SAFETY DATA SHEET



1. Identification

Product identifier BIOTENE TOOTHPASTE SENSITIVE

Other means of identification

Synonyms MFC: LACLEDE 31002532L * SODIUM MONOFLUOROPHOSPHATE AND POTASSIUM

NITRATE, 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	%
GLYCERIN	GLYCEROL * GLYCERIN ANHYDROUS * GLYCERINE * GLYCERITOL * GLYCYL ALCOHOL * 1,2,3-PROPANETRIOL * PROPANETRIOL * GLYROL * GLYSANIN * TRIHYDROXYPROPANE * 1,2,3-TRIHYDROXYPROPANE * OSMOGLYN	56-81-5	24.09
CALCIUM PYROPHOSPHATE		7790-76-3	12.0 - 13.0
TIXOSIL	SILICA GEL, CRYSTAL-FREE * SILICA, AMORPHOUS: SILICA GEL	Unassigned	6
POTASSIUM NITRATE	NITRIC ACID POTASSIUM SALT * NITRIC ACID POTASSIUM SALT (1:1)	7757-79-1	5
SODIUM MONOFLUOROPHOSPHATE	DISODIUM FLUOROPHOSPHATE * DISODIUM MONOFLUOROPHOSPHATE * DISODIUM PHOSPHOROFLUORIDATE * SODIUM FLUOROPHOSPHATE (NA2PO3F) * SODIUM PHOSPHOROFLUORIDATE * SODIUM PHOSPHOROFLURIDATE	10163-15-2	0.76
SODIUM BENZOATE	BENZOIC ACID, SODIUM SALT * BENZOATE OF SODA * SODUIM BENZOIC ACID	532-32-1	0.1

Material name: BIOTENE TOOTHPASTE SENSITIVE

132452 Version #: 02 Revision date: 11-13-2014 Issue date: 11-13-2014 1

Chemical name	Common name and synonyms	CAS number	%
MENTHOL	HEXAHYDROTHYMOL * MENTHACAMPHOR * MENTHOMENTHOL * PEPPERMINT CAMPHOR * NATURAL MENTHOL	89-78-1	0.05
POTASSIUM THIOCYANATE	POTASSIUM ISOTHIOCYANATE * THIOCARA * PHODA-NIDE * POTASSIUM SULFOCYANATE * POTASSIUM RHODANIDE * POTASSIUM RHODANATE * ATERO-CYN * ARTEROCYN * KYONATE * RHOCYN * RODANCA * P-317 * OHS19640 * RTECS XL1925000 * 166 (GW ACN)	333-20-0	0.02
CALCIUM LACTATE	PROPANOIC ACID, 2-HYDROXY-, CALCIUM SALT (2:1) * LACTIC ACID (2:1), CALCIUM SALT * 2-HYDROXYPROPANOIC ACID, CALCIUM SALT (2:1) * CALCIUM 2-HYDROXYPROPIONATE * CALCIUM LACTATE, ANHYDROUS * CALPHOSAN	814-80-2	0.001
GLUCOSE OXIDASE			NA
LACTOFERRIN			NA
LACTOPEROXIDASE		9003-99-0	NA
LYSOZYME			NA
Other components below reportal	ole levels		51.23

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

4. First-aid measures

4. First-aid illeasures	
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention if irritation develops and persists.
Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Do not induce vomiting. Call a POISON CENTER or doctor/physician 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 according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

General information

In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). 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	Alcohol resistant foam. Water fog. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health 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	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	This product is non-flammable.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Methods and materials for containment and cleaning up

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.

Large Spills: Stop the flow of material, if this is without risk. Collect spillage. 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.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Avoid prolonged exposure. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS)

of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK			
Components	Туре	Value	
CALCIUM LACTATE (CAS 814-80-2)	8 HR TWA	5000 mcg/m3	
·	OHC	1	
MENTHOL (CAS 89-78-1)	8 HR TWA	1000 mcg/m3	
POTASSIUM THIOCYANATE (CAS 333-20-0)	8 HR TWA	5000 mcg/m3	
	OHC	1	
SODIUM BENZOATE (CAS 532-32-1)	8 HR TWA	5000 mcg/m3	
US. OSHA Table Z-1 Limits for Air Contar	minants (29 CFR 1910.1000)		
Components	Туре	Value	Form
GLYCERIN (CAS 56-81-5)	PEL	5 mg/m3 15 mg/m3	Respirable fraction. Total dust.
SODIUM MONOFLUOROPHOSPHA TE (CAS 10163-15-2) US. OSHA Table Z-2 (29 CFR 1910.1000)	PEL	2.5 mg/m3	
Components	Туре	Value	Form
SODIUM MONOFLUOROPHOSPHA TE (CAS 10163-15-2) US. OSHA Table Z-3 (29 CFR 1910.1000)	TWA	2.5 mg/m3	Dust.
Components	Туре	Value	
TIXOSIL 73 (CAS Unassigned)	TWA	0.8 mg/m3	
3 ,		20 mppcf	
US. ACGIH Threshold Limit Values			
Components	Туре	Value	
SODIUM MONOFLUOROPHOSPHA TE (CAS 10163-15-2)	TWA	2.5 mg/m3	

