

**Kit SDS Cover Sheet****Pyrogen-5000 Bulk Kit 4500 Test Kit**

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

---

**Product Information**

Product name : Pyrogen-5000 Bulk Kit 4500 Test Kit

Material number : N688

**Components**

Pyrogen-5000 Lysate Vial

SDS attached

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

SDS attached

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

SDS attached

**SAFETY DATA SHEET**

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, 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**

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.

**SAFETY DATA SHEET**

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

---

		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
Hazardous combustion products	:	Chlorine Magnesium oxides Carbon oxides (Cox) Hydrogen chloride (HCl)
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. Avoid dust formation.
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	:	Minimize dust generation and accumulation. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces.

## SAFETY DATA SHEET

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

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/m <sup>3</sup>	AU NOEL
		TWA (Inspirable dust.)	10 mg/m <sup>3</sup>	AU OEL
		TWA	10 mg/m <sup>3</sup>	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.

**SAFETY DATA SHEET**

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**

**SAFETY DATA SHEET**

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.

**SAFETY DATA SHEET**

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 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

## SAFETY DATA SHEET

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

**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

## 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 -



**SAFETY DATA SHEET**

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

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

**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

**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, 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**

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

---

- 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

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

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

**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 : &gt; 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

**SAFETY DATA SHEET**

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

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**

**SAFETY DATA SHEET**

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

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

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

**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**

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**

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

**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

### 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

Print Date 24.07.2021

---

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

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

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/m <sup>3</sup>	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**

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

---

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**

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

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): &gt; 20 g/kg

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : LD50 (Rabbit): &gt; 20 g/kg

**Skin corrosion/irritation**

Species: Rabbit

Result: Mild skin irritation

**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

**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

AIIIC - 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