# SAFETY DATA SHEET

## 1. Identification

**Product identifier** **BIOTENE ORAL BALANCE GEL**

**Other means of identification**

**Synonyms** 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**

**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**

CHEMTREC EMERGENCY NUMBERS
**Telephone:** +(1) 703 527 3887 (International)
24/7; multi-language response
**Contract Number:** CCN9484

VERISK 3E GLOBAL INCIDENT RESPONSE
**Telephone:** +(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 | % |
|---|---|---|---|
| GLYCERIN | GLYCEROL<br>GLYCERIN ANHYDROUS<br>GLYCERINE<br>GLYCERITOL<br>GLYCYL ALCOHOL<br>1,2,3-PROPANETRIOL<br>PROPANETRIOL<br>GLYROL<br>GLYSANIN<br>TRIHYDROXYPROPANE<br>1,2,3-TRIHYDROXYPROPANE<br>OSMOGLYN | 56-81-5 | 15 - < 55 |
| D-SORBITOL | SORBITOL<br>L-GULITOL<br>1,2,3,4,5,6-HEXANEHEXOL<br>D-SORBOL | 50-70-4 | 20 - < 40 |
| SODIUM POLYACRYLATE | POLYACRYLIC ACID, SODIUM SALT<br>ACRYLIC ACID POLYMER, SODIUM SALT<br>SODIUM POLYACRYLATE (ACRYLIC ACID POLYMER) | 9003-04-7 | < 1 |
| HYDROXYETHYL CELLULOSE | CELLULOSE, 2-HYDROXYETHYL ETHE<br>2-HYDROXYETHYL ETHER CELLULOS<br>E CELLOSIZE<br>NATROSOL<br>2-HYDROXYETHYL CELLULOSE<br>HYDROXYETHYL CELLULOSE ETHER<br>2-HYDROXYETHYL CELLULOSE ETHE<br>R HYDROXYETHYL ETHER CELLULOSE<br>CELLULOSE HYDROXYETHYLATE<br>CELLULOSE HYDROXYETHYL ETHER<br>OHS80130<br>RTECS FJ5958000<br>NATROSOL 250G<br>NATROSOL 250M | 9004-62-0 | < 0.3 |
| BENZOIC ACID | BENZENECARBOXYLIC ACID<br>BENZENEMETHANOIC ACID<br>BENZENEFORMIC ACID<br>BENZOATE<br>CARBOXYBENZENE<br>DRACYLIC ACID<br>PHENYL CARBOXYLIC ACID<br>PHENYLFORMIC ACID<br>PHENYLCARBOXYLIC ACID<br>E 210<br>HA 1<br>HA 1(ACID)<br>RETARDEX<br>RETARDER BA<br>SOLVO POWDER<br>TENN-PLAS<br>OHS02720<br>RTECS DG0875000 | 65-85-0 | < 0.1 |

| Chemical name | Common name and synonyms | CAS number | % |
|---|---|---|---|
| DISODIUM HYDROGEN PHOSPHATE | DISODIUM HYDROGEN ORTHOPHOSPHATE<br>PHOSPHORIC ACID, DISODIUM SALT<br>DIBASIC SODIUM PHOSPHATE<br>DISODIUM MONOHYDROGEN PHOSPHATE<br>DSP<br>EXSICCATED SODIUM PHOSPHATE<br>SODA PHOSPHATE<br>DISODIUM PHOSPHORIC ACID<br>SODIUM MONOHYDROGEN PHOSPHATE<br>DISODIUM ACID ORTHOPHOSPHATE<br>DISODIUM HYDROPHOSPHATE<br>HYDROGEN DISODIUM PHOSPHATE<br>DISODIUM HYDROGEN PHOSPHATE ANHYDROUS<br>SODIUM PHOSPHATE DIBASIC<br>DISODIUM PHOSPHATE<br>TRISODIUM PHOSPHATE | 7558-79-4 | 0 - < 0.1 |
| GLUCOSE OXIDASE | | 9001-37-0 | 0 - < 0.1 |
| LACTOFERRIN | | | 0 - < 0.1 |
| LACTOPEROXIDASE | peroxydase | 9003-99-0 | 0 - < 0.1 |
| LYSOZYME | | | 0 - < 0.1 |
| POTASSIUM THIOCYANATE | POTASSIUM ISOTHIOCYANATE<br>THIOCARA<br>PHODA-NIDE<br>POTASSIUM SULFOCYANATE<br>POTASSIUM RHODANIDE<br>POTASSIUM RHODANATE<br>ATERO-CYN<br>ARTEROCYN<br>KYONATE<br>RHOCYN<br>RODANCA<br>P-317<br>OHS19640<br>RTECS XL1925000<br>166 (GW ACN) | 333-20-0 | < 0.1 |
| SORBIC ACID | 2,4-HEXADIENOIC ACID<br>SORBISTAT<br>2,4-HEXADIENOIC ACID, (E,E)-<br>E,E-2,4-HEXADIENOIC ACID<br>(E,E)-2,4-HEXADIENOIC ACID<br>TRANS, TRANS-2,4-HEXADIENOIC ACI<br>D TRANS, TRANS-SORBIC ACID<br>(E,E)-SORBIC ACID<br>2-PROPENYL-ACRYLIC ACID<br>HEXA-2,4-DIENSYRE<br>GI148909X | 110-44-1 | < 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.<br><br>Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.<br><br>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 |
|---|---|---|---|
| BENZOIC ACID (CAS 65-85-0) | OHC | 2 | PROVISIONAL |
| DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4) | 8 HR TWA | 5000 mcg/m3 | |
| | OHC | 1 | |
| HYDROXYETHYL CELLULOSE (CAS 9004-62-0) | OHC | 2 | >100 - </=1000 mcg/m3 PROVISIONAL |
| POTASSIUM THIOCYANATE (CAS 333-20-0) | 8 HR TWA | 5000 mcg/m3 | |
| | OHC | 1 | |
| SODIUM POLYACRYLATE (CAS 9003-04-7) | OHC | 2 | >100 - </=1000 mcg/m3 PROVISIONAL |
| SORBIC ACID (CAS 110-44-1) | 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 | Respirable fraction. |
| | | 15 mg/m3 | 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.

