SAFETY DATA SHEET

HALEON

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

1.1. Product identifier

Trade name or designation of the mixture	BIOTENE ORAL BALANCE GEL (PRESERVATIVE FREE)
Registration number	-
Synonyms	BIOTENE ORAL BALANCE GEL - PRESERVATIVE FREE (PROJECT AROMA GEL) (ANZ) * BIOTENE DRY MOUTH GEL * BIOTENE MOISTURINZING GEL * BIOTENE ORAL BALANCE SALIVA REPLACEMENT GEL * MFC04410 * BIOTENE ORAL BALANCE GEL
Product code	MFC04410
Issue date	21-November-2022
Version number	10
Revision date	18-October-2024
Supersedes date	21-November-2022

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

Identified uses	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.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

Company name	Haleon PLC
Address:	1st Floor, Building 5, The Heights Weybridge, Surrey KT13 0NY, United Kingdom
Telephone:	+44-20-8047-5000 (General Inquiries)
Email:	msds@haleon.com
Website:	www.haleon.com

EMERGENCY CONTACTS

	3E Global Incident Response
Telephone:	+(44) 20 35147487 or 0 800 680 0425 (In country) +(1) 760 476 3961 (International) 24/7; multi-language response
Contract Number:	335879

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

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

This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

2.2. Label elements

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

Hazard pictograms	None.
Signal word	None.
Hazard statements	The mixture does not meet the criteria for classification.

Precautionary statements

Prevention	Not available.
Response	Not available.
Storage	Not available.

Disposal

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Supplemental label 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.

2.3. Other hazards This mixture does not contain substances assessed to be vPvB / PBT according to Regulation (EC) No 1907/2006, Annex XIII. The product does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. The mixture does not contain any substances included in the list established in accordance with REACH Article 59(1) for having endocrine disrupting properties at a concentration equal to or greater than 0.1% by weight.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

The components are not hazardous or are below required disclosure limits.

List of abbreviations and symbols that may be used above

ATE: Acute toxicity estimate.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Union workplace exposure limit(s).
All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments The full text for all H-statements 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.

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 with water. 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 Headache. Nausea, vomiting.

4.3. Indication of any immediate medical attention and special treatment needed Treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1. Extinguishing media

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.

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.

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Wear appropriate personal protective equipment.

For emergency responders Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

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. 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.

6.4. Reference to other sections

For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

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

7.3. Specific end use(s)

Observe industrial sector guidance on best practices.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Haleon Exposure Limits

Components	Type	Value	Form
XYLITOL (CAS 87-99-0)	OHC	1	>1000 - </=5000 mcg/m3

UK. OELs. Workplace Exposure Limits (WELs) (EH40/2005 (Fourth Edition 2020)), Table 1

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.

Biological limit values

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

Recommended monitoring procedures

Follow standard monitoring procedures.

Derived no effect levels (DNELs)

Not available.

Predicted no effect concentrations (PNECs)

Not available.

8.2. Exposure controls

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

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

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.

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

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. Fume scrubbers, filters or engineering modifications to the process equipment may be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state

Liquid.

Form	Gel.
Colour	Not available.
Odour	Not available.
Odour 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.
Vapour pressure	Not available.
Vapour 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.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
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	Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	No hazardous decomposition products are known.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
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	May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms	Headache. Nausea, vomiting.

11.1. Information on toxicological effects

Acute toxicity	Not known.
Skin corrosion/irritation	Due to partial or complete lack of data the classification is not possible.
Serious eye damage/eye irritation	Due to partial or complete lack of data the classification is not possible.
Respiratory sensitisation	Due to partial or complete lack of data the classification is not possible.
Skin sensitisation	Due to partial or complete lack of data the classification is not possible.
Germ cell mutagenicity	Due to partial or complete lack of data the classification is not possible.
Carcinogenicity	Due to partial or complete lack of data the classification is not possible.

Reproductive toxicity	Due to partial or complete lack of data the classification is not possible.
Specific target organ toxicity - single exposure	Due to partial or complete lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	Due to partial or complete lack of data the classification is not possible.
Aspiration hazard	Due to partial or complete lack of data the classification is not possible.
Mixture versus substance information	No information available.

SECTION 12: Ecological information

12.1. Toxicity	Based on available data, the classification criteria are not met for hazardous to the aquatic environment.
12.2. Persistence and degradability	No data is available on the degradability of this product.
12.3. Bioaccumulative potential	No data available for this product.
12.4. Mobility in soil	No data available.
Mobility in general	
12.5. Results of PBT and vPvB assessment	This mixture does not contain substances assessed to be vPvB / PBT according to Regulation (EC) No 1907/2006, Annex XIII.
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	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.
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

14.1. - 14.6.: Not regulated as dangerous goods.

RID

14.1. - 14.6.: Not regulated as dangerous goods.

ADN

14.1. - 14.6.: Not regulated as dangerous goods.

IATA

14.1. - 14.6.: Not regulated as dangerous goods.

IMDG

14.1. - 14.6.: Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

SECTION 15: Regulatory information

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

Retained direct EU regulations

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

Not listed.

Regulation (EU) 2019/1021 On persistent organic pollutants (recast), as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 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, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) 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 - Conditions of restriction given for the associated entry number should be considered

Not listed.

Other regulations

This product is classified and labelled in accordance with the retained CLP Regulation (EC) No 1272/2008, as amended for Great Britain. This Safety Data Sheet is compiled in accordance with REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758.

Follow the requirements of the Control of Substances Hazardous to Health Regulations 2002 [SI 2002/2677], as amended, when using this material.

15.2. Chemical safety assessment No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

ADN: European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways.
ADR: Agreement concerning the International Carriage of Dangerous Goods by Road.
AGW: Occupational threshold limit value (Arbeitsplatzgrenzwert – Germany).
CAS: Chemical Abstract Service.
CEN: European Committee for Standardization.
IATA: International Air Transport Association.
IBC Code: International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk.
IMDG: International Maritime Dangerous Goods.
MAC: Maximum Allowed Concentration.
MARPOL: International Convention for the Prevention of Pollution from Ships.
PBT: Persistent, bioaccumulative and toxic.
RID: Regulations concerning the International Carriage of Dangerous Goods by Rail.
STEL: Short term exposure limit.
TLV: Threshold Limit Value.
TWA: Time Weighted Average.
VLE: Exposure Limit Value.
VME: Exposure Average Value.
vPvB: Very persistent and very bioaccumulative.

References Not available.

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, which are not written out in full under sections 2 to 15 None.

Revision information Product and Company Identification: Product Codes
SECTION 2: Hazards identification: Supplemental label information
SECTION 9: Physical and chemical properties: Form
SECTION 12: Ecological information: Persistence and degradability
SECTION 12: Ecological information: 12.3. Bioaccumulative potential

Training information Follow training instructions when handling this material.

Issued by GSK

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