

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

1.1. Product identifier

Trade name or designation of the mixture: BIOTENE DRY MOUTH GUM

Registration number: -

Synonyms: FORMULA NUMBER 400630 * BIOTENE DENTAL CHEWING GUM * PROJECT SAVANNA * ORAL CARE, FORMULATED PRODUCT

Issue date: 09-August-2013

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1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses: Oral Care

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.

Supplemental label information: Not applicable.

2.3. Other hazards: Expected to be non-combustible.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
N&A CHERRY US-5631 (US FLAVOR CORP)	<1.0	Unassigned	-	-	
Classification:	DSD: -				
	CLP: -				

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
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OIL OF SPEARMINT	<1.0	8008-79-5	-	-	
Classification:	DSD: Xn;R65, Xi;R36/38, R43, N;R51/53 CLP: Flam. Liq. 3;H226, Asp. Tox. 1;H304, Skin Irrit. 2;H315, Skin Sens. 1;H317, Eye Irrit. 2;H319, Aquatic Chronic 2;H411				
PEPPERMINT OIL	<1.0	8006-90-4	-	-	
Classification:	DSD: Xi;R38, R43, N;R51/53 CLP: Skin Irrit. 2;H315, Skin Sens. 1;H317, Aquatic Chronic 2;H411				
Titanium dioxide	<0.1	13463-67-7 236-675-5	-	-	
Classification:	DSD: - CLP: -				

Other components below reportable levels: >97.0

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 Not available.

4.1. Description of first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. 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.

4.2. Most important symptoms and effects, both acute and delayed Direct contact with eyes may cause temporary irritation.

4.3. Indication of any immediate medical attention and special treatment needed Treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards Expected to be non-combustible.

5.1. Extinguishing media

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.

5.2. Special hazards arising from the substance or mixture Not available.

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	In the event of fire, cool tanks with water spray. 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. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.

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.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Avoid prolonged exposure. Use care in handling/storage.

7.2. Conditions for safe storage, including any incompatibilities Store in original tightly closed container. Store in accordance with local/regional/national/international regulation.

7.3. Specific end use(s) Oral Care

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK
Not established

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Titanium dioxide (CAS 13463-67-7)	TWA	4 mg/m3	Respirable.
		10 mg/m3	Inhalable

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.

Individual protection measures, such as personal protective equipment

General information 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 If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

Skin protection

- Hand protection For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other Wear suitable protective clothing. (EN 14605 for splashes, EN ISO 13982 for dust)

Respiratory protection When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

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 Not available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Solid.
Form	Gum.
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)	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 No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	Not available.
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	None under normal conditions.
10.5. Incompatible materials	None known.
10.6. Hazardous decomposition products	No hazardous decomposition products are known.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

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 Irritant effects.

11.1. Information on toxicological effects

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.
<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 sensitisation Due to lack of data the classification is not possible.

Skin sensitisation Due to lack of data the classification is not possible.

Sensitisation

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.

Germ cell mutagenicity**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

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
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.

Mixture versus substance information

Not available.

Other information

Not available.

SECTION 12: Ecological information**12.1. Toxicity**

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.

12.2. Persistence and degradability No data is available on the degradability of this product.

12.3. Bioaccumulative potential No data available for this product.

Partition coefficient n-octanol/water (log Kow) Not available.

12.4. Mobility in soil Not available.

12.5. Results of PBT and vPvB assessment Not available.

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.

EU waste code Not available.

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.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

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(1) 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

Not available.

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

R36/38 Irritating to eyes and skin.
R38 Irritating to skin.
R43 May cause sensitization by skin contact.
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R65 Harmful: may cause lung damage if swallowed.
H226 Flammable liquid and vapour.
H304 May be fatal if swallowed and enters airways.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H411 Toxic to aquatic life with long lasting effects.

Revision information

SECTION 1: Identification of the substance/mixture and of the company/undertaking: Product use
SECTION 7: Handling and storage: 7.3. Specific end use(s)

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.