

# SAFETY DATA SHEET

according to OSHA HCS



**r-Hirudin 2'000 ATU/vial**

**126-11**

## 1 Identification

### Product identifier

Product	r-Hirudin 2'000 ATU/vial
Article number	126-11
Application of the substance / the mixture	Raw material for further processing in diagnostic preparations

### Details of the supplier of the safety data sheet

Manufacturer/Supplier	DSM Nutritional Products Ltd Branch Pentapharm Dornacherstrasse 112 CH-4147 Aesch BL / Switzerland Phone +41 61 706 48 48 Fax +41 61 706 48 00
Information department	pentapharm@pentapharm.com
Emergency telephone number	Tox Info Suisse: +41 44 251 51 51 (24h; 7 days a week)

## 2 Hazard(s) identification

### Classification of the substance or mixture



GHS06 Skull and crossbones

Acute Tox. 3 H311 Toxic in contact with skin.



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

### Label elements

#### GHS label elements

The product is classified and labeled according to OSHA Hazard Communication Standard (29 CFR 1910.1200).

The product is classified and labeled according to the Globally Harmonized System (GHS).

#### *Hazard pictograms*



GHS06

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**Signal word** Danger

**Hazard-determining components of labeling:**

sodium azide

**Hazard statements**

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

**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.

## 3 Composition/information on ingredients

### Chemical characterization

Mixtures

#### **Description**

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

Mixture of the substances listed below with nonhazardous additions.

Dangerous components		
CAS: 26628-22-8	sodium azide	1 - <2.5%

## 4 First aid measures

### 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 soap and water.

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.

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## **Most importance symptoms and effects, both acute and delayed**

Harmful if swallowed.

Toxic in contact with skin.

## **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

## **5 Firefighting measures**

### **Extinguishing media**

Suitable extinguishing agents

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

### **Specific hazards arising from the substance or mixture**

No further relevant information available.

### **Advice for firefighters**

### **Protective equipment**

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

## **6 Accidental release measures**

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

Wear protective equipment. Keep unprotected persons away.

Avoid skin and eye contact and particle inhalation.

### **Environmental precautions**

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

### **Methods and material for containment and cleaning up**

Collect in suitable containers.

Clean the affected area carefully and ensure adequate ventilation.

Avoid dust formation.

### **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.

## **7 Handling and storage**

### **Precautions for safe handling**

Avoid skin and eye contact and particle inhalation.

### **Information about protection against explosions and fires**

No special measures required.

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## 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.

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

## **8 Exposure controls/personal protection**

### Control parameters

Components with limit values that require monitoring at the workplace	
CAS: 26628-22-8	Sodium azide
REL	Ceiling limit value: 0.3** mg/m <sup>3</sup> , 0.1* ppm *as HN <sub>3</sub> ; **as NaN <sub>3</sub> ; Skin
TLV	Ceiling limit value: 0.29** mg/m <sup>3</sup> , 0.11* ppm *as HN <sub>3</sub> vapor **as NaN <sub>3</sub>

### Exposure controls

#### Personal protective equipment

#### General protective and hygienic measures

Ensure good ventilation/exhaustion at the workplace.

Avoid contact with 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/vapors/spray.

#### Breathing equipment

In case of inadequate ventilation wear respiratory protection.

Use suitable respiratory protective device in case TLV are exceeded.

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## Protection of hands



Protective gloves

## Eye protection



Safety glasses

## Limitation and supervision of exposure into the environment

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

## 9 Physical and chemical properties

### Information on basic physical and chemical properties

<b>General Information</b>	
<b>Appearance</b>	
Form	Lyophilized powder.
Color	White.
Odor	Odorless.
Odor threshold	Not determined.
<b>pH-value</b>	Not determined.
<b>Change in condition</b>	
Melting point/Melting range	Not determined.
Boiling point/Boiling range	Not determined.
<b>Flash point</b>	Not applicable.
<b>Flammability (solid, gaseous)</b>	Not determined.
<b>Ignition temperature</b>	
Decomposition temperature	Not determined.
<b>Self-igniting</b>	Product is not self-igniting.
<b>Danger of explosion</b>	Product does not present an explosion hazard.
<b>Explosion limits</b>	
Lower	Not determined.
Upper	Not determined.
Oxidising properties	Not determined.
<b>Vapour pressure</b>	Not applicable.

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<b>Density</b>	
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not applicable.
<b>Solubility in / Miscibility with</b>	
Water	Soluble.
<b>Partition coefficient (n-octanol/water)</b>	
Not determined.	
<b>Viscosity</b>	
Dynamic	Not applicable.
Kinematic	Not applicable.

## 10 Stability and reactivity

### Reactivity

No further relevant information available.

### Chemical stability

No information available.

### Thermal decomposition / conditions to be avoided

No decomposition if used according to specifications.

