

Safety data sheet

according to ChemO 2015 – SR 813.11

Version number 2.0 (replaces version 1.0)

Revision: 22.11.2024

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

1.1 Product identifier

Trade name: **Protac® lyophilized**

Article number: 113-04

UFI: 9850-G0M1-F00H-6GS5

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



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

(Contd. on page 2)

CH/EN

Safety data sheet

according to ChemO 2015 – SR 813.11

Version number 2.0 (replaces version 1.0)

Revision: 22.11.2024

Trade name: Protac® lyophilized

(Contd. of page 1)

Hazard-determining components of labelling:

Glycopeptide

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 dust/fume/gas/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.

Additional information:

5 - 10% of the mixture consists of component(s) of unknown toxicity extracted from snake venom.

Classification of the product is derived from the starting material (snake venom extract) and general knowledge of enzyme properties. This product itself has not been tested.

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: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

CAS: 103469-93-8	Glycopeptide	5-<10%
	 Resp. Sens. 1, H334;  Skin Sens. 1, H317	
CAS: 1310-73-2 EINECS: 215-185-5 Index number: 011-002-00-6	sodium hydroxide	≥0.1-<0.5%
	 Met. Corr. 1, H290; Skin Corr. 1A, H314; Eye Dam. 1, H318	
	Specific concentration limits: Skin Corr. 1A; H314: C ≥ 5 %	
	Skin Corr. 1B; H314: 2 % ≤ C < 5 %	
	Skin Irrit. 2; H315: 0.5 % ≤ C < 2 %	
	Eye Irrit. 2; H319: 0.5 % ≤ C < 2 %	

SVHC: According to current knowledge no SVHC contained.

Additional information: For the wording of the listed hazard phrases refer to section 16.

CH/EN

(Contd. on page 3)

Safety data sheet

according to ChemO 2015 – SR 813.11

Version number 2.0 (replaces version 1.0)

Revision: 22.11.2024

Trade name: **Protac® lyophilized**

(Contd. of page 2)

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.

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: CO₂, 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 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.

Avoid dust formation.

(Contd. on page 4)

CH/EN

Safety data sheet

according to ChemO 2015 – SR 813.11

Version number 2.0 (replaces version 1.0)

Revision: 22.11.2024

Trade name: **Protac® lyophilized**

(Contd. of page 3)

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 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:

Store the product in a dry place 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.

1310-73-2 sodium hydroxide

MAK (Switzerland)	Short-term value: 2 e mg/m ³ Long-term value: 2 e mg/m ³ SSc;
-------------------	---

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.

(Contd. on page 5)

CH/EN

Safety data sheet

according to ChemO 2015 – SR 813.11

Version number 2.0 (replaces version 1.0)

Revision: 22.11.2024

Trade name: **Protac® lyophilized**

(Contd. of page 4)

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 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.

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/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:	Solid
Colour:	White
Odour:	Odourless
Odour threshold:	Not determined.
Melting point/freezing point:	Not determined.
Boiling point or initial boiling point and boiling range:	Not determined.
Flammability:	Not determined
Lower and upper explosion limit	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	Not applicable.
Auto-ignition temperature:	The product is not self-igniting.

(Contd. on page 6)

CH/EN

Safety data sheet

according to ChemO 2015 – SR 813.11

Version number 2.0 (replaces version 1.0)

Revision: 22.11.2024

Trade name: Protac® lyophilized

(Contd. of page 5)

Decomposition temperature:	Not determined.
pH:	Not determined.
Viscosity	
Kinematic:	Not applicable.
Dynamic:	Not applicable.
Solubility	
water:	Soluble.
Partition coefficient n-octanol/water (log value):	Not determined.
Vapour pressure:	Not applicable.
Density and/or relative density	
Relative density:	Not determined.
Vapour density:	Not determined.
Particle characteristics:	Not determined.

9.2 Other information

Appearance

Form: Lyophilized powder

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:

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

(Contd. on page 7)

CH/EN

Safety data sheet

according to ChemO 2015 – SR 813.11

Version number 2.0 (replaces version 1.0)

Revision: 22.11.2024

Trade name: **Protac® lyophilized**

(Contd. of page 6)

Desensitised explosives

Void

SECTION 10: Stability and reactivity

10.1 Reactivity The product is sensitive to moisture and absorbs odours.

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

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

5 - 10% of the mixture consists of component(s) of unknown toxicity extracted from snake venom.

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

May be harmful by inhalation, ingestion, or skin absorption.

LD/LC50 values relevant for classification:

1310-73-2 sodium hydroxide

Oral LD50 2,000 mg/kg (rat)

Specific symptoms in biological assay:

Skin corrosion/irritation No data available.

Serious eye damage/irritation No data available.

Respiratory or skin sensitisation

Classification of the product is derived from the starting material (snake venom extract) and general knowledge of enzyme properties. This product itself has not been tested.

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.

(Contd. on page 8)

CH/EN

Safety data sheet

according to ChemO 2015 – SR 813.11

Version number 2.0 (replaces version 1.0)

Revision: 22.11.2024

Trade name: **Protac® lyophilized**

(Contd. of page 7)

11.2 Information on other hazards

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.

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 06S: chemicals consisting of or containing dangerous substances

S=hazardous waste

Uncleaned packaging

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

CH/EN

(Contd. on page 9)

Safety data sheet

according to ChemO 2015 – SR 813.11

Version number 2.0 (replaces version 1.0)

Revision: 22.11.2024

Trade name: **Protac® lyophilized**

(Contd. of page 8)

SECTION 14: Transport information

14.1 UN number or ID number

ADR/ADN, ADN, IMDG, IATA

Void

14.2 UN proper shipping name

ADR/ADN, ADN, IMDG, IATA

Void

14.3 Transport hazard class(es)

ADR/ADN, ADN, IMDG, IATA

Class

Void

14.4 Packing group

ADR/ADN, IMDG, IATA

Void

14.5 Environmental hazards

Marine pollutant:

No

14.6 Special precautions for user

Not applicable.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

Transport/Additional information:

ADR/ADN

Remarks:

Not classified.

IMDG

Remarks:

Not classified.

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)

(Contd. on page 10)

CH/EN

Safety data sheet

according to ChemO 2015 – SR 813.11

Version number 2.0 (replaces version 1.0)

Revision: 22.11.2024

Trade name: Protac® lyophilized

(Contd. of page 9)

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.

Ordinance on Chemical Products (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:

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

Young people undergoing basic vocational training may only work with this product (this substance / this preparation) 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 (this substance / this preparation). 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.

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

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

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

(Contd. on page 11)

CH/EN

Safety data sheet

according to ChemO 2015 – SR 813.11

Version number 2.0 (replaces version 1.0)

Revision: 22.11.2024

Trade name: Protac® lyophilized

(Contd. of page 10)

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
Met. Corr.1: Corrosive to metals – Category 1
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Resp. Sens. 1: Respiratory sensitisation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1

CH/EN