

1. Identification

Product identifier BIOTENE TOOTHPASTE

Other means of identification

Synonyms

BIOTENE GEL TOOTHPASTE * MFC: LACLEDE 30401172L * BIOTENE PBF TOOTHPASTE * MFC: LACLEDE 30402652L * BIOTENE REGULAR TOOTHPASTE (EU) * MFC 02599 * PROJECT BIONIC * SODIUM MONOFLUOROPHOSPHATE, 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 * TRIHIDROXYPROPANE * 1,2,3-TRIHIDROXYPROPANE * OSMOGLYN	56-81-5	20 - < 30
SILICA, AMORPHOUS HYDRATED	SILCON DIOXIDE HYDRATE * SILICA, HYDRATE * HYDRATED AMORPHOUS SILICA * Zeodent 113 * Zeodent 153	10279-57-9	3 - < 5
SILICON DIOXIDE	SILICA * SILICA GEL * AMORPHOUS SILICA * DIATOMACEOUS EARTH * INFUSORIAL EARTH * CAB-O-SIL M-5	7631-86-9	1 - < 3
ZEODENT 113		112926-00-8	1 - < 3
DI-SODIUM FLUOROPHOSPHATE	DISODIUM FLUOROPHOSPHATE * DISODIUM MONOFLUOROPHOSPHATE * DISODIUM PHOSPHOROFUORIDATE * SODIUM FLUOROPHOSPHATE (NA2PO3F) * SODIUM PHOSPHOROFUORIDATE * SODIUM PHOSPHOROFUORIDATE	10163-15-2	0.76

Chemical name	Common name and synonyms	CAS number	%
SODIUM BENZOATE	BENZOIC ACID, SODIUM SALT * BENZOATE OF SODA * SODIUM BENZOIC ACID	532-32-1	0.11
BRILLIANT BLUE FCF	BENZENEMETHANAMINIUM, N-ETHYL-N-(4-((4-ETHYL((3-SULFOPHEN XYMETHYLEN YL)(2-SULFOPHENYL)METH YLENE)-2,5-CYCLOHEXAD IEN-1-YLIDENE)-3- SULFO-, HYDROXIDE, INNER SALT, DISODIUM SALT * C.I. 42090 * ALPHAZURINE * FD&C BLUE NO.1 * ERIOGLAUCINE	3844-45-9	< 0.1
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	< 0.1
DEXTRANASE		Unassigned	0 - 0.1
MENTHOL	HEXAHYDROTHYMOL * MENTHACAMPHOR * MENTHOMENTHOL * PEPPERMINT CAMPHOR * NATURAL MENTHOL	89-78-1	< 0.1
MUTANASE			0 - 0.1
LACTOFERRIN			<0.04
LACTOPEROXIDASE		9003-99-0	<0.04
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
GLUCOSE OXIDASE			<0.02
LYSOZYME			<0.02
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 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	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.
Methods and materials for containment and cleaning up	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).

8. Exposure controls/personal protection

Occupational exposure limits

GSK Components	Type	Value	
BRILLIANT BLUE FCF (CAS 3844-45-9)	OHC	3	
CALCIUM LACTATE (CAS 814-80-2)	8 HR TWA	5000 mcg/m3	
MENTHOL (CAS 89-78-1)	OHC	1	
POTASSIUM THIOCYANATE (CAS 333-20-0)	8 HR TWA	1000 mcg/m3	
	8 HR TWA	5000 mcg/m3	
SODIUM BENZOATE (CAS 532-32-1)	OHC	1	
	8 HR TWA	5000 mcg/m3	
US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)			
Components	Type	Value	Form
SODIUM MONOFLUOROPHOSPHATE (CAS 10163-15-2)	PEL	2.5 mg/m3	
GLYCERIN (CAS 56-81-5)	PEL	5 mg/m3 15 mg/m3	Respirable fraction. Total dust.
US. OSHA Table Z-2 (29 CFR 1910.1000)			
Components	Type	Value	Form
SODIUM MONOFLUOROPHOSPHATE (CAS 10163-15-2)	TWA	2.5 mg/m3	Dust.
US. OSHA Table Z-3 (29 CFR 1910.1000)			
Components	Type	Value	
SILICA, AMORPHOUS HYDRATED (CAS 10279-57-9)	TWA	0.8 mg/m3	

