SAFETY DATA SHEET

1. Identification

Product identifier **COREGA TABLETS**

Other means of identification

Synonyms COREGA BIO TABLETS * COREGA 5 MINUTE TABLETS * COREGA 3 MINUTE TABLETS * COREGA TABLETS WHITENING * POLIDENT TABLETS WHITENING * POLIDENT TABLETS OVERNIGHT * POLIDENT COMPRESSE TRIPLA FRESCHEZZA (B51008) * COREGA TABLETS, BIOFORMULA * CEDENTA * MFC 51010 * MFC 10791-02-001 * DENTURE CLEANER, FORMULATED PRODUCT

Recommended use Medical Device

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

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
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES:
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 2
	Sensitization, respiratory	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements

Signal word Danger

Hazard statement Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement

Prevention Avoid breathing dust. Wash thoroughly after handling. Wear eye/face protection. In case of inadequate ventilation wear respiratory protection.

Response If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If experiencing respiratory symptoms: Call a poison center/doctor.

Storage Not available.

Disposal Dispose of contents/container (in accordance with related regulations).

Hazard(s) not otherwise classified (HNOC) See section 11 of the SDS for additional information on health hazards.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
SODIUM BICARBONATE	BAKING SODA * BICARBONATE OF SODA * CARBONIC ACID MONOSODIUM SALT * CARBONIC ACID SODIUM SALT (1:1) * MONOSODIUM CARBONATE * MONOSODIUM HYDROGEN CARBONATE * RTECS VZ0950000 * SODIUM ACID CARBONATE * SODIUM HYDROGEN CARBONATE	144-55-8	30 - < 40
CITRIC ACID ANHYDROUS	BETA-HYDROXYTRICARBALLYLIC ACID * ANHYDROUS CITRIC ACID * 2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID * CITIRIC ACID	77-92-9	< = 20
POTASSIUM PEROXYMONOSULFATE	PEROXYMONOSULFURIC ACID, MONOPOTASSIUM SALT * CARO'S ACID POTASSIUM SALT * MONOPOTASSIUM PERSULFATE * POTASSIUM HYDROGEN PERSULFATE * POTASSIUM PERSULFATE TRIPLE SALT * POTASSIUM PEROXYMONOSULPHATE * POTASSIUM CAROATE * POTASSIUM MONOPERSULFATE	10058-23-8	< 15
SODIUM CARBONATE	CARBONIC ACID, DISODIUM SALT * BISODIUM CARBONATE * DISODIUM CARBONATE * SODA ASH	497-19-8	< 10
SODIUM PERCARBONATE	CARBONIC ACID DISODIUM SALT, COMPD. WITH HYDROGEN PEROXIDE (H2O2) * CARBONIC ACID DISODIUM SALT, COMPD. WITH HYDROGEN PEROXIDE (2:3) * PERDOX * PEROXY SODIUM CARBONATE * SODIUM CARBONATE PEROXIDE	15630-89-4	< 10
SODIUM BENZOATE	BENZOIC ACID, SODIUM SALT * BENZOATE OF SODA * SODUIM BENZOIC ACID	532-32-1	< 5
SUBTILISIN	ALCALASEAXATASE MP * ALK-ENZYME * ALPHA AMYLASE * BIOPRASE * COLISTINASE * EVERLASE * PROTEIN DECOMPOSING ENZYMES * PROTEOLYTIC ENZYME	9014-01-1	0.5 - < 2
SODIUM LAURYL SULFOACETATE	SODIUM LAURYL SULFOACETATE * LANTHANOL LAL * NATRIUM-2-(DODECYLOXY)-2-OXOETHAN-1-SULFONAT	1847-58-1	< 2
PEPPERMINT OIL	OIL OF PEPPERMINT * ESSENTIAL PEPPERMINT OIL * PEPPERMINT LEAF OIL * PEPPERMINT TERPENES	8006-90-4	< 1
Other components below reportable levels			<10

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

4. First-aid measures

Inhalation In case of accident by inhalation: remove casualty to fresh air and keep at rest. If not breathing, give artificial respiration. If breathing is difficult, trained personnel should give oxygen. Call a POISON CENTER or doctor/physician if you feel unwell.

