

# Safety data sheet

## according to ChemO 2015 – SR 813.11

Version number 3.0 (replaces version 2.0)

Revision: 22.11.2024

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

#### 1.1 Product identifier

Trade name: **r-Hirudin 2'000 ATU/vial**

Article number: 126-10

UFI: M550-Y0WN-5001-H563

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

Application of the substance / the mixture: Diagnostic reagent

#### 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



skull and crossbones

Acute Tox. 3

H311 Toxic in contact with skin.



Acute Tox. 4

H302 Harmful if swallowed.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

#### 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**



GHS06

**Signal word** Danger

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### Hazard-determining components of labelling:

sodium azide

### Hazard statements

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H412 Harmful to aquatic life with long lasting effects.

### Precautionary statements

P261 Avoid breathing dust.

P273 Avoid release to the environment.

P280 Wear protective gloves / protective clothing.

P312 Call a POISON CENTER if you feel unwell.

### Additional information:

EUH032 Contact with acids liberates very toxic gas.

### 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:

Recombinant Hirudin. Hirudin is the most potent and specific thrombin inhibitor known. It forms a stable equimolar complex with thrombin.

Mixture of substances listed below with nonhazardous additions.

#### Dangerous components:

CAS: 26628-22-8	sodium azide	1-<2.5%
EINECS: 247-852-1	☠ Acute Tox. 2, H300; Acute Tox. 1, H310; ☠ Aquatic Acute 1, H400;	
Index number: 011-004-00-7	Aquatic Chronic 1, H410, EUH032	

**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.

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### After skin contact:

Wash with plenty of water and soap.

Call a POISON CENTER/doctor if you feel unwell.

### 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:** Immediately call a POISON CENTER/doctor.

### 4.2 Most important symptoms and effects, both acute and delayed

Harmful if swallowed.

Toxic in contact with skin.

### 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 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 breathing apparatus and protective clothing to prevent contact with skin and eyes.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

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.

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.

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### SECTION 7: Handling and storage

**7.1 Precautions for safe handling** Avoid skin and eye contact and particle inhalation.

**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:**

Protect from heat and direct sunlight.

Store in dry conditions.

Store between 2 - 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:**

**26628-22-8 sodium azide**

IOELV (EU)	Short-term value: 0.3 mg/m <sup>3</sup> Long-term value: 0.1 mg/m <sup>3</sup> Skin
MAK (Switzerland)	Short-term value: 0.4 e mg/m <sup>3</sup> Long-term value: 0.2 e mg/m <sup>3</sup>

**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:**

Ensure good ventilation/exhaustion at the workplace.

Avoid contact with the eyes and skin.

Do not breathe dust.

Wash hands before breaks and at the end of work.

Immediately remove all soiled and contaminated clothing.

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

**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.

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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.

### 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

<b>Physical state:</b>	Solid
<b>Colour:</b>	White
<b>Odour:</b>	Odourless
<b>Odour threshold:</b>	Not determined.
<b>Melting point/freezing point:</b>	Not determined.
<b>Boiling point or initial boiling point and boiling range:</b>	Not determined.
<b>Flammability:</b>	Not determined.
<b>Lower and upper explosion limit</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
<b>Flash point:</b>	Not determined.
<b>Auto-ignition temperature:</b>	Not determined.
<b>Decomposition temperature:</b>	Not determined.
<b>pH:</b>	Not determined.
<b>Viscosity</b>	
<b>Kinematic:</b>	Not applicable.
<b>Dynamic:</b>	Not applicable.

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### **Solubility**

<b>water:</b>	Completely soluble.
<b>Partition coefficient n-octanol/water (log value):</b>	Not determined.
<b>Vapour pressure:</b>	Not applicable.
<b>Density and/or relative density</b>	
<b>Relative density:</b>	Not determined.
<b>Vapour density:</b>	Not determined.
<b>Particle characteristics:</b>	Not applicable.

### **9.2 Other information**

#### **Appearance**

**Form:** Lyophilised solid

**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 applicable.

#### **9.2.1 Information with regard to physical hazard**

**classes**

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

## **SECTION 10: Stability and reactivity**

**10.1 Reactivity** No further relevant information available.

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**10.2 Chemical stability** No decomposition if used according to specifications.

**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** No further relevant information available.

**10.5 Incompatible materials** Avoid contact with strong acids.

**10.6 Hazardous decomposition products**

Sodium azide develops very toxic gases upon contact with acids.

