

Kit SDS Cover Sheet

PyroGene 192 Test Kit

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

Product Information

Product name : PyroGene 192 Test Kit

Material number : 50-658U

Components

rFC Substrate Vial	SDS attached
rFC Buffer	SDS attached
Endotoxin (E.coli) Low Conc in PEG/Lactose	SDS attached
Water LAL Reagent	SDS attached
Recombinant Factor C Enzyme Solution	SDS attached

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

rFC Substrate Vial

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : rFC Substrate Vial

Manufacturer or supplier's detailsCompany : Capsugel Australia Pty Ltd.
Suite 610, 12 Century Circuit,
Norwest NSW 2153, AustraliaLonza Ltd
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland

Telephone : Tel +61 3 9550 0883

Telefax : Tel +61 3 9550 0890

E-mail address : sds@lonza.com

Emergency telephone number : +41 61 313 94 94 (24h)

Recommended use of the chemical and restrictions on use

Recommended use : For Endotoxin Detection Use

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

No information available.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

If inhaled : No special precautions required.

In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.

SAFETY DATA SHEET

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Revision Date 30.06.2021

Print Date 24.07.2021

- | | | |
|---|---|--|
| If swallowed | : | Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person. |
| Most important symptoms and effects, both acute and delayed | : | No information available. |
| Notes to physician | : | No information available. |

SECTION 5. FIREFIGHTING MEASURES

- | | | |
|---|---|--|
| Suitable extinguishing media | : | Water spray
Dry powder
Foam |
| Hazardous combustion products | : | No hazardous combustion products are known |
| Specific extinguishing methods | : | Use water spray to cool unopened containers. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus. |

SECTION 6. ACCIDENTAL RELEASE MEASURES

- | | | |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment. |
| Environmental precautions | : | Try to prevent the material from entering drains or water courses. |
| Methods and materials for containment and cleaning up | : | Wipe up with absorbent material (e.g. cloth, fleece). |
| | | Dispose of in accordance with local regulations. |

SECTION 7. HANDLING AND STORAGE

- | | | |
|---|---|--|
| Advice on protection against fire and explosion | : | No special precautions required. |
| Advice on safe handling | : | No special precautions required. |
| Hygiene measures | : | Handle in accordance with good industrial hygiene and safety practice. |
| Conditions for safe storage | : | No special storage conditions required. |

SAFETY DATA SHEET

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : Avoid splashes.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Eye protection : Tightly fitting safety goggles

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Colour : no data available

Odour : no data available

Odour Threshold : no data available

pH : no data available

Melting point/freezing point : no data available

Initial boiling point and boiling range : no data available

Flash point : no data available

Evaporation rate : no data available

Flammability (solid, gas) : no data available

Flammability (liquids) : no data available

Upper explosion limit / upper flammability limit : no data available

Lower explosion limit / Lower : no data available

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flammability limit

Vapour pressure : no data available

Relative vapour density : no data available

Relative density : no data available

Density : no data available

Water solubility : no data available

Partition coefficient: n-octanol/water : no data available

Auto-ignition temperature : no data available

Decomposition temperature : no data available

Viscosity, dynamic : no data available

Viscosity, kinematic : no data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Stable under recommended storage conditions.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Stable under normal conditions.

Conditions to avoid : no data available

Incompatible materials : Strong oxidizing agents

Hazardous decomposition products : No decomposition if stored normally.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Acute oral toxicity : Remarks: no data available

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : Remarks: no data available

Skin corrosion/irritation

Remarks: no data available

Serious eye damage/eye irritation

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rFC Substrate Vial

Version 3.0

Revision Date 30.06.2021

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Remarks: no data available

Respiratory or skin sensitisation

Remarks: no data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

Carcinogenicity

Remarks: no data available

Reproductive toxicity

Effects on fertility : Remarks: no data available

STOT - single exposure

Remarks: no data available

STOT - repeated exposure

Remarks: no data available

Further information

Remarks: No data is available on the product itself.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Toxicity to fish : Remarks: no data available

