



SAFETY DATA SHEET

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

1.1. Product identifier

Trade name or designation of the mixture: BIOTENE TOOTHPASTE
Registration number: -
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
Issue date: 07-November-2014
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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.

2.3. Other hazards

None known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
GLYCERIN	20 - < 30	56-81-5 200-289-5	-	-	
Classification:	DSD: -				
	CLP: -				

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
SILICA, AMORPHOUS HYDRATED	3 - < 5	10279-57-9 231-545-4	-	-	
Classification:	DSD: -				
	CLP: -				
Silicon dioxide	1 - < 3	7631-86-9 231-545-4	-	-	
Classification:	DSD: -				
	CLP: -				
ZEODENT 113	1 - < 3	112926-00-8 231-545-4	-	-	
Classification:	DSD: -				
	CLP: -				
DI-SODIUM FLUOROPHOSPHATE	0.76	10163-15-2 233-433-0	-	-	#
Classification:	DSD: Xn;R22				
	CLP: Acute Tox. 4;H302				
DEXTRANASE	0 - 0.1	Unassigned 232-803-9	-	-	
Classification:	DSD: -				
	CLP: -				
MUTANASE	0 - 0.1		-	-	
Classification:	DSD: -				
	CLP: -				
LACTOFERRIN	<0.04		-	-	
Classification:	DSD: -				
	CLP: -				
LACTOPEROXIDASE	<0.04	9003-99-0 232-668-6	-	-	
Classification:	DSD: -				
	CLP: -				
GLUCOSE OXIDASE	<0.02		-	-	
Classification:	DSD: -				
	CLP: -				
LYSOZYME	<0.02		-	-	
Classification:	DSD: -				
	CLP: -				

Other components below reportable levels 60 - < 70

List of abbreviations and symbols that may be used above

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

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.

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 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 CENTRE or doctor/physician if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed Direct contact with eyes may cause temporary irritation.

4.3. Indication of any 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.

SECTION 5: Firefighting measures

General fire hazards This product is non-flammable.

5.1. Extinguishing media

Suitable extinguishing media Alcohol resistant foam. Water fog. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures 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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel 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.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

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

6.3. Methods and material 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.

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling Avoid prolonged exposure. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

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

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	Form
SODIUM MONOFLUOROPHOSPHATE (CAS 10163-15-2)	TWA	2.5 mg/m3	
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.
SILICA, AMORPHOUS HYDRATED (CAS 10279-57-9)	TWA	6 mg/m3	Inhalable dust.
Silicon dioxide (CAS 7631-86-9)	TWA	2.4 mg/m3 6 mg/m3	Respirable dust. Inhalable dust.
ZEODENT 113 (CAS 112926-00-8)	TWA	2.4 mg/m3 6 mg/m3	Respirable dust. Inhalable dust.
		2.4 mg/m3	Respirable dust.

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU

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

Biological limit values

No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures

Follow standard monitoring procedures.

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. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

General information

Not normally needed. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection

Not normally needed. If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

Skin protection

- Hand protection

Not normally needed.

- Other

Not normally needed.

Respiratory protection

No personal respiratory protective equipment normally required.

Thermal hazards

Not available.

Hygiene measures

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.

Environmental exposure controls

Hazard guidance and control recommendations

Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Liquid.
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	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.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Solubility (other)	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

Percent volatile	39.6 % estimated
VOC (Weight %)	22.24 % Switzerland estimated

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
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	Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	None known. 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. Occupational exposure to the substance or mixture may cause adverse effects.

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 Direct contact with eyes may cause temporary irritation.

11.1. 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		
<i>Oral</i>		
LD50	Rat	> 2000 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.

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

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.

IARC Monographs. Overall Evaluation of Carcinogenicity

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.

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

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Not available.

Mixture versus substance information No information available.

Other information None known.

SECTION 12: Ecological information

12.1. Toxicity 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
Silicon dioxide (CAS 7631-86-9)		
Aquatic		
<i>Acute</i>		
Algae	EC50	Green algae (<i>Selenastrum capricornutum</i>) 440 mg/l, 72 hours
	NOEC	Green algae (<i>Selenastrum capricornutum</i>) 60 mg/l, 72 hours
Crustacea	EC50	Water flea (<i>Daphnia magna</i>) > 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (<i>Juvenile Cyprinus carpio</i>) > 10000 mg/l, 72 hours
		Zebra fish (<i>Adult Brachydanio rerio</i>) 5000 mg/l, 96 hours Static test
Microtox	EC50	Microtox 8700 mg/l, 15 minutes

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

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

12.3. Bioaccumulative potential No data available.

Partition coefficient n-octanol/water (log Kow)

GLYCERIN -1.76

Bioconcentration factor (BCF) Not available.

12.4. Mobility in soil No data available.

Mobility in general	Not available.
12.5. Results of PBT and vPvB assessment	Not available.
12.6. Other adverse effects	Not available.

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	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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	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.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

ADN

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(10) 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

Follow national regulation for work with chemical agents.

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

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

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

R22 Harmful if swallowed.
H302 Harmful if swallowed.

Revision information

Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Undisclosed Ingredient Statement

Training information

Follow training instructions when handling this material.

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.