

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

1.1. Product identifier

Trade name or designation of the mixture	CORSODYL DENTAL GEL
Registration number	-
Synonyms	CORSODYL DENTAL GEL (UK) * CORSODYL DENTAL GEL 1.0% * MFC 1383 * CHLORHEXIDINE GLUCONATE, FORMULATED PRODUCT
Issue date	11-April-2014
Version number	07
Revision date	11-April-2014

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

Identified uses Medicinal Product

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

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 Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

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

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.2. Label elements

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

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Supplemental label information Not applicable.

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
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Isopropyl alcohol	4	67-63-0 200-661-7	-	603-117-00-0	
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Classification: **DSD:** F;R11, Xi;R36, R67
CLP: Flam. Liq. 2;H225, Eye Irrit. 2;H319, STOT SE 3;H336

CHLORHEXIDINE DIGLUCONATE	1	18472-51-0 242-354-0	-	-	
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Classification: **DSD:** T+;R26, Xi;R36/38, N;R51/53
CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319, Acute Tox. 2;H330, Aquatic Chronic 2;H411

PEPPERMINT OIL	< 0.2	8006-90-4	-	-	
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Classification: **DSD:** Xi;R38, R43, N;R51/53
CLP: Skin Irrit. 2;H315, Skin Sens. 1;H317, Aquatic Chronic 2;H411

Other components below reportable levels 90 - 100

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 Take off all contaminated clothing immediately. Wash contaminated clothing before reuse. 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.

4.1. Description of 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. Get medical attention immediately.

Skin contact Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately.

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms and effects, both acute and delayed Direct contact with eyes may cause temporary irritation.

4.3. Indication of any immediate medical attention and special treatment needed Thermal burns: Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance. Continue flushing during transport to hospital. 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 Flammable liquid and vapour.

5.1. Extinguishing media

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

Unsuitable extinguishing media Water.

5.2. Special hazards arising from the substance or mixture Vapours may form explosive mixtures with air. Vapours may travel considerable distance to a source of ignition and flash back. 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

In case of fire and/or explosion do not breathe fumes. 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. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

For emergency responders

Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Keep combustibles (wood, paper, oil etc) away from spilled material.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. 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. For waste disposal, see section 13.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Vapours may form explosive mixtures with air. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Do not smoke. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from heat and sources of ignition. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

7.3. Specific end use(s)

Medicinal Product

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****Occupational exposure limits****GSK****Components****Type****Value**

CHLORHEXIDINE
DIGLUCONATE (CAS
18472-51-0)

8 HR TWA

100 mcg/m3

HYDROXYPROPYL
CELLULOSE (CAS
9004-64-2)

OHC

3

OHC

1

UK. EH40 Workplace Exposure Limits (WELs)**Components****Type****Value**

Isopropyl alcohol (CAS
67-63-0)

STEL

1250 mg/m3

500 ppm

TWA

999 mg/m3

400 ppm

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 Explosion-proof general and local exhaust ventilation. 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. 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

General information Follow all local regulations if personal protective equipment (PPE) is used in the workplace. 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 Not normally needed.

Skin protection

- Hand protection 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. Glove selection must take into account any solvents and other hazards present. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other Not normally needed.

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures When using do not smoke. An occupational/industrial hygiene monitoring method has been developed for this material. 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 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 58 - 59 °C (136.4 - 138.2 °F) Closed cup (Estimation based on components).

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.

Oxidizing 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 Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
10.5. Incompatible materials Strong oxidising agents.
10.6. Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Ingestion Health injuries are not known or expected under normal use.
Inhalation Health injuries are not known or expected under normal use.
Skin contact Health injuries are not known or expected under normal use.
Eye contact Avoid contact with eyes. Direct contact with eyes may cause temporary irritation.

Symptoms None known.

