# **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

078364916

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078883473

## SAFETY DATA SHEET



#### 1. Identification

Product identifier BIOTENE MOUTHWASH

Other means of identification

Synonyms MFC: LACLEDE 30600064L BIOTENE DRY MOUTH ORAL RINSE \* MFC02600 BIOTENE

REGULAR MOUTHWASH EU \* MFC04360 BIOTENE PBF ORAL RINSE / MOUTH WASH WITH OPTAMINT FRUITY BUBBLE \* MFC 04301 \* MFC 04302 \* MFC 04304 \* BIOTENE PBF MOUTHWASH \* FORMULATION CODE 30602574L \* BIOTENE ORIGINAL MOUTHWASH (OPTAMINT PEPPERMINT) \* BIOTENE FLAVOUR FREE MOUTHWASH \* BIOTENE

MOUTHWASH 95% BASE \* BIOTENE DRY MOUTH MOUTHWASH \* BIOTENE ORIGINAL ORAL RINSE / MOUTH WASH (S. AROMA CLINICAL) \* BIOTENE ORIGINAL FLAVOUR FREE ORAL RINSE / MOUTH WASH (S. AROMA CLINICAL) \* BIOTENE ORIGINAL ORAL RINSE / MOUTH

WASH - 95% BASE (S. AROMA CLINICAL) \* ORAL CARE, FORMULATED PRODUCT

**Recommended use** Oral Care **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** 

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** 

Material name: BIOTENE MOUTHWASH SDS US

Chemical name	Common name and synonyms	CAS number	%
PROPYLENE GLYCOL	1,2-PROPANEDIOL 1,2-DIHYDROXYPROPANE 2-HYDROXYPROPANOL ISOPROPYLENE GLYCOL METHYLETHYLENE GLYCOL MONOPROPYLENE GLYCOL MONOPROPYLENE GLYCOL 2,3-PROPANEDIOL ALPHA-PROPYLENE GLYCOL 1,2-PROPYLENE GLYCOL (RS)-1,2-PROPANEDIOL 1,2-(RS)-PROPANEDIOL 1,2-PROPANDIOL DL-1,2-PROPANEDIOL DL-1,2-PROPANEDIOL DL-1,2-PROPANEDIOL DL-PROPYLENE GLYCOL PROPANE-1,2-DIOL (PROPYLENE GLYCOL) PROPANE-1-2-DIOL PROPANE-1-2-DIOL PROPANEDIOL,1,2-	57-55-6	3 - 14
XYLITOL	D-XYLITOL 1,2,3,4,5-PENTAHYDROXYPENTANE KLINIT KYLIT XYLITE XYLITON BP-706	87-99-0	7 - 8
GLYCEROL	GLYCERINE 1,2,3-PROPANETRIOL GLYCYL ALCOHOL TRIHYDROXYPROPANE 1,2,3-TRIHYDROXYPROPANE GLYCERIN, ANHYDROUS GLYCERIN 1,2,3-PROPANTRIOL	56-81-5	0 - 10
HYDROXYETHYL CELLULOSE	CELLULOSE, 2-HYDROXYETHYL ETHE R CELLOSIZE 2-HYDROXYETHYL ETHER CELLULOS E NATROSOL 2-HYDROXYETHYL CELLULOSE HYDROXYETHYL ETHER CELLULOSE CELLULOSE HYDROXYETHYLATE CELLULOSE HYDROXYETHYL ETHER OHS80130 RTECS FJ5958000 NATROSOL 250G NATROSOL 250M	9004-62-0	<1
SODIUM BENZOATE	BENZOIC ACID, SODIUM SALT BENZOATE OF SODA SODUIM BENZOIC ACID	532-32-1	0.5
MUTANASE			0 - 0.2
OPTAMINT FRUITY BUBBLE MW		Unassigned	< 0.2

