

SAFETY DATA SHEET

Product name	Product reference
BIOPHEN™ FIX	221801
BIOPHEN™ FIX	221802
BIOPHEN™ FIX	221806

R1	FX(h)-FVIII:C
R2	Activator reagent
R3	Substrate
R4	Buffer

In accordance with OSHA Regulations 1910.1200 (g), a Safety Data Sheet is required only for reagents R1, R2 and R3 (see SDS below).

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

1 Identification

- **Product identifier**
- **Trade name:** FX(h)-FVIII:C
- **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:**

25322-68-3	Polyethylene glycol	<5%
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4 First-aid measures

- **Description of first aid measures**
- **General information:**
No special measures required.
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.

(Contd. on page 2)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: FX(h)-FVIII:C

(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:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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:**

77-86-1	trometamol	18 mg/m ³
25322-68-3	Polyethylene glycol	30 mg/m ³
10035-04-8	calcium chloride, dihydrate	16 mg/m ³
7758-98-7	copper sulphate	7.5 mg/m ³

· **PAC-2:**

77-86-1	trometamol	190 mg/m ³
25322-68-3	Polyethylene glycol	1,300 mg/m ³
10035-04-8	calcium chloride, dihydrate	170 mg/m ³
7758-98-7	copper sulphate	9.9 mg/m ³

· **PAC-3:**

77-86-1	trometamol	1,200 mg/m ³
25322-68-3	Polyethylene glycol	7,700 mg/m ³
10035-04-8	calcium chloride, dihydrate	1,100 mg/m ³
7758-98-7	copper sulphate	59 mg/m ³

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
No special measures required.

(Contd. on page 3)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: FX(h)-FVIII:C

(Contd. of page 2)

- 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:**

25322-68-3 Polyethylene glycol

WEEL	Long-term value: 10 mg/m ³ (H); MW>200
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- **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.

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.

(Contd. on page 4)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: FX(h)-FVIII:C

(Contd. of page 3)

· **Eye protection:** Face protection

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

· **Form:** Like powder

· **Color:** White

· **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 applicable.

· **Solubility in / Miscibility with**

· **Water:** Not determined.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

· **Dynamic:** Not determined.

· **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.

(Contd. on page 5)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: FX(h)-FVIII:C

(Contd. of page 4)

- **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:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **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)

None of the ingredients is listed.

· NTP (National Toxicology Program)
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None of the ingredients is listed.

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

(Contd. on page 6)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: FX(h)-FVIII:C

(Contd. of page 5)

- **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 |

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):**

7758-98-7	copper sulphate
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(Contd. on page 7)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: FX(h)-FVIII:C

(Contd. of page 6)

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

77-86-1	trometamol	ACTIVE
7647-14-5	sodium chloride	ACTIVE
9048-46-8	Albumins, blood serum	ACTIVE
25322-68-3	Polyethylene glycol	ACTIVE
7758-98-7	copper sulphate	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** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **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** 02/27/2024

· **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

(Contd. on page 8)

Safety Data Sheet
acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: FX(h)-FVIII:C

(Contd. of page 7)

TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit

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

US

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

1 Identification

- **Product identifier**
- **Trade name: Activator reagent**
- **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)

2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS08 Health hazard

Toxic to Reproduction 1A H360 May damage fertility or the unborn child.



GHS05 Corrosion

Skin Corrosion 1C H314 Causes severe skin burns and eye damage.

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



GHS05 GHS08

- **Signal word** Danger
- **Hazard-determining components of labeling:**
Imidazole
- **Hazard statements**
Causes severe skin burns and eye damage.
May damage fertility or the unborn child.
- **Precautionary statements**
Obtain special instructions before use.
Do not breathe dust/fume/gas/mist/vapors/spray.
Wear protective gloves/protective clothing/eye protection/face protection.

(Contd. on page 2)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: Activator reagent

(Contd. of page 1)

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a poison center/doctor.
IF exposed or concerned: Get medical advice/attention.

- **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:**

288-32-4	Imidazole	≥1%
25322-68-3	Polyethylene glycol	<3.0%

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:**
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.
- **After eye contact:**
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **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**
During heating or in case of fire poisonous gases are produced.
- **Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

US

(Contd. on page 3)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: Activator reagent

(Contd. of page 2)

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Mount respiratory protective device.
Wear protective equipment. Keep unprotected persons away.
Wear protective clothing.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Use neutralizing agent.
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:**

10035-04-8	calcium chloride, dihydrate	16 mg/m ³
25322-68-3	Polyethylene glycol	30 mg/m ³
7791-18-6	magnesium chloride, hexahydrate	34 mg/m ³

· **PAC-2:**

10035-04-8	calcium chloride, dihydrate	170 mg/m ³
25322-68-3	Polyethylene glycol	1,300 mg/m ³
7791-18-6	magnesium chloride, hexahydrate	370 mg/m ³

· **PAC-3:**

10035-04-8	calcium chloride, dihydrate	1,100 mg/m ³
25322-68-3	Polyethylene glycol	7,700 mg/m ³
7791-18-6	magnesium chloride, hexahydrate	1,600 mg/m ³

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Thorough dedusting.
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:** Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

US

(Contd. on page 4)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: Activator reagent

(Contd. of page 3)

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 following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the remaining constituent has no known exposure limits.

25322-68-3 Polyethylene glycol	
WEEL	Long-term value: 10 mg/m ³ (H); MW>200

- **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.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Store protective clothing separately.

Avoid contact with the eyes and skin.

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:**



Tightly sealed goggles

(Contd. on page 5)

US

Safety Data Sheet
acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: Activator reagent

Face protection

(Contd. of page 4)

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

· **Form:** Like powder

· **Color:** White

· **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 applicable.

· **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.

(Contd. on page 6)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: Activator reagent

(Contd. of page 5)

- **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:**

ATE (Acute Toxicity Estimate)

Oral	LD50	16,140 mg/kg (rat)
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288-32-4 Imidazole

Oral	LD50	970 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

- **Carcinogenic categories**

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

25013-16-5	tert-butyl-4-methoxyphenol	2B
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- **NTP (National Toxicology Program)**

25013-16-5	tert-butyl-4-methoxyphenol	R
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- **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.
Must not reach bodies of water or drainage ditch undiluted or unneutralized.
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.

(Contd. on page 7)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: Activator reagent

(Contd. of page 6)

· **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

- | | |
|--|-----------------|
| · 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 |

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.

(Contd. on page 8)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: Activator reagent

(Contd. of page 7)

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

69-65-8	D-mannitol	ACTIVE
7647-14-5	sodium chloride	ACTIVE
9048-46-8	Albumins, blood serum	ACTIVE
25322-68-3	Polyethylene glycol	ACTIVE
25013-16-5	tert-butyl-4-methoxyphenol	ACTIVE

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

25013-16-5 tert-butyl-4-methoxyphenol

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

· **Hazard pictograms**



GHS05 GHS08

· **Signal word** Danger

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

Imidazole

· **Hazard statements**

Causes severe skin burns and eye damage.

May damage fertility or the unborn child.

· **Precautionary statements**

Obtain special instructions before use.

Do not breathe dust/fume/gas/mist/vapors/spray.

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

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

(Contd. on page 9)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: Activator reagent

(Contd. of page 8)

Immediately call a poison center/doctor.

IF exposed or concerned: Get medical advice/attention.

· **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** 02/27/2024

· **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)

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

Skin Corrosion 1C: Skin corrosion/irritation – Category 1C

Toxic to Reproduction 1A: Reproductive toxicity – Category 1A

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

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

1 Identification

- **Product identifier**
- **Trade name:** Substrate
- **Article number:** R3
- **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:** Void

4 First-aid measures

- **Description of first aid measures**
- **General information:**
No special measures required.
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.

(Contd. on page 2)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: Substrate

(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:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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:
None of the ingredients is listed.

· PAC-2:
None of the ingredients is listed.

· PAC-3:
None of the ingredients is listed.

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

(Contd. on page 3)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: Substrate

(Contd. of page 2)

- **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:**
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.

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:	Like powder
Color:	White
Odor:	Odorless
Odor threshold:	Not determined.

(Contd. on page 4)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: Substrate

(Contd. of page 3)

· 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 applicable.
· 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:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.

(Contd. on page 5)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: Substrate

(Contd. of page 4)

- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **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)**

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 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.

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: Substrate

(Contd. of page 5)

- **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

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):**

69-65-8	D-mannitol	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.

(Contd. on page 7)

Safety Data Sheet acc. to OSHA HCS

Printing date 02/27/2024

Version Number 8

Reviewed on 02/27/2024

Trade name: Substrate

(Contd. of page 6)

· **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** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **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** 02/27/2024

· **Abbreviations and acronyms:**

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PBT: Persistent, Bioaccumulative and Toxic

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NIOSH: National Institute for Occupational Safety

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TLV: Threshold Limit Value

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