

Safety data sheet

according to ChemO 2015 – SR 813.11

Version number 2.0 (replaces version 1.0)

Revision: 05.12.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: **Prionex® 10%**

Article number: 069-03

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

Application of the substance / the mixture:

Biochemical product

Protein stabilizer

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Pentapharm AG

Dornacherstrasse 112

CH- 4147 Aesch / Switzerland

Phone +41 61 706 48 48

Fax +41 61 706 48 00

Further information obtainable from: pentapharm@pentapharm.com

1.4 Emergency telephone number:

Tox Info Suisse

Emergency number (24 h; 7 d a week): +41 (0)44 251 51 51; Short no.: 145 (only from Switzerland)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The product is not classified, according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 Void.

Hazard pictograms Void

Signal word Void

Hazard statements Void

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: According to current knowledge, the product contains no PBT substance.

vPvB: According to current knowledge, the product contains no vPvB substance.

Determination of endocrine-disrupting properties

Taking into account the current state of scientific knowledge, no data on endocrine disrupting properties of the product are available.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

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Dangerous components: Void

SVHC: According to current knowledge no SVHC contained.

Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information: No special measures required.

After inhalation:

Remove person to fresh air and keep comfortable for breathing.

If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

After skin contact:

Wash with plenty of water and soap.

If skin irritation or rash occurs: Get medical advice/attention.

After eye contact:

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.

After swallowing: If symptoms persist consult doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents: CO₂, foam, dry powder or water spray.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Protective equipment:

Wear self-contained respiratory protective device.

Wear protective clothing to prevent contact with skin and eyes.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes.

6.2 Environmental precautions

Do not allow to enter sewers/surface or ground water.

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6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Clean the affected area carefully and ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling Avoid contact with skin and eyes.

Information about fire - and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: No special requirements.

Information about storage in one common storage facility: Not required.

Further information about storage conditions:

Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.
Ensure good ventilation/exhaustion at the workplace.
Keep away from foodstuffs, beverages and feed.
Avoid contact with the eyes and skin.
Wash hands before breaks and at the end of work.

Respiratory protection: Not required.

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Hand protection:



Protective gloves

Material of gloves

Protective gloves must be compliant with the specifications of the Regulation (EU) 2016/425 and be in accordance with the standards EN374. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Eye/face protection



Safety glasses

Protective goggles must be compliant with the specifications of the Regulation (EU) 2016/425 and be in accordance with the standard EN166 (EU) or NIOSH (US).

Environmental exposure controls Do not allow to enter sewers/surface or ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state:	Liquid
Colour:	Clear, pale yellow to amber colored
Odour:	Characteristic
Odour threshold:	Not determined.
Melting point/freezing point:	Not determined.
Boiling point or initial boiling point and boiling range:	Not determined.
Flammability:	Not applicable.
Lower and upper explosion limit	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	Not determined.
Auto-ignition temperature:	Not determined.
Decomposition temperature:	Not determined.
pH:	6.0 - 7.5

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Viscosity	
Kinematic:	Not determined.
Dynamic:	Not determined.
Solubility	
water:	Not determined.
Partition coefficient n-octanol/water (log value):	Not determined.
Vapour pressure:	Not determined.
Density and/or relative density	
Relative density at 20 °C:	1.03 - 1.045 g/cm ³
Vapour density:	Not determined.
Particle characteristics:	Not applicable.

9.2 Other information

Appearance

Form: Liquid

Important information on protection of health and environment, and on safety

Ignition temperature: The product is not self-igniting.

Explosive properties: The product does not present an explosion hazard.

Change in condition

Softening point/range:

Oxidising properties: Not determined.

Evaporation rate: Not determined.

9.2.1 Information with regard to physical hazard classes

Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Void
Flammable solids	Void
Self-reactive substances and mixtures	Void
Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammable gases in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void
Desensitised explosives	Void

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SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical stability No information available.

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions No dangerous reactions known.

10.4 Conditions to avoid Heat may cause this product to decompose.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous decomposition products Nature of decomposition products not known.

SECTION 11: Toxicological information

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

Acute toxicity Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification: No further relevant information available.

Specific symptoms in biological assay:

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive toxicity Based on available data, the classification criteria are not met.

STOT-single exposure Based on available data, the classification criteria are not met.

STOT-repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

11.2 Information on other hazards

Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil No further relevant information available.

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12.5 Results of PBT and vPvB assessment

PBT: According to current knowledge, the product contains no PBT substance.

vPvB: According to current knowledge, the product contains no vPvB substance.

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation: Disposal must be made according to official regulations.

Ordinance of the Federal Department of the Environment, Transport, Energy and Communications (DETEC) on Lists for Waste Traffic (SR 814.610.1)

18 00 00	Abfälle aus der humanmedizinischen oder tierärztlichen Versorgung und Forschung
18 01 00	Abfälle aus Forschung, Geburtshilfe, Diagnose, Behandlung oder Vorbeugung von Krankheiten beim Menschen
18 01 07	Chemikalien mit Ausnahme derjenigen, die unter 18 01 06 fallen

Uncleaned packaging

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information

14.1 UN number or ID number

ADR/ADN, ADN, IMDG, IATA Void

14.2 UN proper shipping name

ADR/ADN, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)

ADR/ADN, ADN, IMDG, IATA
Class Void

14.4 Packing group

ADR/ADN, IMDG, IATA Void

14.5 Environmental hazards

Marine pollutant: No

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14.6 Special precautions for user Not applicable.

14.7 Maritime transport in bulk according to IMO instruments Not applicable.

Transport/Additional information:

ADR/ADN
Remarks: Not classified.

IMDG
Remarks: Not classified.

IATA
Remarks: Not classified.

UN "Model Regulation": Void

SECTION 15: Regulatory information

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

National regulations:

Special handling regulations (follow-up obligations) of the chemical legislation:

No additional regulations.

Ordinance on Air Pollution Control (OAPC; SR 814.318.142.1) Annex 1:

The provisions of the Air Pollution Control (OAPC; SR 814.318.142.1) Annex 1 are to be complied with.

Ordinance on Protection against Major Accidents (Major Accidents Ordinance, MAO; SR 814.012) Annex 1:

Volume threshold according to MAO in kg: without limitation

(Source: FOEN - List 2015 - Volume thresholds in accordance with the Major Accidents Ordinance / Volume Threshold Calculator)

Chemical Risk Reduction Ordinance (ORRChem; SR 814.81):

The product contains no substances subject to authorization according to Annex 1.17 in concentrations $\geq 0.1\%$ w/w or above specific concentration limits (if $< 0.1\%$ w/w).

Chemical Risk Reduction Ordinance (ORRChem; SR 814.81):

The preparation or substances contained therein are not subject to any prohibition or restriction in accordance with Annexes 1 and 2.

Ordinance on Chemical Products (ChemO; SR 813.11):

The product contains no substances of very high concern according to Annex 3 in concentrations $\geq 0.1\%$ w/w.

Waterhazard class: Water hazard class 1 (Self-assessment): slightly hazardous to water

OVOC (CH) 0.00 %

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

All information and instructions provided in this Safety Data Sheet are based on the current state of scientific and technical knowledge at the date indicated on this Safety Data Sheet. Pentapharm AG shall not be held

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responsible for any defect in the product covered by this Safety Data Sheet, should the existence of such a defect not be detectable considering the current state of scientific and technical knowledge.

This safety data sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

An asterisk (*) in the left hand margin indicates an amendment from the previous version.

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

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