



SAFETY DATA SHEET

1. Identification

Product identifier BIOTENE TOOTHPASTE SENSITIVE

Other means of identification

Synonyms MFC: LACLEDE 31002532L * SODIUM MONOFLUOROPHOSPHATE AND POTASSIUM NITRATE, 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
CALCIUM PYROPHOSPHATE	7790-76-3	12.0 - 13.0
Potassium nitrate	7757-79-1	5
Nitric acid potassium salt NITRIC ACID POTASSIUM SALT (1:1)		
SODIUM MONOFLUOROPHOSPHATE	10163-15-2	0.76
DISODIUM FLUOROPHOSPHATE		
DISODIUM MONOFLUOROPHOSPHATE		
DISODIUM PHOSPHOROFUORIDATE		
SODIUM FLUOROPHOSPHATE (NA ₂ PO ₃ F)		
SODIUM PHOSPHOROFUORIDATE		
SODIUM PHOSPHOROFUORIDATE		
GLUCOSE OXIDASE		NA
LACTOFERRIN		NA
LACTOPEROXIDASE	9003-99-0	NA
LYSOZYME		NA
Other components below reportable levels		81.491

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 (CO ₂).
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
SODIUM MONOFLUOROPHOSPHA TE (CAS 10163-15-2)	TWA	2.5 mg/m3

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

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

US. ACGIH Threshold Limit Values

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

UK. EH40 Workplace Exposure Limits (WELs)

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

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 MONOFLUOROPHOSPHA TE (CAS 10163-15-2)	TWA	1 mg/m3	Inhalable fraction.

Biological limit values

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

Components	Value	Determinant	Specimen	Sampling time
SODIUM MONOFLUOROPHOSPHA TE (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 MONOFLUOROPHOSPHA TE (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	36.4 % estimated
VOC (Weight %)	24.1 % 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.
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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.
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Acute toxicity	Health injuries are not known or expected under normal use.
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Skin corrosion/irritation	Health injuries are not known or expected under normal use.
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Serious eye damage/irritation	Not available.
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Respiratory or skin sensitisation

Respiratory sensitisation	Not available.
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Skin sensitisation	Health injuries are not known or expected under normal use.
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Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
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Carcinogenicity	Health injuries are not known or expected under normal use.
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ACGIH Carcinogens

SODIUM MONOFLUOROPHOSPHATE (CAS 10163-15-2)	A4 Not classifiable as a human carcinogen.
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Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.
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Specific target organ toxicity - single exposure	None known.
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Specific target organ toxicity - repeated exposure	None known.
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Aspiration hazard	Not available.
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Other information	None known.
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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.
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Components	Species		Test results
Potassium nitrate (CAS 7757-79-1)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	490 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	420 mg/l, 96 hours Static test
		Guppy (Juvenile Poecilia reticulata)	180 mg/l, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis)	22.5 mg/l, 96 hours Static test

* 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.
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Bioaccumulative potential	No data available.
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Mobility in soil	No data available.
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Mobility in general	Not available.
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Other adverse effects	Not available.
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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.
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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

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

SODIUM MONOFLUOROPHOSPHATE (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

SODIUM MONOFLUOROPHOSPHATE (CAS 10163-15-2)

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

Australia Medicines & Poisons Schedule 3

SODIUM MONOFLUOROPHOSPHATE (CAS 10163-15-2)

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

Australia Medicines & Poisons Schedule 4

SODIUM MONOFLUOROPHOSPHATE (CAS 10163-15-2)

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

Australia Medicines & Poisons Schedule 5

SODIUM MONOFLUOROPHOSPHATE (CAS 10163-15-2)

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

Australia Medicines & Poisons Schedule 6

SODIUM MONOFLUOROPHOSPHATE (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

SODIUM MONOFLUOROPHOSPHATE (CAS 10163-15-2)

10 TONNES/YR Threshold Category: 1

High Volume Industrial Chemicals (HVIC)

Not listed.

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

Not listed.

National Pollutant Inventory (NPI) substance reporting list

SODIUM MONOFLUOROPHOSPHATE (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

SODIUM MONOFLUOROPHOSPHATE (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

Country(s) or region	Inventory name	On inventory (yes/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	13-November-2014
Revision date	13-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 Physical & Chemical Properties: Transport Information: Agency Name, Packaging Type, and Transport Mode Selection