Chemical name	Common name and synonyms	CAS number	%
BENZOIC ACID	BENZENECARBOXYLIC ACID BENZENEMETHANOIC ACID BENZENEFORMIC ACID BENZOATE CARBOXYBENZENE DRACYLIC ACID PHENYL CARBOXYLIC ACID PHENYLFORMIC ACID PHENYLCARBOXYLIC ACID E 210 HA 1 HA 1(ACID) RETARDEX RETARDEX RETARDER BA SOLVO POWDER TENN-PLAS OHS02720 RTECS DG0875000	65-85-0	< 0.1
CALCIUM LACTATE	PROPANOIC ACID, 2-HYDROXY-, CALCIUM SALT (2:1) LACTIC ACID (2:1), CALCIUM SALT 2-HYDROXYPROPANOIC ACID, CALCIUM SALT (2:1) CALCIUM 2-HYDROXYPROPIONATE CALCIUM LACTATE, ANHYDROUS CALPHOSAN	814-80-2	< 0.1
DEXTRANASE		9025-70-1	0 - 0.1
GLUCOSE OXIDASE		9001-37-0	< 0.1
LACTOFERRIN			< 0.1
LACTOPEROXIDASE	peroxydase	9003-99-0	< 0.1
LYSOZYME			< 0.1
METHYL PARABEN	GR30517X METHYL P-HYDROXYBENZOATE P-HYDROXYBENZOIC ACID, METHYL ESTER 4-HYDROXYBENZOIC ACID, METHYL ESTER METHYL P-OXYBENZOATE METHYL PARAHYDROXYBENZOATE	99-76-3	0 - 0.1
POTASSIUM THIOCYANATE	POTASSIUM ISOTHIOCYANATE THIOCARA PHODA-NIDE POTASSIUM SULFOCYANATE POTASSIUM RHODANIDE POTASSIUM RHODANATE ATERO-CYN ARTEROCYN KYONATE RHOCYN RODANCA P-317 OHS19640 RTECS XL1925000 166 (GW ACN)	333-20-0	< 0.1

Chemical name	Common name and synonyms	CAS number	%
PROPYL PARABEN	PROPYL P-HYDROXYBENZOATE PROTABEN 4-HYDROXYBENZOIC ACID, PROPYL ESTER P-HYDROXYBENZOIC ACID, PROPYL ESTER PASEPTOL PARASEPT PROPYL ASEPTOFORM PROPYL P-OXYBENZOATE PROPYL-4-HYDROXYBENZOATE N-PROPYL P-HYDROXYBENZOATE P-HYDROXYPROPYL BENZOATE Propyl 4-hydroxybenzoate Propyl Parahydroxybenzoate	94-13-3	0 - 0.1
SODIUM PHOSPHATE, MONOBASIC	MONOSODIUM PHOSPHATE SODIUM DIHYDROGEN PHOSPHATE MONOSODIUM DIHYDROGEN PHOSPHATE SODIUM BIPHOSPHATE MONOSODIUM ORTHOPHOSPHATE PHOSPHORIC ACID, MONOSODIUM SALT MONOBASIC SODIUM PHOSPHATE MONOSODIUM HYDROGEN PHOSPHATE SODIUM DIPHOSPHATE ANHYDROUS SODIUM PRIMARY PHOSPHATE SODIUM PHOSPHATE	7558-80-7	< 0.1
ZINC GLUCONATE	BIS(D-GLUCONATO-O(SUP1),O(SUP2)Z INC ZINC, BIS(D-GLUCONATO-O(SUP1),O(SUP2) GLUCONAL ZN ZINC, BIS(D-GLUCONATO-O(1),O(2))- ZYMIZINC GLUCONIC ACID, ZINC SALT D-GLUCONIC ACID, ZINC COMPLEX	4468-02-4	< 0.1
Other components below repo	rtable levels		70 - < 80

Other components below reportable levels

#### 4. First-aid measures

Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if Inhalation

symptoms develop or persist. Under normal conditions of intended use, this material is not

expected to be an inhalation hazard.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse.

Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large Ingestion

amount does occur, call a poison control center immediately. Do not induce vomiting without

No specific antidotes are recommended. Treat according to locally accepted protocols. For

additional guidance, refer to the current prescribing information or to the local poison control

advice from poison control center.

Most important

symptoms/effects, acute and

delayed

media

Direct contact with eyes may cause temporary irritation.

Indication of immediate medical attention and special

treatment needed

information center.

General information

In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take

precautions to protect themselves.

## 5. Fire-fighting measures

Suitable extinguishing media Unsuitable extinguishing

Foam. Dry chemical powder. Carbon dioxide (CO2).

Water.

Material name: BIOTENE MOUTHWASH

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

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

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

General fire hazards

This product will support combustion at elevated temperatures.

#### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Avoid breathing mist or vapor. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.

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. 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 to original containers for re-use.

**Environmental precautions** 

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

## 7. Handling and storage

Precautions for safe handling

Keep away from heat/sparks/open flames/hot surfaces. - No smoking. No special control measures required for the normal handling of this product. Avoid prolonged exposure. Use care in handling/storage.

