

1. Identification

Product identifier **BIOTENE PBF MOUTHWASH**

Other means of identification Not available.

Synonym(s) SAVANNA PBF MOUTHWASH (SYMRISE) * BIOTENE PLAQUE BIOFILM DISSOLVING MOUTHWASH * MFC04122 * DEXTRANASE "AMANO" OC MOUTHWASH * 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 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
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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

| Hazardous components | | | |
|----------------------|--|------------|-----|
| Chemical name | Common name and synonyms | CAS number | % |
| SODIUM BENZOATE | BENZOIC ACID, SODIUM SALT BENZOATE OF SODA SODIUM BENZOIC ACID C7H6NaO2 OHS20965 RTECS DH6650000 GR 33388B 427 (GW ACN) | 532-32-1 | 0.5 |

| Hazardous components | | | |
|--|---|------------|-------|
| Chemical name | Common name and synonyms | CAS number | % |
| METHYL PARABEN | GR30517X METHYL P-HYDROXYBENZOATE P-HYDROXYBENZOIC ACID, METHYL ESTER 4-HYDROXYBENZOIC ACID, METHYL ESTER METHYL P-OXYBENZOATE METHYL PARAHYDROXYBENZOATE C8H8O3 OHS14677 RTECS DH2450000 NIPOGIN U124 | 99-76-3 | 0.1 |
| PROPYL PARABEN | PROPYL P-HYDROXYBENZOATE NIPASOL TEGOSEPT P PROTABEN 4-HYDROXYBENZOIC ACID, PROPYL ESTER P-HYDROXYBENZOIC ACID, PROPYL ESTER PASEPTOL PARASEPT ASEPTOFORM P BETACIDE P BONOMOLD OP PROPYL ASEPTOFORM PROPYL P-OXYBENZOATE PROPYL CHEMOSEPT PRESERVAL P CHEMOCIDE PK SOLBROL P PROPYL PARASEPT C10H12O3 OHS19941 RTECS DH2800000 | 94-13-3 | 0.1 |
| DEXTRANASE | | 9025-70-1 | <0.1 |
| OPTAMINT MILD SWEET FRUIT 984112 | | Unassigned | <0.1 |
| Other components below reportable levels | | | >99.0 |

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

4. First-aid measures

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| Inhalation | Move to fresh air. Call a physician if symptoms develop or persist. |
| Skin contact | Wash off with soap and water. 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. Get medical attention if symptoms occur. |
| 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 symptomatically. |
| General information | Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. If you feel unwell, seek medical advice (show the label where possible). Show this safety data sheet to the doctor in attendance. |

5. Fire-fighting measures

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| Suitable extinguishing media | Alcohol resistant foam. Water fog. Dry chemical powder. Carbon dioxide (CO2). |
| Unsuitable extinguishing media | Do not use water jet as an extinguisher, as this will spread the fire. |
| Specific hazards arising from the chemical | During fire, gases hazardous to health may be formed. |

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| 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 | Use standard firefighting procedures and consider the hazards of other involved materials. |

6. Accidental release measures

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| Personal precautions, protective equipment and emergency procedures | 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 of the MSDS. |
| 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. Use water spray to reduce vapors or divert vapor cloud drift. 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 in original containers for re-use. For waste disposal, see section 13 of the MSDS. |
| Environmental precautions | Avoid discharge into drains, water courses or onto the ground. |

7. Handling and storage

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|---|---|
| Precautions for safe handling | Avoid prolonged exposure. Observe good industrial hygiene practices. |
| Conditions for safe storage, including any incompatibilities | Store in accordance with local/regional/national/international regulation. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the MSDS). |

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

| | Type | Value |
|--------------------------------|----------|-------------|
| PROPYL PARABEN (CAS 94-13-3) | 8 HR TWA | 5000 mcg/m3 |
| | OHC | 1 |
| SODIUM BENZOATE (CAS 532-32-1) | 8 HR TWA | 5000 mcg/m3 |
| | OHC | 1 |

| | |
|--|---|
| Biological limit values | No biological exposure limits noted for the ingredient(s). |
| Appropriate engineering controls | Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. |
| Individual protection measures, such as personal protective equipment | |
| Eye/face protection | Wear safety glasses with side shields (or goggles). |
| Hand protection | Wear protective gloves. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Glove selection must take into account any solvents and other hazards present. |
| Other | Wear appropriate chemical resistant clothing. |
| Respiratory protection | In case of insufficient ventilation, wear suitable respiratory equipment. |
| Thermal hazards | Wear appropriate thermal protective clothing, when necessary. |
| General hygiene considerations | 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. |

9. Physical and chemical properties

Appearance

| | |
|-----------------------|----------------|
| Physical state | Liquid. |
| Form | Solution. |
| Color | Not available. |
| Odor | Not available. |
| Odor threshold | Not available. |

