COREGA TABS

SAFETY DATA SHEET

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

1.1. Product identifier

Trade name or designation of the mixture	DENTURE CLEANSER TABLETS
Registration number	-
Synonyms	B51008 POLIDENT TRIPLA FRESCHEZZA * MFC51008 COREGA BIOFORMULA * MFC51009 QUICK CLEANING POLIDENT / COREGA WITH ENZYME * MFC51010 QUICK CLEANING POLIDENT WITH TRIPLEMINT * MFC51013 POLIDENT OVERNIGHT/WHITENING * MFC51014 POLIDENT FOR SMOKERS * MFC51038 POLIDENT ANTIBACTERIAL * MFC51039 POLIDENT FOR PARTIALS * MFC04279 R AND D FORMULATION * MFC04338 DENTURE CLEANSER PLACEBO * SODIUM PERCARBONATE, FORMULATED PRODUCT
Issue date	28-January-2015
Version number	06
Revision date	25-November-2015
Supersedes date	06-July-2015

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

Identified uses	Medical Device
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

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

Health hazards

Acute toxicity, oral	Category 4	H302 - Harmful if swallowed.
Serious eye damage/eye irritation	Category 2	H319 - Causes serious eye irritation.

Hazard summary Causes serious eye damage. Harmful if swallowed.
See section 11 for additional information on health hazards.

2.2. Label elements

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

Contains: POTASSIUM CAROATE, SODIUM LAURYL SULFOACETATE

Hazard pictograms

Signal word Warning

Hazard statements

H302	Harmful if swallowed.
H319	Causes serious eye irritation.

Precautionary statements

Prevention

P102	Keep out of reach of children.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P280	Wear eye protection/face protection.

Response

P301 + P312	IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P330	Rinse mouth.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P337 + P313	If eye irritation persists: Get medical advice/attention.

Storage Not available.

Disposal

P501	Dispose of contents/container to household waste

Supplemental label information EUH208 - Contains PEPPERMINT OIL, SUBTILISIN, OIL OF SPEARMINT, CORNMINT OIL TERPENELESS. May produce an allergic reaction.

2.3. Other hazards 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
CITRIC ACID ANHYDROUS	18 - 20	77-92-9 201-069-1	-	-	
Classification:	Eye Irrit. 2;H319				
Sodium carbonate	9.6	497-19-8 207-838-8	-	011-005-00-2	
Classification:	Eye Irrit. 2;H319				
POTASSIUM CAROATE	0 - 16	70693-62-8 274-778-7	-	-	
Classification:	Acute Tox. 4;H302, Skin Corr. 1;H314, Skin Corr. 1A;H314, STOT SE 3;H335, Aquatic Chronic 3;H412				
SODIUM BENZOATE	2.5	532-32-1 208-534-8	-	-	
Classification:	Eye Irrit. 2;H319				
SODIUM LAURYL SULFOACETATE	1.5	1847-58-1 217-431-7	-	-	
Classification:	Acute Tox. 4;H302				
PEPPERMINT OIL	0.3 - 0.8	8006-90-4 -	-	-	
Classification:	Skin Irrit. 2;H315, Skin Sens. 1;H317, Aquatic Chronic 2;H411				
SUBTILISIN	0 - 0.5	9014-01-1 232-752-2	-	647-012-00-8	
Classification:	Skin Irrit. 2;H315, Eye Dam. 1;H318, Resp. Sens. 1;H334, STOT SE 3;H335				
CORNMINT OIL TERPENELESS	0 - 0.3	68917-18-0 -	-	-	
Classification:	Acute Tox. 4;H302, Asp. Tox. 1;H304, Skin Irrit. 2;H315, Skin Sens. 1;H317, Aquatic Chronic 2;H411				

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
OIL OF SPEARMINT	0 - 0.3	8008-79-5	-	-	

Classification: Flam. Liq. 3;H226, Acute Tox. 4;H302, Asp. Tox. 1;H304, Skin Irrit. 2;H315, Skin Sens. 1;H317, Eye Irrit. 2;H319, Aquatic Chronic 2;H411

Other components below reportable levels 58.28

List of abbreviations and symbols that may be used above

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.

4.1. Description of first aid measures

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop. If breathing is difficult, trained personnel should give oxygen.

Skin contact Take off contaminated clothing and wash before reuse. Immediately flush skin with plenty of water. 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 SWALLOWED: Immediately call a POISON CENTRE or doctor/physician. Do not induce vomiting without advice from poison control center.

4.2. Most important symptoms and effects, both acute and delayed Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

4.3. Indication of any immediate medical attention and special treatment needed No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media None known.

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 Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep upwind. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. 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.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in 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 Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling Avoid contact with eyes. Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities Keep out of the reach of children. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

7.3. Specific end use(s) Medical Device

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value	Note
CITRIC ACID ANHYDROUS (CAS 77-92-9)	8 HR TWA	5000 mcg/m3	
	OHC	1	
SODIUM BENZOATE (CAS 532-32-1)	8 HR TWA	5000 mcg/m3	
SODIUM BICARBONATE (CAS 144-55-8)	8 HR TWA	5000 mcg/m3	
	OHC	1	
Sodium carbonate (CAS 497-19-8)	8 HR TWA	5000 mcg/m3	
	OHC	1	
SODIUM LAURYL SULFOACETATE (CAS 1847-58-1)	OHC	2	
SUBTILISIN (CAS 9014-01-1)	OHC	5	SKIN SENSITISER
		5	RESPIRATORY SENSITISER

Ireland. Occupational Exposure Limits

Components	Type	Value
SUBTILISIN (CAS 9014-01-1)	STEL	0.00006 mg/m3
	TWA	0.00006 mg/m3

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 General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

General information Use personal protective equipment as required. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended. (e.g. EN 166). Eye wash fountain is recommended.

