

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

### 1.1. Product identifier

**Trade name or designation of the mixture** TUMS TABLETS

**Registration number** -

**Synonyms** MFC50899 TUMS FRESHERS COOLMINT AND PLACEBO \* CALCIUM CARBONATE, FORMULATED PRODUCT \* MFC 51081 TUMS FRESHERS SPEARMINT \* MFC 51126A TUMS REGULAR PEPPERMINT 500MG \* MFC 51126B TUMS EXTRA PEPPERMINT 750MG \* MFC 51126C TUMS ULTRA PEPPERMINT 1000MG \* MFC 51127A TUMS REGULAR CHERRY 500MG \* MFC 51127B TUMS EXTRA CHERRY 750MG \* MFC 51127C TUMS ULTRA CHERRY 1000MG \* MFC 51128A TUMS REGULAR ORANGE 500MG \* MFC 51128B TUMS EXTRA ORANGE 750MG \* MFC 51128C TUMS ULTRA ORANGE 1000MG \* MFC 51129A TUMS REGULAR LEMON 500MG \* MFC 51129B TUMS EXTRA LEMON 750MG \* MFC 51129C TUMS ULTRA LEMON 1000MG \* MFC 51130A TUMS REGULAR LIME 500MG \* MFC 51130B TUMS EXTRA LIME 750MG \* MFC 51130C TUMS ULTRA LIME 1000MG \* ANDREWS TUMS ANTACID MIXED FRUIT FLAVOURED TABLETS \* ACD-128 ANDREWS ANTACID REFRESHING (UK) \* TUMS ASSORTED FRUIT (UK) \* TUMS ASSORTED FRUIT ANTACID TABLETS 500MG \* ANDREWS ANTACID FRUIT (UK) \* CALCIUM CARBONATE 600MG AND MAGNESIUM CARBONATE 125MG TABLETS \* FORMULA NUMBERS: 3001111-0017, 3001111-0018, 3001111-0019 AND 3001111-0020 TUMS ULTRA ASSORTED FRUIT (US) \* FORMULA NUMBERS: 3001111-0017, 3001111-0018, 3001111-0019 AND 3001111-0020 TUMS ULTRA STRENGTH ASSORTED FRUIT (CANADA) \* FORMULA NUMBERS: 3001111-0023, 3001111-0024, 3001111-0025 AND 3001111-0026 TUMS ULTRA ASSORTED TROPICAL (US AND CANADA) \* FORMULA NUMBERS: 3001109-0018, 3001109-0019, 3001109-0020 AND 3001109-0021 TUMS EXTRA STRENGTH TROPICAL FRUIT \* FORMULA NUMBERS: 3001109-0018, 3001109-0019, 3001109-0020 AND 3001109-0021 TUMS TROPICAL FRUIT 750MG \* FORMULA NUMBERS: 3001101-0047, 3001101-0048, 3001101-0049 AND 3001101-0050 TUMS ASSORTED FRUIT \* FORMULA NUMBERS: 3001101-0047, 3001101-0048, 3001101-0049 AND 3001101-0050 TUMS REGULAR STRENGTH ASSORTED FRUIT (CANADA AND COLUMBIA) \* FORMULA NUMBERS: 10499-001-0006, 10499-001-0007 AND 10499-001-0008 TUMS EXTRA STRENGTH ASSORTED BERRIES \* FORMULA NUMBERS: 3001111-0036, 3001111-0037 AND 3001111-0038 TUMS ULTRA ASSORTED BERRIES (US AND CANADA) \* FORMULA NUMBER: 3001109-0021 TUMS EX BANANA BERRY \* FORMULA NUMBER: 3001104-0043 ANDREWS TUMS ORANGE TABLETS \* MFC 3001101-0048 ENO TUMS ORANGE \* FORMULA NUMBERS: 3001101-0047 AND 3001101-0048 ENO TUMS ASSORTED FRUIT

**Issue date** 11-November-2014

**Version number** 05

**Revision date** 11-November-2014

### 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

Expected to be non-combustible.