Persistence and degradability

Biodegradability : Result: no data available

Bioaccumulative potential

Bioaccumulation : Remarks: no data available

Mobility in soil

Distribution among environmental compartments : Remarks: no data available

Other adverse effects

Additional ecological information : no data available

SECTION 13. DISPOSAL CONSIDERATIONS

SAFETY DATA SHEET

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rFC Substrate Vial

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Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

SECTION 14. TRANSPORT INFORMATION

IATA

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : no

IMDG

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : Marine pollutant: no

ADR

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : no

RID

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : no

Special precautions for user : none

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Standard for the Uniform Scheduling of Medicines and Poisons

Not applicable

SAFETY DATA SHEET

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SECTION 16. OTHER INFORMATION

Revision Date : 30.06.2021

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Date format : dd.mm.yyyy

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rFC Buffer

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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : rFC Buffer

Manufacturer or supplier's detailsCompany : Capsugel Australia Pty Ltd.
Suite 610, 12 Century Circuit,
Norwest NSW 2153, AustraliaLonza Ltd
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland

Telephone : Tel +61 3 9550 0883

Telefax : Tel +61 3 9550 0890

E-mail address : sds@lonza.com

Emergency telephone number : +41 61 313 94 94 (24h)

Recommended use of the chemical and restrictions on use

Recommended use : For Endotoxin Detection Use

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

No information available.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

If inhaled : No special precautions required.

In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.In case of eye contact : Immediately flush eye(s) with plenty of water.
If eye irritation persists, consult a specialist.

SAFETY DATA SHEET

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- | | | |
|---|---|--|
| If swallowed | : | Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person. |
| Most important symptoms and effects, both acute and delayed | : | No information available. |
| Notes to physician | : | No information available. |

SECTION 5. FIREFIGHTING MEASURES

- | | | |
|---|---|--|
| Suitable extinguishing media | : | Water spray
Dry powder
Foam |
| Hazardous combustion products | : | Carbon oxides (Cox) |
| Specific extinguishing methods | : | Use water spray to cool unopened containers. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus. |

SECTION 6. ACCIDENTAL RELEASE MEASURES

- | | | |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment. |
| Environmental precautions | : | Try to prevent the material from entering drains or water courses. |
| Methods and materials for containment and cleaning up | : | Dispose of in accordance with local regulations. |

SECTION 7. HANDLING AND STORAGE

- | | | |
|---|---|--|
| Advice on protection against fire and explosion | : | No special precautions required. |
| Advice on safe handling | : | No special precautions required. |
| Hygiene measures | : | Handle in accordance with good industrial hygiene and safety practice. |
| Conditions for safe storage | : | No special storage conditions required. |

SAFETY DATA SHEET

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : Avoid splashes.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Eye protection : Safety glasses with side-shields

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Colour : no data available

Odour : no data available

Odour Threshold : no data available

pH : no data available

Melting point/freezing point : no data available

Initial boiling point and boiling range : no data available

Flash point : no data available

Evaporation rate : no data available

Flammability (solid, gas) : no data available

Flammability (liquids) : no data available

Upper explosion limit / upper flammability limit : no data available

Lower explosion limit / Lower : no data available

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flammability limit

Vapour pressure : no data available

Relative vapour density : no data available

Relative density : no data available

Density : no data available

Water solubility : no data available

Partition coefficient: n-octanol/water : no data available

Auto-ignition temperature : no data available

Decomposition temperature : no data available

Viscosity, dynamic : no data available

Viscosity, kinematic : no data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Stable under recommended storage conditions.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Stable under normal conditions.

Conditions to avoid : no data available

Incompatible materials : Strong oxidizing agents

Hazardous decomposition products : No decomposition if stored normally.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Acute oral toxicity : Remarks: no data available

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : Remarks: no data available

Skin corrosion/irritation

Remarks: no data available

Serious eye damage/eye irritation

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Remarks: no data available

Respiratory or skin sensitisation

Remarks: no data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

Carcinogenicity

Remarks: no data available

Reproductive toxicity

Effects on fertility : Remarks: no data available

STOT - single exposure

Remarks: no data available

STOT - repeated exposure

Remarks: no data available

Further information

Remarks: No data is available on the product itself.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Toxicity to fish : Remarks: no data available

