

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Reliant™ Gel System

Version 3.0

Revision Date 16.04.2024

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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Reliant™ Gel System

Material number : 54820

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 research use only.

Restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN
OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Reproductive toxicity : Category 1B

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H360 May damage fertility or the unborn child.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been
read and understood.
P281 Use personal protective equipment as required.

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Response:

P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to a local hazardous waste disposal facility.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Boric acid	10043-35-3	>= 0,3 - < 0,5

SECTION 4. FIRST AID MEASURES

- If inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
Keep respiratory tract clear.
If breathing is irregular or stopped, administer artificial respiration.
- In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.
If on clothes, remove clothes.
In the case of skin irritation or allergic reactions see a physician.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Keep eye wide open while rinsing.
Protect unharmed eye.
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
- Most important symptoms and effects, both acute and delayed : No information available.
- Notes to physician : Treat symptomatically.

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SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Dry chemical
Specific hazards during firefighting	: Heating or fire can release toxic gas.
Hazardous combustion products	: Carbon oxides (COx)
Specific extinguishing methods	: Use a water spray to cool fully closed containers.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: In the case of respirable dust and/or fumes, use self-contained breathing apparatus and dust impervious protective suit. Use personal protective equipment.
Environmental precautions	: Prevent product from entering drains. Prevent further leakage or spillage if safe to do so.
Methods and materials for containment and cleaning up	: Pick up and arrange disposal without creating dust. Shovel into suitable container for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	: Normal measures for preventive fire protection.
Advice on safe handling	: Avoid formation of respirable particles. Do not breathe vapours/dust. Smoking, eating and drinking should be prohibited in the application area. For personal protection see section 8. Provide sufficient air exchange and/or exhaust in work rooms. Dispose of rinse water in accordance with local and national regulations.
Hygiene measures	: Wash hands before breaks and at the end of workday. Avoid contact with skin, eyes and clothing.
Conditions for safe storage	: Observe label precautions. Keep container tightly closed. Keep in a well-ventilated place. To maintain product quality, do not store in heat or direct sunlight.
Further information on storage conditions	: Avoid moisture.
Further information on storage stability	: No decomposition if stored and applied as directed.

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Boric acid	10043-35-3	TWA (Inhalable particulate matter)	2 mg/m ³ (Borate)	ACGIH
		STEL (Inhalable particulate matter)	6 mg/m ³ (Borate)	ACGIH

Engineering measures : Use only in area provided with appropriate exhaust ventilation.

Personal protective equipment

Respiratory protection : Half mask with a particle filter P2 (EN 143)

Hand protection

Material : Nitrile rubber

Remarks : Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact). Impervious gloves Break through time : > 480 min

Eye protection : Safety glasses

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place. Dust impervious protective suit

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : gel

Colour : clear

Odour : odourless

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

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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	:	Not applicable
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	:	soluble
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	:	Not applicable
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No decomposition if stored and applied as directed.
Chemical stability	:	Stable under recommended storage conditions.
Possibility of hazardous reactions	:	Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	:	Heat
Incompatible materials	:	Oxidizing agents Strong acids and strong bases
Hazardous decomposition products	:	No decomposition if used as directed.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes	:	Eyes Skin
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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

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

Aspiration toxicity

No aspiration toxicity classification

Further information

Remarks : No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity**

Toxicity to fish :
Remarks: No data available

Persistence and degradability

Biodegradability : Remarks: No data available

Bioaccumulative potential

Bioaccumulation : Remarks: No data available

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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 contents/container in accordance with local regulation.
Contact waste disposal services.
Do not dispose of waste into sewer.

Contaminated packaging : Dispose of as unused product.
Do not re-use empty containers.

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

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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

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Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

ACGIH / STEL : Short-term exposure limit

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 -

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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

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