

SAFETY DATA SHEET

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

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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, 300111-0018, 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](tel:+448708200418)

International toll call:

+[1 703 527 3887](tel:+17035273887)

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
D-SORBITOL	0 - 83	50-70-4 200-061-5		-	-
Classification:	DSD:	-			
Classification:	CLP:	-			
Calcium carbonate	0 - 75	471-34-1 207-439-9		-	-
Classification:	DSD:	-			
Classification:	CLP:	-			
Talc	0 - <12	14807-96-6 238-877-9		-	-
Classification:	DSD:	-			
Classification:	CLP:	-			
MAGNESIUM CARBONATE	0 - < 9	546-93-0 208-915-9		-	-
Classification:	DSD:	-			
Classification:	CLP:	-			
Malic acid	0 - < 6	6915-15-7 230-022-8		-	-
Classification:	DSD:	C;R35			
Classification:	CLP:	Skin Corr. 1;H314			
Starch	0 - 6	9005-25-8 232-679-6		-	-
Classification:	DSD:	-			
Classification:	CLP:	-			
CALCIUM STEARATE	0 -3,5	1592-23-0 216-472-8		-	-
Classification:	DSD:	-			
Classification:	CLP:	-			
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

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 (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

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

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.

- Other

Wear appropriate chemical resistant clothing.

Respiratory protection

In case of insufficient ventilation, wear suitable respiratory equipment.

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.

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

Dust explosion properties	
St class	No studies have been conducted.
Minimum Ignition Energy (MIE) - dust cloud	No studies have been conducted.
Train fire	No studies have been conducted.

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	Acids. Fluorine.
10.6. Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
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Information on likely routes of exposure

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

Symptoms	Irritant effects.
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11.1. Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use.
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Components	Species	Test results
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Calcium carbonate (CAS 471-34-1)

Acute		
<i>Oral</i>		
LD50	Rat	6450 mg/kg

CALCIUM STEARATE (CAS 1592-23-0)

Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg

Components	Species	Test results
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.		
Skin corrosion/irritation	Health injuries are not known or expected under normal use. Prolonged skin contact may cause temporary irritation.	
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.	
Respiratory sensitisation	Not applicable.	
Skin sensitisation	Health injuries are not known or expected under normal use.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Carcinogenicity	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.	
Reproductive toxicity	Health injuries are not known or expected under normal use. Contains no ingredient listed as toxic to reproduction	
Specific target organ toxicity - single exposure	None known.	
Specific target organ toxicity - repeated exposure	None known.	
Aspiration hazard	Due to partial or complete lack of data the classification is not possible.	
Mixture versus substance information	No information available.	
Other information	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 killifish (Adult Oryzias latipes)
Microtox	EC50	Microtox
266 mg/l, 96 hours		
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

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

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^3/mol Estimated

Malic acid

0 atm m^3/mol, 25 C Estimated

12.5. Results of PBT and vPvB assessment

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.