11.1. Information on toxicological effects

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

Components	Species	Test results
CHLORHEXIDINE DIGLUCONATE (CAS 18472-51-0)		
Acute		
<i>Inhalation</i>		
LC50	Rat	0.3 - 0.43 mg/l chlorhexidine diacetate
<i>Oral</i>		
LD50	Rat	2000 mg/kg
Subchronic		
<i>Dermal</i>		
LOEL	Rabbit	250 mg/kg/day minimal irritation-chlorhexidine diacetate
NOAEL	Rabbit	500 mg/kg/day liver- chlorhexidine diacetate
Isopropyl alcohol (CAS 67-63-0)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	12.8 g/kg
<i>Inhalation</i>		
LC50	Rat	39 mg/l 8-hr
<i>Oral</i>		
LD50	Rat	5045 mg/kg
Subchronic		
<i>Inhalation</i>		
LOEL	Mouse	1500 ppm
	Rat	1500 ppm
NOEL	Mouse	500 ppm, 13 weeks
	Rat	500 ppm, 13 weeks

Components	Species	Test results
PEPPERMINT OIL (CAS 8006-90-4)		
Acute		
<i>Oral</i>		
LD50	Rat	2426 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		
CHLORHEXIDINE DIGLUCONATE		OECD 404, chlorhexidine diacetate Result: negative Species: Rabbit
Irritation Corrosion - Skin		
ISOPROPYL ALCOHOL		Acute dermal irritation; OECD 404 Result: Non-irritant Notes: UN SIDS evaluation: 2-Propanol
Serious eye damage/eye irritation	Avoid contact with eyes. Direct contact with eyes may cause temporary irritation.	
Eye		
ISOPROPYL ALCOHOL		OECD 405 Result: Mild irritant Species: Rabbit Notes: UN SIDS evaluation: 2-Propanol
CHLORHEXIDINE DIGLUCONATE		OECD 405, chlorhexidine diacetate Result: Severe Species: Rabbit
Respiratory sensitisation	No data recorded.	
Skin sensitisation	Health injuries are not known or expected under normal use.	
Sensitisation		
CHLORHEXIDINE DIGLUCONATE		Occupational exposure, Sensitive individuals Result: positive Species: Human
Germ cell mutagenicity	Health injuries are not known or expected under normal use.	
Mutagenicity		
ISOPROPYL ALCOHOL		Ames Result: negative
CHLORHEXIDINE DIGLUCONATE		Ames, chlorhexidine digluconate Result: negative Chromosomal Aberration Assay In Vitro, chlorhexidine digluconate Result: negative Dominant lethal assay, chlorhexidine digluconate Result: negative Species: Mouse
ISOPROPYL ALCOHOL		In vivo Micronucleus Result: negative Species: Mouse
CHLORHEXIDINE DIGLUCONATE		Micronucleus Test, chlorhexidine digluconate Result: negative Species: Mouse
ISOPROPYL ALCOHOL		SA7 - Sister Chromatid Exchange Result: negative Sister Chromatid Exchange, V79 cells Result: negative
CHLORHEXIDINE DIGLUCONATE		in vivo cytogenetics assay, chlorhexidine digluconate Result: negative Species: Hamster
ISOPROPYL ALCOHOL		mammalian cell mutation assay (CHO/HGPRT forward mutation assay) Result: negative
Carcinogenicity	Health injuries are not known or expected under normal use.	
ISOPROPYL ALCOHOL		2 year bioassay, Inhalation study Result: negative Species: Rat Notes: UN SIDS evaluation: 2-Propanol

Carcinogenicity

ISOPROPYL ALCOHOL

Inhalation study
 Result: negative
 Species: Mouse
 Notes: UN SIDS evaluation: 2-Propanol

Reproductive toxicity

Health injuries are not known or expected under normal use.

