

## SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

### UltraCULTURE SF Medium, w/o L-Gln

Version 3.0

Revision Date 16.04.2024

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#### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : UltraCULTURE SF Medium, w/o L-Gln

Material number : BP12-725F

##### 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 : 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

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### 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.
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

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	practice.
Conditions for safe storage	: No special storage conditions required.
Recommended storage temperature	: 2 - 8 °C
Further information on storage stability	: Recommended storage temperature

## 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	: 7,0 - 7,4
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

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Flammability (liquids)	: No data available
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	: 1,006 g/cm <sup>3</sup>
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

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## 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.

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## 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
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### 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

### 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.

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## 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

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## 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

**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

**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** : 16.04.2024

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

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### Full text of other abbreviations

AIIIC - 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

**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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