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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D-SORBITOL	0 - 83	50-70-4 200-061-5	-	-	
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<b>Classification:</b>	<b>DSD:</b> -
	<b>CLP:</b> -

Calcium carbonate	0 - 75	471-34-1 207-439-9	-	-	
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<b>Classification:</b>	<b>DSD:</b> -
	<b>CLP:</b> -

Talc	0 - <12	14807-96-6 238-877-9	-	-	
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<b>Classification:</b>	<b>DSD:</b> -
	<b>CLP:</b> -

MAGNESIUM CARBONATE	0 - < 9	546-93-0 208-915-9	-	-	
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<b>Classification:</b>	<b>DSD:</b> -
	<b>CLP:</b> -

Malic acid	0 - < 6	6915-15-7 230-022-8	-	-	
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<b>Classification:</b>	<b>DSD:</b> C;R35
	<b>CLP:</b> Skin Corr. 1;H314

Starch	0 - 6	9005-25-8 232-679-6	-	-	
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<b>Classification:</b>	<b>DSD:</b> -
	<b>CLP:</b> -

CALCIUM STEARATE	0 -3.5	1592-23-0 216-472-8	-	-	
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<b>Classification:</b>	<b>DSD:</b> -
	<b>CLP:</b> -

Other components below reportable levels 25 - 60

## 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** Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

### 4.1. Description of first aid measures

**Inhalation** In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

**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).

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

**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 local poison control information centre.

## SECTION 5: Firefighting measures

**General fire hazards** Expected to be non-combustible.

### 5.1. Extinguishing media

**Suitable extinguishing media** Alcohol resistant foam. Water spray. Water fog. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**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** Use water spray to cool unopened containers.

**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. 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. 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** Do not get this material in contact with eyes. Avoid contact with skin. Avoid prolonged exposure. Avoid contact with clothing. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

**7.2. Conditions for safe storage, including any incompatibilities**

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**

Not established

**Ireland. Occupational Exposure Limits Components**

Components	Type	Value	Form
Calcium carbonate (CAS 471-34-1)	TWA	4 mg/m <sup>3</sup>	Respirable dust.
		10 mg/m <sup>3</sup>	Total inhalable dust.
CALCIUM STEARATE (CAS 1592-23-0)	TWA	10 mg/m <sup>3</sup>	
Starch (CAS 9005-25-8)	TWA	4 mg/m <sup>3</sup>	Respirable dust.
		10 mg/m <sup>3</sup>	Total inhalable dust.
Talc (CAS 14807-96-6)	TWA	10 mg/m <sup>3</sup>	Total inhalable dust.
		0.8 mg/m <sup>3</sup>	Respirable dust.

**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.

**8.2. Exposure controls****Appropriate engineering controls**

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Eye wash facilities and emergency shower must be available when handling this product.

**Individual protection measures, such as personal protective equipment****General information**

Use personal protective equipment as required. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

**Eye/face protection**

Wear safety glasses with side shields (or goggles) and a face shield. (eg. EN 166)

**Skin protection****- Hand protection**

For prolonged or repeated skin contact use suitable protective gloves. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

**- Other**

Wear appropriate chemical resistant clothing. (EN 14605 for splashes, EN ISO 13982 for dust)

**Respiratory protection**

In case of insufficient ventilation, wear suitable respiratory equipment. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

**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.

**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.

<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Solubility (other)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Explosive properties</b>	Not available.
<b>Oxidizing properties</b>	Not available.

## 9.2. Other information

### Dust explosion properties

<b>St class</b>	No studies have been conducted.
<b>Minimum Ignition Energy (MIE) - dust cloud</b>	No studies have been conducted.

<b>Train fire</b>	No studies have been conducted.
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## SECTION 10: Stability and reactivity

<b>10.1. Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>10.2. Chemical stability</b>	Material is stable under normal conditions.
<b>10.3. Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>10.4. Conditions to avoid</b>	Contact with incompatible materials.
<b>10.5. Incompatible materials</b>	Acids. Fluorine.
<b>10.6. Hazardous decomposition products</b>	None known. Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## SECTION 11: Toxicological information

<b>General information</b>	Occupational exposure to the substance or mixture may cause adverse effects.
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### Information on likely routes of exposure

<b>Inhalation</b>	Health injuries are not known or expected under normal use. Inhalation of dusts may cause respiratory irritation.
<b>Skin contact</b>	Health injuries are not known or expected under normal use. Dust or powder may irritate the skin.
<b>Eye contact</b>	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.
<b>Ingestion</b>	Health injuries are not known or expected under normal use.