Persistence and degradability

Biodegradability : Result: no data available

Bioaccumulative potential

Bioaccumulation : Remarks: no data available

Mobility in soil

Distribution among environmental compartments : Remarks: no data available

Other adverse effects

Additional ecological information : no data available

SECTION 13. DISPOSAL CONSIDERATIONS

SAFETY DATA SHEET

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Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

SECTION 14. TRANSPORT INFORMATION

IATA

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : no

IMDG

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : Marine pollutant: no

ADR

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : no

RID

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : no

Special precautions for user : none

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Standard for the Uniform Scheduling of Medicines and Poisons

Not applicable

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Endotoxin (E.coli) Low Conc in PEG/Lactose

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Endotoxin (E.coli) Low Conc in PEG/Lactose

Manufacturer or supplier's details

Company : Capsugel Australia Pty Ltd.
Suite 610, 12 Century Circuit,
Norwest NSW 2153, Australia

Lonza Ltd
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland

Telephone : Tel +61 3 9550 0883

Telefax : Tel +61 3 9550 0890

E-mail address : sds@lonza.com

Emergency telephone number : +41 61 313 94 94 (24h)

Recommended use of the chemical and restrictions on use

Recommended use : For Endotoxin Detection Use

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

May form combustible dust concentrations in air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Substances with a workplace exposure limit		
Polyethylene glycol 8000	25322-68-3	

SECTION 4. FIRST AID MEASURES

If inhaled : Remove to fresh air.
If breathing is irregular or stopped, administer artificial respiration.
If symptoms persist, call a physician.

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Endotoxin (E.coli) Low Conc in PEG/Lactose

Version 3.0

Revision Date 30.06.2021

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In case of skin contact	: Wash off with soap and water.
In case of eye contact	: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Call a physician immediately.
If swallowed	: Clean mouth with water and drink afterwards plenty of water.
Most important symptoms and effects, both acute and delayed	: No information available.
Notes to physician	: No information available.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Dry powder Water spray Foam
Hazardous combustion products	: Carbon oxides (Cox)
Specific extinguishing methods	: Use water spray to cool unopened containers.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Avoid dust formation. Use personal protective equipment.
Environmental precautions	: No special environmental precautions required. Clean contaminated floors and objects thoroughly while observing environmental regulations.
Methods and materials for containment and cleaning up	: After cleaning, flush away traces with water. Dispose of in accordance with local regulations.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	: Avoid dust formation. Take precautionary measures against static discharges.
Advice on safe handling	: Avoid formation of respirable particles. Provide sufficient air exchange and/or exhaust in work rooms. Avoid contact with skin and eyes.
Hygiene measures	: Wash hands before breaks and immediately after handling the

SAFETY DATA SHEET

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Endotoxin (E.coli) Low Conc in PEG/Lactose

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product.
Avoid contact with skin, eyes and clothing.

Conditions for safe storage : Keep tightly closed in a dry and cool place.

Recommended storage temperature : 2 - 8 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Polyethylene glycol 8000	25322-68-3	TWA	10 mg/m3	WEEL

Engineering measures : Provide sufficient air exchange and/or exhaust in work rooms.

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.

Hand protection

Material : Nitrile rubber
Rate of permeability : > 480 min

Eye protection : Safety glasses with side-shields

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : white

Odour : odourless

Odour Threshold : no data available

pH : Not applicable

Melting point/freezing point : no data available

Initial boiling point and boiling range : no data available

SAFETY DATA SHEET

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Flash point	: Not applicable
Evaporation rate	: no data available
Flammability (solid, gas)	: no data available
Flammability (liquids)	: no data available
Upper explosion limit / upper flammability limit	: Not applicable
Lower explosion limit / Lower flammability limit	: Not applicable
Vapour pressure	: no data available
Relative vapour density	: Not applicable
Relative density	: no data available
Density	: no data available
Water solubility	: partly soluble
Partition coefficient: n-octanol/water	: no data available
Auto-ignition temperature	: Not applicable
Decomposition temperature	: no data available
Viscosity, dynamic	: no data available
Viscosity, kinematic	: Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: Stable under recommended storage conditions.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Stable under normal conditions.
Conditions to avoid	: Keep away from heat and sources of ignition.
Incompatible materials	: Strong oxidizing agents
Hazardous decomposition products	: No decomposition if stored normally.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