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|---|----------------|
| pH | 6.0 - 7.0 |
| 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) | 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

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|---|---|
| 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 | Not available. |
| 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 | Due to lack of data the classification is not possible. Health injuries are not known or expected under normal use. |
| Inhalation | Due to lack of data the classification is not possible. Health injuries are not known or expected under normal use. |
| Skin contact | Due to lack of data the classification is not possible. Health injuries are not known or expected under normal use. |
| Eye contact | Due to lack of data the classification is not possible. Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation. |

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

Information on toxicological effects

Acute toxicity Due to lack of data the classification is not possible.

| Components | Species | Test Results |
|------------------------------|----------------|---------------------|
| METHYL PARABEN (CAS 99-76-3) | | |
| Acute | | |
| <i>Oral</i> | | |
| LD50 | Mouse | > 8 g/kg |

| Components | Species | Test Results |
|------------------------------|---------|--------------|
| PROPYL PARABEN (CAS 94-13-3) | | |
| 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 lack of data the classification is not possible. Health injuries are not known or expected under normal use. |
| Serious eye damage/eye irritation | Due to lack of data the classification is not possible. Direct contact with eyes may cause temporary irritation. |
| Respiratory sensitization | Due to lack of data the classification is not possible. |
| Skin sensitization | Due to lack of data the classification is not possible. Health injuries are not known or expected under normal use. |
| Germ cell mutagenicity | Due to lack of data the classification is not possible. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. |
| Carcinogenicity | Due to lack of data the classification is not possible. Health injuries are not known or expected under normal use. |
| Reproductive toxicity | Due to lack of data the classification is not possible. This product is not expected to cause reproductive or developmental effects. |
| Specific target organ toxicity - single exposure | Due to lack of data the classification is not possible. |
| Specific target organ toxicity - repeated exposure | Due to lack of data the classification is not possible. |
| Aspiration hazard | Not available. |
| Further information | This product has no known adverse effect on human health. |

12. Ecological information

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| 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 |
|--------------------------------|------|---|---------------------------------------|
| SODIUM BENZOATE (CAS 532-32-1) | | | |
| Aquatic | | | |
| Acute | | | |
| Crustacea | EC50 | Water flea (Daphnia magna) | > 100 mg/L, 96 hours, Static test |
| Fish | EC50 | Fathead minnow (Juvenile Pimephales promelas) | 484 mg/L, 96 hours, Flow-through 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. |
|--------------------------------------|--|

Biodegradability

Percent degradation (Anaerobic biodegradation)

| | |
|-----------------|--|
| SODIUM BENZOATE | 93 %, 7 days Other degradation test system, Mixed Residential/Industrial |
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| | |
|----------------------------------|--------------------|
| Bioaccumulative potential | No data available. |
|----------------------------------|--------------------|

Partition coefficient n-octanol / water (log Kow)

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|-----------------|------|
| SODIUM BENZOATE | 1.89 |
| METHYL PARABEN | 1.96 |
| PROPYL PARABEN | 3.04 |

| | |
|-------------------------|--------------------|
| Mobility in soil | No data available. |
|-------------------------|--------------------|

Adsorption

Soil/sediment sorption - log Koc

| | |
|-----------------|-----------------|
| SODIUM BENZOATE | 1.16 Calculated |
|-----------------|-----------------|

Mobility in general

Distribution

Octanol/water distribution coefficient log DOW

| | |
|----------------|------|
| PROPYL PARABEN | 3.04 |
|----------------|------|

| | |
|------------------------------|---|
| Other adverse effects | No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component. |
|------------------------------|---|

13. Disposal considerations

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| 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

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| DOT | Not regulated as a dangerous good. |
| IATA | Not regulated as a dangerous good. |
| IMDG | Not regulated as a dangerous good. |
| 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

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| US federal regulations | |
| TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) | Not regulated. |
| CERCLA Hazardous Substance List (40 CFR 302.4) | Not listed. |
| US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) | Not listed. |
| SARA 304 Emergency release notification | Not regulated. |
| Superfund Amendments and Reauthorization Act of 1986 (SARA) | |
| Hazard categories | Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No |
| SARA 302 Extremely hazardous substance | No |
| SARA 311/312 Hazardous chemical | No |
| 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. |
| Food and Drug Administration (FDA) | Not regulated. |
| US state regulations | |
| US. Massachusetts RTK - Substance List | Not regulated. |
| US. New Jersey Worker and Community Right-to-Know Act | Not regulated. |
| US. Pennsylvania RTK - Hazardous Substances | Not regulated. |
| US. Rhode Island RTK | Not regulated. |

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 |
| 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 | 08-09-2013 |
| Revision date | 08-09-2013 |
| 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. |
| 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 Toxicological information: Carcinogenicity Regulatory Information: United States |