



SAFETY DATA SHEET

1. Identification

Product identifier TUMS CHEWY BITES WITH GAS RELIEF (STRAWBERRY AND LEMON)

Other means of identification
Synonyms FORMULATION CODE: BC-17-1701-05 * FORMULATION CODE: BC-17-1701-06 * PROJECT OZ - STRAWBERRY LEMON AND PANNED CHEWS * CALCIUM 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

COMPANY NAME GlaxoSmithKline US
Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA
Telephone: +1-888-825-5249 (General Inquiries)
Email: msds@gsk.com
Website: www.gsk.com

EMERGENCY CONTACTS

Telephone: CHEMTREC EMERGENCY NUMBERS
+(1) 703 527 3887 (International)
24/7; multi-language response
Contract Number: CCN9484

Telephone: VERISK 3E GLOBAL INCIDENT RESPONSE
+(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response
Contract Number: 334878

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	%
CALCIUM CARBONATE	CARBONIC ACID, CALCIUM SALT CALCIUM MONOCARBONATE PRECIPITATED CALCIUM CARBONATE CHALK	471-34-1	23.62
COCONUT OIL	COCOS NUCIFERA COCOANUT OIL COPRA OIL COCONUT BUTTER COCONUT PALM OIL	8001-31-8	4.97

Chemical name	Common name and synonyms	CAS number	%
SIMETHICONE	DIMETHYL POLYSILOXANE DIMETHICONE ACTIVATED DIMETHICONE ACTIVATED POLYMETHYLSILOXANE ANTIFOAM A MYLICON MAZU(R) DF 200SP DIMETICON OHS76398 RTECS VW6200000	8050-81-5	2.64
VANILLA CREME FLAVOR		Unassigned	0.36
GENERESSENCE (TM) STRAWBERRY		Mixture	< 0.2
LEMONADE FLAVOR NAT & ART (862.2257U)		Mixture	< 0.2
PHOSPHORIC ACID, LIQUID	WHITE PHOSPHORIC ACID PHOSPHORIC ACID ORTHO-PHOSPHORIC ACID PHOSPHORIC ACID, 85%	7664-38-2	< 0.1
TITANIUM DIOXIDE	TITANIUM OXIDE TITANIUM(IV) OXIDE TITANIUM PEROXIDE (TiO ₂) PIGMENT WHITE 6	13463-67-7	< 0.1
Other components below reportable levels			60 - < 70

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

4. First-aid measures

Inhalation	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 immediately with plenty of water for at least 15 minutes.
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.
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. 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.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	By heating and fire, harmful vapors/gases 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	In the event of fire, cool tanks with water spray.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.
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. Wear protective clothing and equipment consistent with the degree of hazard. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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. Dike far ahead of spill for later disposal. 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

Not available.

7. Handling and storage

Precautions for safe handling

Do not get this material in contact with eyes. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling.

Conditions for safe storage, including any incompatibilities

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

Not established

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

Components	Type	Value	Form
CALCIUM CARBONATE (CAS 471-34-1)	PEL	5 mg/m ³	Respirable fraction.
COCONUT OIL (CAS 8001-31-8)	PEL	15 mg/m ³	Total dust.
		5 mg/m ³	Respirable fraction.
PHOSPHORIC ACID, LIQUID (CAS 7664-38-2)	PEL	15 mg/m ³	Total dust.
		1 mg/m ³	
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m ³	Total dust.

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

Components	Type	Value	Form
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value
PHOSPHORIC ACID, LIQUID (CAS 7664-38-2)	STEL	3 mg/m ³
	TWA	1 mg/m ³
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m ³

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
CALCIUM CARBONATE (CAS 471-34-1)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Total
COCONUT OIL (CAS 8001-31-8)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Mist.
PHOSPHORIC ACID, LIQUID (CAS 7664-38-2)	STEL	3 mg/m ³	
	TWA	1 mg/m ³	

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	No particular ventilation requirements. 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.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Glove selection must take into account any solvents and other hazards present.
Other	Not normally needed. Where contact is likely, wear chemical-resistant gloves, a chemical suit, rubber boots, and chemical safety goggles plus a face shield.
Respiratory protection	No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	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.
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.

10. Stability and reactivity

Reactivity Not available.

Chemical stability Not available.

Possibility of hazardous reactions Not available.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Fluorine.

Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the products 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.

Skin contact Health injuries are not known or expected under normal use.

Eye contact Direct contact with eyes may cause temporary irritation.

Ingestion Health injuries are not known or expected under normal use.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

Information on toxicological effects

Acute toxicity Not known. 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
TITANIUM DIOXIDE (CAS 13463-67-7)		
Acute		
Inhalation		
LC50	Rat	6820 mcg/m ³
Oral		
LD50	Rat	> 24 g/kg
Chronic		
Inhalation		
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		
Inhalation		
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.
Oral		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.

Components	Species	Test Results
Subchronic Inhalation 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	Direct contact with eyes may cause temporary irritation.	
Eye TITANIUM DIOXIDE		OECD 405, Literature data Result: Mild irritant Species: Rabbit
Respiratory or skin sensitization		
Respiratory sensitization	None known.	
Skin sensitization	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	Health injuries are not known or expected under normal use. Contains a material (titanium dioxide) classified as a carcinogen by external agencies. High concentrations or doses administered over an extended period of time were required to produce adverse effects.	
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 - Literature data.
 Result: Negative
 Species: Rat
 25000 - 50000 ppm, Dietary study
 Result: Negative
 Species: Mouse
 7.2 - 14.8 mg/m³, Literature data
 Result: Lung tumour
 Species: Rat
 Test Duration: 24 months

IARC Monographs. Overall Evaluation of Carcinogenicity

TITANIUM DIOXIDE (CAS 13463-67-7)

2B Possibly carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity 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** Not likely, due to the form of the product.**Further information** Occupational exposure to the substance or mixture may cause adverse effects.**12. Ecological information****Ecotoxicity** 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 (<i>Gambusia affinis</i>) > 56000 mg/l, 24 hours
PHOSPHORIC ACID, LIQUID (CAS 7664-38-2)		
Aquatic		
<i>Acute</i>		
Fish	EC50	Fish 100 - 1000 mg/l, 96 hours
TITANIUM DIOXIDE (CAS 13463-67-7)		
Aquatic		
Fish	LC50	Mummichog (<i>Fundulus heteroclitus</i>) > 1000 mg/l, 96 hours
<i>Acute</i>		
Crustacea	EC50	Water flea (<i>Daphnia magna</i>) > 1000 mg/l, 48 hours Static test

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

Persistence and degradability No data is available on the degradability of this product.**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** Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international 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).
Contaminated packaging	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 Not applicable.

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)

PHOSPHORIC ACID, LIQUID (CAS 7664-38-2) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
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)

Not regulated.

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.

FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

PHOSPHORIC ACID, LIQUID (CAS 7664-38-2) High priority

US state regulations

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

TITANIUM DIOXIDE (CAS 13463-67-7) Listed: September 2, 2011

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

PHOSPHORIC ACID, LIQUID (CAS 7664-38-2)

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	04-13-2018
Version #	01
Further information	HMIS® is a registered trade and service mark of the ACA. The HMIS and NFPA ratings are based on available information.
HMIS® ratings	Health: 1 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 1 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.