

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 : B50-300L

Components

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

SDS attached

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

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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.

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|---|---|--|
| If swallowed | : | Immediately give large quantities of water to drink.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person. |
| Most important symptoms and effects, both acute and delayed | : | No information available. |
| 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. |

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : Avoid splashes.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Eye protection : Tightly fitting safety goggles

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Colour : colourless

Odour : no data available

Odour Threshold : no data available

pH : 7,3 - 7,5

Melting point/freezing point : no data available

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

Flash point : no data available

Evaporation rate : no data available

Flammability (solid, gas) : no data available

Flammability (liquids) : no data available

Upper explosion limit / upper flammability limit : no data available

Lower explosion limit / Lower : no data available

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flammability limit

Vapour pressure : no data available

Relative vapour density : no data available

Relative density : no data available

Density : no data available

Water solubility : no data available

Partition coefficient: n-octanol/water : no data available

Auto-ignition temperature : no data available

Decomposition temperature : no data available

Viscosity, dynamic : no data available

Viscosity, kinematic : no data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Stable under recommended storage conditions.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Stable under normal conditions.

Conditions to avoid : no data available

Incompatible materials : Strong oxidizing agents

Hazardous decomposition products : No decomposition if stored normally.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Acute oral toxicity : Remarks: no data available

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : Remarks: no data available

Skin corrosion/irritation

Remarks: no data available

Serious eye damage/eye irritation

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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

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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

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SECTION 16. OTHER INFORMATION

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Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Date format : dd.mm.yyyy

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