Skin protection

- Hand protection	Wear suitable gloves. The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time). Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Not normally needed. Wear suitable protective clothing. (EN 14605 for splashes, EN ISO 13982 for dust).
Respiratory protection	No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. 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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.
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	Solid.
Form	Tablet.
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 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)	
Solubility (water)	Not available.
Solubility (other)	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.
Oxidising properties	Not available.
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. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin contact Health injuries are not known or expected under normal use. May cause an allergic skin reaction.

Eye contact Causes serious eye irritation.

Ingestion Harmful if swallowed.

Symptoms Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

11.1. Information on toxicological effects

Acute toxicity Harmful if swallowed.

Components	Species	Test results
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Acute		
Oral		
LD50	Rat	3000 mg/kg
OIL OF SPEARMINT (CAS 8008-79-5)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
PEPPERMINT OIL (CAS 8006-90-4)		
Acute		
Oral		
LD50	Rat	2426 mg/kg
SODIUM LAURYL SULFOACETATE (CAS 1847-58-1)		
Acute		
Oral		
LD50	Rat	700 mg/kg

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

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation. Based on available data, the classificatio criteria are not met.

Corrosivity

PEPPERMINT OIL	Literature search Result: Positive

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

CITRIC ACID ANHYDROUS	OECD 404 Result: Mild to moderate irritant. Species: Rabbit

Serious eye damage/eye irritation Causes serious eye damage.

Eye

Sodium carbonate	Acute ocular irritation; OECD 405 Result: Moderate Irritant Species: Rabbit
CITRIC ACID ANHYDROUS	Acute ocular irritation; OECD 405 Result: Severe Irritant Species: Rabbit
PEPPERMINT OIL	Literature search Result: Mild/moderate Irritant

Respiratory sensitisation Under normal conditions of intended use, this material is not expected to be an inhalation hazard. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation	Health injuries are not known or expected under normal use. May cause an allergic skin reaction.
Sensitisation	
PEPPERMINT OIL	Literature search Result: Positive
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. Based on available data, the classification criteria are not met.
Carcinogenicity	Not classifiable as to carcinogenicity to humans.
Reproductive toxicity	Based on available data, the classification criteria are not met. Contains no ingredient listed as toxic to reproduction
Specific target organ toxicity - single exposure	Based on available data, the classification criteria are not met.
Specific target organ toxicity - repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Due to partial or complete lack of data the classification is not possible.
Mixture versus substance information	No information available.
Other information	May cause allergic respiratory and skin reactions.

SECTION 12: Ecological information

12.1. Toxicity Harmful to aquatic life.

Components		Species	Test results
CITRIC ACID ANHYDROUS (CAS 77-92-9)			
Aquatic			
Acute			
Algae	NOEC	Green algae (Scenedesmus quadricauda)	425 mg/l, 8 days Static Test
Crustacea	EC50	Water flea (Daphnia magna)	120 mg/l, 72 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	1516 mg/l, 96 hours Static test
		Golden ide/orfe (Adult Leuciscus idus)	440 - 760 mg/l, 96 hours Static test
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 carbonate (CAS 497-19-8)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	> 800 mg/l
Crustacea	EC50	Water flea (Daphnia magna)	265 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	300 mg/l, 96 hours Static test
		Fathead minnow (Juvenile Pimephales promelas)	< 850 mg/l, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis)	740 mg/l, 96 hours Static test
SUBTILISIN (CAS 9014-01-1)			
Aquatic			
Acute			
Fish	EC50	Guppy (Juvenile Poecilia reticulata)	25 mg/l, 24 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	5 mg/l, 24 hours Static test

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

12.2. Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

CITRIC ACID ANHYDROUS	98 %, 2 days Modified Zahn-Wellens, Activated sludge

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

Partition coefficient n-octanol/water (log Kow)

SODIUM BENZOATE	1.89

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

SODIUM BENZOATE	1.16 Calculated

Mobility in general

Volatility

Henry's law

CITRIC ACID ANHYDROUS	< 0 atm m^3/mol Calculated, 25 °C

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

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

Read safety instructions, SDS and emergency procedures before handling.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

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 and II, as amended

Not listed.

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

Not listed.

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

Not listed.

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

Not listed.

Other EU regulations

Directive 2012/18/EU on 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, as amended

Sodium carbonate (CAS 497-19-8)
SUBTILISIN (CAS 9014-01-1)

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

SUBTILISIN (CAS 9014-01-1)

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 H-statements not written out in full under Sections 2 to 15	H226 Flammable liquid and vapour. H302 Harmful if swallowed. H304 May be fatal if swallowed and enters airways. H314 Causes severe skin burns and eye damage. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H319 Causes serious eye irritation. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335 May cause respiratory irritation. H411 Toxic to aquatic life with long lasting effects. H412 Harmful to aquatic life with long lasting effects.
Revision information	Product and Company Identification: Material Processes SECTION 2: Hazards identification: Prevention Composition / Information on Ingredients: Disclosure Overrides
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.