



SAFETY DATA SHEET

1. Identification

Product identifier LISKONUM TABLETS

Other means of identification

Synonyms

LISKONUM CONTROLLED RELEASE TABLETS 450 MG * ESKALITH CONTROLLED RELEASE TABLETS 450 MG * QILONUM SR TABLETS * QILONUM 450 MG SR TABLETS * QILONIUM-R TABLETS * LITHIUM CARBONATE, FORMULATED PRODUCT

Recommended use of the chemical and restrictions on use

Recommended use Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Restrictions on use No other uses are advised.

Details of manufacturer or importer

Manufacturer

GlaxoSmithKline Australia
1061 Mountain Highway
Melbourne, Victoria 3155
Australia
Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS
(available 24hrs/7days: multi-language response)
Australia Toll Free +(61) 2 9037 2994
International Toll Call +(1) 703 527 3887

2. Hazard(s) identification

Classification of the hazardous chemical

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements, including precautionary statements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Other hazards which do not result in classification

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
LITHIUM CARBONATE Carbonic acid, dilithium salt DILITHIUM CARBONATE CARBONIC ACID, LITHIUM SALT	554-13-2	< 65
POVIDONE 30 Poly(1-ethenylpyrrolid-2-one) CROSPVIDONE POLY(1-VINYL-2-PYRROLIDINONE) 2-PYRROLIDINONE, 1-VINYL-, POLYMERS	9003-39-8	< 15

Talc	14807-96-6	< 10
TALCUM, NON-ASBESTOS FORM		
Talc		
HYDROUS MAGNESIUM SILICATE		
Titanium dioxide	13463-67-7	< 0.25
TITANIUM OXIDE		
TITANIUM(IV) OXIDE		
TITANIUM PEROXIDE (TiO ₂)		
PIGMENT WHITE 6		
Other components below reportable levels		< 20

4. First-aid measures

Description of necessary first aid measures

Inhalation	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center.
Personal protection for first-aid responders	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
Symptoms caused by exposure	Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. The following adverse effects have been noted with therapeutic use of this material: anorexia; dry mouth; nausea; vomiting; diarrhoea; tremor; thirst; mental impairment.
Medical attention and special treatment	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for fire fighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Hazchem Code	Not available.
General fire hazards	No unusual fire or explosion hazards noted.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

Environmental precautions	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

7. Handling and storage

Precautions for safe handling	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact with eyes. Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store locked up. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls and personal protection

Control parameters	Follow standard monitoring procedures.
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Occupational exposure limits

GSK

Components	Type	Value	Note
LITHIUM CARBONATE (CAS 554-13-2)	8 HR TWA	400 mcg/m3	
	OHC	2	Reproductive hazard

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value	Form
Talc (CAS 14807-96-6)	TWA	2.5 mg/m3	
Titanium dioxide (CAS 13463-67-7)	TWA	10 mg/m3	Inhalable dust.

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value	Form
Talc (CAS 14807-96-6)	TWA	2.5 mg/m3	
Titanium dioxide (CAS 13463-67-7)	TWA	10 mg/m3	Inspirable dust.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Talc (CAS 14807-96-6)	TWA	2 mg/m3	Respirable fraction.
Titanium dioxide (CAS 13463-67-7)	TWA	10 mg/m3	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Talc (CAS 14807-96-6)	TWA	1 mg/m3	Respirable dust.
Titanium dioxide (CAS 13463-67-7)	TWA	4 mg/m3	Respirable.
		10 mg/m3	Inhalable

Biological limit values	No biological exposure limits noted for the ingredient(s).
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Exposure guidelines