SAFETY DATA SHEET

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Acute inhalation toxicity : Remarks: no data available

Skin corrosion/irritation

Remarks: no data available

Serious eye damage/eye irritation

Remarks: no data available

Respiratory or skin sensitisation

Remarks: no data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

Carcinogenicity

Remarks: no data available

Reproductive toxicity

Effects on fertility : Remarks: no data available

STOT - single exposure

Remarks: no data available

STOT - repeated exposure

Remarks: no data available

Further information

Remarks: No data is available on the product itself.

The following toxicological data refer to:

Polyethylene glycol(CAS-No.: 25322-68-3)

Acute toxicity

Acute oral toxicity : LD50 (Rat): > 20 g/kg

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : LD50 (Rabbit): > 20 g/kg

Skin corrosion/irritation

Species: Rabbit

Result: Mild skin irritation

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Serious eye damage/eye irritation

Species: Rabbit

Result: Mild eye irritation

Respiratory or skin sensitisation

Species: Guinea pig

Result: not sensitizing

Germ cell mutagenicity

Genotoxicity in vitro

: Test Type: Ames test

Result: negative

STOT - single exposure

Remarks: no data available

STOT - repeated exposure

Remarks: no data available

Aspiration toxicity

No aspiration toxicity classification

Further information

Remarks: no data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Toxicity to fish

: Remarks: no data available

Persistence and degradability

Biodegradability

: Result: no data available

Bioaccumulative potential

Bioaccumulation

: Remarks: no data available

Mobility in soil

Distribution among environmental compartments

: Remarks: no data available

Other adverse effects

Additional ecological information

: No data is available on the product itself.

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Endotoxin (E.coli) Low Conc in PEG/Lactose

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

SECTION 14. TRANSPORT INFORMATION

IATA

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : no

IMDG

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : Marine pollutant: no

ADR

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : no

RID

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : no

Special precautions for user : none

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not applicable

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Endotoxin (E.coli) Low Conc in PEG/Lactose

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Standard for the Uniform Scheduling of Medicines and Poisons

Not applicable

SECTION 16. OTHER INFORMATION

Revision Date : 30.06.2021

Full text of other abbreviations

WEEL : US. OARS. WEELs Workplace Environmental Exposure Level Guide, as amended

WEEL / TWA : Time weighted average

AIRC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Date format : dd.mm.yyyy

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Endotoxin (E.coli) Low Conc in PEG/Lactose

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

AU / EN

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Water LAL Reagent

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Water LAL Reagent

Manufacturer or supplier's detailsCompany : Capsugel Australia Pty Ltd.
Suite 610, 12 Century Circuit,
Norwest NSW 2153, AustraliaLonza Ltd
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland

Telephone : Tel +61 3 9550 0883

Telefax : Tel +61 3 9550 0890

E-mail address : sds@lonza.com

Emergency telephone number : +41 61 313 94 94 (24h)

Recommended use of the chemical and restrictions on use

Recommended use : Scientific research and development

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

No information available.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Substance

CAS-No. : 7732-18-5

Hazardous components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

If inhaled : No hazards which require special first aid measures.

In case of skin contact : No hazards which require special first aid measures.

In case of eye contact : No hazards which require special first aid measures.

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Water LAL Reagent

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

- | | | |
|---|---|--|
| If swallowed | : | No hazards which require special first aid measures. |
| Most important symptoms and effects, both acute and delayed | : | No information available. |
| Notes to physician | : | No information available. |

SECTION 5. FIREFIGHTING MEASURES

- | | | |
|---|---|---|
| Suitable extinguishing media | : | Not combustible.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| Hazardous combustion products | : | No hazardous combustion products are known |
| Specific extinguishing methods | : | Use water spray to cool unopened containers. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus. |