Material name: BIOTENE TOOTHPASTE SENSITIVE

132452 Version #: 02 Revision date: 11-13-2014 Issue date: 11-13-2014 3 / 10

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Туре	Value
SODIUM MONOFLUOROPHOSPHA TE (CAS 10163-15-2)	TWA	2.5 mg/m3
TIXOSIL 73 (CAS Unassigned)	TWA	6 mg/m3

Biological limit values

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling Time	
SODIUM MONOFLUOROPHOS TE (CAS 10163-15-2)	3 mg/l SPHA	Fluoride	Urine	*	
	2 mg/l	Fluoride	Urine	*	

^{* -} For sampling details, please see the source document.

Appropriate engineering

No special ventilation requirements. General ventilation normally adequate.

controls

Individual protection measures, such as personal protective equipment

Tridual 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.

Other Not normally needed.

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Not available.

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

Liquid. **Physical state** Paste. **Form** Not available. Color Odor Not available. Not available. **Odor threshold** Not available. рH Not available. Melting point/freezing point Not available. Initial boiling point and boiling range Flash point Not available. Not available. **Evaporation rate** Not available. Flammability (solid, gas) 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.

SDS US

132452 Version #: 02 Revision date: 11-13-2014 Issue date: 11-13-2014

Solubility(ies)

Solubility (water) Not available. Not available. Partition coefficient

(n-octanol/water)

Not available. **Auto-ignition temperature Decomposition temperature** Not available. Not available. **Viscosity**

Other information

36.4 % estimated Percent volatile

VOC (Weight %) 24.1 % Switzerland estimated

10. Stability and reactivity

Not available. Reactivity

Material is stable under normal conditions. Chemical stability

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Contact with incompatible materials. Conditions to avoid

Incompatible materials Strong oxidizing agents.

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

decomposition. products

11. Toxicological information

Information on likely routes of exposure

Under normal conditions of intended use, this material is not expected to be an inhalation hazard. Inhalation

Health injuries are not known or expected under normal use. Skin contact Direct contact with eyes may cause temporary irritation. Eye contact 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.

Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.

Components	Species	Test Results
GLYCERIN (CAS 56-81-5)		
Acute		
Oral		

LD50

Rat > 2000 mg/kg

MENTHOL (CAS 89-78-1)

Acute Oral

LD50 Rat 3200 mg/kg

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Irritation Corrosion - Skin

MENTHOL 0. Literature data

> Result: Irritating to skin Species: Rabbit Notes: IUCLID data

Serious eve damage/eve

irritation

Direct contact with eyes may cause temporary irritation.

Eve

MENTHOL 0, Literature data

> Result: MIId-moderate Species: Rabbit

Material name: BIOTENE TOOTHPASTE SENSITIVE

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

Respiratory or skin sensitization

Respiratory sensitization Not available.

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

Sensitization MENTHOL rioditi injunes are net morni er expected ander nemar dee.

Buehler assay, Literature data Result: Negative

Species: Guinea pig Notes: IUCLID data

Epidemiology, Literature data

Result: Low incidence of contact hypersensitivity.

Notes: IUCLID data

Modified Draize, Literature data

Result: Positive Species: Guinea pig Notes: IUCLID data

Open repetitive dermal test, Literature data

Result: Negative Species: Guinea pig Notes: IUCLID data

Germ cell mutagenicity

No data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Mutagenicity

MENTHOL 7

725 mg/kg In vivo-In vitro Replicative DNA synthesis

Result: Positive Species: Rat

Alkaline Elution Assay In Vitro, Literature data

Result: Negative Notes: IUCLID data

Ames, Literature dataLiterature data

Result: Negative Notes: IUCLID data

BlueScreen mammalian cell mutation assay, Literature data

Result: Negative Notes: IUCLID data

Chromosomal Aberration Assay In Vitro, CHO cells,

Literature data Result: Negative Notes: IUCLID data

Chromosomal Aberration Assay In Vitro, human

lymphocytes, Literature data

Result: Negative Notes: IUCLID data

GreenScreen mammalian cell mutation assay, Literature dat

a Result: Negative Notes: IUCLID data

L5178Y mouse lymphoma thymidine kinase locus assay,

Literature data Result: Negative Notes: IUCLID data

Micronucleus Test, Literature data

Result: Negative Species: Mouse Notes: IUCLID data

Mutation in Drosophila melanogaster, Literature data

Result: Negative Notes: IUCLID data

sister chromatid exchange, Literature data

Result: Negative Notes: IUCLID data

Carcinogenicity
MENTHOL

Health injuries are not known or expected under normal use.