Reproductivity

CHLORHEXIDINE DIGLUCONATE

15.63 mg/kg/day Embryofetal Development, chlorhexidine diacetate

Result: Maternal NOAEL

Species: Rat

62.5 mg/kg/day Embryofetal Development, chlorhexidine diacetate

Result: Developmental NOAEL - High dose

Species: Rat

ISOPROPYL ALCOHOL

< 1200 mg/kg/day Embryo-foetal development, Developmental neurotoxicity

Result: Foetal NOAEL

Species: Rabbit

Notes: UN SIDS evaluation: 2-Propanol

< 240 mg/kg/day Epidemiology

Result: Maternal NOAEL

Species: Human

< 400 mg/kg/day Embryo-foetal development

Result: Maternal NOAEL

Species: Rabbit

Notes: UN SIDS evaluation: 2-Propanol

< 480 mg/kg/day Epidemiology

Result: Foetal NOAEL

Species: Human

< 500 mg/kg/day Two generation study

Result: Maternal toxicity; adverse effects on offspring.

Species: Rat

Notes: UN SIDS evaluation: 2-Propanol

Specific target organ toxicity - single exposure

None known.

ISOPROPYL ALCOHOL

Result: Narcosis

Organ: Central nervous system.

Specific target organ toxicity - repeated exposure

None known.

Aspiration hazard

Not an aspiration hazard.

Mixture versus substance information

No information available.

Other information

Not available.

SECTION 12: Ecological information**12.1. Toxicity**

The product contains a substance which may cause long-term adverse effects in the environment.

Components	Species	Test results
CHLORHEXIDINE DIGLUCONATE (CAS 18472-51-0)		
Aquatic		
<i>Acute</i>		
Fish	EC50	Brown trout (Adult Salmo trutta) 3.2 mg/l, 96 hours Static test
Isopropyl alcohol (CAS 67-63-0)		
Aquatic		
<i>Acute</i>		
Activated Sludge Respiration	IC50	Industrial sludge > 1000 mg/l, 3 hours
Algae	EC50	Green algae (Scenedesmus subspicatus) > 1000 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna) 13299 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Juvenile Lepomis macrochirus) > 1400 mg/l, 96 hours Static test
		Fathead minnow (Juvenile Pimephales promelas) 6550 - 10400 mg/l, 96 hours Flow-through test

Components	Species	Test results
	Mosquito fish (Juvenile <i>Gambusia affinis</i>)	> 1400 mg/l, 96 hours Static test

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

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

Photolysis

Half-life (Photolysis-atmospheric)

Isopropyl alcohol 3.1 - 14.5 Days Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

Isopropyl alcohol 99.9 %, 28 days Coupled Unit test (OECD 303A), Activated sludge

Percent degradation (Aerobic biodegradation-ready)

Isopropyl alcohol 95 %, 20 Days Batch activated sludge (BAS), Activated sludge

12.3. Bioaccumulative potential No data available for this product.

Partition coefficient n-octanol/water (log Kow)

Isopropyl alcohol 0.26

12.4. Mobility in soil No data available.

Mobility in general Not available.

Volatility

Henry's law

Isopropyl alcohol 0.000008 atm m³/mol Measured, 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. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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.

Read safety instructions, SDS and emergency procedures before handling. Read safety instructions, SDS and emergency procedures before handling.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

SECTION 15: Regulatory information

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

EU regulations

Material name: CORSODYL DENTAL GEL

4216 Version No.: 07 Revision date: 11-April-2014 Issue date: 11-April-2014

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

Not listed.

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

Not listed.

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

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 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

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) 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

Isopropyl alcohol (CAS 67-63-0)

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

Not listed.

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

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of 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

Isopropyl alcohol (CAS 67-63-0)

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

Not listed.

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 statements or R-phrases and H-statements under Sections 2 to 15

R11 Highly flammable.
R26 Very toxic by inhalation.
R36 Irritating to eyes.
R36/38 Irritating to eyes and skin.
R38 Irritating to skin.
R43 May cause sensitization by skin contact.
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R67 Vapours may cause drowsiness and dizziness.
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H330 Fatal if inhaled.
H336 May cause drowsiness or dizziness.
H411 Toxic to aquatic life with long lasting effects.

Revision information

Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Regulatory Information: Risk Phrases - Class.
GHS: Classification

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.