

# Kit SDS Cover Sheet TheraPEAK™ MSCGM™ BulletKit, 1L

Version 2.0 Revision Date 30.06.2021 Print Date 19.04.2024

## **Product Information**

Product name : TheraPEAK™ MSCGM™ BulletKit, 1L

Material number : BEBP18-936

## Components

TheraPEAK™ MSCBM™ SDS attached
TheraPEAK™ MSCGM™ Supplement SDS attached

Ref. KT-0000777 / KT-0000777 Page 1 (17)



LONZO SAFETY DATA SHEET according to Work Health and Safety Regulations 2011

## TheraPEAK™ MSCBM™

Version 2.0 Revision Date 30.06.2021 Print Date 19.04.2024

#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

: TheraPEAK™ MSCBM™ Product name

Manufacturer or supplier's details

: Capsugel Australia Pty Ltd. Company

> 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 Further Manufacturing or Laboratory Use. Performance

characteristics have not been established.

#### **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.

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

according to Work Health and Safety Regulations 2011

## TheraPEAK™ MSCBM™

Print Date 19.04.2024 Version 2.0 Revision Date 30.06.2021

If eye irritation persists, consult a specialist.

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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according to Work Health and Safety Regulations 2011

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Version 2.0 Revision Date 30.06.2021 Print Date 19.04.2024

#### 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 : no data available

Odour : no data available

Odour Threshold : no data available

pH : 6,8 - 7,3

Melting point/freezing point : no data available

Initial boiling point and boiling range : no data available

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



according to Work Health and Safety Regulations 2011

## TheraPEAK™ MSCBM™

Version 2.0 Revision Date 30.06.2021 Print Date 19.04.2024

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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## TheraPEAK™ MSCBM™

Version 2.0 Revision Date 30.06.2021 Print Date 19.04.2024

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**



according to Work Health and Safety Regulations 2011

## TheraPEAK™ MSCBM™

Version 2.0 Revision Date 30.06.2021 Print Date 19.04.2024

**Disposal methods** 

Waste from residues : Dispose of contents/container in accordance with local

regulation.

Contact waste disposal services.

Solutions with high pH-value must be neutralized before

discharge.

#### **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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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

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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



according to Work Health and Safety Regulations 2011

## TheraPEAK™ MSCBM™

Version 2.0 Revision Date 30.06.2021 Print Date 19.04.2024

#### **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

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.

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according to Work Health and Safety Regulations 2011

# TheraPEAK™ MSCBM™

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Lonza

according to Work Health and Safety Regulations 2011

## TheraPEAK™ MSCGM™ Supplement

Version 2.0 Revision Date 30.06.2021 Print Date 19.04.2024

#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : TheraPEAK™ MSCGM™ Supplement

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 Further Manufacturing or Laboratory Use. Performance

characteristics have not been established.

#### **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.

according to Work Health and Safety Regulations 2011

## TheraPEAK™ MSCGM™ Supplement

Version 2.0 Revision Date 30.06.2021 Print Date 19.04.2024

If eye irritation persists, consult a specialist.

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

Nitrogen oxides (NOx) 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

Environmental precautions

procedures

Methods and materials for

containment and cleaning up

Prevent product from entering drains.

Use personal protective equipment.

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.

: No special precautions required. Advice on safe handling

: Handle in accordance with good industrial hygiene and safety Hygiene measures

practice.

: No special storage conditions required. Conditions for safe storage

according to Work Health and Safety Regulations 2011



## TheraPEAK™ MSCGM™ Supplement

Version 2.0 Revision Date 30.06.2021 Print Date 19.04.2024

#### 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 no data available

Odour no data available

Odour Threshold no data available

рΗ no data available

Melting point/freezing point no data available

Initial boiling point and boiling range no data available

no data available Flash point

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



according to Work Health and Safety Regulations 2011

## TheraPEAK™ MSCGM™ Supplement

Version 2.0 Revision Date 30.06.2021 Print Date 19.04.2024

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

Lonza

according to Work Health and Safety Regulations 2011

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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**



according to Work Health and Safety Regulations 2011

## TheraPEAK™ MSCGM™ Supplement

Version 2.0 Revision Date 30.06.2021 Print Date 19.04.2024

**Disposal methods** 

Waste from residues : Dispose of contents/container in accordance with local

regulation.

Contact waste disposal services.

Solutions with high pH-value must be neutralized before

discharge.

#### **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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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

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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



according to Work Health and Safety Regulations 2011

## TheraPEAK™ MSCGM™ Supplement

Version 2.0 Revision Date 30.06.2021 Print Date 19.04.2024

#### **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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Date format : dd.mm.yyyy

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