

## Kit SDS Cover Sheet

### Pyrogen-5000 Bulk Kit 100 Vials/Kit

Version 2.0

Revision Date 30.06.2021

Print Date 24.07.2021

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#### Product Information

Product name : Pyrogen-5000 Bulk Kit 100 Vials/Kit

Material number : T50-300U

#### Components

Pyrogen-5000 Lysate Vial

SDS attached

## SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

### Pyrogent-5000 Lysate Vial

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#### 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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		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.

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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/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.

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**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**

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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.

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



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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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