

1. Identification

Product identifier

LISKONUM TABLETS

Other means of identification

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

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.

Recommended restrictions

No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

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

Label elements

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

Hazard(s) not otherwise classified (HNOC)

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

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
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	TALCUM, NON-ASBESTOS FORM * TALC * HYDROUS MAGNESIUM SILICATE	14807-96-6	< 10
MAIZE STARCH	STARCH, EDIBLE * STARCH (CORN)	9005-25-8	< 5
TITANIUM DIOXIDE	TITANIUM OXIDE * TITANIUM(IV) OXIDE * TITANIUM PEROXIDE (TiO ₂) * PIGMENT WHITE 6	13463-67-7	< 0.25

Chemical name	Common name and synonyms	CAS number	%
POLYETHYLENE GLYCOL 6000	ALKAPOL PEG- 6000 * CARBOWAX * ALPHA-HYDRO- OMEGA-HYDROXYPOLY(OXY-1,2-ETHAN EDIYL) * JORCHEM 400 ML * LUTROL * PLURACOL E-6000 * POLY(ETHYLENE OXIDE) * POLY-G SERIES * POLYOX * POLY(OXY-1,2-ETHANEDIYL), ALPHA-HYDRO-OMEGA-HYDROXY-	25322-68-3	< 0.1
Other components below reportable levels			< 20

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. 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 center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, 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.
Indication of 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 center.
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.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
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 firefighters	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.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	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 of the SDS.
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.
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.

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/personal protection

Occupational exposure limits

GSK

Components

Type

Value

Note

LITHIUM CARBONATE
(CAS 554-13-2)

8 HR TWA

400 mcg/m3

OHC

2

REPRODUCTIVE
HAZARD

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components

Type

Value

Form

MAIZE STARCH (CAS
9005-25-8)

PEL

5 mg/m3

Respirable fraction.

TITANIUM DIOXIDE (CAS
13463-67-7)

PEL

15 mg/m3

Total dust.

15 mg/m3

Total dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components

Type

Value

Form

TALC (CAS 14807-96-6)

TWA

0.3 mg/m3

Total dust.

0.1 mg/m3

Respirable.

20 mppcf

2.4 mppcf

Respirable.

US. ACGIH Threshold Limit Values

Components

Type

Value

Form

MAIZE STARCH (CAS
9005-25-8)

TWA

10 mg/m3

TALC (CAS 14807-96-6)

TWA

2 mg/m3

Respirable fraction.

TITANIUM DIOXIDE (CAS
13463-67-7)

TWA

10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components

Type

Value

Form

MAIZE STARCH (CAS
9005-25-8)

TWA

5 mg/m3

Respirable.

TALC (CAS 14807-96-6)

TWA

10 mg/m3

Total

2 mg/m3

Respirable.

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components

Type

Value

Form

POLYETHYLENE GLYCOL
6000 (CAS 25322-68-3)

TWA

10 mg/m3

Particulate.

Biological limit values

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

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.

Individual protection measures, such as personal protective equipment

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	Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. No personal respiratory protective equipment normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	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.
Color	Not available.
Odor	Not available.
Odor 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.

Vapor pressure	Not available.
Vapor 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 likely 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 the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. Exposed individuals 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.

Information on toxicological effects

Acute toxicity	Harmful if swallowed. Expected to be a low hazard for usual industrial or commercial handling by trained personnel.
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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
POLYETHYLENE GLYCOL 6000 (CAS 25322-68-3)		
Acute		
<i>Oral</i>		
LD50	Rat	> 20 g/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.

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 or skin sensitization		
Respiratory sensitization	None known.	
Skin sensitization	None known. This product is not expected to cause skin sensitization.	
Sensitization 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

Carcinogenicity

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

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)

3 Not classifiable as to carcinogenicity to humans.

TITANIUM DIOXIDE (CAS 13463-67-7)

2B Possibly carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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.

Chronic effects

Prolonged exposure may cause chronic effects.

Further 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 Oncorhyncus mykiss)	9.3 mg/l, 28 days Static renewal test
POLYETHYLENE GLYCOL 6000 (CAS 25322-68-3)			
Aquatic			
Acute			
Microtox	EC50	Microtox	> 100000 mg/L, 15 minutes
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
TITANIUM DIOXIDE (CAS 13463-67-7)			
Aquatic			
Acute			
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)

POLYETHYLENE GLYCOL 6000	53 - 56 %, 28 days Batch activated sludge (BAS), Activated sludge
POVIDONE 30	0 %, 28 days Modified MITI test, Activated sludge

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

13. Disposal considerations

Disposal instructions	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.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	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

DOT

Not regulated as a dangerous good.

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

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.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

No

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
LITHIUM CARBONATE	554-13-2	< 65

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

LITHIUM CARBONATE (CAS 554-13-2)
MAIZE STARCH (CAS 9005-25-8)
TALC (CAS 14807-96-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

US. New Jersey Worker and Community Right-to-Know Act

LITHIUM CARBONATE (CAS 554-13-2)
TALC (CAS 14807-96-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

US. Pennsylvania Worker and Community Right-to-Know Law

MAIZE STARCH (CAS 9005-25-8)
TALC (CAS 14807-96-6)
TITANIUM DIOXIDE (CAS 13463-67-7)

US. Rhode Island RTK

LITHIUM CARBONATE (CAS 554-13-2)

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

TITANIUM DIOXIDE (CAS 13463-67-7)

Listed: September 2, 2011

US - California Proposition 65 - CRT: Listed date/Developmental toxin

LITHIUM CARBONATE (CAS 554-13-2)

Listed: January 1, 1991

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
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, including date of preparation or last revision

Issue date	11-04-2014
Revision date	11-04-2014
Version #	14
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 2* Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 0 Instability: 0
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