<= 1000 mg/kg/day, Literature data, dietary study.

Result: Negative Species: Rat

Test Duration: 103 weeks Notes: IUCLID data

Material name: BIOTENE TOOTHPASTE SENSITIVE

132452 Version #: 02 Revision date: 11-13-2014 Issue date: 11-13-2014 6 / 10

MENTHOL <= 2143 mg/kg/day, Literature data, dietary study.

Result: Negative Species: Mouse Notes: IUCLID data

IARC Monographs. Overall Evaluation of Carcinogenicity

TIXOSIL (CAS Unassigned) 3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Reproductivity

MENTHOL 185 mg/kg/day Embryo-foetal development, Literature data

Result: NOAEL-Highest dose.

Species: Mouse Notes: IUCLID data

218 mg/kg/day Embryo-foetal development - Oral, Literature

data

Result: NOAEL-Highest dose.

Species: Rat Notes: IUCLID data

405 mg/kg/day Embryo-foetal development - Oral, Literature

Result: NOAEL-Highest dose.

Species: Hamster Notes: IUCLID data

475 mg/kg/day Embryo-foetal development - Oral, Literature

data

Result: NOAEL-Highest dose.

Species: Rabbit Notes: IUCLID data

Specific target organ toxicity -

single exposure

None known.

Specific target organ toxicity -

repeated exposure

None known.

Not available. **Aspiration hazard Further information** None known.

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. Species Toot Populto Componente

Components		Species	lest Results
POTASSIUM NITRAT	E (CAS 7757-79-1)		
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	490 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	420 mg/l, 96 hours Static test
		Guppy (Juvenile Poecilia reticulata)	180 mg/l, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis)	22.5 mg/l, 96 hours Static test
SODIUM BENZOATE	(CAS 532-32-1)		
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 100 mg/L, 96 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	484 mg/L, 96 hours Flow-through test

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

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

132452 Version #: 02 Revision date: 11-13-2014 Issue date: 11-13-2014

Biodegradability

Percent degradation (Anaerobic biodegradation)

SODIUM BENZOATE 93 %, 7 days Other degradation test system, Mixed

Residential/Industrial

No data available. Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

GLYCERIN -1.76**MENTHOL** 3.4 SODIUM BENZOATE 1.89

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

SODIUM BENZOATE 1.16 Calculated

Mobility in general Not available.

Volatility

Henry's law

MENTHOL 0.000015 atm m^3/mol, 25 C Estimated

Other adverse effects Not available.

13. Disposal considerations

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of **Disposal instructions**

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).

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

the IBC Code

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.

SDS US 132452 Version #: 02 Revision date: 11-13-2014 Issue date: 11-13-2014

Superfund Amendments and Reauthorization Act of 1986 (SARA)

No

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

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.	
POTASSIUM NITRATE	7757-79-1	5	

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

Not regulated.

(SDWA)

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

GLYCERIN (CAS 56-81-5)

POTASSIUM NITRATE (CAS 7757-79-1)

TIXOSIL (CAS Unassigned)

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

GLYCERIN (CAS 56-81-5)

POTASSIUM NITRATE (CAS 7757-79-1)

SODIUM MONOFLUOROPHOSPHATE (CAS 10163-15-2)

TIXOSIL (CAS Unassigned)

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

GLYCERIN (CAS 56-81-5)

POTASSIUM NITRATE (CAS 7757-79-1)

SODIUM MONOFLUOROPHOSPHATE (CAS 10163-15-2)

US. Rhode Island RTK

POTASSIUM NITRATE (CAS 7757-79-1)

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

Material name: BIOTENE TOOTHPASTE SENSITIVE

SDS US

Country(s) or region Inventory name On inventory (yes/no)*

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

*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 11-13-2014 **Revision date** 11-13-2014

Version # 02

Further information HMIS® is a registered trade and service mark of the NPCA.

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.

Revision Information Product and Company Identification: Product and Company Identification

Composition / Information on Ingredients: Undisclosed Ingredient Statement

Physical & Chemical Properties:

Transport Information: Agency Name, Packaging Type, and Transport Mode Selection

132452 Version #: 02 Revision date: 11-13-2014 Issue date: 11-13-2014