

# SAFETY DATA SHEET

According to 1907/2006/EC, Article 31



**Haemocoagulase Sol.25 IU/ml**

**100-05**

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

### 1.1 Product identifier

Trade name Haemocoagulase Sol.25 IU/ml  
Article number 100-05

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

Application of the substance / the mixture API

### 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  
The product is not classified according to the CLP regulation.

### 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 Void  
Hazard pictograms Void  
Signal word Void  
Hazard statements Void

#### **Additional information**

The health hazards for this substance have not been thoroughly investigated.

#### **Additional information**

0.1-1% of the mixture consists of component(s) of unknown toxicity extracted from snake venom.  
Non-classification of the product is based on the calculation method.

EUH208 Contains Mixture of serine proteinases from Bothrops atrox snake venom (MW 42'000 - 66'000 ). May produce an allergic reaction.

EUH210 Safety data sheet available on request

### 2.3 Other hazards

#### **Results of PBT and vPvB assessment**

PBT: According to current knowledge, the product contains no PBT substance.

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vPvB: According to current knowledge, the product contains no vPvB substance.

### 3 Composition/information on ingredients

#### 3.2 Chemical characterization

##### Description

Mixture of substances listed below with nonhazardous additions.

Dangerous components		
	Mixture of serine proteinases from Bothrops atrox snake venom (MW 42'000 - 66'000)  Resp. Sens. 1, H334;  Skin Sens. 1, H317	0.1 - 1%
CAS: 108-95-2 EINECS: 203-632-7	phenol  Acute Tox. 3, H301; Acute Tox. 3, H311, Acute Tox 3, H331;  Muta. 2, H341; STOT RE 2, H373;  Skin Corr. 1B, H314;  Aquatic Chronic 2, H411	0.1 - 1%

##### 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.

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

##### 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.

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

No further relevant information available.

## **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

CO<sub>2</sub>, 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 respiratory protective device.

Wear protective clothing to prevent contact with skin and eyes.

## **6 Accidental release measures**

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

Avoid contact with skin and eyes.

### **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**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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.

## **7 Handling and storage**

### **7.1 Precautions for safe handling**

Avoid skin and eye contact.

Information about fire - and explosion protection

No special measures required.

### **7.2 Conditions for safe storage, including any incompatibilities**

Storage

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### 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 at a temperature between + 2 to 8 °C.

### 7.3 Specific end use(s)

No further relevant information available.

## 8 Exposure controls/personal protection

Additional information about design of technical facilities: No further data; see item 7

### 8.1 Control parameters

#### Ingredients with limit values that require monitoring at the workplace

108-95-2 phenol	
MAK (Switzerland)	Short-term value: 19 mg/m <sup>3</sup> , 5 ppm Long-term value: 19 mg/m <sup>3</sup> , 5 ppm H B M <sub>3</sub> ;
AGW (Germany)	Long-term value: 8 mg/m <sup>3</sup> , 2 ppm 2(II);EU, H, 11
IOELV (EU)	Short-term value: 16 mg/m <sup>3</sup> , 4 ppm Long-term value: 8 mg/m <sup>3</sup> , 2 ppm Skin

#### Ingredients with biological limit values

108-95-2 phenol	
BAT (Switzerland)	250 mg/g creatinine Medium: Urine Sampling time: End of shift (or end of exposure) Biol. parameter: Phenol
BGW (Germany)	120 mg/g creatinine Medium: Urine Sampling time: End of shift (or end of exposure) Parameter: Phenol (with hydrolysis)

### Additional information

The lists valid during the making were used as basis.

### 8.2 Exposure controls

#### Personal protective equipment

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### General protective and hygienic measures

The usual precautionary measures are to be adhered to when handling chemicals.

Ensure good ventilation/exhaustion at the workplace.

Keep away from foodstuffs, beverages and feed.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work

### Respiratory protection

Use suitable respiratory protective device in case of insufficient ventilation.

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.

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.

### 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

Solution

Colour

Colourless to yellowish

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Odour	Odourless
Odour threshold	Not determined.
pH-value	6.3 - 6.7
Change in condition	
Melting point/Melting range	Not determined.
Boiling point/Boiling range	Not determined.
Flash point	Not applicable.
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 hazard.
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 applicable.
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 information available.

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### 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.

### 10.6 Hazardous decomposition products

Nature of decomposition products not known.

## 11 Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

0.1-1% of the mixture consists of component(s) of unknown toxicity extracted from snake venom.

Non-classification of the product is based on the calculation method.

The toxicological properties of this product have not been thoroughly investigated

#### LD/L50 values relevant for classification

No data available.

#### Skin corrosion/irritation

No data available.

#### Serious eye damage/irritation

No data available.

#### Respiratory or skin sensitisation

May produce an allergic reaction.

The sensitizing properties of this product have not been thoroughly investigated

#### Repeated dose toxicity

No data available.

#### 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.

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### 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 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)	
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.

### 14 Transport information

#### 14.1 UN-number

ADR, ADN, ADN, IMDG, IATA

Void



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## 14.2 UN Proper shipping name

ADR, ADN, IMDG, IATA Void

## 14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA  
Class Void

## 14.4 Packing group

ADR, AND, IMDG, IATA Void

## 14.5 Environmental hazards

Marine pollutant No

## 14.6 Special precautions for user

Not applicable.

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

Not applicable.

Transport/Additional information

ADR

Remark Not classified.

IMDG

Remark Not classified.

IATA

Remark Not classified.

UN "Model Regulation" Void

## 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.

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## Relevant phrases

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H331 Toxic if inhaled.

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

H341 Suspected of causing genetic defects.

H373 May cause damage to organs through prolonged or repeated exposure.

H411 Toxic to aquatic life with long lasting effects.

## 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 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. 3: Acute toxicity, Hazard Category 3

Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Muta. 2: Germ cell mutagenicity, Hazard Category 2

STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2

Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2