



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** BIOTENE MOUTHSPRAY (MFC04626, MFC04627)

**Other means of identification**

**Synonyms** PRESLEY BIOTENE MOUTH SPRAY WITH OPTAGUARD SILK 703970 \* PRESLEY BIOTENE MOUTH SPRAY WITH OPTAGUARD CASHMERE 703974 \* MFC04626 \* MFC04627 \* CETYLPYRIDINIUM CHLORIDE, 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  
Website: www.gsk.com

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

Chemical name	Common name and synonyms	CAS number	%
HYDROXYPROPYL CELLULOSE	CELLULOSE, 2-HYDROXYPROPYL ETHER CELLULOSE HYDROXYPROPYL ETHER 2-HYDROXYPROPYL CELLULOSE HYDROXYPROPYL CELLULOSE ETHER HYDROXYPROPYL ETHER OF CELLULOS E OXYPROPYLATED CELLULOSE KLUCEL HPC HYDROPROPYL CELLULOSE OHS11282 RTECS NF9050000	9004-64-2	3 - < 5
POTASSIUM SORBATE	SORBIC ACID, POTASSIUM SALT SORBISTAT-K SORBISTAT-POTASSIUM 2,4-HEXADIENOIC ACID, POTASSIUM SALT, (E,E)- (E,E)-2,4-HEXADIENOIC ACID, POTASSIUM SALT POTASSIUM-2,4-HEXADIENOATE	24634-61-5	< 1
OPTAGUARD CASHMERE 703974		Unassigned	< 0.3

Chemical name	Common name and synonyms	CAS number	%
OPTAGUARD SILK 703970		Unassigned	< 0.3
SODIUM PHOSPHATE, MONOBASIC	MONOSODIUM PHOSPHATE SODIUM DIHYDROGEN PHOSPHATE MONOSODIUM DIHYDROGEN PHOSPHAT E SODIUM BIPHOSPHATE MONOSODIUM ORTHOPHOSPHATE PHOSPHORIC ACID, MONOSODIUM SALT MONOBASIC SODIUM PHOSPHATE MONOSODIUM HYDROGEN PHOSPHATE SODIUM DIPHOSPHATE ANHYDROUS SODIUM PRIMARY PHOSPHATE SODIUM PHOSPHATE	7558-80-7	< 0.2
CETYLPYRIDINIUM CHLORIDE	PYRIDINIUM, 1-HEXADECYL-, CHLORIDE 1-HEXADECYLPYRIDINIUM CHLORIDE 1-CETYLPYRIDINIUM CHLORIDE N-HEXADECYLPYRIDINIUM CHLORIDE BIOSEPT	123-03-5	< 0.1
SUCRALOSE	MICRONIZED SUCRALOSE POWDERED SUCRALOSE NEAT SUCRALOSE	56038-13-2	< 0.1
Other components below reportable levels			>90

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

#### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	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.
<b>Most important symptoms/effects, acute and delayed</b>	Not established.
<b>Indication of immediate medical attention and special treatment needed</b>	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.
<b>General information</b>	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.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Water.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	This product will support combustion at elevated temperatures.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. 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.
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**Methods and materials for containment and cleaning up**

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

**Environmental precautions****7. Handling and storage****Precautions for safe handling**

No special control measures required for the normal handling of this product. Avoid prolonged exposure.

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

Keep away from heat, sparks and open flame. 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****Components****Type****Value**

CETYLPYRIDINIUM  
CHLORIDE (CAS 123-03-5)  
HYDROXYPROPYL  
CELLULOSE (CAS  
9004-64-2)  
SODIUM PHOSPHATE,  
MONOBASIC (CAS  
7558-80-7)  
SUCRALOSE (CAS  
56038-13-2)

OHC  
OHC  
OHC  
OHC

3  
1  
1  
1

**Biological limit values**

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

**Exposure guidelines****Appropriate engineering controls**

General ventilation normally adequate. 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.

**Other**

Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

**Respiratory protection**

No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. 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**

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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

**9. Physical and chemical properties****Appearance****Physical state**

Liquid.

**Form**

Solution.

**Color**

Not available.

**Odor**

Not available.

**Odor threshold**

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>	> 375.8 °F (> 191 °C) estimated
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</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.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Keep away from heat, sparks and open flame. Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	Health injuries are not known or expected under normal use. However, ingestion is not likely to be a primary route of occupational exposure.

