

**Pepsin**

Version  
1.6

Revision Date:  
03-23-2021

Date of last issue: 04-17-2019  
Date of first issue: 09-11-2015

**SECTION 1. IDENTIFICATION**

Product name : Pepsin  
Product code : 10108057001

**Manufacturer or supplier's details**

Company name of supplier : Roche Diagnostics Deutschland GmbH

Address : 116 Sandhoferstrasse  
Mannheim, 68305  
Germany

Telephone : +496217590  
Telefax : +496217592890  
E-mail address : mannheim.umweltschutz@roche.com

Emergency telephone  
In case of emergencies: : CHEMTREC +1 703-741-5970 /  
1-800-424-9300

**Recommended use of the chemical and restrictions on use**

Restrictions on use : For professional users only.

---

**SECTION 2. HAZARDS IDENTIFICATION**

**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Skin irritation : Category 2  
Eye irritation : Category 2A  
Respiratory sensitization : Category 1  
Specific target organ toxicity : Category 3 (Respiratory system)  
- single exposure

**GHS label elements**

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : 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.

# SAFETY DATA SHEET



## Pepsin

Version  
1.6

Revision Date:  
03-23-2021

Date of last issue: 04-17-2019  
Date of first issue: 09-11-2015

Precautionary Statements

:

### Prevention:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.  
P264 Wash skin thoroughly after handling.  
P271 Use only outdoors or in a well-ventilated area.  
P280 Wear protective gloves/ eye protection/ face protection.  
P285 In case of inadequate ventilation wear respiratory protection.

### Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
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/ doctor.  
P362 Take off contaminated clothing and wash before reuse.

### Storage:

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.  
P405 Store locked up.

### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards

None known.

---

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Substance  
Substance name : Pepsin, from porcine gastric mucosa  
CAS-No. : 9001-75-6

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Pepsin A	9001-75-6	<= 100

Actual concentration is withheld as a trade secret

---

## SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.  
Show this material safety data sheet to the doctor in atten-

# SAFETY DATA SHEET



## Pepsin

Version  
1.6

Revision Date:  
03-23-2021

Date of last issue: 04-17-2019  
Date of first issue: 09-11-2015

- dance.  
Do not leave the victim unattended.
- If inhaled : Call a physician or poison control center immediately.  
Move to fresh air.  
If unconscious, place in recovery position and seek medical advice.
- In case of skin contact : If skin irritation persists, call a physician.  
If on skin, rinse well with water.  
If on clothes, remove clothes.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.  
Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Take victim immediately to hospital.
- Most important symptoms and effects, both acute and delayed : Causes skin irritation.  
Causes serious eye irritation.  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
May cause respiratory irritation.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

---

### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : No hazardous combustion products are known
- Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.



**Pepsin**

Version  
1.6

Revision Date:  
03-23-2021

Date of last issue: 04-17-2019  
Date of first issue: 09-11-2015

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Avoid dust formation.  
Avoid breathing dust.  
Ensure adequate ventilation.
- Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

**SECTION 7. HANDLING AND STORAGE**

- Advice on protection against fire and explosion : Avoid dust formation.  
Provide appropriate exhaust ventilation at places where dust is formed.
- Advice on safe handling : Avoid formation of respirable particles.  
Do not breathe vapors/dust.  
Avoid exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Provide sufficient air exchange and/or exhaust in work rooms.  
Dispose of rinse water in accordance with local and national regulations.  
Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis



**Pepsin**

Version  
1.6

Revision Date:  
03-23-2021

Date of last issue: 04-17-2019  
Date of first issue: 09-11-2015

Pepsin A	9001-75-6	IOEL	0.00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)
----------	-----------	------	---------------	---

**Personal protective equipment**

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.  
Dust safety masks are recommended when the dust concentration is more than 10 mg/m3.  
Effective dust mask

Hand protection

In case of contact through splashing:  
Material : Nitrile rubber  
Break through time : > 30 min  
Glove thickness : > 0.11 mm

In case of full contact:  
Material : butyl-rubber  
Break through time : > 480 min  
Glove thickness : > 0.4 mm

Remarks : Wear appropriate protective gloves to prevent skin contact.  
Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water  
Tightly fitting safety goggles  
Wear face-shield and protective suit for abnormal processing problems.

Skin and body protection : Dust impervious protective suit  
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures : When using do not eat or drink.  
When using do not smoke.  
Wash hands before breaks and at the end of workday.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : solid, (lyophilized)

Color : white

Odor : none

Odor Threshold : Not applicable

pH : 4 - 5 (68 °F / 20 °C)  
Concentration: 20 g/l

## Pepsin

Version  
1.6

Revision Date:  
03-23-2021

Date of last issue: 04-17-2019  
Date of first issue: 09-11-2015

Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Sustains combustion
Flammability (liquids)	:	Sustains combustion
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	Not applicable
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	20 g/l soluble (68 °F / 20 °C)
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	Hazardous decomposition products formed under fire conditions.
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

---

### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Reacts with the following substances:



**Pepsin**

Version 1.6                      Revision Date: 03-23-2021                      Date of last issue: 04-17-2019  
Date of first issue: 09-11-2015

- tions                                      Oxidizing agents  
   Alcohol  
   No decomposition if stored and applied as directed.
- Conditions to avoid                      : Exposure to moisture.
- Incompatible materials                      : Oxidizing agents  
   Alcohol  
   Heavy metal salts  
   Bases
- Hazardous decomposition products                      : Hazardous decomposition products formed under fire conditions.