Conditions for safe storage, including any incompatibilities

Keep away from heat, sparks and open flame. Store in original tightly closed container.

## 8. Exposure controls/personal protection

#### Occupational exposure limits

GSK			
Components	Туре	Value	Note
BENZOIC ACID (CAS 65-85-0)	OHC	2	PROVISIONAL
CALCIUM LACTATE (CAS 814-80-2)	8 HR TWA	5000 mcg/m3	
	OHC	1	
HYDROXYETHYL CELLULOSE (CAS 9004-62-0)	OHC	2	>100 - =1000 mcg/m3<br PROVISIONAL
POTASSIUM THIOCYANATE (CAS 333-20-0)	8 HR TWA	5000 mcg/m3	
	OHC	1	
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	
SODIUM PHOSPHATE, MONOBASIC (CAS 7558-80-7)	OHC	1	
XYLITOL (CAS 87-99-0)	OHC	1	>1000 - =5000 mcg/m3</td
ZINC GLUCONATE (CAS 4468-02-4)	OHC	2	

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US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)					
Components	Туре	Value	Form		
GLYCEROL (CAS 56-81-5)	PEL	5 mg/m3	Respirable fraction.		
		15 mg/m3	Total dust.		
US. Workplace Environmental Exp	oosure Level (WEEL) Guides				
Components	Туре	Value	Form		
PROPYLENE GLYCOL	TWA	10 mg/m3	Aerosol.		

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

**Exposure guidelines** 

(CAS 57-55-6)

Appropriate engineering

controls

General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection

**Hand protection** Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Other Not normally needed. Wear suitable protective clothing as protection against splashing or

contamination.

Respiratory protection No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved

respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

**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. 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 Bottle.

Color Not available.

Odor Not available.

Odor threshold Not available.

PH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling Not available.

range

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

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 densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Not available.

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Partition coefficient (n-octanol/water)

Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

**Explosive properties** Not explosive. **Oxidizing properties** Not oxidizing.

## 10. Stability and reactivity

**Reactivity**The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous Hazardous polymerization does not occur.

reactions

**Conditions to avoid** Keep away from heat, sparks and open flame. Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition None known. Irritating and/or toxic fumes and gases may be emitted upon the product's

**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** Health injuries are not known or expected under normal use. Direct contact with eyes may cause

temporary irritation.

Ingestion Health injuries are not known or expected under normal use. However, ingestion is not likely to be

> 8 g/kg

a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation.

#### Information on toxicological effects

**Acute toxicity** Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components Species Test Results

METHYL PARABEN (CAS 99-76-3)

Acute Oral

LD50 Mouse

PROPYL PARABEN (CAS 94-13-3)

Acute Oral

LD50 Rat > 2000 mg/kg

SODIUM BENZOATE (CAS 532-32-1)

Acute Oral

LD50 Rat 2000 mg/kg

SODIUM PHOSPHATE, MONOBASIC (CAS 7558-80-7)

<u>Acute</u>

Oral

LD50 Rat 8290 mg/kg

ZINC GLUCONATE (CAS 4468-02-4)

Acute Oral

LD50 Mouse > 1290 mg/kg

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Components Species Test Results

Rat > 5000 mg/kg

\* Estimates for product may be based on additional component data not shown.

**Skin corrosion/irritation** Health injuries are not known or expected under normal use.

Corrosivity

SODIUM BENZOATE OECD 404

Result: Negative Species: Rabbit

Irritation Corrosion - Skin: P.I.I. value

ZINC GLUCONATE (

Serious eye damage/eye irritation

Health injuries are not known or expected under normal use. Direct contact with eyes may cause

temporary irritation.

Eye

SODIUM BENZOATE Acute ocular irritation; OECD 405

Result: Mild irritant Species: Rabbit

Respiratory or skin sensitization

**Respiratory sensitization** No studies have been conducted.

**Skin sensitization** None known. This product is not expected to cause skin sensitization.

**Buehler test** 

BENZOIC ACID Result: Negative

Species: Guinea pig

Maximisation assay (Magnusson and Kligman)

BENZOIC ACID Result: Negative

Species: Guinea pig

Sensitization

SODIUM BENZOATE Local lymph node assay

Result: Negative Species: Mouse

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

mutagenic or genotoxic.

Mutagenicity

SODIUM BENZOATE Ames

Result: Negative

Chromosomal aberration assay

Result: Negative Species: Rat

Carcinogenicity Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result

of occupational exposure.

SODIUM BENZOATE 2 year study, Male + Female

Result: Negative - dietary

Species: Rat

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.

Reproductivity

SODIUM BENZOATE Embryofetal Development

Result: Negative

Reproduction/Fertility Study

Result: Negative Species: Rat

Specific target organ toxicity -

single exposure

Not assigned.

Specific target organ toxicity - Not assigned.

repeated exposure

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140t assigned

**Aspiration hazard** Not established.

**Further information** Occupational exposure to the substance or mixture may cause adverse effects.

## 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
METHYL PARABEN (	CAS 99-76-3)		
Aquatic	•		
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	11.2 mg/l, 48 hours
Fish	LC50	Medaka, high-eyes (Oryzias latipes)	59.5 mg/l, 96 hours
Chronic			
Crustacea	NOEC	Water flea (Daphnia magna)	0.2 mg/l, 21 days OECD 211
PROPYLENE GLYCO	L (CAS 57-55-6)		
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	19000 mg/l, 14 days
	NOEC	Green algae (Selenastrum capricornutum)	15000 mg/l, 14 days
Crustacea	EC50	Daphnia	43500 mg/l, 48 hours
	NOEC	Daphnia	28500 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	51400 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	51600 mg/l, 96 hours Static test
	NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	42000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	51400 mg/l, 30 minutes
SODIUM BENZOATE	(CAS 532-32-1)		
<b>Aquatic</b> <i>Acute</i>	,		
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

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Components Species Test Results

SODIUM PHOSPHATE, MONOBASIC (CAS 7558-80-7)

Aquatic

Acute

Fish EC50 Golden ide/orfe (Adult Leuciscus idus) > 2400 mg/l, 48 hours Static test

Mosquito fish (Adult Gambusia affinis) 186 mg/l, 96 hours Static test

#### Persistence and degradability

**Photolysis** 

Half-life (Photolysis-aqueous)

PROPYLENE GLYCOL 1.3 - 2.3 Years Estimated

Half-life (Photolysis-atmospheric)

BENZOIC ACID < 2 Days Estimated PROPYLENE GLYCOL 32 Hours 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

PROPYLENE GLYCOL 62 %, 5 days BOD5, Activated sludge 79 %, 20 Days BOD20, Activated sludge

XYLITOL 82 %, 14 days BOD 14, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

METHYL PARABEN 89 %, 28 days, OECD 301B

SODIUM BENZOATE 100 %, 28 days Modified OECD Screening Test (OECD

301E), Sea water

50 %, 7 days

90 %, 7 days Modified Sturm test., Activated sludge

Percent degradation (Aerobic biodegradation-soil)

BENZOIC ACID

Percent degradation (Anaerobic biodegradation)

PROPYLENE GLYCOL 100 %, 9 days

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

Residential/Industrial

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

 BENZOIC ACID
 1.87

 GLYCEROL
 -1.76

 METHYL PARABEN
 1.96

 PROPYL PARABEN
 3.04

 PROPYLENE GLYCOL
 -1.35

 SODIUM BENZOATE
 1.89

**Bioconcentration factor (BCF)** 

PROPYLENE GLYCOL < 1 Estimated

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

BENZOIC ACID 2.26 Measured SODIUM BENZOATE 1.16 Calculated

Mobility in general

Volatility

Henry's law

BENZOIC ACID 0 atm m^3/mol Estimated PROPYLENE GLYCOL 0 atm m^3/mol Estimated

Distribution

Octanol/water distribution coefficient log DOW

PROPYL PARABEN 3.04

Other adverse effects Not available.

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<sup>\*</sup> Estimates for product may be based on additional component data not shown.

#### 13. Disposal considerations

**Disposal instructions**Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not

discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable

regulations.

**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

Contaminated packaging

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). Avoid discharge into water courses or onto the ground.

Since emptied containers may retain product residue, follow label warnings even after container is

emptied. Empty containers should be taken to an approved waste handling site for recycling or

disposal.

## 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 Not established.

Annex II of MARPOL 73/78 and

the IBC Code

#### 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)** 

BENZOIC ACID (CAS 65-85-0) Listed. ZINC GLUCONATE (CAS 4468-02-4) 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 Not regulated.

(SDWA)

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

TRADE SECRET (CAS Proprietary)

Other Flavoring Substances with OSHA PEL's

**US** state regulations

#### 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.

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# US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

TRADE SECRET (CAS Proprietary)

#### 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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No

<sup>\*</sup>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).

Toxic Substances Control Act (TSCA) Inventory

## 16. Other information, including date of preparation or last revision

 Issue date
 04-26-2018

 Revision date
 05-17-2019

Version # 07

United States & Puerto Rico

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

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 Toxicological information: Reproductivity

Material name: BIOTENE MOUTHWASH

SDS US

No

## SAFETY DATA SHEET



#### 1. Identification

**Product identifier BIOTENE MOUTHWASH** 

Other means of identification

**Synonyms** MFC: LACLEDE 30600064L BIOTENE DRY MOUTH ORAL RINSE \* MFC02600 BIOTENE

REGULAR MOUTHWASH EU \* MFC04360 BIOTENE PBF ORAL RINSE / MOUTH WASH WITH OPTAMINT FRUITY BUBBLE \* MFC 04301 \* MFC 04302 \* MFC 04304 \* BIOTENE PBF MOUTHWASH \* FORMULATION CODE 30602574L \* BIOTENE ORIGINAL MOUTHWASH (OPTAMINT PEPPERMINT) \* BIOTENE FLAVOUR FREE MOUTHWASH \* BIOTENE

MOUTHWASH 95% BASE \* BIOTENE DRY MOUTH MOUTHWASH \* BIOTENE ORIGINAL ORAL RINSE / MOUTH WASH (S. AROMA CLINICAL) \* BIOTENE ORIGINAL FLAVOUR FREE ORAL RINSE / MOUTH WASH (S. AROMA CLINICAL) \* BIOTENE ORIGINAL ORAL RINSE / MOUTH WASH - 95% BASE (S. AROMA CLINICAL) \* ORAL CARE, FORMULATED PRODUCT

Recommended use Oral Care

No other uses are advised. **Recommended restrictions** 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

CHEMTREC EMERGENCY PHONE NUMBERS -

TRANSPORT EMERGENCIES: Customer Number: CCN9484

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** 

Material name: BIOTENE MOUTHWASH 1 / 11 135784 Version #: 06 Revision date: 09-23-2016 Issue date: 12-04-2013

SDS US

Chemical name	Common name and synonyms	CAS number	%
PROPYLENE GLYCOL	1,2-PROPANEDIOL 1,2-DIHYDROXYPROPANE 2-HYDROXYPROPANOL ISOPROPYLENE GLYCOL METHYLETHYLENE GLYCOL MONOPROPYLENE GLYCOL MONOPROPYLENE GLYCOL 2,3-PROPANEDIOL ALPHA-PROPYLENE GLYCOL 1,2-PROPYLENE GLYCOL (RS)-1,2-PROPANEDIOL 1,2-(RS)-PROPANEDIOL 1,2-PROPANEDIOL DL-1,2-PROPANEDIOL DL-1,2-PROPANEDIOL DL-PROPYLENE GLYCOL PROPANE-1,2-DIOL (PROPYLENE GLYCOL) PROPANE-1-2-DIOL PROPANEDIOL,1,2-	57-55-6	3 - 14
XYLITOL	D-XYLITOL 1,2,3,4,5-PENTAHYDROXYPENTANE KLINIT KYLIT XYLITE XYLITON BP-706	87-99-0	7 - 8
GLYCEROL	GLYCERINE 1,2,3-PROPANETRIOL GLYCYL ALCOHOL TRIHYDROXYPROPANE 1,2,3-TRIHYDROXYPROPANE GLYCERIN, ANHYDROUS GLYCERIN 1,2,3-PROPANTRIOL	56-81-5	0 - 10
SODIUM BENZOATE	BENZOIC ACID, SODIUM SALT BENZOATE OF SODA SODUIM BENZOIC ACID	532-32-1	0.5
MUTANASE			0 - 0.2
OPTAMINT FRUITY BUBBLE MW 413027		Unassigned	< 0.2
BENZOIC ACID	BENZENECARBOXYLIC ACID BENZENEMETHANOIC ACID BENZENEFORMIC ACID BENZOATE CARBOXYBENZENE DRACYLIC ACID PHENYL CARBOXYLIC ACID PHENYLFORMIC ACID PHENYLFORMIC ACID PHENYLCARBOXYLIC ACID E 210 HA 1 HA 1(ACID) RETARDEX RETARDEX RETARDER BA SOLVO POWDER TENN-PLAS OHS02720 RTECS DG0875000	65-85-0	< 0.1
CALCIUM LACTATE	PROPANOIC ACID, 2-HYDROXY-, CALCIUM SALT (2:1) LACTIC ACID (2:1), CALCIUM SALT 2-HYDROXYPROPANOIC ACID, CALCIUM SALT (2:1) CALCIUM 2-HYDROXYPROPIONATE CALCIUM LACTATE, ANHYDROUS CALPHOSAN	814-80-2	< 0.1

Chemical name	Common name and synonyms	CAS number	%
DEXTRANASE		9025-70-1	0 - 0.1
GLUCOSE OXIDASE		9001-37-0	< 0.1
LACTOFERRIN			< 0.1
LACTOPEROXIDASE	peroxydase	9003-99-0	< 0.1
LYSOZYME			< 0.1
METHYL PARABEN	GR30517X METHYL P-HYDROXYBENZOATE P-HYDROXYBENZOIC ACID, METHYL ESTER 4-HYDROXYBENZOIC ACID, METHYL ESTER METHYL P-OXYBENZOATE METHYL PARAHYDROXYBENZOATE	99-76-3	0 - 0.1
POTASSIUM THIOCYANATE	POTASSIUM ISOTHIOCYANATE THIOCARA PHODA-NIDE POTASSIUM SULFOCYANATE POTASSIUM RHODANIDE POTASSIUM RHODANATE ATERO-CYN ARTEROCYN KYONATE RHOCYN RODANCA P-317 OHS19640 RTECS XL1925000 166 (GW ACN)	333-20-0	< 0.1
PROPYL PARABEN	PROPYL P-HYDROXYBENZOATE PROTABEN 4-HYDROXYBENZOIC ACID, PROPYL ESTER P-HYDROXYBENZOIC ACID, PROPYL ESTER PASEPTOL PARASEPT PROPYL ASEPTOFORM PROPYL P-OXYBENZOATE	94-13-3	0 - 0.1
SODIUM PHOSPHATE, MONOBASIC	MONOSODIUM PHOSPHATE SODIUM DIHYDROGEN PHOSPHATE MONOSODIUM DIHYDROGEN PHOSPHAT E SODIUM BIPHOSPHATE MONOSODIUM ORTHOPHOSPHATE PHOSPHORIC ACID, MONOSODIUM SALT MONOBASIC SODIUM PHOSPHATE MONOSODIUM HYDROGEN PHOSPHATE SODIUM DIPHOSPHATE ANHYDROUS SODIUM PRIMARY PHOSPHATE SODIUM PHOSPHATE	7558-80-7	< 0.1
ZINC GLUCONATE	BIS(D-GLUCONATO-O(SUP1),O(SUP2)ZIN C ZINC, BIS(D-GLUCONATO-O(SUP1),O (SUP2) GLUCONAL ZN ZINC, BIS(D-GLUCONATO-O(1),O(2))- ZYMIZINC GLUCONIC ACID, ZINC SALT D-GLUCONIC ACID, ZINC COMPLEX	4468-02-4	< 0.1

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

#### 4. First-aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if

symptoms develop or persist. Under normal conditions of intended use, this material is not

expected to be an inhalation hazard.

**Skin contact** Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse.

Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

**Ingestion** If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large

amount does occur, call a poison control center immediately. Do not induce vomiting without

advice from poison control center.

Most important symptoms/effects, acute and

symptoms/effects, acute and delayed

Direct contact with eyes may cause temporary irritation.

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 current prescribing information or to the local poison control information center.

**General information** 

In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take

precautions to protect themselves.

## 5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing media

Water.

Specific hazards arising from

the chemical

During fire, gases hazardous to health may be formed.

Foam. Dry chemical powder. Carbon dioxide (CO2).

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

General fire hazards

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

This product will support combustion at elevated temperatures.

#### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Avoid breathing mist or vapor. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. 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. 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 to 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 Keep away from heat/sparks/open flames/hot surfaces. - No smoking. No special control

measures required for the normal handling of this product. Avoid prolonged exposure. Use care in

handling/storage.

Conditions for safe storage, including any incompatibilities

Keep away from heat, sparks and open flame. Store in original tightly closed container. Store away

from incompatible materials (see Section 10 of the SDS).

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## 8. Exposure controls/personal protection

## Occupational exposure limits

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Components	Туре	Value	Form
BENZOIC ACID (CAS 65-85-0)	OHC	2	PROVISIONAL
CALCIUM LACTATE (CAS 814-80-2)	8 HR TWA	5000 mcg/m3	
,	OHC	1	
POTASSIUM THIOCYANATE (CAS 333-20-0)	8 HR TWA	5000 mcg/m3	
,	OHC	1	
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	
SODIUM PHOSPHATE, MONOBASIC (CAS 7558-80-7)	OHC	1	
ZINC GLUCONATE (CAS 4468-02-4)	OHC	2	
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.
US. AIHA Workplace Environment	al Exposure Level (WEEL) Guides		
Components	Туре	Value	Form
PROPYLENE GLYCOL (CAS 57-55-6)	TWA	10 mg/m3	Aerosol.

**Biological limit values** 

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

**Exposure guidelines** 

Appropriate engineering

controls

General ventilation normally adequate.

#### Individual protection measures, such as personal protective equipment

Not normally needed. If contact is likely, safety glasses with side shields are recommended. Eye/face protection

Skin protection

Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Hand protection

Other Not normally needed. Wear suitable protective clothing as protection against splashing or

contamination.

No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved Respiratory protection

respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

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. 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. Bottle. **Form** Color Not available.

Not available. Odor **Odor threshold** Not available.

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pH Not available.Melting point/freezing point Not available.Initial boiling point and boiling Not available.

range

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower

r Not available.

(%)

Flammability limit - upper

Not available.

(%)

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

por pressure Not available.

Vapor pressureNot available.Vapor densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

**Explosive properties** Not explosive. **Oxidizing properties** Not oxidizing.

## 10. Stability and reactivity

**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous Hazardous polymerization does not occur.

reactions

Conditions to avoid Keep away from heat, sparks and open flame. Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

incompatible materials — onong oxidizing agen

Hazardous decomposition

products

None known. Irritating and/or toxic fumes and gases may be emitted upon the product's

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** Health injuries are not known or expected under normal use. Direct contact with eyes may cause

temporary irritation.

Ingestion Health injuries are not known or expected under normal use. However, ingestion is not likely to be

a primary route of occupational exposure.

Symptoms related to the physical, chemical and

toxicological characteristics

Direct contact with eyes may cause temporary irritation.

#### Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

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Components Species Test Results

METHYL PARABEN (CAS 99-76-3)

<u>Acute</u>

Oral

LD50 Mouse > 8 g/kg

PROPYL PARABEN (CAS 94-13-3)

Acute Oral

LD50 Rat > 2000 mg/kg

SODIUM PHOSPHATE, MONOBASIC (CAS 7558-80-7)

Acute Oral

LD50 Rat 8290 mg/kg

ZINC GLUCONATE (CAS 4468-02-4)

Acute Oral

LD50 Rat > 5000 mg/kg

\* Estimates for product may be based on additional component data not shown.

**Skin corrosion/irritation** Health injuries are not known or expected under normal use.

Irritation Corrosion - Skin: P.I.I. value

ZINC GLUCONATE

Serious eye damage/eye irritation

Health injuries are not known or expected under normal use. Direct contact with eyes may cause

temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization No studies have been conducted.

**Skin sensitization**None known. This product is not expected to cause skin sensitization.

**Buehler test** 

BENZOIC ACID Result: Negative

Species: Guinea pig

Maximisation assay (Magnusson and Kligman)

BENZOIC ACID Result: Negative

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** Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result

of occupational exposure.

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 Contains no ingredient listed as toxic to reproduction

Specific target organ

toxicity - single exposure

Not assigned.

Specific target organ toxicity - repeated

exposure

Not assigned.

Aspiration hazard Not established.

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**Further information** Occupational exposure to the substance or mixture may cause adverse effects.

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.

sds us **7 / 11** 

Material name: BIOTENE MOUTHWASH

Components		Species	Test Results
BENZOIC ACID (CAS	65-85-0)		
Acute	1050		1000 # 01
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
<i>Acute</i> 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
METHYL PARABEN (	CAS 99-76-3)		
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	11.2 mg/l, 48 hours
Fish	LC50	Medaka, high-eyes (Oryzias latipes)	59.5 mg/l, 96 hours
Chronic			
Crustacea	NOEC	Water flea (Daphnia magna)	0.2 mg/l, 21 days OECD 211
PROPYLENE GLYCO	L (CAS 57-55-6)		
Acute	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aguatia	1030	Activated studge	> 1000 High, 3 Hours
Aquatic  Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	19000 mg/l, 14 days
	NOEC	Green algae (Selenastrum capricornutum)	15000 mg/l, 14 days
Crustacea	EC50	Daphnia	43500 mg/l, 48 hours
	NOEC	Daphnia	28500 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	51400 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	51600 mg/l, 96 hours Static test
	NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	42000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	51400 mg/l, 30 minutes
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
SODIUM PHOSPHAT	E, MONOBASIC (C	AS 7558-80-7)	
Aquatic			
<i>Acute</i> Fish	EC50	Golden ide/orfe (Adult Leuciscus idus)	> 2400 mg/l, 48 hours Static test
L1911	E000	•	-
		Mosquito fish (Adult Gambusia affinis)	186 mg/l, 96 hours Static test

<sup>\*</sup> Estimates for product may be based on additional component data not shown.

## Persistence and degradability

**Photolysis** 

Half-life (Photolysis-aqueous)

1.3 - 2.3 Years Estimated PROPYLENE GLYCOL

Half-life (Photolysis-atmospheric)

**BENZOIC ACID** < 2 Days Estimated PROPYLENE GLYCOL 32 Hours Estimated

UV/visible spectrum wavelength

279 nm BENZOIC ACID

**Biodegradability** 

Percent degradation (Aerobic biodegradation-inherent)

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

PROPYLENE GLYCOL 62 %, 5 days BOD5, Activated sludge 79 %, 20 Days BOD20, Activated sludge

**XYLITOL** 82 %, 14 days BOD 14, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

METHYL PARABEN 89 %, 28 days, OECD 301B

100 %, 28 days Modified OECD Screening Test (OECD SODIUM BENZOATE

301E), Sea water

90 %, 7 days Modified Sturm test., Activated sludge

Percent degradation (Aerobic biodegradation-soil)

BENZOIC ACID 50 %, 7 days

Percent degradation (Anaerobic biodegradation)

PROPYLENE GLYCOL 100 %, 9 days

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

Residential/Industrial

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

**BENZOIC ACID** 1.87 **GLYCEROL** -1.76METHYL PARABEN 1.96 PROPYL PARABEN 3.04 PROPYLENE GLYCOL -1.35SODIUM BENZOATE 1.89

**Bioconcentration factor (BCF)** 

PROPYLENE GLYCOL < 1 Estimated

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

BENZOIC ACID 2.26 Measured SODIUM BENZOATE 1.16 Calculated

Mobility in general

Volatility

Henry's law

**BENZOIC ACID** 0 atm m<sup>3</sup>/mol Estimated PROPYLENE GLYCOL 0 atm m^3/mol Estimated

Distribution

Octanol/water distribution coefficient log DOW

3.04 PROPYL PARABEN

Other adverse effects Not available.

13. Disposal considerations

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not

discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable

regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

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

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). Avoid discharge into water courses or onto the ground.

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#### Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

#### 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 Not established. Annex II of MARPOL 73/78 and

the IBC Code

## 15. Regulatory information

#### US federal regulations

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

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)** 

BENZOIC ACID (CAS 65-85-0) Listed.
ZINC GLUCONATE (CAS 4468-02-4) 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 - No

Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous No

chemical

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

Not regulated.

(SDWA)

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

GLYCEROL (CAS 56-81-5)

Other Flavoring Substances with OSHA PEL's

#### **US state regulations**

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd.

(a))

METHYL PARABEN (CAS 99-76-3)

PROPYL PARABEN (CAS 94-13-3)

**US. Massachusetts RTK - Substance List** 

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BENZOIC ACID (CAS 65-85-0)

GLYCEROL (CAS 56-81-5)

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Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

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

BENZOIC ACID (CAS 65-85-0) GLYCEROL (CAS 56-81-5)

PROPYLENE GLYCOL (CAS 57-55-6) ZINC GLUCONATE (CAS 4468-02-4)

#### US. Pennsylvania Worker and Community Right-to-Know Law

BENZOIC ACID (CAS 65-85-0) GLYCEROL (CAS 56-81-5)

PROPYLENE GLYCOL (CAS 57-55-6)

#### **US. Rhode Island RTK**

BENZOIC ACID (CAS 65-85-0) ZINC GLUCONATE (CAS 4468-02-4)

#### **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.

Australian Inventory of Chemical Substances (AICS)

#### **International Inventories**

Australia

Canada

Canada

Country(s) or region

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

<sup>\*</sup>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).

Toxic Substances Control Act (TSCA) Inventory

## 16. Other information, including date of preparation or last revision

Inventory name

Domestic Substances List (DSL)

Non-Domestic Substances List (NDSL)

 Issue date
 12-04-2013

 Revision date
 09-23-2016

Version # 06

United States & Puerto Rico

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

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**This document has undergone significant changes and should be reviewed in its entirety.

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On inventory (yes/no)\*

No

Nο

No

No