### Possibility of hazardous reactions

No dangerous reactions known.

### Conditions to avoid

No further relevant information available.

### Incompatible materials

Avoid contact with strong acids.

### Hazardous decomposition products

Sodium azide develops very toxic gases upon contact with acids.

## 11 Toxicological information

### Information on toxicological effects

#### **Acute toxicity**

Harmful if swallowed.

Toxic in contact with skin.

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

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LD/LC50 values that are relevant for classification		
CAS: 26628-22-8		Sodium azide
Oral	LD50	27 mg/kg (rat)
Dermal	LD50	20 mg/kg /rabbit)

## 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.

## Sensitization

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.

## Specific target organ toxicity - single exposure

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

## Specific target organ toxicity - 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.

**Subacute to chronic toxicity:** No data available.

OSHA-Ca (Occupational Safety & Health Administration)
None of the ingredients is listed.

## 12 Ecological information

### Toxicity

#### **Aquatic toxicity**

Harmful to aquatic life with long lasting effects.

#### **Persistence and degradability**

Not easily biodegradable.

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## Bioaccumulative potential

No further relevant information available.

## Mobility in soil

No further relevant information available.

## Other adverse effects

No further relevant information available.

## **13 Disposal considerations**

### Waste treatment methods

#### **Product**

Recommendation: Dispose of according to federal, state, and local law.

#### **Uncleaned packaging**

Recommendation: Dispose of according to federal, state, and local law.

## **14 Transport information**

### UN-number

DOT, ADR/ADN, IMDG, IATA

UN2811

### UN proper shipping name

DOT

Toxic solids, organic, n.o.s. (sodium azide)

ADR/ADN

2811 TOXIC SOLID, ORGANIC, N.O.S. (sodium azide)

IMDG, IATA

TOXIC SOLID, ORGANIC, N.O.S. (sodium azide)

### Transport hazard class(es)

DOT



Class

6.1 Toxic substances.

Label

6.1

ADR, ADN, IMDG, IATA



Class

6.1 Toxic substances.

Label

6.1

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## Packing group

DOT, ADR/ADN, IMDG, IATA

III

## Environmental hazards

Not applicable.

## Special precautions for user

Warning: Toxic substances.

Hazard identification (Kemler code)

60

EMS Number

F-A,S-A

Stowage Category

A

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

Not applicable.

## Transport/Additional information

### **ADR/ADN**

Excepted quantities (EQ)

Code: E1

Maximum net quantity per inner packaging: 30 g

Maximum net quantity per outer packaging: 1000 g

### **IMDG**

Limited quantities (LQ)

5 kg

Excepted quantities (EQ)

Code: E1

Maximum net quantity per inner packaging: 30 g

Maximum net quantity per outer packaging: 1000 g

### **UN "Model Regulation"**

UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (SODIUM AZIDE), 6.1, III

## **15 Regulatory information**

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

HMIS-ratings (scale 0-4): Not determined.

SARA Section 355 (extremely hazardous substances)		
CAS: 26628-22-8	Sodium azide	
SARA Section 313 (Specific toxic chemical listings)		
CAS: 26628-22-8	Sodium azide	
TSCA (Toxic Substances Control Act):		
CAS: 56-40-6	Glycine	Active
CAS: 7732-18-5	Water, distilled, conductivity or of similar purity	Active
CAS: 26628-22-8	Sodium azide	Active

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<b>Hazardous Air Pollutants</b>
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None of the ingredients is listed.
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**California Proposition 65**

<b>Chemicals known to cause cancer</b>
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None of the ingredients is listed.
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<b>Chemicals known to cause reproductive toxicity for females</b>
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None of the ingredients is listed.
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<b>Chemicals known to cause reproductive toxicity for males</b>
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None of the ingredients is listed.
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<b>Chemicals known to cause developmental toxicity</b>
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None of the ingredients is listed.
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**Carcinogenicity categories**

<b>EPA (Environmental Protection Agency)</b>
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None of the ingredients is listed.
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<b>IARC (International Agency for Research on Cancer)</b>
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None of the ingredients is listed.
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<b>TLV (Threshold Limit Value)</b>
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CAS: 26628-22-8	Sodium azide	A4
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<b>NIOSH-Ca (National Institute for Occupational Safety and Health)</b>
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None of the ingredients is listed.
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## 16 Other information

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

**NFPA-ratings (scale 0 - 4)**

Health = 2

Fire = 0

Reactivity = 0

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## Date of preparation / last revision

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## 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

DOT: US Department of Transportation

IATA: International Air Transport Association

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health Administration

OSHA-Ca: U.S. OSHA designated carcinogen list

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Acute Tox. 4: Acute toxicity - Category 4

Acute Tox. 3: Acute toxicity - Category 3

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