**Skin protection**

**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**

| | |
|---|---|
| **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 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** | | |
| **Oral** | | |
| LD50 | Rat | 17 g/kg |
| D-SORBITOL (CAS 50-70-4) | | |
| **Acute** | | |
| **Oral** | | |
| LD50 | Rat | 15.9 g/kg |
| GLYCERIN (CAS 56-81-5) | | |
| **Acute** | | |
| **Oral** | | |
| 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. |

**Buehler test**

| | |
|---|---|
| BENZOIC ACID | Result: Negative<br>Species: Guinea pig |

**Maximisation assay (Magnusson and Kligman)**

| | |
|---|---|
| BENZOIC ACID | Result: Negative<br>Species: Guinea pig |

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

**Carcinogenicity**

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not regulated.

**US. National Toxicology Program (NTP) Report on Carcinogens**

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 |
|---|---|---|---|
| BENZOIC ACID (CAS 65-85-0) | | | |
| *Acute* | | | |
| | IC50 | Activated sludge | > 1000 mg/l, 3 hours |
| **Aquatic** | | | |
| *Acute* | | | |
| Algae | EC50 | Green algae (Scenedesmus quadricauda) | > 10 mg/l, 14 days Static test |
| Crustacea | EC50 | Water flea (Daphnia magna) | 500 mg/l, 24 hours |
| Fish | EC50 | Mosquito fish (Juvenile Gambusia affinis) | 180 mg/l, 96 hours Static test |
| Microtox | EC50 | Microtox | 16.9 mg/l, 30 minutes |
| DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4) | | | |
| **Aquatic** | | | |
| *Acute* | | | |
| 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.

**Photolysis**

**Half-life (Photolysis-atmospheric)**

| | |
|---|---|
| BENZOIC ACID | < 2 Days Estimated |

**UV/visible spectrum wavelength**

| | |
|---|---|
| BENZOIC ACID | 279 nm |

**Biodegradability**

**Percent degradation (Aerobic biodegradation-inherent)**

| | |
|---|---|
| BENZOIC ACID | > 90 %, 2 days Modified Zahn-Wellens, Activated sludge |

**Percent degradation (Aerobic biodegradation-soil)**

| | |
|---|---|
| BENZOIC ACID | 50 %, 7 days |

**Bioaccumulative potential** No data available.

**Partition coefficient n-octanol / water (log Kow)**

| | |
|---|---|
| BENZOIC ACID | 1.87 |
| D-SORBITOL | -2.2 |
| GLYCERIN | -1.76 |
| SORBIC ACID | 1.33 |

**Bioconcentration factor (BCF)**

| | |
|---|---|
| D-SORBITOL | 1 Estimated |

**Mobility in soil** No data available.

**Adsorption**

**Soil/sediment sorption - log Koc**

| | |
|---|---|
| BENZOIC ACID | 2.26 Measured |
| D-SORBITOL | 0.3 Estimated |

**Mobility in general** Not available.

**Volatility**

**Henry's law**

| | |
|---|---|
| BENZOIC ACID | 0 atm m^3/mol Estimated |

**Volatility**

**Henry's law**

| | |
|---|---|
| D-SORBITOL | 0 atm m^3/mol Estimated |

**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)**

| | |
|---|---|
| BENZOIC ACID (CAS 65-85-0) | Listed. |
| DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4) | Listed. |

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not regulated.

**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.

**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, including date of preparation or last revision

**Issue date** 05-09-2018

**Revision date** 05-09-2018

**Version #** 02

**Further information** HMIS® is a registered trade and service mark of the NPCA.

**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: Synonyms
Composition / Information on Ingredients: Undisclosed Ingredient Statement
Physical & Chemical Properties: Multiple Properties
Regulatory Information: United States
Other information, including date of preparation or last revision: References