

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture: BIOTENE DRY MOUTH TOOTHPASTE

Registration number: -

Synonyms: MFC: LACLEDE 310000022L * SODIUM MONOFLUOROPHOSPHATE, FORMULATED PRODUCT

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1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses: Oral Care

Uses advised against: No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::

UK In-country toll call: +(44)-870-8200418

International toll call: +1 703 527 3887

available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Supplemental label information: Not applicable.

2.3. Other hazards: This product is non-flammable.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
CALCIUM PYROPHOSPHATE	11.0 - 14.0	7790-76-3 232-221-5	-	-	
Classification:	DSD: -				
	CLP: -				

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
DI-SODIUM FLUOROPHOSPHATE	<1.0	10163-15-2 233-433-0	-	-	#
Classification:	DSD: Xn;R22 CLP: Acute Tox. 4;H302				
GLUCOSE OXIDASE	NA		-	-	
Classification:	DSD: - CLP: -				
LACTOFERRIN	NA		-	-	
Classification:	DSD: - CLP: -				
LACTOPEROXIDASE	NA	9003-99-0 232-668-6	-	-	
Classification:	DSD: - CLP: -				
LYSOZYME	NA		-	-	
Classification:	DSD: - CLP: -				
Other components below reportable levels >85.0					

SECTION 4: First aid measures

General information Get medical attention if symptoms occur.

4.1. Description of 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.

4.2. Most important symptoms and effects, both acute and delayed Not available.

4.3. Indication of any immediate medical attention and special treatment needed Treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards This product is non-flammable.

5.1. Extinguishing media

Suitable extinguishing media Water. Carbon dioxide (CO2). Dry powder. Foam.
Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture Not available.

5.3. Advice for firefighters

Special protective equipment for firefighters Wear suitable protective equipment.
Special fire fighting procedures Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel 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.

For emergency responders Keep unnecessary personnel away.

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

6.3. Methods and material for containment and cleaning up Stop the flow of material, if this is without risk. Following product recovery, flush area with water. See Section 8 for personal protective equipment.

6.4. Reference to other sections For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. 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.

7.2. Conditions for safe storage, including any incompatibilities Room temperature - normal conditions. Store in original tightly closed container.

7.3. Specific end use(s) Oral Care

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK
Not established

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
SODIUM MONOFLUORO PHOSPHATE (CAS 10163-15-2)	TWA	2.5 mg/m ³

Recommended monitoring procedures Not available.

Derived No Effect Level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

Appropriate engineering controls No special ventilation requirements.

Individual protection measures, such as personal protective equipment

General information Not available.

Eye/face protection Wear safety glasses with side shields. (eg. EN 166)

Skin protection

- **Hand protection** Not normally needed.

- **Other** No special protective equipment required.

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Not available.

Hygiene measures Wash hands before breaks and immediately after handling the product.

Environmental exposure controls

Hazard guidance and control recommendations Not available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state Solid.

Form Paste.

Colour Not available.

Odour	Not available.
Odour 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.
Vapour pressure	Not available.
Vapour 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.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	Not available.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	None under normal conditions.
10.5. Incompatible materials	Not available.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information	Health injuries are not known or expected under normal use.
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	None known.
11.1. 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 sensitisation	Not available.
Skin sensitisation	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.
Mixture versus substance information	Not available.
Other information	None known.

SECTION 12: Ecological information

12.1. Toxicity	No information is available about the potential of this material to produce adverse environmental effects.
12.2. Persistence and degradability	No data is available on the degradability of this product.
12.3. Bioaccumulative potential	Not available.
12.4. Mobility in soil	Not available.
Mobility in general	Not available.
12.5. Results of PBT and vPvB assessment	Not available.
12.6. Other adverse effects	Not available.
12.7. Additional information	None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

ADR	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I	Not listed.
Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II	Not listed.
Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended	Not listed.
Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended	Not listed.
Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended	Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended
Not listed.
Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended
Not listed.
Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry
Not listed.
Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA
Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended
Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended
Not listed.
Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work
Not listed.
Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding
Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances
Not listed.
Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work
Not listed.
Directive 94/33/EC on the protection of young people at work
Not listed.

Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws.
This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations

Not available.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

Not available.

References

GSK Hazard Determination

Information on evaluation method leading to the classification of mixture

Not available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R22 Harmful if swallowed.
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
H302 Harmful if swallowed.

Revision information

Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Transport Information: Agency Name and Packaging Type/Transport Mode Selection

Training information

Not available.

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.