---

**SECTION 11. TOXICOLOGICAL INFORMATION**

**Acute toxicity**

Not classified based on available information.

**Skin corrosion/irritation**

Causes skin irritation.

**Product:**

Remarks                                      : May cause skin irritation in susceptible persons.

**Components:**

**Pepsin A:**

Result    : Irritating to skin.

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Product:**

Remarks                                      : May cause irreversible eye damage.

**Components:**

**Pepsin A:**

Result    : Irritating to eyes.

**Respiratory or skin sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Components:**

**Pepsin A:**

Assessment                                      : May cause sensitization by inhalation.



**Pepsin**

Version  
1.6

Revision Date:  
03-23-2021

Date of last issue: 04-17-2019  
Date of first issue: 09-11-2015

**Germ cell mutagenicity**

Not classified based on available information.

**Carcinogenicity**

Not classified based on available information.

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**

Not classified based on available information.

**STOT-single exposure**

May cause respiratory irritation.

**Components:**

**Pepsin A:**

Assessment : May cause respiratory irritation.

**STOT-repeated exposure**

Not classified based on available information.

**Aspiration toxicity**

Not classified based on available information.

---

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Pepsin A:**

Toxicity to microorganisms : EC0: > 2,000 mg/l  
Exposure time: 7 d

**Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available





**Pepsin**

Version  
1.6

Revision Date:  
03-23-2021

Date of last issue: 04-17-2019  
Date of first issue: 09-11-2015

**Persistence and degradability**

No data available

**Bioaccumulative potential**

**Components:**

**Pepsin A:**

Partition coefficient: n-octanol/water : Remarks: No data available

**Mobility in soil**

No data available

**Other adverse effects**

**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances  
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

---

**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.  
Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

---

**SECTION 14. TRANSPORT INFORMATION**

**International Regulations**

**UNRTDG**

Not regulated as a dangerous good

**IATA-DGR**

Not regulated as a dangerous good

**IMDG-Code**

Not regulated as a dangerous good

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable



**Pepsin**

Version  
1.6

Revision Date:  
03-23-2021

Date of last issue: 04-17-2019  
Date of first issue: 09-11-2015

**Domestic regulation**

**49 CFR**

Not regulated as a dangerous good

---

**SECTION 15. REGULATORY INFORMATION**

**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Respiratory or skin sensitization  
Skin corrosion or irritation  
Serious eye damage or eye irritation  
Specific target organ toxicity (single or repeated exposure)

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

**US State Regulations**

**Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

**Pennsylvania Right To Know**

Pepsin A 9001-75-6

**Maine Chemicals of High Concern**

Product does not contain any listed chemicals

**Vermont Chemicals of High Concern**

# SAFETY DATA SHEET



## Pepsin

Version  
1.6

Revision Date:  
03-23-2021

Date of last issue: 04-17-2019  
Date of first issue: 09-11-2015

Product does not contain any listed chemicals

### Washington Chemicals of High Concern

Product does not contain any listed chemicals

### The ingredients of this product are reported in the following inventories:

DSL : None of the components of this product are on the Canadian DSL, but all are on the NDSL

Pepsin A

AICS : On the inventory, or in compliance with the inventory

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : On the inventory, or in compliance with the inventory

PICCS : On the inventory, or in compliance with the inventory

IECSC : On the inventory, or in compliance with the inventory

TCSI : On the inventory, or in compliance with the inventory

TSCA : All substances listed as active on the TSCA inventory

### TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

---

## SECTION 16. OTHER INFORMATION

# SAFETY DATA SHEET



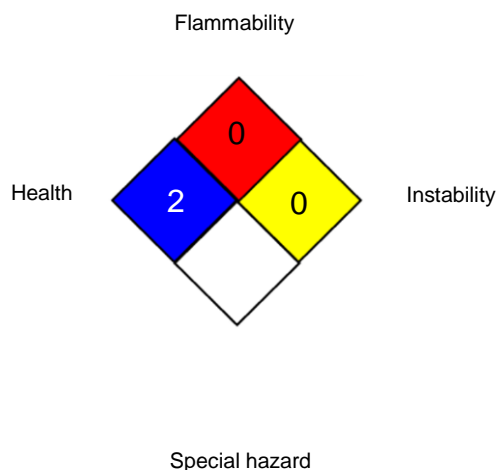
## Pepsin

Version  
1.6

Revision Date:  
03-23-2021

Date of last issue: 04-17-2019  
Date of first issue: 09-11-2015

### NFPA 704:



### HMIS® IV:

HEALTH	*	2
FLAMMABILITY		0
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Distributor

MilliporeSigma  
3050 Spruce Street  
SAINT LOUIS  
MO 63103 USA

### Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation,

# SAFETY DATA SHEET



## Pepsin

Version  
1.6

Revision Date:  
03-23-2021

Date of last issue: 04-17-2019  
Date of first issue: 09-11-2015

Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 03-23-2021

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.

US / Z8 / 2004