

Kit SDS Cover Sheet**PYROGENT-5000 RECONSTITUTION BUFFER**

Version 2.0

Revision Date 30.06.2021

Print Date 24.07.2021

Product Information

Product name : PYROGENT-5000 RECONSTITUTION BUFFER

Material number : B50-600U

Components

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

SDS attached

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

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

Version 2.0

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

Telephone : Tel +61 3 9550 0883

Telefax : Tel +61 3 9550 0890

E-mail address : sds@lonza.com

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

Recommended use of the chemical and restrictions on use

Recommended use : For Endotoxin Detection Use

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

No information available.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

If inhaled : No special precautions required.

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

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

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

Version 2.0

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 2.0

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 : > 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 2.0

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 2.0

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 2.0

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 2.0

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

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