

Kit SDS Cover Sheet
PYROGENT Plus 64 Tests 0.06 EU/ml Sens

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

Product Information

Product name : PYROGENT Plus 64 Tests 0.06 EU/ml Sens

Material number : N283-06

Components

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

SDS attached

Pyrogent, 1.8 ml Vial 0.06 EU/ml

SDS attached

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 ³	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): > 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

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 informationRemarks: 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.

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SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Pyrogen, 1.8 ml Vial 0.06 EU/ml

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Pyrogen, 1.8 ml Vial 0.06 EU/ml

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**

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 2A

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H315 Causes skin irritation.
H319 Causes serious eye irritation.Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.**Response:**P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water
for several minutes. Remove contact lenses, if present and
easy to do. Continue rinsing.
P332 + P313 If skin irritation occurs: Get medical advice/
attention.

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Pyrogen, 1.8 ml Vial 0.06 EU/ml

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

P337 + P313 If eye irritation persists: Get medical advice/attention.

P362 Take off contaminated clothing.

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)
Sodium hydroxide	1310-73-2	>= 0,5 - < 1

SECTION 4. FIRST AID MEASURES

- If inhaled : Remove to fresh air.
If breathing is irregular or stopped, administer artificial respiration.
- In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.
Consult a physician.
- 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 : Call a physician immediately.
Clean mouth with water and drink afterwards plenty of water.
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 : Chlorine
Magnesium oxides
Nitrogen oxides (NOx)
Carbon oxides (Cox)
Hydrogen chloride (HCl)

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Pyrogen, 1.8 ml Vial 0.06 EU/ml

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

- 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 : 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 : Provide sufficient air exchange and/or exhaust in work rooms.
Avoid formation of respirable particles.
Avoid contact with skin and eyes.
- Minimize dust generation and accumulation.
Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces.
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 : Avoid contact with skin, eyes and clothing.
Wash hands before breaks and immediately after handling the product.
- 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

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Pyrogen, 1.8 ml Vial 0.06 EU/ml

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

Sodium hydroxide	1310-73-2	PEAK	2 mg/m3	AU NOEL
			2 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 : 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 : (lyophilised)
- Colour : no data available
- 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) : no data available

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Pyrogen, 1.8 ml Vial 0.06 EU/ml

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

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

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

Skin corrosion/irritation

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Pyrogen, 1.8 ml Vial 0.06 EU/ml

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

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

Components:**Sodium hydroxide:**

Partition coefficient: n-octanol/water : Remarks: Not applicable

Mobility in soil

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Pyrogen, 1.8 ml Vial 0.06 EU/ml

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

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.

Contaminated packaging : Dispose of as unused product.

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

Pyrogen, 1.8 ml Vial 0.06 EU/ml

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

ACGIH / : Maximum limit value:
 AU NOEL / PEAK : Peak Limitation:

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

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Pyrogen, 1.8 ml Vial 0.06 EU/ml

Version 3.0

Revision Date 30.06.2021

Print Date 24.07.2021

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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