



SAFETY DATA SHEET

1. Identification

Product identifier **BIOTENE ORAL BALANCE GEL**

Other means of identification Not available.

Synonym(s) MFC04085 BIOTENE ORAL BALANCE GEL WITH LOW WATER ACTIVITY * MFC03004 BIOTENE ORAL BALANCE GEL US * MFC03003 BIOTENE ORAL BALANCE GEL * ORAL CARE, FORMULATED PRODUCT

Recommended use Cosmetic Product
Medicinal Product

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 No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

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	%
GLYCERIN	GLYCEROL GLYCERIN ANHYDROUS GLYCERINE GLYCERITOL GLYCYL ALCOHOL 1,2,3-PROPANETRIOL PROPANETRIOL GLYROL GLYSANIN TRIHIDROXYPROPANE 1,2,3-TRIHIDROXYPROPANE OSMOGLYN	56-81-5	15 - < 55
D-SORBITOL	SORBITOL L-GULITOL 1,2,3,4,5,6-HEXANEHEXOL D-SORBOL	50-70-4	20 - < 40

Chemical name	Common name and synonyms	CAS number	%
DISODIUM HYDROGEN PHOSPHATE	DISODIUM HYDROGEN ORTHOPHOSPHATE PHOSPHORIC ACID, DISODIUM SALT DIBASIC SODIUM PHOSPHATE DISODIUM MONOHYDROGEN PHOSPHATE E DSP EXSICCATED SODIUM PHOSPHATE SODA PHOSPHATE DISODIUM PHOSPHORIC ACID SODIUM MONOHYDROGEN PHOSPHATE DISODIUM ACID ORTHOPHOSPHATE DISODIUM HYDROPHOSPHATE HYDROGEN DISODIUM PHOSPHATE DISODIUM HYDROGEN PHOSPHATE ANHYDROUS SODIUM PHOSPHATE DIBASIC DISODIUM PHOSPHATE TRISODIUM PHOSPHATE	7558-79-4	0 - < 0.1
GLUCOSE OXIDASE		9001-37-0	0 - < 0.1
LACTOFERRIN			0 - < 0.1
LACTOPEROXIDASE		9003-99-0	0 - < 0.1
LYSOZYME			0 - < 0.1
SORBIC ACID	2,4-HEXADIENOIC ACID SORBISTAT 2,4-HEXADIENOIC ACID, (E,E)- E,E-2,4-HEXADIENOIC ACID (E,E)-2,4-HEXADIENOIC ACID TRANS, TRANS-2,4-HEXADIENOIC ACID TRANS, TRANS-SORBIC ACID (E,E)-SORBIC ACID 2-PROPENYL-ACRYLIC ACID HEXA-2,4-DIENSYRE GI148909X	110-44-1	0 - < 0.1
Other components below reportable levels			> 20

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

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. 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 CENTER or doctor/physician if you feel unwell.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation.
Indication of 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.
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 fog. Foam. 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 firefighters	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.
Specific methods	Move containers from fire area if you can do so without risk.

General fire hazards Assume that this product is capable of sustaining combustion.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up 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. 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. For waste disposal, see section 13 of the SDS.

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

7. Handling and storage

Precautions for safe handling Avoid prolonged exposure. 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/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)	8 HR TWA	5000 mcg/m3	
D-SORBITOL (CAS 50-70-4)	OHC	1	
SORBIC ACID (CAS 110-44-1)	OHC	1	
	OHC	2	SKIN SENSITISER

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

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

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

Appropriate engineering controls No particular ventilation requirements. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

Individual protection measures, such as personal protective equipment

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Hand protection Not normally needed.

Other Not normally needed.

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Not available.

General hygiene considerations 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 Gel.

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 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.
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.

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 oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Health injuries are not known or expected under normal use.
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.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation.

Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.

Components	Species	Test Results
DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)		
Acute		
<i>Oral</i>		
LD50	Rat	17 g/kg
D-SORBITOL (CAS 50-70-4)		
Acute		
<i>Oral</i>		
LD50	Rat	15.9 g/kg
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 Due to partial or complete lack of data the classification is not possible.

Serious eye damage/eye irritation Due to partial or complete lack of data the classification is not possible.

Respiratory or skin sensitization

Respiratory sensitization None known.

Skin sensitization Due to partial or complete lack of data the classification is not possible.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity - single exposure Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure Due to partial or complete lack of data the classification is not possible.

Aspiration hazard Not available.

Further 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
DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) 252 mg/l

* 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)

D-SORBITOL	-2.2
GLYCERIN	-1.76
SORBIC ACID	1.33

Bioconcentration factor (BCF)

D-SORBITOL	1 Estimated
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Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

D-SORBITOL	0.3 Estimated
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Mobility in general Not available.

Volatility

Henry's law

D-SORBITOL	0 atm m ³ /mol Estimated
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Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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).

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

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

SORBIC ACID (CAS 110-44-1) 1.0 % One-Time Export Notification only.

CERCLA Hazardous Substance List (40 CFR 302.4)

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4) Listed.

SARA 304 Emergency release notification

Not regulated.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

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.

US state regulations

US. Massachusetts RTK - Substance List

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)
GLYCERIN (CAS 56-81-5)

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)
GLYCERIN (CAS 56-81-5)

US. Rhode Island RTK

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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

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

Issue date	03-21-2014
Revision date	03-21-2014
Version #	02
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 1* Flammability: 1 Physical hazard: 0
NFPA ratings	Health: 1 Flammability: 1 Instability: 0
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: Multiple Properties Regulatory Information: United States