Appropriate engineering controls	An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. General ventilation normally adequate.
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Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	For prolonged or repeated skin contact use suitable protective gloves.
Other	Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Tablet.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Peroxides. Phenols.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on possible routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
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Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Ingestion	Health injuries are not known or expected under normal use. Harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms related to exposure	Direct contact with eyes may cause temporary irritation. Exposed may experience eye tearing, redness, and discomfort. The following adverse effects have been noted with therapeutic use of this material: anorexia; dry mouth; nausea; vomiting; diarrhoea; tremor; thirst; mental impairment.
Acute toxicity	Harmful if swallowed. Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test results
LITHIUM CARBONATE (CAS 554-13-2)		
Acute		
<i>Inhalation</i>		
	Human	>= 1 mg/m3 Respiratory irritation
<i>Oral</i>		
LD50	Rat	600 mg/kg
POVIDONE 30 (CAS 9003-39-8)		
Acute		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
Titanium dioxide (CAS 13463-67-7)		
Acute		
<i>Inhalation</i>		
LC50	Rat	6820 mcg/m3
<i>Oral</i>		
LD50	Rat	> 24 g/kg
Chronic		
<i>Inhalation</i>		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose 5 mg/m3, 24 months
Subacute		
<i>Inhalation</i>		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks No evidence of significant inflammation in respiratory tract.
<i>Oral</i>		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
<i>Inhalation</i>		
LOEC	Rat	3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation	Health injuries are not known or expected under normal use.
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Irritation Corrosion - Skin		
TITANIUM DIOXIDE		0, Literature data Result: Non-irritant Species: Guinea pig 0, Literature data Result: Non-irritant Species: Human Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit
Serious eye damage/irritation	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.	
Eye		
LITHIUM CARBONATE		OECD 405 Result: Irritant Species: Rabbit Notes: Literature Reference
TITANIUM DIOXIDE		OECD 405, Literature data Result: Mild irritant Species: Rabbit
Respiratory or skin sensitisation		
Respiratory sensitisation	None known.	
Skin sensitisation	None known. This product is not expected to cause skin sensitisation.	
Sensitisation		
TITANIUM DIOXIDE		5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: negative Species: Guinea pig Test Duration: 48 hour exposure Patch test, Literature data Result: negative Species: Human
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
TITANIUM DIOXIDE		Ames, Literature data Result: negative Micronucleus Assay in vitro, CHO cells, Literature data Result: negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: positive Syrian Hamster Embryo (SHE) cell transformation assay Result: negative WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: positive
Carcinogenicity	Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure.	
LITHIUM CARBONATE		0.02 mmol/L, NOAEL Species: Rat Notes: Literature Reference
TITANIUM DIOXIDE		0.5 mg/m3, Literature data Result: negative Species: Rat Test Duration: 24 months 0.72 - 14.8 mg/m3, Literature data Result: negative Species: Mouse 10 - 250 mg/m3, Dietary study - Literature data. Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration. Species: Rat Test Duration: 24 months

Carcinogenicity**TITANIUM DIOXIDE**

25000 - 50000 ppm, Dietary study

Result: negative

Species: Mouse

25000 - 50000 ppm, Dietary study - Literature data.

Result: negative

Species: Rat

7.2 - 14.8 mg/m3, Literature data

Result: Lung tumour

Species: Rat

Test Duration: 24 months

ACGIH Carcinogens

Talc (CAS 14807-96-6)

A4 Not classifiable as a human carcinogen.

Titanium dioxide (CAS 13463-67-7)

A4 Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

POVIDONE 30 (CAS 9003-39-8)

3 Not classifiable as to carcinogenicity to humans.

Titanium dioxide (CAS 13463-67-7)

2B Possibly carcinogenic to humans.

Reproductive toxicity

Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

Specific target organ toxicity - single exposure

Central nervous system.

LITHIUM CARBONATE

Organ: Central nervous system.

Notes: Literature Reference

Specific target organ toxicity - repeated exposure

Kidneys.

LITHIUM CARBONATE

Organ: Kidney

Notes: Literature Reference

Aspiration hazard

Not likely, due to the form of the product.

Chronic effects

Prolonged exposure may cause chronic effects.

Other information

Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information**Ecotoxicity**

Not expected to be harmful to aquatic organisms.

Components**Species****Test results**

LITHIUM CARBONATE (CAS 554-13-2)

Aquatic*Acute*

Crustacea

EC50

Water flea (Daphnia magna)

1.2 mg/l, 48 hours Static test

Fish

EC50

Rainbow trout (Adult Oncorhynchus mykiss)

9.3 mg/l, 28 days Static renewal test

POVIDONE 30 (CAS 9003-39-8)

Acute

IC50

Activated sludge

> 1000 mg/l, 3 hours Static test

Aquatic*Acute*

Crustacea

EC50

Water flea (Daphnia magna)

84 mg/l, 48 hours Static test

NOEC

Water flea (Daphnia magna)

32 mg/l, 48 hours Static test

Talc (CAS 14807-96-6)

Aquatic*Acute*

Fish

EC50

Zebra fish (Adult Brachydanio rerio)

> 100 g/l, 24 hours Static renewal test

Components	Species	Test results
Titanium dioxide (CAS 13463-67-7)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna)
		> 1000 mg/l, 48 hours Static test

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

POVIDONE 30 0 %, 28 days Modified MITI test, Activated sludge

Bioaccumulative potential	No data available.
Mobility in soil	No data available for this product.
Mobility in general	Not available.
Other adverse effects	Not available.

13. Disposal considerations

Disposal methods	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.
Residual waste	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

15. Regulatory information

Safety, health and environmental regulations

National regulations This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

POVIDONE 30 (CAS 9003-39-8)

Low toxicity. Veterinary

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Talc (CAS 14807-96-6)

100000 - 999999 TONNES See the regulation for additional information.

Titanium dioxide (CAS 13463-67-7)

100000 - 999999 TONNES See the regulation for additional information.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations**Stockholm Convention**

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date	04-November-2014
Revision date	04-November-2014
References	GSK Hazard Determination
Disclaimer	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.
Revision Information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: Toxicological Information: Ecological information: Transport Information: Material Transportation Information Regulatory Information: Risk Phrases - Class. GHS: Classification