SAFETY DATA SHEET

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

<table>
<thead>
<tr>
<th>Hazardous components</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>CALCIUM PYROPHOSPHATE</td>
<td></td>
<td>7790-76-3</td>
<td>11.0 - 14.0</td>
</tr>
<tr>
<td>DI-SODIUM FLUOROPHOSPHATE</td>
<td>DISODIUM FLUOROPHOSPHATE</td>
<td>10163-15-2</td>
<td>&lt;1.0</td>
</tr>
<tr>
<td></td>
<td>DISODIUM MONOFLUOROPHOSPHATE</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>DISODIUM PHOSPHOROFLUORIDATE</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SODIUM FLUOROPHOSPHATE (NA2PO3F)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SODIUM PHOSPHOROFLUORIDATE</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SODIUM PHOSPHOROFLURIDATE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

GLUCOSE OXIDASE
LACTOFERRIN
LACTOPEROXIDASE
LYSOZYME

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)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM MONOFLUORO PHOSPHATE (CAS 10163-15-2)</td>
<td>PEL</td>
<td>2.5 mg/m3</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM MONOFLUORO PHOSPHATE (CAS 10163-15-2)</td>
<td>TWA</td>
<td>2.5 mg/m3</td>
<td>Dust.</td>
</tr>
</tbody>
</table>

US. ACGIH Threshold Limit Values

<table>
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<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
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US. NIOSH: Pocket Guide to Chemical Hazards

<table>
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<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM MONOFLUORO PHOSPHATE (CAS 10163-15-2)</td>
<td>TWA</td>
<td>2.5 mg/m3</td>
</tr>
</tbody>
</table>

Biological limit values

<table>
<thead>
<tr>
<th>Components</th>
<th>Value</th>
<th>Determinant</th>
<th>Specimen</th>
<th>Sampling Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM MONOFLUORO PHOSPHATE (CAS 10163-15-2)</td>
<td>3 mg/l</td>
<td>Fluoride</td>
<td>Urine</td>
<td>*</td>
</tr>
</tbody>
</table>
ACGIH Biological Exposure Indices

<table>
<thead>
<tr>
<th>Components</th>
<th>Value</th>
<th>Determinant</th>
<th>Specimen</th>
<th>Sampling Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoride</td>
<td>2 mg/l</td>
<td>Urine</td>
<td>*</td>
<td></td>
</tr>
</tbody>
</table>

* - 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)
  Not regulated.
- US. Rhode Island RTK
  Not regulated.
- US. California Proposition 65
  Not Listed.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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**
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection