

according to ChemO 2015 - SR 813.11

Version number 2 (replaces version 1) Revision: 24.06.2025

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

1.1 Product identifier

Trade name: Aprotinin Powder, Lyoph.

Article number: 800277

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

Application of the substance / the mixture: For research use only

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

Emercency number (24 h; 7 d a week): +41 (0)44 251 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



GHS08 health hazard

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



Skin Sens. 1 H317 May cause an allergic skin reaction.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms



Signal word Danger

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Hazard-determining components of labelling:

Aprotinin

Hazard statements

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317 May cause an allergic skin reaction.

Precautionary statements

P261 Avoid breathing dust.

P280 Wear protective gloves / protective clothing.

P284 In case of inadequate ventilation wear respiratory protection.

P304+P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position

comfortable for breathing.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

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.

Dangerous components:

CAS: 9087-70-1 Aprotinin & Resp. Sens. 1, H334; Skin Sens. 1, H317 50-<100%

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:

If breathing is difficult, remove victim to fresh air and keep at rest in a position 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.

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Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

After swallowing: Immediately call a POISON CENTER/doctor.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.

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

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 eye and skin contact and particle inhalation.

6.2 Environmental precautions Do not allow product to reach sewage system or any water course.

6.3 Methods and material for containment and cleaning up

Collect in suitable containers.

Clean the affected area carefully and ensure adequate ventilation.

Avoid dust formation.

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 eye and skin contact and particle inhalation. **Information about fire - and explosion protection:** No special measures required.

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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 the product in a dry place protected from light at a temperature between +2°C and +8°C.

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: A limit value has not been defined. Additional information:

The lists valid during the making were used as basis.

The professional use of this product by young people is restricted or prohibited altogether. The corresponding legal bases and precise regulations are set out in section 15.

8.2 Exposure controls

Individual protection measures, such as personal protective equipment General protective and hygienic measures:

Ensure good ventilation/exhaustion at the workplace.

Avoid contact with the eyes and skin.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Respiratory protection:

In case of inadequate ventilation wear respiratory protection.

Respiratory protection must be compliant with the specifications of the Regulation (EU) 2016/425 and be in accordance with the EN standards resulting thereof.

Hand protection:



Protective 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.

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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 product to reach ground water, water course or sewage system.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state:SolidColour:Almost whiteOdour:OdourlessOdour threshold:Not determined.Melting point/freezing point:Not determined.

Boiling point or initial boiling point and boiling

range:Not determined.Flammability:Not determined

Lower and upper explosion limit

Lower:Not determined.Upper:Not determined.Flash point:Not applicable.

Auto-ignition temperature: The product is not self-igniting.

Decomposition temperature: Not determined. **pH:** Not determined.

Viscosity

Kinematic:Not applicable.Dynamic:Not applicable.

Solubility

water: Soluble.

Partition coefficient n-octanol/water (log value):Not determined.Vapour pressure:Not applicable.

Density and/or relative density

Relative density:Not determined.Vapour density:Not determined.Particle characteristics:Not determined.

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9.2 Other information

Appearance

Form: Lyophilized powder

Important information on protection of health and

environment, and on safety

Ignition temperature: The product is not self-igniting.

Explosive properties: Not determined.

Change in condition Softening point/range:

Oxidising properties:Not determined.Evaporation rate:Not applicable.

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

Substances and mixtures
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

SECTION 10: Stability and reactivity

- 10.1 Reactivity The product is sensitive to moisture and absorbs odours.
- 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 None known

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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.

Primary irritant effect:

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

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

May cause an allergic skin reaction.

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: Based on the ingredients not classified as harmful for the environment.

- 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.

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.

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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: Wastes from human or animal health care and/or related research (except kitchen and restaurant wastes not arising from immediate health care)

18 01 00: Wastes from natal care, diagnosis, treatment or prevention of disease in humans

18 01 06S: chemicals consisting of or containing dangerous substances

S = hazardous waste

Uncleaned packaging

Recommendation: Disposal must be made according to official regulations.

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

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	
14.6 Special precautions for user	Not applicable.	
14.7 Maritime transport in bulk accord	ing to	
IMO instruments	Not applicable.	
Transport/Additional information:		
ADR/ADN		
Remarks:	Not classified.	
IMDG		
Remarks:	Not classified.	

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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 ≥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.

Chemicals Ordinance (ChemO; SR 813.11):

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

Information about limitation of use:

Ordinance on the protection of young people in the workplace (SR 822.115, Article 4 paragraph 4) and Ordinance of the EAER on hazardous work for young people (SR 822.115.2, Article 1 lit. f):

Young people undergoing basic vocational training may only work with this product (this substance / this preparation) if the relevant training ordinance makes provision for them to do so with a view to enabling them to achieve their training objectives and if the preconditions for the training plan have been met and the applicable age restrictions have been complied with. Young people who are not completing any basic vocational training are not permitted to work with this product (this substance / this preparation). Employees of either sex who are under 18 years old are classed as young people.

Waterhazard class: Swiss Waterhazard class B (self classification) **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 responsible for any defect in the product covered by this Safety Data Sheet, should the existence of such a (Contd. on page 10)

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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.

Relevant phrases

H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

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 Resp. Sens. 1: Respiratory sensitisation – Category 1

Skin Sens. 1: Skin sensitisation - Category 1