SECTION 6. ACCIDENTAL RELEASE MEASURES

- | | | |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Refer to protective measures listed in sections 7 and 8. |
| Environmental precautions | : | No special environmental precautions required. |
| Methods and materials for containment and cleaning up | : | Wipe up with absorbent material (e.g. cloth, fleece). |

SECTION 7. HANDLING AND STORAGE

- | | | |
|---|---|--|
| Advice on protection against fire and explosion | : | Stable under normal conditions. |
| Hygiene measures | : | Handle in accordance with good industrial hygiene and safety practice. |
| Conditions for safe storage | : | No special storage conditions required.
Keep container tightly closed.
To maintain product quality, do not store in heat or direct sunlight. |

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Water LAL Reagent

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : Provide sufficient air exchange and/or exhaust in work rooms.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Remarks : Wear suitable gloves. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time.

Eye protection : No special precautions required.

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place. No special protective equipment required.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Colour : colourless

Odour : odourless

Odour Threshold : no data available

pH : no data available

Melting point/freezing point : 0,1 °C

Initial boiling point and boiling range : 100 °C

Flash point : does not flash

Evaporation rate : no data available

Flammability (solid, gas) : no data available

Flammability (liquids) : Does not sustain combustion.

Upper explosion limit / upper flammability limit : no data available

Lower explosion limit / Lower : no data available

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Water LAL Reagent

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

flammability limit	
Vapour pressure	: 23 mbar (20 °C)
Relative vapour density	: no data available
Relative density	: 1
Density	: 1 g/cm ³ (4 °C)
Water solubility	: soluble
Partition coefficient: n-octanol/water	: no data available
Auto-ignition temperature	: no data available
Decomposition temperature	: no data available
Viscosity, dynamic	: no data available
Viscosity, kinematic	: no data available
Molecular weight	: 18,01 g/mol

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: Stable under recommended storage conditions.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Stable under normal conditions.
Conditions to avoid	: Not applicable
Incompatible materials	: none
Hazardous decomposition products	: No decomposition if stored normally.

SECTION 11. TOXICOLOGICAL INFORMATION

Germ cell mutagenicity

Genotoxicity in vitro	: Test Type: Ames test Result: negative
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Further information

Remarks: No data is available on the product itself.

SECTION 12. ECOLOGICAL INFORMATION

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Water LAL Reagent

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

Ecotoxicity

Toxicity to fish : Remarks: Not applicable

Persistence and degradability

Biodegradability : Remarks: Not applicable

Bioaccumulative potential

Bioaccumulation : Remarks: Not applicable

Mobility in soil

Distribution among environmental compartments : Remarks: Not applicable

Other adverse effects

Additional ecological information : Not applicable

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

SECTION 14. TRANSPORT INFORMATION

IATA

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : no

IMDG

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : Marine pollutant: no

ADR

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : no

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Water LAL Reagent

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

RID : Not dangerous goods

UN number : Not applicable
Proper shipping name : Not applicable
Transport hazard class : Not applicable
Packing group : Not applicable
Environmental hazards : no

Special precautions for user : none

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Standard for the Uniform Scheduling of Medicines and Poisons

Not applicable

SECTION 16. OTHER INFORMATION

Revision Date : 30.06.2021

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Water LAL Reagent

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System
Date format : dd.mm.yyyy

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SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Recombinant Factor C Enzyme Solution

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Recombinant Factor C Enzyme Solution

Manufacturer or supplier's details

Company : Capsugel Australia Pty Ltd.
Suite 610, 12 Century Circuit,
Norwest NSW 2153, Australia

Lonza Ltd
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland

Telephone : Tel +61 3 9550 0883

Telefax : Tel +61 3 9550 0890

E-mail address : sds@lonza.com

Emergency telephone number : +41 61 313 94 94 (24h)

Recommended use of the chemical and restrictions on use

Recommended use : For Endotoxin Detection Use

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

No information available.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Substances with a workplace exposure limit		
Sucrose	57-50-1	

SECTION 4. FIRST AID MEASURES

If inhaled : No special precautions required.

In case of skin contact : Wash with water and soap as a precaution.
If skin irritation persists, call a physician.

