

Kit SDS Cover Sheet

Endotoxin Challenge Vials 25 vials/kit

Version 2.0

Revision Date 30.06.2021

Print Date 24.07.2021

Product Information

Product name : Endotoxin Challenge Vials 25 vials/kit

Material number : 00192568

Components

Lipopolysaccharides from Escherichia coli High Concentration

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 : Lipopolysaccharides from Escherichia coli High Concentration

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 : Endotoxin Indicator for Depyrogenation

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 : Substance
Substance name : Lipopolysaccharide

Hazardous components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

If inhaled : No special precautions required.

In case of skin contact : Wash off with soap and water.

In case of eye contact : Immediately flush eye(s) with plenty of water.

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- If eye irritation persists, consult a specialist.
- 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 : 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.
Avoid dust formation.
- 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.
During processing, dust may form explosive mixture in air.
- Advice on safe handling : 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 : Handle in accordance with good industrial hygiene and safety practice.

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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

Contains no substances with occupational exposure limit values.

Engineering measures : Provide sufficient air exchange and/or exhaust in work rooms.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder, (lyophilised)

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

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

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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	: no data available
Incompatible materials	: Strong oxidizing agents
Hazardous decomposition products	: No decomposition if stored normally.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Acute inhalation toxicity : Remarks: no data available

Skin corrosion/irritation

Remarks: no data available

Serious eye damage/eye irritation

Remarks: no data available

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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

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

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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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