

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 Regulation (EC) No. 1907/2006, a Safety Data Sheet is required only for reagents R1, R2 and R3 (see SDS below).

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

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

- **Product identifier**
- **Trade name: FX(h)-FVIII:C**
- **Article number: R1**
- **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**
The product is not classified, according to the GB CLP regulation.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**
Safety data sheet available on request.
- **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: 10035-04-8	calcium chloride, dihydrate	⚠ Eye Irrit. 2, H319	<5%
EC number: 600-075-5			

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

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: FX(h)-FVIII:C

(Contd. of page 1)

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.
- **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.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Open and handle receptacle with care.
- **Information about fire - and explosion protection:** 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.

GB

(Contd. on page 3)

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: FX(h)-FVIII:C

(Contd. of page 2)

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:**
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
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:	Like powder
Colour:	White
Odour:	Odourless
Odour threshold:	Not determined.

- **pH-value:** Not determined.

- **Change in condition**

Melting point/freezing point:	Undetermined.
--------------------------------------	---------------

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: FX(h)-FVIII:C

(Contd. of page 3)

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.
Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour 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** Based on available data, the classification criteria are not met.
- **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** Based on available data, the classification criteria are not met.

(Contd. on page 5)

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: FX(h)-FVIII:C

(Contd. of page 4)

- **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** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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 1 (German Regulation) (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**
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.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

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

(Contd. on page 6)

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: FX(h)-FVIII:C

(Contd. of page 5)

· Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· ADR, IMDG, IATA	not regulated
· 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.

- **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**

H319 Causes serious eye irritation.

· **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

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

(Contd. on page 7)

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: FX(h)-FVIII:C

(Contd. of page 6)

vPvB: very Persistent and very Bioaccumulative
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

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

GB

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

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

- **Product identifier**
- **Trade name: Activator reagent**
- **Article number: R2**
- **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. 1A H360D May damage the unborn child.



corrosion

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

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



GHS05 GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**
Imidazole
- **Hazard statements**
Causes severe skin burns and eye damage.
May damage the unborn child.

(Contd. on page 2)

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: Activator reagent

(Contd. of page 1)

· **Precautionary statements**

- P201 Obtain special instructions before use.
- P260 Do not breathe dust/fume/gas/mist/vapours/spray.
- P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P310 Immediately call a POISON CENTER/doctor.

· **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: 288-32-4 EINECS: 206-019-2	Imidazole ⚠ Repr. 1A, H360D; ⚠ Skin Corr. 1C, H314; ⚠ Acute Tox. 4, H302	≥1%
CAS: 10035-04-8 EC number: 600-075-5	calcium chloride, dihydrate ⚠ Eye Irrit. 2, H319	<5%

- **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:**

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 Firefighting measures

· **Extinguishing media**

- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.

(Contd. on page 3)

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: Activator reagent

(Contd. of page 2)

- **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.

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 neutralising 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.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Thorough dedusting.
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:** Keep container tightly sealed.
- **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.

(Contd. on page 4)

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: Activator reagent

(Contd. of page 3)

- **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.
- **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:**



Tightly sealed goggles

Face protection

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Like powder
Colour:	White
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **pH-value:** Not determined.
- **Change in condition**

Melting point/freezing point:	Undetermined.
-------------------------------	---------------

(Contd. on page 5)

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: Activator reagent

(Contd. of page 4)

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.
Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour 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** Based on available data, the classification criteria are not met.

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

ATE (Acute Toxicity Estimates)

Oral	LD50	16,140 mg/kg (rat)
------	------	--------------------

288-32-4 Imidazole

Oral	LD50	970 mg/kg (rat)
------	------	-----------------

(Contd. on page 6)

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: Activator reagent

(Contd. of page 5)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**
Causes severe skin burns and eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **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**
May damage the unborn child.
- **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.
Must not reach sewage water or drainage ditch undiluted or unneutralised.
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.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

GB

(Contd. on page 7)

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: Activator reagent

(Contd. of page 6)

14 Transport information

· UN-Number	
· ADR, IMDG, IATA	not regulated
· UN proper shipping name	
· ADR, IMDG, IATA	not regulated
· Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· ADR, IMDG, IATA	not regulated
· 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.

- **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**

- H302 Harmful if swallowed.
- H314 Causes severe skin burns and eye damage.
- H319 Causes serious eye irritation.
- H360D May damage the unborn child.

(Contd. on page 8)

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: Activator reagent

(Contd. of page 7)

· **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

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. 4: Acute toxicity – Category 4

Skin Corr. 1C: Skin corrosion/irritation – Category 1C

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Repr. 1A: Reproductive toxicity – Category 1A

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

GB

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

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

- **Product identifier**
- **Trade name:** Substrate
- **Article number:** R3
- **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**
The product is not classified, according to the GB CLP regulation.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**
Contains Trypsin inhibitor. May produce an allergic reaction.
Safety data sheet available on request.
- **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:** Void
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: Substrate

(Contd. of page 1)

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.
- **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.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Open and handle receptacle with care.
- **Information about fire - and explosion protection:** 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.

GB

(Contd. on page 3)

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: Substrate

(Contd. of page 2)

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:**
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
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:	Like powder
Colour:	White
Odour:	Odourless
Odour threshold:	Not determined.

- **pH-value:** Not determined.

- **Change in condition**

Melting point/freezing point:	Undetermined.
--------------------------------------	---------------

(Contd. on page 4)

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: Substrate

(Contd. of page 3)

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.
Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour 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** Based on available data, the classification criteria are not met.
- **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** Based on available data, the classification criteria are not met.

(Contd. on page 5)

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: Substrate

(Contd. of page 4)

- **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** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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 1 (German Regulation) (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**
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.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

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

(Contd. on page 6)

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

Printing date 05.02.2024

Version number 8

Revision: 05.02.2024

Trade name: Substrate

(Contd. of page 5)

· Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· ADR, IMDG, IATA	not regulated
· 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.

- **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.

· **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

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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