Skin contact Immediately flush skin with plenty of water. Get medical attention if irritation develops and persists. Take off contaminated clothing and wash before reuse.

Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
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.
Most important symptoms/effects, acute and delayed	Difficulty in breathing. Severe eye irritation. Dusts may irritate the respiratory tract, skin and eyes.
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 local poison control information centre.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.
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	Use water spray to cool unopened containers.
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. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. 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	Stop the flow of material, if this is without risk. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Collect dust using a vacuum cleaner equipped with HEPA filter. Minimize dust generation and accumulation. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Sweep up or vacuum up spillage and collect in suitable container for disposal. 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	Provide appropriate exhaust ventilation at places where dust is formed. Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes. Avoid prolonged exposure. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK Components	Type	Value	Note
CITRIC ACID ANHYDROUS (CAS 77-92-9)	8 HR TWA	5000 mcg/m3	
	OHC	1	

GSK

Components	Type	Value	Note
POTASSIUM PEROXYMONOSULFATE (CAS 10058-23-8)	OHC	3	CORROSIVE
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

US. ACGIH Threshold Limit Values

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

US. NIOSH: Pocket Guide to Chemical Hazards

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

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

Appropriate engineering controls Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Ventilation should be sufficient to effectively remove and prevent buildup of any dusts or fumes that may be generated during handling or thermal processing. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. Provide eyewash station. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

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. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. 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 For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. 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	Solid.
Form	Tablet.
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 available.
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 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.

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. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Prolonged inhalation may be harmful. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Inhalation of dusts may cause respiratory irritation.
Skin contact	Dust or powder may irritate the skin. Health injuries are not known or expected under normal use.
Eye contact	Causes serious eye irritation. Dust in the eyes will cause irritation.
Ingestion	May be harmful if swallowed.
Symptoms related to the physical, chemical and toxicological characteristics	Difficulty in breathing. Severe eye irritation. Dusts may irritate the respiratory tract, skin and eyes.

Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.

Components	Species	Test Results
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Acute		
Oral		
LD50	Rat	3000 mg/kg
PEPPERMINT OIL (CAS 8006-90-4)		
Acute		
Oral		
LD50	Rat	2426 mg/kg
SODIUM BICARBONATE (CAS 144-55-8)		
Acute		
Oral		
LD50	Rat	4220 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 Health injuries are not known or expected under normal use. Prolonged skin contact may cause temporary irritation.

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 irritation. Dust in the eyes will cause irritation.

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 or skin sensitization

Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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

Sensitization

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. Health injuries are not known or expected under normal use.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Health injuries are not known or expected under normal use.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Health injuries are not known or expected under normal use.

Specific target organ toxicity - single exposure Not available.

Specific target organ toxicity - repeated exposure Not available.

Aspiration hazard Not available.

Chronic effects Prolonged inhalation may be harmful.

12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.

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 BICARBONATE (CAS 144-55-8)			
Aquatic			
Acute			
Algae	EC50	Algae (Nitscheria linearis)	650 mg/l, 5 days
Crustacea	EC50	Water flea (Daphnia magna)	2350 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	8250 - 9000 mg/l, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis)	7550 mg/l, 96 hours Static 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.

Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

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

Percent degradation (Anaerobic biodegradation)

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

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

SODIUM BENZOATE	1.89

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

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

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 Annex II of MARPOL 73/78 and the IBC Code MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

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)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

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.

US state regulations

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

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

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

Not listed.

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

Not listed.

US. Rhode Island RTK

Not regulated.

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.

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
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 02-17-2015

Revision date 02-17-2015

Version # 08

Further information	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 2* Flammability: 1 Physical hazard: 0
NFPA ratings	Health: 2 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	Product and Company Identification: Synonyms