

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	BIOTENE PBF MOUTHWASH
Registration number	-
Synonyms	SAVANNA PBF MOUTHWASH (SYMRISE) * BIOTENE PLAQUE BIOFILM DISSOLVING MOUTHWASH * MFC04122 * DEXTRANASE "AMANO" OC MOUTHWASH * ORAL CARE, FORMULATED PRODUCT
Issue date	09-August-2013
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Supersedes date	24-June-2013

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses 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.

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Supplemental label information None.

2.3. Other hazards

Expected to be non-combustible.
See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
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SODIUM BENZOATE	0.5	532-32-1 208-534-8	-	-	
Classification:	DSD:	Xi;R36/37/38			
	CLP:	Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335			

METHYL PARABEN	0.1	99-76-3 202-785-7	-	-	
Classification:	DSD:	Xi;R36, R43			
	CLP:	Skin Sens. 1;H317, Eye Irrit. 2;H319			

PROPYL PARABEN	0.1	94-13-3 202-307-7	-	-	
Classification:	DSD:	Xi;R36			
	CLP:	Eye Irrit. 2;H319			

DEXTRANASE	<0.1	9025-70-1 232-803-9	-	-	
Classification:	DSD:	-			
	CLP:	-			

OPTAMINT MILD SWEET FRUIT 984112	<0.1	Unassigned -	-	-	
Classification:	DSD:	R10, R43, N;R51/53			
	CLP:	Flam. Liq. 3;H226, Skin Sens. 1;H317, Aquatic Chronic 2;H411			

Other components below reportable levels >99.0

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

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.
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4.1. Description of first aid measures

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.

4.2. Most important symptoms and effects, both acute and delayed	Direct contact with eyes may cause temporary irritation.
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4.3. Indication of any immediate medical attention and special treatment needed	Treat symptomatically.
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SECTION 5: Firefighting measures

General fire hazards	Expected to be non-combustible.
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5.1. Extinguishing media

Suitable extinguishing media	Alcohol resistant foam. Water fog. Dry chemical powder. Carbon dioxide (CO2).
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Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
5.2. Special hazards arising from the substance or mixture	During fire, gases hazardous to health may be formed.
5.3. Advice for firefighters	
Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Move containers from fire area if you can do so without risk.

SECTION 6: Accidental release measures

6.1. 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 MSDS.

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

6.3. Methods and material 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 vapours or divert vapour 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.

6.4. Reference to other sections For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Avoid prolonged exposure. Observe good industrial hygiene practices.

7.2. 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).

7.3. Specific end use(s) Oral Care

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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).

Recommended monitoring procedures Follow standard monitoring procedures.

Derived No Effect Level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

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

General information Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection	If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)
Skin protection	
- Hand protection	For prolonged or repeated skin contact use suitable 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. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Wear suitable protective clothing. (EN 14605 for splashes, EN ISO 13982 for dust)
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	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.
Environmental exposure controls	
Hazard guidance and control recommendations	Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Liquid.
Form	Solution.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
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.
Vapour pressure	Not available
Vapour 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
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	Not available.
10.2. Chemical stability	Material is stable under normal conditions.

10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	None under normal conditions.
10.5. Incompatible materials	Not available.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information Not available.

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 Not available.

11.1. 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
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 sensitisation	Due to lack of data the classification is not possible.
Skin sensitisation	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.
Mixture versus substance information	Not available.
Other information	This product has no known adverse effect on human health.

SECTION 12: Ecological information

12.1. Toxicity 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.

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

Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

SODIUM BENZOATE 100 %, 28 days Modified OECD Screening Test (OECD 301E), Sea water
90 %, 7 days Modified Sturm test., Activated sludge

Percent degradation (Anaerobic biodegradation)

SODIUM BENZOATE 93 %, 7 days Other degradation test system, Mixed Residential/Industrial

12.3. Bioaccumulative potential No data available.

Partition coefficient

n-octanol/water (log Kow)

METHYL PARABEN 1.96
PROPYL PARABEN 3.04
SODIUM BENZOATE 1.89

12.4. 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

12.5. Results of PBT and vPvB assessment Not available.

12.6. 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.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

Not available.

References

GSK Hazard Determination

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R10 Flammable.

R36 Irritating to eyes.
R36/37/38 Irritating to eyes, respiratory system and skin.
R43 May cause sensitization by skin contact.
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
H226 Flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H411 Toxic to aquatic life with long lasting effects.

Revision information

Product and Company Identification: Synonyms
SECTION 1: Identification of the substance/mixture and of the company/undertaking: Product use
SECTION 7: Handling and storage: 7.3. Specific end use(s)
SECTION 11: Toxicological information: Carcinogenicity
Regulatory Information: United States

Training information

Follow training instructions when handling this material.

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.