
Mandatory respiratory tract protection	Filter mask for gases and vapours (Filter type: P3/FFP3)	CE CAT III	EN 405:2002+A1:2010	Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment.

C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
Mandatory hand protection	Chemical protective gloves (Material: Nitrile, Breakthrough time: > 480 min, Thickness: 0,11 mm)	CE CAT III	EN ISO 21420:2020	Replace the gloves at any sign of deterioration.

D.- Eye and face protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
Mandatory face protection	Panoramic glasses against splash/projections.	CE CAT II	EN 166:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacturer´s instructions. Use if there is a risk of splashing.

E.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing	CE CAT I		Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 6529:2013, EN ISO 6530:2005, EN ISO 13688:2013, EN 464:1994.
	Anti-slip work shoes	CE CAT II	EN ISO 20347:2022	Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 20345:2022 y EN 13832-1:2019

F.- Additional emergency measures

It is advised to implement additional emergency equipments in workplaces that are particularly exposed to the product or in situations where risk assessments highlight the necessity of such equipments.

Emergency measure	Standards	Emergency measure	Standards
Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

Environmental exposure controls:

To comply with environmental protection regulations, it is recommended to prevent any spillage of the product and its container. For more detailed information, please refer to subsection 7.1.D.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	0 % weight
V.O.C. density at 20 ºC:	0 kg/m³ (0 g/L)
Average carbon number:	Not relevant
Average molecular weight:	Not relevant

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 ºC:	Solid
Appearance:	Not relevant *
Colour:	White
Odour:	Not relevant *
Odour threshold:	Not relevant *

Volatility:

Boiling point at atmospheric pressure:	Not relevant *
Vapour pressure at 20 ºC:	Not relevant *
Vapour pressure at 50 ºC:	Not relevant *
Evaporation rate at 20 ºC:	Not relevant *

Product description:

Density at 20 ºC:	1100 kg/m³
Relative density at 20 ºC:	1,1
Dynamic viscosity at 20 ºC:	Not relevant *
Kinematic viscosity at 20 ºC:	Not relevant *
Kinematic viscosity at 40 ºC:	Not relevant *
Concentration:	Not relevant *
pH:	Not relevant *
Vapour density at 20 ºC:	Not relevant *
Partition coefficient n-octanol/water 20 ºC:	Not relevant *
Solubility in water at 20 ºC:	Not relevant *
Solubility properties:	Not relevant *
Decomposition temperature:	Not relevant *
Melting point/freezing point:	Not relevant *

Flammability:

Flash Point:	Not relevant *
Flammability (solid, gas):	Not relevant *
Autoignition temperature:	Not relevant *
Lower flammability limit:	Not relevant *
Upper flammability limit:	Not relevant *

Explosive (Solid):

Lower explosive limit:	Not relevant *
Upper explosive limit:	Not relevant *

*Not relevant due to the nature of the product, not providing information property of its hazards.

- CONTINUED ON NEXT PAGE -

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Particle characteristics:

Median equivalent diameter:	Not relevant *

9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties:	Not relevant *
Oxidising properties:	Not relevant *
Corrosive to metals:	Not relevant *
Heat of combustion:	Not relevant *
Aerosols-total percentage (by mass) of flammable components:	Not relevant *

Other safety characteristics:

Surface tension at 20 ºC:	Not relevant *
Refraction index:	Not relevant *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7 from Safety Data Sheet.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Not applicable	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO_2), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008:

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for consumption. For more information see section 3
- Corrosivity/Irritability: The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.

B- Inhalation (acute effect):

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Causes irritation in respiratory passages, which is normally reversible and limited to the upper respiratory passages.

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Produces skin inflammation.
- Contact with the eyes: Produces eye damage after contact.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for the effects mentioned. For more information see section 3.
  IARC: Not relevant
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Prolonged exposure can result in specific respiratory hypersensitivity.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

Causes irritation in respiratory passages, which is normally reversible and limited to the upper respiratory passages.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

Other information:

Not relevant

Product-specific toxicological information:

Acute toxicity		Genus
LD50 oral	4000 mg/kg	Rat

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
Papain CAS: 9001-73-4 EC: 232-627-2	LD50 oral	4000 mg/kg	Rat
	LD50 dermal		
	LC50 inhalation		

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product does not meet the criteria.

Other information

Not relevant

SECTION 12: ECOLOGICAL INFORMATION

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

12.1 Toxicity:

Not relevant

12.2 Persistence and degradability:

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SECTION 12: ECOLOGICAL INFORMATION (continued)

Not relevant

12.3 Bioaccumulative potential:

Not relevant

12.4 Mobility in soil:

Not relevant

12.5 Results of PBT and vPvB assessment:

Product does not meet PBT/vPvB criteria

12.6 Endocrine disrupting properties:

Endocrine-disrupting properties: The product does not meet the criteria.

12.7 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Type of waste (Regulation (EU) No 1357/2014):

HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity, HP13 Sensitising, HP4 Irritant – skin irritation and eye damage

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC, The Waste Regulations 2011, 2011 No. 988). As under 15 01 (2014/955/EU) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-hazardous residue. Waste should not be disposed of to drains. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated
Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport (ADR/RID,IMDG,IATA)

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

- Article 95, REGULATION (EU) No 528/2012: Not relevant
- Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Not relevant
- Regulation (EU) 2019/1021 on persistent organic pollutants: Not relevant
- Regulation (EU) 2024/590, about substances that deplete the ozone layer: Not relevant
- REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Not relevant
- Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Not relevant

Seveso III:

Not relevant

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc ….):

Not relevant

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG 2009), SI 2009 No 1348
The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) Regulations 2011, 2011 No.

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SECTION 15: REGULATORY INFORMATION (continued)

1885
Control of Substances Hazardous to Health Regulations 2002 (as amended)
EH40/2005 Workplace exposure limits
The Waste Regulations 2011, 2011 No. 988

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878)

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

Not relevant

Texts of the legislative phrases mentioned in section 2:

H315: Causes skin irritation.
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335: May cause respiratory irritation.
H319: Causes serious eye irritation.

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Eye Irrit. 2: H319 - Causes serious eye irritation.
Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Irrit. 2: H315 - Causes skin irritation.
STOT SE 3: H335 - May cause respiratory irritation.

Advice related to training:

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

http://echa.europa.eu
http://eur-lex.europa.eu

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road
IMDG: International maritime dangerous goods code
IATA: International Air Transport Association
ICAO: International Civil Aviation Organisation
COD: Chemical Oxygen Demand
BOD5: 5day biochemical oxygen demand
BCF: Bioconcentration factor
LD50: Lethal Dose 50
LC50: Lethal Concentration 50
EC50: Effective concentration 50
LogPOW: Octanolwater partition coefficient
Koc: Partition coefficient of organic carbon
UFI: unique formula identifier
IARC: International Agency for Research on Cancer

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -