

SAFETY DATA SHEET

Product name	Product reference
BIOPHEN™ AT anti-(h)-Xa LRT	221123
BIOPHEN™ AT anti-(h)-Xa LRT	221127

R1	Human Factor Xa
R2	Factor Xa substrate

Safety Data Sheet acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

1 Identification

- **Product identifier**
- **Trade name:** Human Factor Xa
- **Article number:** R1
- **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**
The product is not classified, according to the Globally Harmonized System (GHS).
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **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:**

56-81-5	glycerol	<30%
---------	----------	------

4 First-aid measures

- **Description of first aid measures**
- **General information:**
No special measures required.
Seek immediate medical advice.
- **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

(Contd. on page 2)

Safety Data Sheet acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

Trade name: Human Factor Xa

(Contd. of page 1)

- **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:**
Dilute with plenty of water.
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).
- **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:**

56-81-5	glycerol	45 mg/m ³
25322-68-3	Polyethylene glycol	30 mg/m ³
1185-53-1	2-amino-2-(hydroxymethyl)propane-1,3-diolhydrochloride	12 mg/m ³
7647-01-0	hydrogen chloride	1.8 ppm
6381-92-6	Ethylenediaminetetraacetic Acid, Disodium Salt Dihydrate	30 mg/m ³
26628-22-8	sodium azide	0.026 mg/m ³

· **PAC-2:**

56-81-5	glycerol	180 mg/m ³
25322-68-3	Polyethylene glycol	1,300 mg/m ³
1185-53-1	2-amino-2-(hydroxymethyl)propane-1,3-diolhydrochloride	130 mg/m ³
7647-01-0	hydrogen chloride	22 ppm
6381-92-6	Ethylenediaminetetraacetic Acid, Disodium Salt Dihydrate	330 mg/m ³
26628-22-8	sodium azide	0.29 mg/m ³

· **PAC-3:**

56-81-5	glycerol	1,100 mg/m ³
25322-68-3	Polyethylene glycol	7,700 mg/m ³
1185-53-1	2-amino-2-(hydroxymethyl)propane-1,3-diolhydrochloride	790 mg/m ³

(Contd. on page 3)

Safety Data Sheet acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

Trade name: Human Factor Xa

		(Contd. of page 2)
7647-01-0	hydrogen chloride	100 ppm
6381-92-6	Ethylenediaminetetraacetic Acid, Disodium Salt Dihydrate	2,000 mg/m ³
26628-22-8	sodium azide	5.3 mg/m ³

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
No special measures required.
Open and handle receptacle with care.
- **Information about protection against explosions and fires:** 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:**

56-81-5 glycerol

PEL Long-term value: 15* 5** mg/m³
mist; *total dust **respirable fraction

TLV TLV withdrawn-insufficient data human occup. exp.

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
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.

(Contd. on page 4)

Safety Data Sheet acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

Trade name: Human Factor Xa

(Contd. of page 3)

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
· Color:	Colorless
· Odor:	Odorless
· Odor threshold:	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	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:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapor pressure:** Not determined.

· Density:	Not determined.
· Relative density	Not determined.
· Vapor 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.

(Contd. on page 5)

Safety Data Sheet acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

Trade name: Human Factor Xa

(Contd. of page 4)

Kinematic:	Not determined.
· Solvent content: VOC content:	0.00 %
· 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:**

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

56-81-5 glycerol

Oral	LD50	12,600 mg/kg (rat)
------	------	--------------------

- **Additional toxicological information:**

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- **Carcinogenic categories**

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

7647-01-0	hydrogen chloride	3
-----------	-------------------	---

- **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.

(Contd. on page 6)

Safety Data Sheet acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

Trade name: Human Factor Xa

(Contd. of page 5)

- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
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:**
Smaller quantities can be disposed of with household waste.
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.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | |
| · DOT, IMDG, IATA | not regulated |
| · UN proper shipping name | |
| · DOT, IMDG, IATA | not regulated |
| · 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 |

US

(Contd. on page 7)

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

Trade name: Human Factor Xa

(Contd. of page 6)

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):**

7647-01-0	hydrogen chloride
26628-22-8	sodium azide

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

7647-01-0	hydrogen chloride
26628-22-8	sodium azide

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

7732-18-5	water, distilled, conductivity or of similar purity	ACTIVE
56-81-5	glycerol	ACTIVE
7647-14-5	sodium chloride	ACTIVE
25322-68-3	Polyethylene glycol	ACTIVE
1185-53-1	2-amino-2-(hydroxymethyl)propane-1,3-diolhydrochloride	ACTIVE
7647-01-0	hydrogen chloride	ACTIVE
26628-22-8	sodium azide	ACTIVE

- **Hazardous Air Pollutants**

7647-01-0	hydrogen chloride
-----------	-------------------

- **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.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value)**

7647-01-0	hydrogen chloride	A4
26628-22-8	sodium azide	A4

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

None of the ingredients is listed.