### SECTION 11: Toxicological information

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

##### Acute toxicity

Harmful if swallowed.

Toxic in contact with skin.

The toxicological properties of this product have not been thoroughly investigated.

##### LD/LC50 values relevant for classification:

##### 26628-22-8 sodium azide

Oral	LD50	27 mg/kg (rat)
Dermal	LD50	20 mg/kg (rabbit)

##### 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.

##### Other information:

The toxicological properties of this product have not been thoroughly investigated. Use appropriate precautions.

#### 11.2 Information on other hazards

##### Endocrine disrupting properties

None of the ingredients is listed.

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### SECTION 12: Ecological information

#### 12.1 Toxicity

**Aquatic toxicity:** Harmful to aquatic life with long lasting effects.

**12.2 Persistence and degradability** Not easily biodegradable.

**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.

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

**Recommendation:** Disposal must be made according to official regulations.

#### Uncleaned packaging

**Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

#### 14.1 UN number or ID number

ADR/ADN, IMDG, IATA UN2811

#### 14.2 UN proper shipping name

ADR/ADN 2811 TOXIC SOLID, ORGANIC, N.O.S. (sodium azide)  
IMDG, IATA TOXIC SOLID, ORGANIC, N.O.S. (sodium azide)

#### 14.3 Transport hazard class(es)

ADR/ADN, IMDG, IATA



**Class**

6.1 Toxic substances.

**Label**

6.1

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<b>14.4 Packing group</b> ADR/ADN, IMDG, IATA	III
<b>14.5 Environmental hazards</b>	Not applicable.
<b>14.6 Special precautions for user</b> <i>Hazard identification number (Kemler code):</i> <i>EMS Number:</i> <i>Stowage Category</i>	Warning: Toxic substances. 60 F-A,S-A A
<b>14.7 Maritime transport in bulk according to IMO instruments</b>	Not applicable.
<b>Transport/Additional information:</b>	
<b>ADR/ADN</b> <i>Limited quantities (LQ)</i> <i>Excepted quantities (EQ)</i>	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
<b>Transport category</b> <b>Tunnel restriction code</b>	2 E
<b>IMDG</b> <i>Limited quantities (LQ)</i> <i>Excepted quantities (EQ)</i>	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
<b>UN "Model Regulation":</b>	UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (SODIUM AZIDE), 6.1, III

## SECTION 15: Regulatory information

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

#### National regulations:

Special handling requirements (follow-up requirements) of the chemicals legislation:

Substance or preparation in Group 2 (Annex 5 ChemO):

To be kept inaccessible to unauthorised persons (Article 62 ChemO).

To be filled into and stored in containers only if these are labelled with the appropriate danger symbols or hazard pictograms (Art. 62 ChemO).

Must not be offered on a self-service basis to private users (Art. 63 ChemO).

To be commercially supplied only to persons having capacity to act (Art. 64 ChemO).

To be supplied to minors only if they are capable of judgement and have to handle these substances or preparations in the course of their training or in a professional or commercial capacity (Article 64 ChemO).

Suppliers are obliged, at the time of supply, to explicitly inform private users of the precautions required and the correct method of disposal (Article 65 ChemO).

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Supply only to persons who can be assumed by the supplier to be capable of judgement and able to comply with the duty of care specified in Article 8 ChemO and the requirements set out in Article 28 of the EPA (Article 65 ChemO).

Special knowledge is required in order to commercially supply the product to private users (Article 66 ChemO).

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: 20'000 kg

(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.

**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

The data and information given in this product information sheet are based on the current state of our knowledge at the publishing date indicated in this product information sheet. The product information sheet shall give you indications for the safe handling, storage and use, however the information included herein is not intended to be all-inclusive. The data and information can not be transferred to other products or other uses as the one declared in this product information sheet. The data and information in this product information sheet describe the safety requirements, but they do not represent any product specifications.

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

H300 Fatal if swallowed.

H310 Fatal in contact with skin.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

EUH032 Contact with acids liberates very toxic gas.

#### 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)

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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  
Acute Tox. 2: Acute toxicity – Category 2  
Acute Tox. 4: Acute toxicity – Category 4  
Acute Tox. 1: Acute toxicity – Category 1  
Acute Tox. 3: Acute toxicity – Category 3  
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1  
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1  
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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