



SAFETY DATA SHEET

1. Identification

Product identifier BIOTENE ORIGINAL ORAL RINSE / MOUTH WASH
Other means of identification
Synonyms MFC 03665 * PROJECT SAVANNA * ORAL CARE, FORMULATED PRODUCT
Recommended use Oral Care

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

COMPANY NAME GlaxoSmithKline US
Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA
Telephone: +1-888-825-5249 (General Inquiries)
Email: msds@gsk.com
Website: www.gsk.com

EMERGENCY CONTACTS

Telephone: VERISK 3E GLOBAL INCIDENT RESPONSE
+(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response
Contract Number: 334878

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

Chemical name	Common name and synonyms	CAS number	%
GLYCEROL	GLYCERINE 1,2,3-PROPANETRIOL GLYCYL ALCOHOL TRIHIDROXYPROPANE 1,2,3-TRIHIDROXYPROPANE GLYCERIN, ANHYDROUS GLYCERIN 1,2,3-PROPANTRIOL	56-81-5	10
XYLITOL	D-XYLITOL 1,2,3,4,5-PENTAHYDROXYPENTANE KLINIT KYLIT XYLITE XYLITON BP-706	87-99-0	7.0 - 8.0
Other components below reportable levels			>82.0

4. 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. Remove and isolate contaminated clothing and shoes. Get medical attention immediately.
Eye contact	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Ingestion	Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
Most important symptoms/effects, acute and delayed	Not available.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
General information	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.

5. Fire-fighting measures

Suitable extinguishing media	Water. Dry powder. Foam. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Not applicable.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
General fire hazards	This product is non-flammable.

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. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate personal protective equipment. Do not touch or walk through spilled material. Ensure adequate ventilation. Avoid inhalation of vapors or mists.
Methods and materials for containment and cleaning up	Remove sources of ignition. Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Use water spray to reduce vapors or divert vapor cloud drift. 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 in original containers for re-use.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. No special environmental precautions required.

7. Handling and storage

Precautions for safe handling	Do not get this material in contact with eyes. Avoid breathing mist or vapor. Avoid contact with skin. Avoid prolonged exposure. Handle and open container with care. Use care in handling/storage.
Conditions for safe storage, including any incompatibilities	Room temperature - normal conditions. Keep away from heat and sources of ignition. Store in tightly closed original container in a well-ventilated place.

8. Exposure controls/personal protection

Occupational exposure limits

GSK Components	Type	Value	Note
XYLITOL (CAS 87-99-0)	OHC	1	>1000 - <=5000 mcg/m ³

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
GLYCEROL (CAS 56-81-5)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	No special ventilation requirements.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear safety glasses with side shields.
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.
General hygiene considerations	Wash hands before breaks and immediately after handling the product.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Solution
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 > 203 °F (> 95 °C) Closed Cup (Estimation based on components).

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)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Percent volatile 71.5 % 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	None under normal conditions.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Not available.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	May be irritating to eyes.
Ingestion	Health injuries are not known or expected under normal use.

Symptoms related to the physical, chemical and toxicological characteristics Not available.

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 or skin sensitization

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 No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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 Based on available data, the classification criteria are not met. Due to lack of data the classification is not possible. Not available.

Further information None known.

12. Ecological information

Ecotoxicity No ecotoxicity data noted for the ingredient(s).

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

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

XYLITOL 82 %, 14 days BOD 14, Activated sludge

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

GLYCEROL -1.76

Mobility in soil Not available.
Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Contract with a disposal operator licensed by the Law on Disposal and Cleaning. 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. Dispose in accordance with all applicable regulations. When your own wastewater treatment plant is not available, collect entire waste and then charge to a licensed industrial waste management professional with manifests for industrial waste.

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). Not applicable.

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

DOT
Not regulated as a dangerous good.

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 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

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 313 (TRI reporting)

Not regulated.

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.

FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

TRADE SECRET (CAS Proprietary)

Other Flavoring Substances with OSHA PEL's

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

Country(s) or region	Inventory name	On inventory (yes/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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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, including date of preparation or last revision

Issue date	08-12-2013
Revision date	05-17-2019
Version #	03
Further information	This material has not been assessed for HMIS or NFPA ratings. HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 0 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 0 Flammability: 0 Instability: 0

References

GSK Hazard Determination
ACGIH
EPA: AQUIRE database
NLM: Hazardous Substances Data Base
US. IARC Monographs on Occupational Exposures to Chemical Agents
Korea. Accidental Release Prevention Substances (Presidential Decree of Toxic Chemical Control Law, Executive Order No. 19203)
Korea. Dangerous Substances Threshold Quantity (Presidential Decree of Dangerous Substances Safety Management Act No. 18406, Schedule 1)
Korea. Harmful Substances Prohibited from Manufacturing (Presidential Decree on the Industrial Safety and Health Act (No. 13053), Article 29)
Korea. Harmful Substances Requiring Permission for Manufacture or Use (Presidential Decree on the Industrial Safety and Health Act (No. 13053), Article 30)
Korea. Non-Toxic Chemicals List (National Institute of Environment Research (NIER) Public Notice No. 1997-10, as amended)
Korea. Observational Chemicals (Ministerial Decree of TCCL Article 6)
Korea. OELs. Regulation for Permitted Concentration of Hazardous Substances (Ministry of Labor (MOL) Public Notice No. 1986-45, as amended)
Korea. Prohibited Chemical Substances (TCCL Article 11)
Korea. Regulated volatile organic compounds (VOCs) (MOE Notice No. 2001-36, March 8, 2001, as amended)
Korea. Restricted Chemical Substances (TCCL Article 11)
Korea. Toxic Chemical Control Law (TCCL), Existing Chemicals Inventory (KECI)
Korea. Toxic Chemical Control Law (TCCL), pre-1997 List
Korea. Toxic Chemicals (TCCL Article 10)
Korea. Toxic Release Inventory (TRI) Chemicals (TCCL Article 14)
Taiwan. Dangerous Materials (Rules on Hazard Communication of Dangerous Materials and Toxic Materials)
Taiwan. Industrial Precursor Chemicals (Categories and Regulations Governing Inspection and Declaration of Industrial Precursor Chemicals, MOEA Decree No. 87, as amended)
Taiwan. OELs. (Standards on Workplace Atmosphere of Dangerous and Hazardous Materials)
Taiwan. Toxic Chemical Substances (TCS) (List of Toxic Chemical Substances announced by the Environmental Protection Administration)
Taiwan. Toxic Materials (Rules on Hazard Communication of Dangerous Materials and Toxic Materials)
HSDB® - Hazardous Substances Data Bank
IARC Monographs. Overall Evaluation of Carcinogenicity
National Toxicology Program (NTP) Report on Carcinogens
ACGIH Documentation of the Threshold Limit Values and Biological Exposure Indices
Japan Society for Occupational Health, Recommendation of Occupational Exposure Limits
GOST 30333-2007 - Chemical production safety passport. General requirements
JJIS Z 7250: 2010 Safety data sheet for chemical products-Content and order of sections
JIS Z 7251: 2010 Labeling of chemicals based on GHS

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

Physical and chemical properties: Form
Toxicological information: Reproductivity
Other information, including date of preparation or last revision: References
GHS: Classification