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Recombinant Factor C Enzyme Solution

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

In case of eye contact	: Immediately flush eye(s) with plenty of water. If eye irritation persists, consult a specialist.
If swallowed	: Immediately give large quantities of water to drink. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	: No information available.
Notes to physician	: No information available.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Dry powder Foam
Hazardous combustion products	: No hazardous combustion products are known
Specific extinguishing methods	: Use water spray to cool unopened containers.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment.
Environmental precautions	: Prevent product from entering drains.
Methods and materials for containment and cleaning up	: Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	: Take precautionary measures against static discharges.
Advice on safe handling	: No special precautions required.
Hygiene measures	: Handle in accordance with good industrial hygiene and safety practice.
Conditions for safe storage	: No special storage conditions required.

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Recombinant Factor C Enzyme Solution

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sucrose	57-50-1	TWA (Inhalable dust.)	10 mg/m ³	AU NOEL
		TWA (Inspirable dust.)	10 mg/m ³	AU OEL
		TWA	10 mg/m ³	ACGIH

Engineering measures : Avoid splashes.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Eye protection : Tightly fitting safety goggles

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Colour : clear, yellow

Odour : no data available

Odour Threshold : no data available

pH : 5,7 - 6,3

Melting point/freezing point : no data available

Initial boiling point and boiling range : no data available

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Recombinant Factor C Enzyme Solution

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

Flash point	: no data available
Evaporation rate	: no data available
Flammability (solid, gas)	: no data available
Flammability (liquids)	: no data available
Upper explosion limit / upper flammability limit	: no data available
Lower explosion limit / Lower flammability limit	: no data available
Vapour pressure	: no data available
Relative vapour density	: no data available
Relative density	: no data available
Density	: no data available
Water solubility	: no data available
Partition coefficient: n-octanol/water	: no data available
Auto-ignition temperature	: no data available
Decomposition temperature	: no data available
Viscosity, dynamic	: no data available
Viscosity, kinematic	: no data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: Stable under recommended storage conditions.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Stable under normal conditions.
Conditions to avoid	: no data available
Incompatible materials	: Strong oxidizing agents
Hazardous decomposition products	: No decomposition if stored normally.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Recombinant Factor C Enzyme Solution

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

Acute oral toxicity : Remarks: no data available

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : Remarks: no data available

Skin corrosion/irritation

Remarks: no data available

Serious eye damage/eye irritation

Remarks: no data available

Respiratory or skin sensitisation

Remarks: no data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

Carcinogenicity

Remarks: no data available

Reproductive toxicity

Effects on fertility : Remarks: no data available

STOT - single exposure

Remarks: no data available

STOT - repeated exposure

Remarks: no data available

Further information

Remarks: No data is available on the product itself.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Toxicity to fish : Remarks: no data available

Persistence and degradability

Biodegradability : Result: no data available

Bioaccumulative potential

Bioaccumulation : Remarks: no data available

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Recombinant Factor C Enzyme Solution

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

Mobility in soil

Distribution among environmental compartments : Remarks: no data available

Other adverse effects

Additional ecological information : no data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

SECTION 14. TRANSPORT INFORMATION

IATA

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : no

IMDG

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : Marine pollutant: no

ADR

Not dangerous goods

UN number : Not applicable
 Proper shipping name : Not applicable
 Transport hazard class : Not applicable
 Packing group : Not applicable
 Environmental hazards : no

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Recombinant Factor C Enzyme Solution

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

RID	:	Not dangerous goods
UN number	:	Not applicable
Proper shipping name	:	Not applicable
Transport hazard class	:	Not applicable
Packing group	:	Not applicable
Environmental hazards	:	no
Special precautions for user	:	none
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	:	Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Standard for the Uniform Scheduling of Medicines and Poisons

Not applicable

SECTION 16. OTHER INFORMATION

Revision Date : 30.06.2021

Full text of other abbreviations

ACGIH	:	US. ACGIH Threshold Limit Values
AU NOEL	:	Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A), as amended
AU OEL	:	Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)
ACGIH / TWA	:	Time weighted average
AU NOEL / TWA	:	Time weighted average
AU OEL / TWA	:	Time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Recombinant Factor C Enzyme Solution

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Date format : dd.mm.yyyy

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