

Kit SDS Cover Sheet PYROGENT-5000 100 Test Kit

Version 3.0 Revision Date 30.06.2021 Print Date 24.07.2021

Product Information

Product name : PYROGENT-5000 100 Test Kit

Material number : N383

Components

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

PBS-1X, W/O CA++, MG++

SDS attached

Pyrogent-5000 Lysate Vial

SDS attached

Ref. KT-0000056 / KT-0000056 Page 1 (25)



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 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.



according to Work Health and Safety Regulations 2011

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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.

No information available. Notes to physician

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



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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	Control	Basis
		(Form of	parameters /	
		exposure)	Permissible	
			concentration	
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



according to Work Health and Safety Regulations 2011

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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



according to Work Health and Safety Regulations 2011

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

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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.



according to Work Health and Safety Regulations 2011

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

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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

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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

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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



according to Work Health and Safety Regulations 2011

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

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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

AllC - 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



according to Work Health and Safety Regulations 2011

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according to Work Health and Safety Regulations 2011

PBS-1X, W/O CA++, MG++

Version 3.0 Revision Date 30.06.2021 Print Date 24.07.2021

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : PBS-1X, W/O CA++, MG++

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

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.



according to Work Health and Safety Regulations 2011

PBS-1X, W/O CA++, MG++

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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.

No information available. Notes to physician

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

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).

Use personal protective equipment.

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.

Handle in accordance with good industrial hygiene and safety Hygiene measures

practice.

Conditions for safe storage : No special storage conditions required.

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PBS-1X, W/O CA++, MG++

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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 : colourless

Odour : no data available

Odour Threshold : no data available

pH : 7,3 - 7,5

Melting point/freezing point : no data available

Initial boiling point and boiling range : ca. 100 °C

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



according to Work Health and Safety Regulations 2011

PBS-1X, W/O CA++, MG++

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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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according to Work Health and Safety Regulations 2011

PBS-1X, W/O CA++, MG++

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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



according to Work Health and Safety Regulations 2011

PBS-1X, W/O CA++, MG++

Version 3.0 Revision Date 30.06.2021 Print Date 24.07.2021

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

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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

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RID Not dangerous goods

UN number: Not applicableProper shipping name: Not applicableTransport hazard class: Not applicablePacking 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



according to Work Health and Safety Regulations 2011

PBS-1X, W/O CA++, MG++

Version 3.0 Revision Date 30.06.2021 Print Date 24.07.2021

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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AU / EN

Lonza

according to Work Health and Safety Regulations 2011

Pyrogent-5000 Lysate Vial

Version 3.0 Revision Date 30.06.2021 Print Date 24.07.2021

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Pyrogent-5000 Lysate Vial

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		
Pentaerythritol	115-77-5	

SECTION 4. FIRST AID MEASURES

If inhaled : No special precautions required.

In case of skin contact : After contact with skin, wash immediately with plenty of soap

and water.

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Pyrogent-5000 Lysate Vial

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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.

If swallowed : If swallowed, do not induce vomiting - seek medical advice.

Immediately give large quantities of water to drink.

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 : Dry powder

Water spray Foam

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Chlorine
Magnesium oxides
Carbon oxides (Cox)

Hydrogen chloride (HCI)

Specific extinguishing methods : Use water spray to cool unopened containers.

Special protective equipment for

Hazardous combustion products

firefighters

In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective

equipment and emergency

procedures

Environmental precautions

: Use personal protective equipment.

Avoid dust formation.

: 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 : Minimize dust generation and accumulation.

Routine housekeeping should be instituted to ensure that dusts

do not accumulate on surfaces.

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Pyrogent-5000 Lysate Vial

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Dry powders can build static electricity charges when subjected

to the friction of transfer and mixing operations.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Hygiene measures : Handle in accordance with good industrial hygiene and safety

practice.

Conditions for safe storage : No special storage conditions required.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Pentaerythritol	115-77-5	TWA (Inhalable dust.)	10 mg/m3	AU NOEL
		TWA (Inspirable dust.)	10 mg/m3	AU OEL
		TWA	10 mg/m3	ACGIH

Engineering measures : It is recommended that all dust control equipment such as

local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen

deficient environment.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Use only appropriately classified electrical equipment and

powered industrial trucks.

Personal protective equipment

Respiratory protection : Respirator must be worn if exposed to dust.

Hand protection

Material : Nitrile rubber Rate of permeability : > 480 min

Eye protection : Safety glasses with side-shields

Skin and body protection : No special protective equipment required.

Lonza

according to Work Health and Safety Regulations 2011

Pyrogent-5000 Lysate Vial

Version 3.0 Revision Date 30.06.2021 Print Date 24.07.2021

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : (lyophilised)

Colour : white

Odour : no data available

Odour Threshold : no data available

pH : Not applicable

Melting point/freezing point : no data available

Initial boiling point and boiling range : no data available

Flash point : Not applicable

Evaporation rate : no data available

Flammability (solid, gas) : May form combustible dust concentrations in air.

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 : no data available

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



according to Work Health and Safety Regulations 2011

Pyrogent-5000 Lysate Vial

Version 3.0 Revision Date 30.06.2021 Print Date 24.07.2021

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

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.

Lonza

according to Work Health and Safety Regulations 2011

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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

Disposal methods

Waste from residues : Dispose of contents/container in accordance with local

regulation.

Contact waste disposal services.

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

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ADR

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according to Work Health and Safety Regulations 2011

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Not dangerous goods

UN number Not applicable Not applicable Proper shipping name Not applicable **Transport hazard class** Packing group Not applicable

Environmental hazards

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

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Full text of other abbreviations

ACGIH US. ACGIH Threshold Limit Values

Australia. National Workplace OELs (Workplace Exposure **AU NOEL**

Standards for Airborne Contaminants, Appendix A), as

amended

Australia. OELs. (Adopted National Exposure Standards for **AU OEL**

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 -



according to Work Health and Safety Regulations 2011

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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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