**Symptoms related to the physical, chemical and toxicological characteristics** Not established.

### Information on toxicological effects

**Acute toxicity** Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

<b>Components</b>	<b>Species</b>	<b>Test Results</b>
CETYLPIRIDINIUM CHLORIDE (CAS 123-03-5)		
<u>Acute</u>		
<b>Inhalation</b>		
LC50	Rat	90 mg/m <sup>3</sup> , 4 Hours 4 hr. exposure

Components	Species	Test Results
<b>Oral</b> LD50	Rat	200 mg/kg
POTASSIUM SORBATE (CAS 24634-61-5)		
<b>Acute</b> <b>Oral</b> LD50	Rat	4340 mg/kg
SODIUM PHOSPHATE, MONOBASIC (CAS 7558-80-7)		
<b>Acute</b> <b>Oral</b> LD50	Rat	8290 mg/kg
SUCRALOSE (CAS 56038-13-2)		
<b>Acute</b> <b>Oral</b> LD50	Rat	10 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.

**Irritation Corrosion - Skin: P.I.I. value**

SUCRALOSE 0

**Serious eye damage/eye irritation** Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

**Eye / Kay and Calandra class - Intact**

SUCRALOSE 4

**Respiratory or skin sensitization**

**Respiratory sensitization** No studies have been conducted.

**Skin sensitization** None known. This product is not expected to cause skin sensitization.

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Carcinogenicity** Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Reproductive toxicity** Contains no ingredient listed as toxic to reproduction

**Specific target organ toxicity - single exposure** Not assigned.

**Specific target organ toxicity - repeated exposure** Not assigned.

**Aspiration hazard** Not established.

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

**12. Ecological information**

**Ecotoxicity** Contains a substance which causes risk of hazardous effects to the environment.

Components	Species	Test Results
CETYLPIRIDINIUM CHLORIDE (CAS 123-03-5)		
<b>Aquatic</b>		
<i>Acute</i>		
Activated Sludge Respiration	IC50 Residential sludge	20 mg/L
Crustacea	EC50 Water flea (Daphnia magna)	0.0014 mg/L, 48 hours Static test
	NOEC Water flea (Daphnia magna)	0.0006 mg/L, 48 hours Static test

Components	Species	Test Results
<b>POTASSIUM SORBATE (CAS 24634-61-5)</b>		
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) 750 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss) > 500 mg/l, 96 hours Static test
		Zebra fish (Adult Brachydanio rerio) 1250 mg/l, 48 hours
		> 1000 mg/l, 96 hours
<i>Chronic</i>		
Crustacea	EC50	Water flea (Daphnia magna) 901 mg/l, 24 hours
Other	EC50	Bacteria 5000 mg/l, 21 hours
<b>SODIUM PHOSPHATE, MONOBASIC (CAS 7558-80-7)</b>		
<b>Aquatic</b>		
<i>Acute</i>		
Fish	EC50	Golden ide/orfe (Adult Leuciscus idus) > 2400 mg/l, 48 hours Static test
		Mosquito fish (Adult Gambusia affinis) 186 mg/l, 96 hours Static test
<b>SUCRALOSE (CAS 56038-13-2)</b>		
<i>Acute</i>		
	IC50	Activated sludge > 1000 mg/l, 3 hours
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) > 100 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna) 100 mg/l, 48 hours Static test

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

#### Persistence and degradability

##### Biodegradability

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

POTASSIUM SORBATE	95 %, 6 days Zahn-Wellens
SUCRALOSE	1 %, 28 days Modified Zahn-Wellens, Activated sludge

##### Bioaccumulative potential

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

CETYLPYRIDINIUM CHLORIDE 1.71

###### Bioconcentration factor (BCF)

CETYLPYRIDINIUM CHLORIDE 2 Estimated

##### Mobility in soil

###### Adsorption

###### Soil/sediment sorption - log Koc

CETYLPYRIDINIUM CHLORIDE 2.3 Estimated

##### Mobility in general

Other adverse effects Not available.

### 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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). Avoid discharge into water courses or onto the ground.

**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.

**14. Transport information****DOT**

Not regulated as a dangerous good.  
Not available.

**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 established.

**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.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**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

**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.

**US state regulations****US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

**US. Massachusetts RTK - Substance List**

Not regulated.

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

Not listed.

**US. Pennsylvania Worker and Community Right-to-Know Law**

Not listed.

**US. Rhode Island RTK**

Not regulated.

## US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

### 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

<b>Issue date</b>	06-24-2015
<b>Version #</b>	01
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 2 Flammability: 1 Physical hazard: 0
<b>NFPA ratings</b>	Health: 2 Flammability: 1 Instability: 0
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	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.