

# Safety data sheet

according to ChemO 2015 – SR 813.11

Version number 1

Revision: 23.08.2022

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

### 1.1 Product identifier

Trade name: **RB-Cephalin, freeze dried**

Article number: 801682

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

Application of the substance / the mixture: Diagnostic ingredient (bulk)

### 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

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

### 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: Void

SVHC According to current knowledge no SVHC contained.

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

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## 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.

Get medical advice/attention.

**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:**

Rinse mouth.

Get medical advice/attention.

### 4.2 Most important 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.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

**Suitable extinguishing agents:** CO<sub>2</sub>, foam, dry powder or water.

### 5.2 Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors such as carbon oxides.

### 5.3 Advice for firefighters

**Protective equipment:**

Wear protective clothing to prevent contact with skin and eyes.

Mouth respiratory protective device.

## 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 to enter sewers/ surface or ground water.

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

Pick up mechanically.  
Collect in suitable containers.  
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.

## 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:** Keep respiratory protective device available.

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

#### Storage:

**Requirements to be met by storerooms and receptacles:** Store in a dry place. Store in a closed container.

**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 of -18 to -22 °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:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

**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:

The usual precautionary measures are to be adhered to when handling chemicals.  
Do not breathe dust.  
Avoid contact with the eyes and skin.  
Ensure good ventilation/exhaustion at the workplace.  
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 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 Directive 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

Protective goggles must be compliant with the specifications of Directive 2016/425 and be in accordance with the standard EN166 (EU) or NIOSH (US).



Safety glasses

**Body protection:** Protective work clothing

**Environmental exposure controls** Do not allow to enter sewers/ surface or ground water.

## 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>	Yellowish
<b>Odour:</b>	Not determined.
<b>Odour threshold:</b>	Not determined.
<b>Dissociation constants</b>	
<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>Ignition temperature:</b>	Not determined.
<b>Decomposition temperature:</b>	Not determined.
<b>pH</b>	Not applicable.
<b>Viscosity:</b>	
<b>Kinematic viscosity</b>	Not applicable.
<b>Dynamic:</b>	Not applicable.
<b>Solubility</b>	
<b>water:</b>	Not determined.

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**organic solvents:**

**Partition coefficient n-octanol/water (log value)** Not applicable.

**Log Kow**

**Vapour pressure:** Not applicable.

**Density and/or relative density**

**Relative density:** Not determined.

**Vapour density:** Not determined.

**Particle characteristics:** Not applicable.

**9.2 Other information**

**Appearance**

**Form:** Lyophilised solid

**Important information on protection of health and environment, and on safety.**

**Auto-ignition temperature:** Product is not self-igniting.

**Explosive properties:** Product does not present an explosion hazard.

**Solvent content:**

**VOC (EC)** Not determined.

**Change in condition**

**Softening point/range:** Not determined.

**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

**Desensitised explosives** Void

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## SECTION 10: Stability and reactivity

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

### 10.2 Chemical stability

**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** No further relevant information available.

### 10.6 Hazardous decomposition products

Thermal decomposition can lead to release of irritating gases and vapors such as carbon oxides.

## SECTION 11: Toxicological information

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

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

**LD/LC50 values relevant for classification:** No data available.

**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.

### 11.2 Information on other hazards

#### Endocrine disrupting properties

Taking into account the current state of scientific knowledge, no data on endocrine disrupting properties of the product are available.

None of the ingredients is listed.

## SECTION 12: Ecological information

### 12.1 Toxicity

**Aquatic toxicity:** Based on the ingredients not classified as harmful for the environment.

**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.

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## 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

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	Abfälle aus der humanmedizinischen oder tierärztlichen Versorgung und Forschung
18 01 00	Abfälle aus Forschung, Geburtshilfe, Diagnose, Behandlung oder Vorbeugung von Krankheiten beim Menschen
18 01 07	Chemikalien mit Ausnahme derjenigen, die unter 18 01 06 fallen

### Uncleaned packaging

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

## 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

Not applicable.

### 14.6 Special precautions for user

Not applicable.

### 14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

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UN "Model Regulation":

Void

### SECTION 15: Regulatory information

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

##### National regulations:

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 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)

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).

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.

**Waterhazard class:** Swiss Waterhazard class B (self classification)

**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.

##### 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)

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

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