

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

Version 3.0

Revision Date 30.04.2024

Print Date 18.05.2025

Product Information

Product name : TheraPEAK™ MSCGM™ BulletKit, 1L

Material number : BEBP18-936

Components

TheraPEAK™ MSCBM™

SDS attached

TheraPEAK™ MSCGM™ Supplement

SDS attached

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

TheraPEAK™ MSCBM™

Version 3.0

Revision Date 30.04.2024

Print Date 18.05.2025

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : TheraPEAK™ MSCBM™

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 : Suitable for GMP manufacturing.

Restrictions on use : Not for human or animal in vivo or diagnostic 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.

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

TheraPEAK™ MSCBM™

Version 3.0

Revision Date 30.04.2024

Print Date 18.05.2025

		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.
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.

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

TheraPEAK™ MSCBM™

Version 3.0

Revision Date 30.04.2024

Print Date 18.05.2025

Conditions for safe storage : No special storage conditions required.

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

No data available

Evaporation rate : No data available

Flammability (solid, gas) : No data available

Flammability (liquids) : No data available

SAFETY DATA SHEET

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TheraPEAK™ MSCBM™

Version 3.0

Revision Date 30.04.2024

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Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
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

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

TheraPEAK™ MSCBM™

Version 3.0

Revision Date 30.04.2024

Print Date 18.05.2025

Acute dermal toxicity

: Remarks: No data available

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

TheraPEAK™ MSCBM™

Version 3.0

Revision Date 30.04.2024

Print Date 18.05.2025

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

ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

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

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

TheraPEAK™ MSCBM™

Version 3.0

Revision Date 30.04.2024

Print Date 18.05.2025

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.**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**IMDG**

Not dangerous goods

UN number : Not applicable
Proper shipping name : Not applicable
Transport hazard class(es) : 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

TheraPEAK™ MSCBM™

Version 3.0

Revision Date 30.04.2024

Print Date 18.05.2025

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

Therapeutic Goods (Poisons Standard) Instrument

Not applicable

SECTION 16. OTHER INFORMATION

Revision Date : 30.04.2024

Date format : dd.mm.yyyy

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)

SAFETY DATA SHEET

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TheraPEAK™ MSCBM™

Version 3.0

Revision Date 30.04.2024

Print Date 18.05.2025

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

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

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TheraPEAK™ MSCGM™ Supplement

Version 3.0

Revision Date 30.04.2024

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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : TheraPEAK™ MSCGM™ Supplement

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 : Suitable for GMP manufacturing.

Restrictions on use : Not for human or animal in vivo or diagnostic 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.

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

TheraPEAK™ MSCGM™ Supplement

Version 3.0

Revision Date 30.04.2024

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		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.
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	:	Nitrogen oxides (NOx) 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	:	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.

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

TheraPEAK™ MSCGM™ Supplement

Version 3.0

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Conditions for safe storage : No special storage conditions required.

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 : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

No data available

Evaporation rate : No data available

Flammability (solid, gas) : No data available

Flammability (liquids) : No data available

SAFETY DATA SHEET

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TheraPEAK™ MSCGM™ Supplement

Version 3.0

Revision Date 30.04.2024

Print Date 18.05.2025

Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
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

SAFETY DATA SHEET

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TheraPEAK™ MSCGM™ Supplement

Version 3.0

Revision Date 30.04.2024

Print Date 18.05.2025

Acute dermal toxicity

: Remarks: No data available

SAFETY DATA SHEET

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TheraPEAK™ MSCGM™ Supplement

Version 3.0

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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

ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

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

SAFETY DATA SHEET

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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.**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**IMDG**

Not dangerous goods

UN number : Not applicable
Proper shipping name : Not applicable
Transport hazard class(es) : 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

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TheraPEAK™ MSCGM™ Supplement

Version 3.0

Revision Date 30.04.2024

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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

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Therapeutic Goods (Poisons Standard) Instrument

Not applicable

SECTION 16. OTHER INFORMATION

Revision Date : 30.04.2024

Date format : dd.mm.yyyy

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)

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