

## SAFETY DATA SHEET

Product name	Product reference
BIOPHEN™ Protein C LRT	221211

R1	Protac®
R2	SaPC-21

In accordance with OSHA Regulations 1910.1200 (g), a Safety Data Sheet is required only for reagent R2 (see SDS below).

## Safety Data Sheet acc. to OSHA HCS

Printing date 01/30/2024

Version Number 6

Reviewed on 01/30/2024

### 1 Identification

- **Product identifier**
- **Trade name: SaPC-21**
- **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
- **Information department:**  
info@hyphen-biomed.com  
+33/1/34 40 65 10
- **Emergency telephone number:**  
INFOTRAC emergency phone number (for USA, Puerto Rico and Canada only): 1-800-535-5053  
(24-hours)

### 2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS08 Health hazard

Toxic to Reproduction 2 H361 Suspected of damaging fertility or the unborn child.



GHS07

Sensitization - Skin 1 H317 May cause an allergic skin reaction.

- **Label elements**
- **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Warning
- **Hazard-determining components of labeling:**  
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 or the unborn child.
- **Precautionary statements**  
Obtain special instructions before use.  
Wear protective gloves/protective clothing/eye protection/face protection.  
If on skin: Wash with plenty of soap and water.

(Contd. on page 2)

## Safety Data Sheet acc. to OSHA HCS

Printing date 01/30/2024

Version Number 6

Reviewed on 01/30/2024

**Trade name: SaPC-21**

(Contd. of page 1)

IF exposed or concerned: Get medical advice/attention.  
If skin irritation or rash occurs: Get medical advice/attention.  
Take off contaminated clothing and wash it before reuse.  
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 characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

7647-17-8	caesium chloride	<5%
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%

### 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 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **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.

(Contd. on page 3)

## Safety Data Sheet acc. to OSHA HCS

Printing date 01/30/2024

Version Number 6

Reviewed on 01/30/2024

**Trade name: SaPC-21**

(Contd. of page 2)

- **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.
- **Protective Action Criteria for Chemicals**

· **PAC-1:**

7647-17-8	caesium chloride	21 mg/m <sup>3</sup>
87-69-4	(+)-tartaric acid	1.6 mg/m <sup>3</sup>

· **PAC-2:**

7647-17-8	caesium chloride	230 mg/m <sup>3</sup>
87-69-4	(+)-tartaric acid	17 mg/m <sup>3</sup>

· **PAC-3:**

7647-17-8	caesium chloride	400 mg/m <sup>3</sup>
87-69-4	(+)-tartaric acid	100 mg/m <sup>3</sup>

### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Open and handle receptacle with care.
- **Information about protection against explosions and fires:**  
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 systems:** No further data; see section 7.
- **Control parameters**
- **Components 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 that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.

(Contd. on page 4)

## Safety Data Sheet acc. to OSHA HCS

Printing date 01/30/2024

Version Number 6

Reviewed on 01/30/2024

**Trade name: SaPC-21**

(Contd. of page 3)

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.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **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:**

· <b>Form:</b>	Fluid
· <b>Color:</b>	Colorless
· <b>Odor:</b>	Odorless
· <b>Odor threshold:</b>	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	Undetermined.

· **Flash point:** Not applicable.

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

· **Decomposition temperature:** Not determined.

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

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

· <b>Lower:</b>	Not determined.
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(Contd. on page 5)

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 01/30/2024

Version Number 6

Reviewed on 01/30/2024

**Trade name: SaPC-21**

(Contd. of page 4)

<b>Upper:</b>	Not determined.
· <b>Vapor pressure:</b>	Not determined.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapor density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water:</b>	Not determined.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
<b>VOC content:</b>	0.00 %
· <b>Other information</b>	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:**

· **LD/LC50 values that are 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)

- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**  
The product shows the following dangers according to internally approved calculation methods for preparations:  
Irritant

(Contd. on page 6)

## Safety Data Sheet acc. to OSHA HCS

Printing date 01/30/2024

Version Number 6

Reviewed on 01/30/2024

**Trade name: SaPC-21**

(Contd. of page 5)

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

### 12 Ecological information

· **Toxicity**

· **Aquatic toxicity:** No further relevant information available.

· **Persistence and degradability** No further relevant information available.

· **Behavior 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 (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 of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

· **Recommendation:**

Disposal must be made according to official regulations.

Dispose of packaging according to regulations on the disposal of packagings.

### 14 Transport information

· **UN-Number**

· **DOT, IMDG, IATA**

not regulated

· **UN proper shipping name**

· **DOT, IMDG, IATA**

not regulated

(Contd. on page 7)

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 01/30/2024

Version Number 6

Reviewed on 01/30/2024

**Trade name: SaPC-21**

(Contd. of page 6)

- **Transport hazard class(es)**
- **DOT, ADN, IMDG, IATA**
- **Class** not regulated
- **Packing group**
- **DOT, IMDG, IATA** not regulated
- **Environmental hazards:** Not applicable.
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 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**  
No further relevant information available.
- **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

7732-18-5	water, distilled, conductivity or of similar purity	ACTIVE
7647-17-8	caesium chloride	ACTIVE
69-65-8	D-mannitol	ACTIVE
87-69-4	(+)-tartaric acid	ACTIVE
9005-65-6	Sorbitan monooleate, ethoxylated	ACTIVE

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

(Contd. on page 8)

## Safety Data Sheet acc. to OSHA HCS

Printing date 01/30/2024

Version Number 6

Reviewed on 01/30/2024

**Trade name: SaPC-21**

(Contd. of page 7)

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

· **Hazard-determining components of labeling:**

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 or the unborn child.

· **Precautionary statements**

Obtain special instructions before use.

Wear protective gloves/protective clothing/eye protection/face protection.

If on skin: Wash with plenty of soap and water.

If exposed or concerned: Get medical advice/attention.

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

Take off contaminated clothing and wash it before reuse.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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.

· **Contact:**

· **Date of preparation / last revision** 01/30/2024

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

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

vPvB: very Persistent and very Bioaccumulative

(Contd. on page 9)

**Safety Data Sheet**  
**acc. to OSHA HCS**

Printing date 01/30/2024

Version Number 6

Reviewed on 01/30/2024

**Trade name: SaPC-21**

(Contd. of page 8)

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Sensitization - Skin 1: Skin sensitisation – Category 1

Toxic to Reproduction 2: Reproductive toxicity – Category 2

· \* **Data compared to the previous version altered.**

US