SAFETY DATA SHEET

According to 1907/2006/EC, Article 31

r-Hirudin EC-2000 ATU/vial 126-10

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

1.1 Product identifier

Trade name r-Hirudin EC-2000 ATU/vial

Article number 126-10

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

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

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)

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 substance is classified and labelled according to the CLP regulation.

Hazard pictograms

GHS06

Signal word

Danger

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.

P280 Wear protective gloves / protective clothing.

P273 Avoid release to the environment.

P312 Call a POISON CENTER if you feel unwell.

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.

3 Composition/information on ingredients

3.2 Chemical characterization

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 EINECS: 247-852-1	sodium azide  Acute Tox. 2, H300, Acute Tox. 1, H310;  Aquatic Acute 1, H400 ; Aquatic Chronic 1, H410	1 – 2.5%

SVHC

According to current knowledge no SVHC contained.

Additional information

For the wording of the listed risk phrases refer to section 16.

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 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 CENTRE/doctor.

4.2 Most importance 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.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

CO2, foam, dry powder, or water.

5.2 Specific 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.

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.

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.

8 Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace	
26628-22-8 sodium azide	
MAK (Switzerland)	Short-term value: 0,4 e mg/m³ Long-term value: 0,2 e mg/m³
AGW (Germany)	Long-term value: 0,2 mg/m³ 2(I);DFG, EU
IOELV (EU)	Short-term value: 0,3 mg/m³ Long-term value: 0,1 mg/m³ Skin

Additional information

The lists valid during the making were used as basis.

8.2 Exposure controls

Personal protective equipment

General protective and hygienic measures

Ensure good ventilation/exhaustion at the workplace.

Avoid contact with the eyes and skin.

Do not breath 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.

Respiratory protection

In case of inadequate ventilation war respiratory protection.

Respiratory protection must be compliant with the specifications of Directive 89/686/EEC and be in accordance with the EN standards resulting thereof.

Protection of hands

Protective gloves

Material of gloves

Protective gloves must be compliant with the specifications of EU Directive 89/686/EEC and be in accordance with the standard EN374. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Eye protection

Safety glasses

Protective goggles must be compliant with the specifications of Directive 89/686 / EEC and be in accordance with the standard EN166.

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

9.1 Information on basic physical and chemical properties

General Information	
Appearance	
Form	Lyophilised solid
Colour	White
Odour	Odourless
Odour threshold	Not determined.
pH-value	Not determined.
Change in condition	
Melting point/Melting range	Not determined.
Boiling point/Boiling range	Not determined.
Flash point	Not determined.
Flammability (solid, gaseous)	Not determined.
Ignition temperature	
Decomposition temperature	Not determined.
Self-igniting	Product is not self-igniting.
Danger of explosion	Product does not present an explosion
Explosion limits	
Lower	Not determined.
Upper	Not determined.
Oxidising properties	Not determined.
Vapour pressure	Not applicable.
Density	
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
Water	Completely soluble.
Partition coefficient (n-octanol/water)	Not determined.
Viscosity	
Dynamic	Not applicable.
Kinematic	Not applicable.
Solvent content	
VOC (EC)	Not determined.
VOCV (CH)	Not determined.

9.2 Other information

No further relevant information available.

10 Stability and reactivity

10.1 Reactivity

No further relevant information available.

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 acides.

10.6 Hazardous decomposition products

Sodium azide develops very toxic gases upon contact with acids.

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity

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

Harmful if swallowed.

LD/LC50 values relevant for classification		
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.
Respiratory or skin 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.
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..

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.

Additional ecological information

General notes: Harmful to aquatic organisms

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 Other adverse effects

No further relevant information available.

13 Disposal considerations

13.1 Waste treatment methods

Recommendation: Disposal must be made according to official regulations.

European waste catalogue The Swiss waste code is identical In Switzerland codes for hazardous waste are marked with an „S“ (“Sonderabfall”) instead of an asterisk.	
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.

14 Transport information

14.1 UN-number

ADR, ADN, IMDG, IATA	UN2811

14.2 UN Proper shipping name

ADR, ADN	2811 TOXIC SOLID, ORGANIC, N.O.S. (sodium azide)
IMDG	TOXIC SOLID, ORGANIC, N.O.S. (sodium azide)
IATA	Toxic solids, organic, n.o.s. (sodium azide)

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class	6.1 Toxic substances.
Label	6.1

14.4 Packing group

ADR, ADN, IMDG, IATA	III

14.5 Environmental hazards Product contains environmentally hazardous substances: sodium azide

14.6 Special precautions for user Warning: toxic substances.

Danger code (Kemler)	60
EMS Number	F-A,S-A
Stowage Category	A

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

Transport/Additional information

ADR/ADN

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
Transport category	2
Tunnel restriction code	E

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

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

Directive 2012/18/EU

Named dangerous substances - ANNEX I

None of the ingredients is listed.

National regulations

Waterhazard class

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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. DSM Nutritional Products Ltd Branch Pentapharm 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.

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

Abbreviations and acronyms

ADR: Accord européen sur le transport 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)

VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)

VOC: Volatile Organic Compounds (USA, EU)

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, Hazard Category 2

Acute Tox. 4: Acute toxicity, Hazard Category 4

Acute Tox. 1: Acute toxicity, Hazard Category 1

Acute Tox. 3: Acute toxicity, Hazard Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

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