

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

FlashGel™ System

Version 4.0

Revision Date 16.04.2024

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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : FlashGel™ System

Material number : 57031

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

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 2A

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H315 Causes skin irritation.
H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.

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Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P332 + P313 If skin irritation occurs: Get medical advice/ attention.
 P337 + P313 If eye irritation persists: Get medical advice/ attention.
 P362 Take off contaminated clothing.

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)
Tetrabutylammonium hydroxide	2052-49-5	>= 1 - < 3

SECTION 4. FIRST AID MEASURES

- If inhaled : Move to fresh air.
 Consult a physician after significant exposure.
 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 : Rinse immediately with plenty of lukewarm water, also under the eyelids, for at least 15 minutes.
 Call a physician immediately.
 Remove contact lenses.
 Keep eye wide open while rinsing.
 Protect unharmed eye.
- 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
Unsuitable extinguishing media	: High volume water jet
Specific hazards during firefighting	: Heating or fire can release toxic gas.
Hazardous combustion products	: Nitrogen oxides (NOx) Carbon oxides (COx) Sulphur oxides (SOx)
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	: Use personal protective equipment. Use respirator when performing operations involving potential exposure to vapour of the product.
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	: 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	: No special precautions required.
	Normal measures for preventive fire protection.
Advice on safe handling	: Do not breathe vapours/dust. Avoid contact with skin and eyes. 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. When using do not eat, drink or smoke. Avoid contact with skin, eyes and clothing.
Conditions for safe storage	: Observe label precautions. Keep container tightly closed. Keep in a well-ventilated place.

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To maintain product quality, do not store in heat or direct sunlight.

Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

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

Personal protective equipment

Respiratory protection : Respirator with a vapour filter (EN 141)

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 goggles

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place. Lightweight protective clothing

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : gel

Colour : clear

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Boiling point/boiling range : No data available

Flash point : 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	: 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	: 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	: None known. 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

Acute toxicity

Acute inhalation toxicity	: Remarks: No data available
Acute dermal toxicity	: Remarks: No data available

Skin corrosion/irritation

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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

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 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 |

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

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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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Date format : dd.mm.yyyy

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

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