

# Safety data sheet

## according to ChemO 2015 – SR 813.11

Version number 2 (replaces version 1)

Revision: 27.09.2023

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

#### 1.1 Product identifier

Trade name: **Aprotinin concentrated solution**

Article number: 073-70

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

Application of the substance / the mixture: Active Pharmaceutical Ingredient

#### 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 : +41 44 251 51 51 (24h; 7 days a week)

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008



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**



GHS08

**Signal word** Danger

**Hazard-determining components of labelling:**

Aprotinin

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#### **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 mist/vapours/spray.

P280 Wear protective gloves / protective clothing.

P285 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:**

Aprotinin is a polyvalent reversible inhibitor of serine proteinases. Aprotinin is a polypeptide of 58 amino acids, aqueous solution.

#### **Dangerous components:**

CAS: 9087-70-1	Aprotinin	⚠ Resp. Sens. 1, H334; ⚠ Skin Sens. 1, H317	5-10%
EINECS: 232-994-9			

**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:** CO<sub>2</sub>, foam, dry powder or water.

**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 skin and eye 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.

### 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, eyes and clothing.

Avoid breathing dust/fume/gas/mist/vapours/spray.

**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 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

##### **Material of gloves**

Protective gloves must be compliant with the specifications of 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:**

Liquid

**Colour:**

Clear

Colourless to slightly yellowish

**Odour:**

Odourless

**Odour threshold:**

Not determined.

**Melting point/freezing point:**

Not determined.

**Boiling point or initial boiling point and boiling range:**

Approx. as water

**Flammability:**

Not applicable.

**Lower and upper explosion limit**

**Lower:**

Not determined.

**Upper:**

Not determined.

**Flash point:**

Not applicable.

**Auto-ignition temperature:**

Not determined.

**Decomposition temperature:**

Not determined.

**pH:**

5.5 - 6.5

**Viscosity**

**Kinematic:**

Not applicable.

**Dynamic:**

Not applicable.

**Solubility**

**water:**

Fully miscible.

**Partition coefficient n-octanol/water (log value):**

Not determined.

**Vapour pressure:**

Not applicable.

**Density and/or relative density**

**Relative density at 20 °C:**

1.005 - 1.015 g/cm<sup>3</sup>

**Vapour density:**

Not determined.

**Particle characteristics:**

Not applicable.

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#### 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:** Not determined.

**Change in condition**

**Softening point/range:** Not applicable.

**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** Void

**Oxidising liquids** Void

**Oxidising solids** Void

**Organic peroxides** Void

**Corrosive to metals** Void

**Desensitised explosives** Void

## 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** 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.

**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**

The product does not contain substances with 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.

#### 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 06\*: chemicals consisting of or containing dangerous substances

\* = hazardous waste

### 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

<b>14.1 UN number or ID number</b> ADR/ADN, ADN, IMDG, IATA	Void
<b>14.2 UN proper shipping name</b> ADR/ADN, ADN, IMDG, IATA	Void
<b>14.3 Transport hazard class(es)</b> ADR/ADN, ADN, IMDG, IATA <i>Class</i>	Void
<b>14.4 Packing group</b> ADR/ADN, IMDG, IATA	Void
<b>14.5 Environmental hazards</b> Marine pollutant:	No
<b>14.6 Special precautions for user</b>	Not applicable.
<b>14.7 Maritime transport in bulk according to IMO instruments</b>	Not applicable.
<b>Transport/Additional information:</b>	
<b>ADR/ADN</b> <i>Remarks:</i>	Not classified.
<b>IMDG</b> <i>Remarks:</i>	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  $\geq 0.1\%$  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.

Chemicals Ordinance (ChemO; SR 813.11):

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

**Information about limitation of use:**

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

Young people undergoing basic vocational training may only work with this product 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. Employees of either sex who are under 18 years old are classed as young people.

**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 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.

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

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

#### **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

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