- **GHS label elements** Void

- **Hazard pictograms** Void

- **Signal word** Void

- **Hazard statements** Void

(Contd. on page 8)

Safety Data Sheet acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

Trade name: Human Factor Xa

(Contd. of page 7)

· **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** 03/22/2024

· **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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

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

Safety Data Sheet acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

1 Identification

- **Product identifier**
- **Trade name:** Factor Xa substrate
- **Article number:** R2
- **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)
(800)424-9300 (CHEMTREC)

2 Hazard(s) identification

- **Classification of the substance or mixture**



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

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



- **Signal word** Warning
- **Hazard-determining components of labeling:**
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.
- **Precautionary statements**
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin: Wash with plenty of soap and water.
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.

(Contd. on page 2)

Safety Data Sheet acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

Trade name: Factor Xa substrate

(Contd. of page 1)

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description**
7732-18-5 water, distilled, conductivity or of similar purity
- **Identification number(s)**
- **EC number:** 231-791-2

· **Dangerous components:**

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)	<0.1%
------------	---	-------

4 First-aid measures

- **Description of first aid measures**
- **General information:**
Immediately remove any clothing soiled by the product.
Seek immediate medical advice.
- **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
- **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:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.

(Contd. on page 3)

Safety Data Sheet acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

Trade name: Factor Xa substrate

(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.
- **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:**

87-69-4	(+)-tartaric acid	1.6 mg/m ³
---------	-------------------	-----------------------

- **PAC-2:**

87-69-4	(+)-tartaric acid	17 mg/m ³
---------	-------------------	----------------------

- **PAC-3:**

87-69-4	(+)-tartaric acid	100 mg/m ³
---------	-------------------	-----------------------

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Open and handle receptacle with care.
- **Information about protection against explosions and fires:** 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:** Not required.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
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.

(Contd. on page 4)

Safety Data Sheet acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

Trade name: Factor Xa substrate

(Contd. of page 3)

· **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.

· **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
· Color:	Colorless
· Odor:	Odorless
· Odor threshold:	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	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:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapor pressure:** Not determined.

· Density:	Not determined.
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.

(Contd. on page 5)

Safety Data Sheet acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

Trade name: Factor Xa substrate

(Contd. of page 4)

- | | |
|---|--|
| · Solubility in / Miscibility with Water: | Not determined. |
| · Partition coefficient (n-octanol/water): | Not determined. |
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |
| VOC content: | 0.00 %
0.0 g/l / 0.00 lb/gal |
| · 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:**
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
- **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.

(Contd. on page 6)

Safety Data Sheet acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

Trade name: Factor Xa substrate

(Contd. of page 5)

- **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.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- | | |
|--|-----------------|
| <ul style="list-style-type: none"> · UN-Number · DOT, IMDG, IATA | not regulated |
| <ul style="list-style-type: none"> · UN proper shipping name · DOT, IMDG, IATA | not regulated |
| <ul style="list-style-type: none"> · Transport hazard class(es) · DOT, ADN, IMDG, IATA · Class | not regulated |
| <ul style="list-style-type: none"> · Packing group · DOT, IMDG, IATA | not regulated |
| <ul style="list-style-type: none"> · Environmental hazards: | Not applicable. |
| <ul style="list-style-type: none"> · Special precautions for user | Not applicable. |
| <ul style="list-style-type: none"> · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| <ul style="list-style-type: none"> · UN "Model Regulation": | not regulated |

US

(Contd. on page 7)

Safety Data Sheet acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

Trade name: Factor Xa substrate

(Contd. of page 6)

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
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.

- **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 substance is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS07

- **Signal word** Warning

(Contd. on page 8)

Safety Data Sheet acc. to OSHA HCS

Printing date 03/22/2024

Version Number 4

Reviewed on 03/22/2024

Trade name: Factor Xa substrate

(Contd. of page 7)

- **Hazard-determining components of labeling:**
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.
- **Precautionary statements**
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin: Wash with plenty of soap and water.
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** 03/22/2024
- **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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
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