

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	LISKONUM TABLETS
Registration number	-
Synonyms	LISKONUM CONTROLLED RELEASE TABLETS 450 MG * ESKALITH CONTROLLED RELEASE TABLETS 450 MG * QUILONUM SR TABLETS * QUILONUM 450 MG SR TABLETS * QUILONIUM-R TABLETS * LITHIUM CARBONATE, FORMULATED PRODUCT
Issue date	04-November-2014
Version number	14
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1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses 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.

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

2.3. Other hazards Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
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LITHIUM CARBONATE	< 65	554-13-2 209-062-5	-	-	
Classification:	DSD:	Repr. Cat. 1;R61, Xn;R22, Xi;R36, R64			
	CLP:	Acute Tox. 4;H302, Eye Irrit. 2;H319, STOT SE 3;H335, Repr. 1A;H360FD			

POVIDONE 30	< 15	9003-39-8	-	-	
Classification:	DSD:	R52/53			
	CLP:	Aquatic Chronic 3;H412			

Talc	< 10	14807-96-6 238-877-9	-	-	
Classification:	DSD:	-			
	CLP:	-			

Titanium dioxide	< 0,25	13463-67-7 236-675-5	-	-	
Classification:	DSD:	-			
	CLP:	-			

Other components below reportable levels < 20

List of abbreviations and symbols that may be used above

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information 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.

4.1. Description of 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.

4.2. Most important symptoms and effects, both acute and delayed 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.

4.3. Indication of any immediate medical attention and special treatment needed 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.

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.

5.2. Special hazards arising from the substance or mixture	During fire, gases hazardous to health may be formed.
5.3. Advice for firefighters	
Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. 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.
6.2. Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material 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.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. 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. Observe good industrial hygiene practices.
7.2. 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).
7.3. Specific end use(s)	Medicinal Product.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

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

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

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no-effect level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

Exposure guidelines

8.2. Exposure controls

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.

Individual protection measures, such as personal protective equipment

General information	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.
Eye/face protection	If contact is likely, safety glasses with side shields are recommended. (e.g. EN 166). Not normally needed.
Skin protection	

- Hand protection	For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time). Not normally needed.
- Other	Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust). Not normally needed.
Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. No personal respiratory protective equipment normally required.
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.
Environmental exposure controls	
Hazard guidance and control recommendations	Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic 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.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Solubility (other)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Peroxides. Phenols.

10.6. Hazardous decomposition products

None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

SECTION 11: Toxicological information**General information**

Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure**Inhalation**

Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

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

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.

11.1. Information on toxicological effects**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/m ³ 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/m ³
<i>Oral</i>		
LD50	Rat	> 24 g/kg
Chronic		
<i>Inhalation</i>		
LOEC	Rat	8,6 mg/m ³ , 1 years TiO ₂ accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.
NOAEC	Rat	250 mg/m ³ , 2 years Highest dose 5 mg/m ³ , 24 months
Subacute		
<i>Inhalation</i>		
LOEL	Rat	0,1 - 35 mg/m ³ , 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m ³ , 3 weeks No evidence of significant inflammation in respiratory tract.
<i>Oral</i>		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.

Components	Species	Test results
Subchronic <i>Inhalation</i> LOEC	Rat	3,2 - 20 mg/m ³ , 8 min Accumulation of TiO ₂ 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.	
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/eye 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 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/m ³ , Literature data Result: negative Species: Rat Test Duration: 24 months 0,72 - 14,8 mg/m ³ , Literature data Result: negative Species: Mouse

Carcinogenicity
TITANIUM DIOXIDE

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
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

IARC Monographs. Overall Evaluation of Carcinogenicity

POVIDONE 30 (CAS 9003-39-8)
Titanium dioxide (CAS 13463-67-7)

3 Not classifiable as to carcinogenicity to humans.
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.

Reproductivity

LITHIUM CARBONATE

10 - 200 mg/kg/day Reproduction/Fertility Study
Result: Reduced reproductive capacity, increased pup mortality and delayed post-natal development.
Species: Mouse
Notes: Literature Reference
2 mg/kg/day Fertility, Male, Possibly species-specific.
Result: Inhibition of spermatogenesis.
Species: Rat
Notes: Literature Reference
Clinical use
Result: Cardiovascular malformations.
Species: Human
Notes: Literature Reference

Specific target organ toxicity - single exposure

LITHIUM CARBONATE

Central nervous system.

Organ: Central nervous system.
Notes: Literature Reference

Specific target organ toxicity - repeated exposure

LITHIUM CARBONATE

Kidneys.

Organ: Kidney
Notes: Literature Reference

Aspiration hazard

Not likely, due to the form of the product.

Mixture versus substance information

No information available.

Other information

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

SECTION 12: Ecological information

12.1. Toxicity

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 Oncorhyncus 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

Components		Species	Test results
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours Static test
Talc (CAS 14807-96-6)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 100 g/l, 24 hours Static renewal test
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.

12.2. Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

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

12.3. Bioaccumulative potential No data available.

Partition coefficient Not available.
n-octanol/water (log Kow)

12.4. Mobility in soil Not available.

Mobility in general Not available.

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	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.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations

Young people under 18 years old are not allowed to work with this product according to the EU Directive 94/33/EC on the protection of young people at work. Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

Not available.

References

GSK Hazard Determination

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R22 Harmful if swallowed.
R36 Irritating to eyes.
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R61 May cause harm to the unborn child.
R64 May cause harm to breastfed babies.
H302 Harmful if swallowed.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H360FD May damage fertility. May damage the unborn child.
H412 Harmful to aquatic life with long lasting effects.

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

Training information

Follow training instructions when handling this material.

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.