

1. Identification

Product identifier **BIOTENE DRY MOUTH TOOTHPASTE**

Other means of identification Not available.

Synonym(s) MFC: LACLEDE 310000022L * 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

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
CALCIUM PYROPHOSPHATE		7790-76-3	11.0 - 14.0
DI-SODIUM FLUOROPHOSPHATE	DISODIUM FLUOROPHOSPHATE DISODIUM MONOFLUOROPHOSPHATE DISODIUM PHOSPHOROFUORIDATE SODIUM FLUOROPHOSPHATE (NA2PO3F) SODIUM PHOSPHOROFUORIDATE SODIUM PHOSPHOROFUORIDATE	10163-15-2	<1.0
GLUCOSE OXIDASE			NA
LACTOFERRIN			NA
LACTOPEROXIDASE		9003-99-0	NA
LYSOZYME			NA
Other components below reportable levels			>85.0

4. First-aid measures

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

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.

Most important symptoms/effects, acute and delayed Not available.

Indication of immediate medical attention and special treatment needed

Treat symptomatically.

General information

Get medical attention if symptoms occur.

5. Fire-fighting measures

Suitable extinguishing media

Water. Carbon dioxide (CO2). Dry powder. Foam.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

Not applicable.

Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

Fire-fighting equipment/instructions

Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Local authorities should be advised if significant spillages cannot be contained. Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Ensure adequate ventilation.

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. See Section 8 of the MSDS for Personal Protective Equipment.

Environmental precautions

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

7. Handling and storage

Precautions for safe handling

No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

Conditions for safe storage, including any incompatibilities

Room temperature - normal conditions. Store in original tightly closed container.

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
SODIUM MONOFLUORO PHOSPHATE (CAS 10163-15-2)	PEL	2.5 mg/m3

US. OSHA Table Z-2 (29 CFR 1910.1000)

Components	Type	Value	Form
SODIUM MONOFLUORO PHOSPHATE (CAS 10163-15-2)	TWA	2.5 mg/m3	Dust.

US. ACGIH Threshold Limit Values

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

US. NIOSH: Pocket Guide to Chemical Hazards

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

Biological limit values

ACGIH Biological Exposure Indices

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

ACGIH Biological Exposure Indices				
Components	Value	Determinant	Specimen	Sampling Time
	2 mg/l	Fluoride	Urine	*
* - For sampling details, please see the source document.				
Appropriate engineering controls	No special ventilation requirements.			
Individual protection measures, such as personal protective equipment				
Eye/face protection	Wear safety glasses with side shields.			
Hand protection	Not normally needed.			
Other	No special protective equipment required.			
Respiratory protection	No personal respiratory protective equipment normally required.			
Thermal hazards	Not available.			
General hygiene considerations	Wash hands before breaks and immediately after handling the product.			

9. Physical and chemical properties

Appearance

Physical state	Solid.
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	Expected to be non-flammable based on components present.
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	Not available.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Health injuries are not known or expected under normal use.
Inhalation	Not available.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	May be irritating to eyes.

Symptoms related to the physical, chemical and toxicological characteristics None known.

Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use.
Skin corrosion/irritation	Health injuries are not known or expected under normal use.
Serious eye damage/eye irritation	May be irritating to eyes.
Respiratory sensitization	Not available.
Skin sensitization	Health injuries are not known or expected under normal use.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	Health injuries are not known or expected under normal use.
Reproductive toxicity	Contains no ingredient listed as toxic to reproduction.
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	No information is available about the potential of this material to produce adverse environmental effects.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Mobility in general	Not available.
Other adverse effects	Not available.

13. Disposal considerations

Disposal instructions	Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazardous waste code	Not regulated.
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	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 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

This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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

SARA 302 Extremely hazardous substance

No

SARA 311/312 Hazardous chemical

No

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.

Food and Drug Administration (FDA)

Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

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

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

Not Listed.

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
Revision date	08-09-2013
Version #	02
Further information	This material has not been assessed for HMIS or NFPA ratings. HMIS® is a registered trade and service mark of the NPCA.
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: Ingredients Physical & Chemical Properties: Transport Information: Agency Name, Packaging Type, and Transport Mode Selection