<b>Symptoms</b>	Irritant effects.
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### 11.1. Information on toxicological effects

Acute toxicity		Health injuries are not known or expected under normal use.	
Components	Species	Test results	
Calcium carbonate (CAS 471-34-1)			
Acute			
Oral			
LD50	Rat	6450 mg/kg	
CALCIUM STEARATE (CAS 1592-23-0)			
Acute			
Oral			
LD50	Rat	> 2000 mg/kg	
D-SORBITOL (CAS 50-70-4)			
Acute			
Oral			
LD50	Rat	15.9 g/kg	

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

<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use. Prolonged skin contact may cause temporary irritation.		
<b>Serious eye damage/eye irritation</b>	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.		
<b>Respiratory sensitisation</b>	Not applicable.		
<b>Skin sensitisation</b>	Health injuries are not known or expected under normal use.		
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.		
<b>Carcinogenicity</b>	Health injuries are not known or expected under normal use. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Contains a material (talc) classified as a carcinogen by external agencies. These effects are suspected to be due to impurities that are not expected to be present in purified material used in this product.		
<b>Reproductive toxicity</b>	Health injuries are not known or expected under normal use. Contains no ingredient listed as toxic to reproduction		
<b>Specific target organ toxicity - single exposure</b>	None known.		
<b>Specific target organ toxicity - repeated exposure</b>	None known.		
<b>Aspiration hazard</b>	Due to partial or complete lack of data the classification is not possible.		
<b>Mixture versus substance information</b>	No information available.		
<b>Other information</b>	Not available.		

## SECTION 12: Ecological information

**12.1. Toxicity** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components	Species		Test results
Calcium carbonate (CAS 471-34-1)			
Aquatic			
Fish	LC50	Western mosquitofish (Gambusia affinis)	> 56000 mg/l, 24 hours
CALCIUM STEARATE (CAS 1592-23-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	266 mg/l, 96 hours
Microtox	EC50	Microtox	25.6 mg/l, 15 minutes
Talc (CAS 14807-96-6)			
Aquatic			
Acute			
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 100 g/l, 24 hours Static renewal test

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

## 12.2. Persistence and degradability

No data is available on the degradability of this product.

### Photolysis

#### Half-life (Photolysis-aqueous)

Malic acid 940 Days Estimated

#### Half-life (Photolysis-atmospheric)

CALCIUM STEARATE 17 Hours Estimated

Malic acid 2 Days Estimated

### Biodegradability

#### Percent degradation (Aerobic biodegradation-inherent)

CALCIUM STEARATE 77 %, 28 days BOD

Malic acid 68 %, 5 days BOD5, Activated sludge

#### Percent degradation (Aerobic biodegradation-ready)

CALCIUM STEARATE 95 %, 22 days Modified Sturm test.

#### Percent degradation (Aerobic biodegradation-soil)

CALCIUM STEARATE > 50 %, 13 days

## 12.3. Bioaccumulative potential

### Partition coefficient

#### n-octanol/water (log Kow)

D-SORBITOL -2.2

### Bioconcentration factor (BCF)

CALCIUM STEARATE > 1000 Estimated

D-SORBITOL 1 Estimated

Malic acid 0.1 - 0.3 Estimated

## 12.4. Mobility in soil

### Adsorption

#### Soil/sediment sorption - log Koc

CALCIUM STEARATE 5.86 Estimated

D-SORBITOL 0.3 Estimated

### Mobility in general

#### Volatility

##### Henry's law

D-SORBITOL 0 atm m<sup>3</sup>/mol Estimated

Malic acid 0 atm m<sup>3</sup>/mol, 25 C Estimated

## 12.5. Results of PBT

Not available.

### and vPvB

### assessment

## 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).

#### 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. Dispose of contents/container in accordance with local/regional/national/international 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.

Read safety instructions, SDS and emergency procedures before handling.

**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**

R35 Causes severe burns.  
R36/38 Irritating to eyes and skin.  
H314 Causes severe skin burns and eye damage.

**Revision information**

Product and Company Identification: Synonyms  
Composition / Information on Ingredients: Undisclosed Ingredient Statement  
Transport Information: Material Transportation Information  
Regulatory Information: United States

**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.