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

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	20 millions of particle 0.8 mg/m3
ZEODENT 113 (CAS 112926-00-8)	TWA	20 mppcf 0.8 mg/m3
		20 mppcf

US. ACGIH Threshold Limit Values

Components	Type	Value
SODIUM MONOFLUOROPHOSPHATE (CAS 10163-15-2)	TWA	2.5 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
SODIUM MONOFLUOROPHOSPHATE (CAS 10163-15-2)	TWA	2.5 mg/m3
SILICA, AMORPHOUS HYDRATED (CAS 10279-57-9)	TWA	6 mg/m3
SILICON DIOXIDE (CAS 7631-86-9)	TWA	6 mg/m3
ZEODENT 113 (CAS 112926-00-8)	TWA	6 mg/m3

Biological limit values**ACGIH Biological Exposure Indices**

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

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

Appropriate engineering controls No special ventilation requirements. General ventilation normally adequate.

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.

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**

Physical state Liquid.
Form Paste.
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	
Percent volatile	39.6 % estimated
VOC (Weight %)	22.24 % Switzerland estimated

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	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None known. 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.
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Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use.
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Components	Species	Test Results
BRILLIANT BLUE FCF (CAS 3844-45-9)		
Acute		
<i>Oral</i>		
LD50	Rat	11.3 g/kg
GLYCERIN (CAS 56-81-5)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
MENTHOL (CAS 89-78-1)		
Acute		
<i>Oral</i>		
LD50	Rat	3200 mg/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		
MENTHOL		0, Literature data Result: Irritating to skin Species: Rabbit Notes: IUCLID data
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Eye		
MENTHOL		0, Literature data Result: Mild-moderate Species: Rabbit
Respiratory or skin sensitization		
Respiratory sensitization	Not available.	
Skin sensitization	Health injuries are not known or expected under normal use.	
Sensitization		
MENTHOL		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		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 data Literature data Result: Negative Notes: IUCLID data BlueScreen mammalian cell mutation assay, Literature data Result: Negative Notes: IUCLID data

Mutagenicity
MENTHOL

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 data
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
≤ 2143 mg/kg/day, Literature data, dietary study.
Result: Negative
Species: Mouse
Notes: IUCLID data

IARC Monographs. Overall Evaluation of Carcinogenicity

BRILLIANT BLUE FCF (CAS 3844-45-9)	3 Not classifiable as to carcinogenicity to humans.
SILICA, AMORPHOUS HYDRATED (CAS 10279-57-9)	3 Not classifiable as to carcinogenicity to humans.
SILICON DIOXIDE (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.
ZEODENT 113 (CAS 112926-00-8)	3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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 data
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.

Aspiration hazard Not available.

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.

Components		Species	Test Results
BRILLIANT BLUE FCF (CAS 3844-45-9)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 97 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	> 96 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhynchus mykiss)	> 96 mg/l, 96 hours Static test
SILICON DIOXIDE (CAS 7631-86-9)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile Cyprinus carpio)	> 10000 mg/l, 72 hours
		Zebra fish (Adult Brachydanio rerio)	5000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes
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.

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

Biodegradability

Percent degradation (Anaerobic biodegradation)

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

Bioaccumulative potential No data available.

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 m³/mol, 25 C Estimated

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.
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	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.

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 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.

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

BRILLIANT BLUE FCF (CAS 3844-45-9)

GLYCERIN (CAS 56-81-5)

SILICA, AMORPHOUS HYDRATED (CAS 10279-57-9)

SILICON DIOXIDE (CAS 7631-86-9)

ZEODENT 113 (CAS 112926-00-8)

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

DI-SODIUM FLUOROPHOSPHATE (CAS 10163-15-2)

GLYCERIN (CAS 56-81-5)

SILICON DIOXIDE (CAS 7631-86-9)

ZEODENT 113 (CAS 112926-00-8)

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

DI-SODIUM FLUOROPHOSPHATE (CAS 10163-15-2)

GLYCERIN (CAS 56-81-5)

SILICA, AMORPHOUS HYDRATED (CAS 10279-57-9)

SILICON DIOXIDE (CAS 7631-86-9)

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

Issue date	11-07-2014
Revision date	11-07-2014
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