

SAFETY DATA SHEET



Revision date 11-Aug-2022

Revision Number 1

1. Identification

Product identifier

Product Name Papain

Other means of identification

Catalog Number(s) 805030

Safety data sheet number 186120

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic Restricted to professional users

Details of the supplier of the safety data sheet

Corporate Headquarters

Bio-Rad Laboratories Inc.
1000 Alfred Nobel Drive
Hercules, CA 94547
USA

Manufacturer Address

Bio-Rad Medical Diagnostics GmbH
Industriestr. 1
63303 Dreieich
Germany
e-mail: contact.bmd@bio-rad.com

Legal Entity / Contact Address

Bio-Rad Laboratories
Clinical Diagnostics
4000 Alfred Nobel Drive
Hercules, California 94547
USA

Technical Service 1-800-224-6723
TechSupport.USSD@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC USA: 1 (800) 424-9300

2. Hazard(s) identification

Classification

Acute toxicity - Inhalation (Dusts/Mists)	Category 3
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Respiratory sensitization	Category 1
Specific target organ toxicity (single exposure)	Category 3

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Toxic if inhaled
Causes skin irritation
Causes serious eye irritation
May cause allergy or asthma symptoms or breathing difficulties if inhaled
May cause respiratory irritation

**Appearance** No information available**Physical state** Solid**Odor** No information available**Precautionary Statements - Prevention**

Avoid breathing dust/fume/gas/mist/vapors/spray
 Use only outdoors or in a well-ventilated area
 Wash face, hands and any exposed skin thoroughly after handling
 In case of inadequate ventilation wear respiratory protection
 Wear protective gloves/eye protection/face protection

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
 If eye irritation persists: Get medical advice/attention
 IF ON SKIN: Wash with plenty of water and soap
 If skin irritation occurs: Get medical advice/attention
 Take off contaminated clothing and wash it before reuse
 IF INHALED: Remove person to fresh air and keep comfortable for breathing
 Call a POISON CENTER or doctor

Precautionary Statements - Storage

Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements - Disposal

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Unknown acute toxicity

67.502 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Other information

Harmful to aquatic life with long lasting effects. Harmful to aquatic life.

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

Chemical name	CAS No	Weight-%	Trade secret
Papain	9001-73-4	35 - 50	*
Cysteine hydrochloride, L-(+)-, monohydrate	7048-04-6	10 - 20	*
Glycine, N,N-1,2-ethanediybis[N-(carboxymethyl)-, disodium salt, dihydrate	6381-92-6	10 - 20	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures**General advice**

Show this safety data sheet to the doctor in attendance. Immediate medical attention is

	required.
Inhalation	May cause allergic respiratory reaction. If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Get immediate medical advice/attention. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.
Skin contact	May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician. Wash off immediately with soap and plenty of water for at least 15 minutes.
Ingestion	May produce an allergic reaction. Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.
Self-protection of the first aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. See section 8 for more information. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Coughing and/ or wheezing. Itching. Rashes. Hives. May cause redness and tearing of the eyes. Burning sensation. Difficulty in breathing.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	May cause sensitization in susceptible persons. Treat symptomatically.
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5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards arising from the chemical	Product is or contains a sensitizer. May cause sensitization by inhalation and skin contact.
Explosion data	
Sensitivity to mechanical impact	None.
Sensitivity to static discharge	None.
Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away
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from and upwind of spill/leak. Avoid generation of dust. Do not breathe dust.

Other information Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Provide extract ventilation to points where emissions occur. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Take off contaminated clothing and wash before reuse. Handle product only in closed system or provide appropriate exhaust ventilation. Avoid breathing vapors or mists.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children. Store according to product and label instructions.

8. Exposure controls/personal protection

Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves. Impervious gloves.

Skin and body protection Wear suitable protective clothing. Long sleeved clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Do not breathe dust. Take off contaminated

clothing and wash before reuse. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	No information available
Color	No information available
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH		None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	Soluble in water	
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		Kinematic viscosity No data available
None known		Dynamic viscosity No data available
None known		

Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	No information available
VOC content	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	Excessive heat.
Incompatible materials	Strong acids. Strong bases. Strong oxidizing agents.
Hazardous decomposition products	None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available. May cause sensitization in susceptible persons. (based on components). May cause irritation of respiratory tract. Toxic by inhalation.
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.
Skin contact	Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). Causes skin irritation.
Ingestion	Specific test data for the substance or mixture is not available. May cause additional affects as listed under "Inhalation". Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain, or flushing. Coughing and/ or wheezing. Redness. May cause redness and tearing of the eyes. Difficulty in breathing.
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Acute toxicity

Numerical measures of toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	5,236.60 mg/kg
ATEmix (dermal)	7,993.60 mg/kg
ATEmix (inhalation-dust/mist)	0.830 mg/l

Unknown acute toxicity

67.502 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Papain 9001-73-4	> 4 g/kg (Rat)	-	-

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	Classification based on data available for ingredients. Causes skin irritation.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes serious eye irritation.
Respiratory or skin sensitization	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.

Reproductive toxicity	No information available.
STOT - single exposure	May cause respiratory irritation.
STOT - repeated exposure	No information available.
Target organ effects	Respiratory system, Eyes, Skin.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity	Harmful to aquatic life with long lasting effects.
Persistence and degradability	No information available.
Bioaccumulation	There is no data for this product.
Other adverse effects	No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

14. Transport information

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>MEX</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG</u>	Not regulated

15. Regulatory information

International Inventories

Contact supplier for inventory compliance status

US Federal Regulations**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

<u>NFPA</u>	Health hazards 3	Flammability 0	Instability 0	Special hazards -
<u>HMIS</u>	Health hazards 2 *	Flammability 0	Physical hazards 0	Personal protection X
<i>Chronic Hazard Star Legend</i>		<i>* = Chronic Health Hazard</i>		

Key or legend to abbreviations and acronyms used in the safety data sheet**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal

Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
National Institute of Technology and Evaluation (NITE)
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision date 11-Aug-2022

Revision Note Significant changes throughout SDS. Review all sections.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet