

1. Identification

Product identifier BIOTENE ORAL BALANCE GEL (PRESERVATIVE FREE)

Other means of identification

Product code MFC04410

Synonyms BIOTENE ORAL BALANCE GEL - PRESERVATIVE FREE (PROJECT AROMA GEL) (ANZ) * BIOTENE DRY MOUTH GEL * BIOTENE MOISTURIZING GEL * BIOTENE ORAL BALANCE SALIVA REPLACEMENT GEL * MFC04410 * BIOTENE ORAL BALANCE GEL

Recommended use Consumer Healthcare Product

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

COMPANY NAME Haleon PLC

Address: 184 Liberty Corner Road, Suite 200
Warren, NJ 07059 USA

Telephone: +1-908-293-4000 (General Inquiries)

Email: msds@haleon.com

Website: www.haleon.com

EMERGENCY CONTACTS

Telephone: 3E GLOBAL INCIDENT RESPONSE
+(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 335879

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention Not available.

Response Not available.

Storage Not available.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information

77.02% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 77.02% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

3. Composition/information on ingredients**Mixtures**

Chemical name	Common name and synonyms	CAS number	%
GLYCERIN	GLYCEROL GLYCERIN ANHYDROUS GLYCERINE GLYCERITOL GLYCYL ALCOHOL 1,2,3-PROPANETRIOL PROPANETRIOL GLYROL GLYSANIN TRIHIDROXYPROPANE 1,2,3-TRIHIDROXYPROPANE OSMOGLYN	56-81-5	50 - < 60
XYLITOL	D-XYLITOL 1,2,3,4,5-PENTAHIDROXYPENTANE KLINIT KYLIT XYLITE XYLITON BP-706	87-99-0	5 - < 10
2-PROPENOIC ACID HOMOPOLYMER	CARBOPOL RESINS CARBOMER RESINS CARBOPOL 980 NF CARBOPOL 940 CARBOPOL 941 CARBOPOL 960 CARBOPOL 961 CARBOMER 934 CARBOMER(R) 934 CARBOMER 940 NF CARBOPOL 981 CARBOXYVINYL POLYMER CARBOPOL 971P NF CARBOPOL 974P NF	9003-01-4	< 1
HYDROXYETHYL CELLULOSE	CELLULOSE, 2-HIDROXYETHYL ETHER R CELLOSIZ 2-HIDROXYETHYL ETHER CELLULOSE E NATROSOL 2-HIDROXYETHYL CELLULOSE HYDROXYETHYL ETHER CELLULOSE CELLULOSE HIDROXYETHYLATE CELLULOSE HIDROXYETHYL ETHER OHS80130 RTECS FJ5958000 NATROSOL 250G NATROSOL 250M	9004-62-0	< 0.2
SODIUM HIDROXIDE	CAUSTIC SODA LYE SODIUM HYDRATE HIDROXIDO SODICO HIDRÓXIDO DE SÓDIO CAUSTIC SODA SOLUTION Caustic soda (as NaOH) Soda lye Soda, caustic	1310-73-2	< 0.1
Other components below reportable levels			40 - < 50

4. 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 with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Headache. Nausea, vomiting.

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.

5. Fire-fighting measures

Suitable extinguishing media

Alcohol resistant foam. Dry 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.

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

No unusual fire or explosion hazards noted.

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. 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

Avoid prolonged exposure. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Haleon Exposure Limits

Components	Type	Value	Form
2-PROPENOIC ACID HOMOPOLYMER (CAS 9003-01-4)	OHC	3	>10 - ≤100 mcg/m3
HYDROXYETHYL CELLULOSE (CAS 9004-62-0)	OHC	2	>100 - <=1000 mcg/m3 PROVISIONAL
XYLITOL (CAS 87-99-0)	OHC	1	>1000 - <=5000 mcg/m3

US. OSHA Table Z-1 Permissible Exposure Limits (PEL) 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.
SODIUM HYDROXIDE (CAS 1310-73-2)	PEL	2 mg/m3	

US. ACGIH Threshold Limit Values (TLV)

Components	Type	Value
SODIUM HYDROXIDE (CAS 1310-73-2)	Ceiling	2 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards Recommended Exposure Limits (REL)

Components	Type	Value
SODIUM HYDROXIDE (CAS 1310-73-2)	Ceiling	2 mg/m3

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Good general ventilation 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).
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Other	Wear suitable protective 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	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 applicable.
Upper/lower flammability or explosive limits	
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.
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 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	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Prolonged inhalation may be harmful.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics Headache. Nausea, vomiting.

Information on toxicological effects

Acute toxicity Not known.

Components	Species	Test Results
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2-PROPENOIC ACID HOMOPOLYMER (CAS 9003-01-4)

Acute

Oral

LD50	Rat	> 2500 mg/kg
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GLYCERIN (CAS 56-81-5)

Acute

Oral

LD50	Rat	> 2000 mg/kg
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Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

SODIUM HYDROXIDE

Literature search
Result: Causes severe burns.

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye

SODIUM HYDROXIDE

Literature search
Result: Causes severe burns.

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

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.

IARC Monographs. Overall Evaluation of Carcinogenicity

2-PROPENOIC ACID HOMOPOLYMER (CAS 9003-01-4) 3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not an aspiration hazard.
Chronic effects	Prolonged inhalation may be harmful.

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	
2-PROPENOIC ACID HOMOPOLYMER (CAS 9003-01-4)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	> 168 to < 280 mg/l, 96 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	> 580 to < 2000 mg/l, 96 hours Static test
SODIUM HYDROXIDE (CAS 1310-73-2)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Mosquito fish (Adult Gambusia affinis)	125 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhynchus mykiss)	45.4 mg/l, 96 hours Static test

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

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

XYLITOL 82 %, 14 days BOD 14, Activated sludge

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

GLYCERIN -1.76

Mobility in soil No data available.

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

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 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.

Read safety instructions, SDS and emergency procedures before handling.

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 Not established.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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)

SODIUM HYDROXIDE (CAS 1310-73-2) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**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.**FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace**

GLYCERIN (CAS 56-81-5) Other Flavoring Substances with OSHA PEL's

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

SODIUM HYDROXIDE (CAS 1310-73-2)

California Proposition 65California 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. For more information go to www.P65Warnings.ca.gov.**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
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)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
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	11-21-2022
Revision date	10-18-2024
Version #	10

HMIS® ratings

Health: 0
Flammability: 1
Physical hazard: 0

NFPA ratings

Health: 0
Flammability: 1
Instability: 0

Disclaimer

Haleon cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.

Revision information

Product and Company Identification: Product Codes
Hazard(s) identification: Supplemental information
Physical and chemical properties: Form
Ecological information: Persistence / degradability
Ecological information: Bioaccumulative potential