

1. Identification

Product identifier **BIOTENE DRY MOUTH GUM**

Other means of identification Not available.

Synonym(s) FORMULA NUMBER 400630 * BIOTENE DENTAL CHEWING GUM * PROJECT SAVANNA * ORAL CARE, FORMULATED PRODUCT

Recommended use Oral Care

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
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 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

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
N&A CHERRY US-5631 (US FLAVOR CORP)		Unassigned	<1.0
OIL OF SPEARMINT	OILS, SPEARMINT CURLED MINT OIL SPEARMINT OIL	8008-79-5	<1.0
PEPPERMINT OIL	OILS, PEPPERMINT OIL OF PEPPERMINT ESSENTIAL OILS, MENTHA PIPERITA ESSENTIAL OILS, PEPPERMINT ESSENTIAL PEPPERMINT OIL MENTHA PIPERITA LEAF OIL MENTHA PIPERITA OIL OILS, ESSENTIAL, PEPPERMINT OILS, MENTHA PIPERITA PEPPERMINT LEAF OIL PEPPERMINT TERPENES PEPPERMINT OIL (150-557)	8006-90-4	<1.0

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
TITANIUM DIOXIDE	ANATASE BROOKITE RUTILE TITANIUM OXIDE TITANIUM DIOXIDE (TiO ₂) C.I. PIGMENT WHITE 6 C.I. 77891 TITANIUM(IV) OXIDE TITANIUM(4+) OXIDE TITANIUM PEROXIDE (TiO ₂) TITANIA (TiO ₂) PIGMENT WHITE 6 TITANIA KRONOS TITANIC OXIDE O ₂ Ti OHS23510 RTECS XR2275000 DIOXIDO DE TITANIO TITANOKSIIID	13463-67-7	<0.1

Other components below reportable levels:

>97.0

*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. Call a physician if symptoms develop or persist.
Skin contact	Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Get medical advice/attention if you feel unwell.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Not applicable.
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. Use standard firefighting procedures and consider the hazards of other involved materials.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the MSDS.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Following product recovery, flush area with water. For waste disposal, see section 13 of the MSDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid prolonged exposure. Use care in handling/storage.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store in accordance with local/regional/national/international regulation.

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
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m3

Biological limit values

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

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.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Hand protection

For prolonged or repeated skin contact use suitable protective gloves.

Other

Wear suitable protective clothing.

Respiratory protection

Not available.

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.

9. Physical and chemical properties

Appearance

Physical state

Solid.

Form

Gum.

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)

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	Not available.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None under normal conditions.
Incompatible materials	None known.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Due to lack of data the classification is not possible.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	Due to lack of data the classification is not possible.
Eye contact	Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical and toxicological characteristics Irritant effects.

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
OIL OF SPEARMINT (CAS 8008-79-5)		
Acute		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
PEPPERMINT OIL (CAS 8006-90-4)		
Acute		
<i>Oral</i>		
LD50	Rat	2426 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.

Components	Species	Test Results
<i>Oral</i> NOAEL	Rat	100000 ppm, 14 Day, Dietary study, highest dose tested.
Subchronic <i>Inhalation</i> LOEC	Rat	3.2 - 20 mg/m3, 8 min, Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.
* Estimates for product may be based on additional component data not shown.		
Skin corrosion/irritation	Due to lack of data the classification is not possible.	
Irritation Corrosion - Skin TITANIUM DIOXIDE	Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit Literature data Result: Non-irritant Species: Guinea pig Literature data Result: Non-irritant Species: Human	
Serious eye damage/eye irritation	Due to lack of data the classification is not possible.	
Eye TITANIUM DIOXIDE	OECD 405, Literature data Result: Mild irritant Species: Rabbit	
Respiratory sensitization	Due to lack of data the classification is not possible.	
Skin sensitization	Due to lack of data the classification is not possible.	
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.	
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	Titanium dioxide produced carcinogenic effects in a lifetime study in mice. High concentrations or doses administered over an extended period of time were required to produce adverse effects.	
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	

Carcinogenicity

TITANIUM DIOXIDE

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

TITANIUM DIOXIDE (CAS 13463-67-7)

2B Possibly carcinogenic to humans.

Reproductive toxicity

Due to lack of data the classification is not possible.

Specific target organ toxicity - single exposure

Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure

Due to lack of data the classification is not possible.

Aspiration hazard

Due to lack of data the classification is not possible.

12. Ecological information

Ecotoxicity

Not expected to be harmful to aquatic organisms.

Components	Species	Test Results
TITANIUM DIOXIDE (CAS 13463-67-7)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50 Water flea (Daphnia magna)	> 1000 mg/l, 48 hours, Static test

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

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

No data available for this product.

Mobility in soil

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

Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as a dangerous good.

IMDG

Not regulated as a dangerous good.

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.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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SARA 302 Extremely hazardous substance	No
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SARA 311/312 Hazardous chemical	No
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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.
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Food and Drug Administration (FDA)	Not regulated.
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US state regulations**US. Massachusetts RTK - Substance List**

TITANIUM DIOXIDE (CAS 13463-67-7)

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

TITANIUM DIOXIDE (CAS 13463-67-7)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

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

TITANIUM DIOXIDE (CAS 13463-67-7)

Listed: September 2, 2011

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	08-09-2013
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Revision date	08-09-2013
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Version #	05
Further information	Not available.
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.