

SAFETY DATA SHEET

| Product name | Product reference |
|------------------------|-------------------|
| BIOPHEN™ Protein C LRT | 221211 |

| | |
|----|---------|
| R1 | Protac® |
| R2 | SaPC-21 |

In accordance with Regulation (EC) No. 1907/2006, a Safety Data Sheet is required only for reagent R2 (see SDS below).

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 30.01.2024

Version number 6

Revision: 30.01.2024

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

- **Product identifier**
- **Trade name:** **SaPC-21**
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** In vitro medical device for professional use
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
HYPHEN BioMed
155 rue d'Eragny
F-95000 NEUVILLE-SUR-OISE
FRANCE
- **Further information obtainable from:**
info@hyphen-biomed.com
+33/1/34 40 65 10
- **Emergency telephone number:**
Members of the public seeking specific information on poisons should contact:
In England and Wales: NHS 111 - dial 111
In Scotland: NHS 24 - dial 111

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



health hazard

Repr. 2 H361f Suspected of damaging fertility.



Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**



GHS07



GHS08

- **Signal word** Warning
- **Hazard-determining components of labelling:**
caesium chloride
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)
- **Hazard statements**
May cause an allergic skin reaction.
Suspected of damaging fertility.

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Precautionary statements

- P201 Obtain special instructions before use.
- P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P302+P352 IF ON SKIN: Wash with plenty of soap and water.
- P308+P313 IF exposed or concerned: Get medical advice/attention.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards
Results of PBT and vPvB assessment

- PBT:** Not applicable.
- vPvB:** Not applicable.

3 Composition/information on ingredients

Chemical characterisation: Mixtures
Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

| | | |
|-------------------|---|--------|
| CAS: 7647-17-8 | caesium chloride | <5% |
| EINECS: 231-600-2 | ⚠ Repr. 2, H361f | |
| CAS: 55965-84-9 | reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1) | <0.01% |
| | ⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330; ⚠ Skin Corr. 1C, H314; Eye Dam. 1, H318; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠ Skin Sens. 1A, H317 | |

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

4 First aid measures

Description of first aid measures
General information: Seek immediate medical advice.

After inhalation:

In case of unconsciousness place patient stably in side position for transportation. Supply fresh air and to be sure call for a doctor.

After skin contact: Immediately wash with water and soap and rinse thoroughly.

Information for doctor:
Most important symptoms and effects, both acute and delayed

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

Extinguishing media
Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.

Special hazards arising from the substance or mixture No further relevant information available.

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- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective clothing.
- **Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
- **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

- **Handling:**
- **Precautions for safe handling** Open and handle receptacle with care.
- **Information about fire - and explosion protection:**
Keep respiratory protective device available.
No special measures required.
- **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:**
None.
2 - 8°C
- **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 section 7.
- **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.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.

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Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Store protective clothing separately.

Do not eat or drink while working.

· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

· **Material of gloves**

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.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** Face protection

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

| | |
|------------------|-----------------|
| Form: | Fluid |
| Colour: | Colourless |
| Odour: | Odourless |
| Odour threshold: | Not determined. |

· **pH-value:** Not determined.

· **Change in condition**

| | |
|--|---------------|
| Melting point/freezing point: | Undetermined. |
| Initial boiling point and boiling range: | Undetermined. |

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not applicable.

· **Decomposition temperature:** Not determined.

· **Ignition temperature:** Product is not selfigniting.

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

· **Explosion limits:**

| | |
|--------|-----------------|
| Lower: | Not determined. |
|--------|-----------------|

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| | |
|--|--|
| Upper: | Not determined. |
| · Vapour pressure: | Not determined. |
| · Density: | Not determined. |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |
| · Evaporation rate | Not determined. |
| · Solubility in / Miscibility with water: | Not determined. |
| · Partition coefficient: n-octanol/water: | Not determined. |
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |
| · Other information | No further relevant information available. |

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **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:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

- **LD/LC50 values relevant for classification:**

7647-17-8 caesium chloride

| | | |
|--------|------|-------------------|
| Oral | LD50 | 2,600 mg/kg (rat) |
| | | mg/kg (rabbit) |
| Dermal | LD50 | 1,500 mg/kg (rat) |

- **Primary irritant effect:**
- **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**
May cause an allergic skin reaction.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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**
Suspected of damaging fertility.

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- **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

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
Avoid transfer into the environment.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:**
Disposal must be made according to official regulations.
Dispose of packaging according to regulations on the disposal of packagings.

14 Transport information

- | | |
|--|---------------|
| <ul style="list-style-type: none"> · UN-Number · ADR, IMDG, IATA | not regulated |
| <ul style="list-style-type: none"> · UN proper shipping name · ADR, IMDG, IATA | not regulated |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class | not regulated |
| <ul style="list-style-type: none"> · Packing group · ADR, IMDG, IATA | not regulated |

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- | | |
|---|-----------------|
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | not regulated |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Poisons Act**
- **Regulated explosives precursors**
None of the ingredients is listed.
- **Regulated poisons**
None of the ingredients is listed.
- **Reportable explosives precursors**
None of the ingredients is listed.
- **Reportable poisons**
None of the ingredients is listed.
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category E2** Hazardous to the Aquatic Environment
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
H301 Toxic if swallowed.
H310 Fatal in contact with skin.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H330 Fatal if inhaled.
H361f Suspected of damaging fertility.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
- **Department issuing SDS:**
- **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

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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
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 2: Acute toxicity – Category 2
Skin Corr. 1C: Skin corrosion/irritation – Category 1C
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1A: Skin sensitisation – Category 1A
Repr. 2: Reproductive toxicity – Category 2
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
* **Data compared to the previous version altered.**

GB