



SAFETY DATA SHEET

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 of the chemical and restrictions on use

Recommended use Oral Care

Restrictions on use No other uses are advised.

Details of manufacturer or importer

Manufacturer

GlaxoSmithKline Australia
1061 Mountain Highway
Melbourne, Victoria 3155
Australia
Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS
(available 24hrs/7days: multi-language response)
Australia Toll Free +(61) 2 9037 2994
International Toll Call +(1) 703 527 3887

2. Hazard(s) identification

Classification of the hazardous chemical

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

Label elements, including precautionary statements

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

Other hazards which do not result in classification

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

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
GLYCERIN	56-81-5	20 - < 30
Glycerol		
GLYCERIN ANHYDROUS		
Glycerine		
GLYCERITOL		
GLYCYL ALCOHOL		
1,2,3-Propanetriol		
PROPANETRIOL		
GLYROL		
GLYSANIN		
TRIHIDROXYPROPANE		
1,2,3-TRIHIDROXYPROPANE		
OSMOGLYN		
SILICA, AMORPHOUS HYDRATED	10279-57-9	3 - < 5
SILCON DIOXIDE HYDRATE		
SILICA, HYDRATE		
HYDRATED AMORPHOUS SILICA		
Zeodent 113		
Zeodent 153		

Silicon dioxide	7631-86-9	1 - < 3
Silica		
Silica gel		
Amorphous silica		
DIATOMACEOUS EARTH		
INFUSORIAL EARTH		
CAB-O-SIL M-5		
ZEODENT 113	112926-00-8	1 - < 3
DI-SODIUM FLUOROPHOSPHATE	10163-15-2	0.76
DISODIUM FLUOROPHOSPHATE		
DISODIUM MONOFLUOROPHOSPHATE		
DISODIUM PHOSPHOROFUORIDATE		
SODIUM FLUOROPHOSPHATE (NA2PO3F)		
SODIUM PHOSPHOROFUORIDATE		
SODIUM PHOSPHOROFUORIDATE		
DEXTRANASE	Unassigned	0 - 0.1
MUTANASE		0 - 0.1
LACTOFERRIN		<0.04
LACTOPEROXIDASE	9003-99-0	<0.04
GLUCOSE OXIDASE		<0.02
LYSOZYME		<0.02
Other components below reportable levels		60 - < 70

4. First-aid measures

Description of necessary 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.

Personal protection for first-aid responders If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. 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.

Symptoms caused by exposure Direct contact with eyes may cause temporary irritation.

Medical attention and special treatment Provide general supportive measures and treat symptomatically. Symptoms may be delayed. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

5. Fire-fighting measures

Extinguishing media

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 fire fighters 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.

Hazchem Code Not available.

General fire hazards	This product is non-flammable.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

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.

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

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.

7. Handling and storage

Precautions for safe handling	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 and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

GSK
Not established

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

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

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

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

US. ACGIH Threshold Limit Values

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

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.

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value	Form
SODIUM MONOFLUOROPHOSPHATE (CAS 10163-15-2)	TWA	1 mg/m3	Inhalable fraction.
GLYCERIN (CAS 56-81-5)	TWA	50 mg/m3	Inhalable fraction.

Biological limit values**Germany. TRGS 903, BAT List (Biological Limit Values)**

Components	Value	Determinant	Specimen	Sampling time
SODIUM MONOFLUOROPHOSPHATE (CAS 10163-15-2)	7 mg/g	Fluorid	Creatinine in urine	*
	4 mg/g	Fluorid	Creatinine in urine	*

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

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.

Exposure guidelines

No exposure standards allocated.

Appropriate engineering controls

No special ventilation requirements. General ventilation normally adequate.

Individual protection measures, for example personal protective equipment (PPE)

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.

Hygiene measures

When using, do not eat, drink or smoke. 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.
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.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.

Vapour pressure	Not available.
Vapour 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 physical and chemical parameters

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 oxidising 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 possible 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 exposure Direct contact with eyes may cause temporary irritation.

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/irritation Not available.

Respiratory or skin sensitisation

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.

ACGIH Carcinogens

DI-SODIUM FLUOROPHOSPHATE (CAS 10163-15-2) A4 Not classifiable as a human carcinogen.

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.

Other 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
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

* 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.

Bioaccumulative potential No data available.

Partition coefficient
n-octanol / water (log Kow)

GLYCERIN

-1.76

Mobility in soil No data available.

Mobility in general Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal methods 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.

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.

14. Transport information

ADG

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

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 Not available.

15. Regulatory information

Safety, health and environmental regulations

National regulations This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

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

For advice, contact a Poisons information Centre (Phone eg Australia 131 - 126; New Zealand 03 - 4747 - 000) or a doctor (at once).

For advice, contact a Poisons information Centre (Phone eg Australia 131 - 126; New Zealand 03 - 4747 - 000) or a doctor (at once)., Urgent hospital treatment is likely to be needed. (Note - the words 'at once' to be added to instruction A)., If swallowed, do NOT induce vomiting., If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes., If skin or hair contact occurs, remove

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

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

applies to all preparations in any concentration Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 3

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

applies to all preparations in any concentration Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 4

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

for human use Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 5

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

in preparations Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 6

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

applies to all preparations in any concentration Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

Australia National Pollutant Inventory (NPI): Threshold quantity

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

10 TONNES/YR Threshold Category: 1

High Volume Industrial Chemicals (HVIC)

GLYCERIN (CAS 56-81-5)

1000 - 9999 TONNES See the regulation for additional information.

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

1000 - 9999 TONNES See the regulation for additional information.

Silicon dioxide (CAS 7631-86-9)

1000 - 9999 TONNES See the regulation for additional information.

ZEODENT 113 (CAS 112926-00-8)

1000 - 9999 TONNES See the regulation for additional information.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

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

2000 TONNES/YR Threshold Category: 2B

400 TONNES/YR Threshold Category: 2A

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations**Stockholm Convention**

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

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

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

Issue date 07-November-2014

Revision date 07-November-2014

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