



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

CHLORHEXIDINE MOUTHWASH, ALCOHOL FREE

Registration number

-

Synonyms

0.06% CHLORHEXIDINE MOUTHWASH * ASTRING-O-SOL GUM CARE * ASTRING-O-SOL SPECIALIST * CHLORHEXAMED CHLORHEXIDINE 0.06% MOUTHWASH * CORSODAILY MOUTHWASH * CORSODAILY MUNNVANN * CORSODAILY MUNDSKYL * CORSODYL 2 MG/ML MUNNSKYLLEVÆSKE * CORSODYL MUNNSKYLLEMIDDEL TIL DAGLIG BRUK * CORSODYL DAILY ICY MINT MOUTHWASH * CORSODYL DAILY COOL MINT MOUTHWASH * CORSODYL DAILY FRESH MINT MOUTHWASH * CORSODYL GUM-FLUID * CORSODYL ZAHNFLEISCH-FLUID * PARODONTAX DAILY MOUTHWASH * PARODONTAX ELIXIR DIÁRIO * DNEVNA USTNA VODA PARODONTAX * PARODONTAX DAILY MOUTHWASH ALCOHOL FREE * ПАРОДОНТАКС БЕЗ СПИРТА * PARODONTAX® БЕЗ СПИРТА * PARODONTAX ALCOHOL FREE DAILY MOUTHWASH * ОПОЛІСКУВАЧ РОТОВОЇ ПОРОЖНИНИ ПАРОДОНТАКС БЕЗ СПИРТУ * PARODONTAX KASDIENIS BURNOS SKALAVIMO SKYSTIS BE ALKOHOLIO * PARODONTAX IKDIENAS MUTES SKALOJAMAIŠ LĪDZEKLIS BEZ ALKOHOL * PARODONTAX IGAPĀEVANE SUUVESI * PARODONTAX ICY MINT MOUTHWASH * PARODONTAX ICY MINT COLLUTORIO * PARODONTAX MOUTHWASH * PARODONTAX BAIN DE BOUCHE * PARODONTAX MUNDSPÜLUNG * PARODONTAX DNEVNA VODICA ZA ISPIRANJE USTA * PARODONTAX COLUTORIO * PARODONTAX MONDWATER * PARODONTAX SZÁJVÍZ * PARODONTAX MOUTHWASH (ALC FREE) * PARODONTAX ORIGINAL MOUTHWASH * PARODONTAX ORIGINAL COLLUTORIO * MFC01572 0.2% CHX * MFC02869 * MFC03461 * MFC04517 * CHLORHEXIDINE, FORMULATED PRODUCT

Issue date

27-April-2018

Version number

07

Revision date

27-April-2018

Supersedes date

27-January-2018

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

Identified uses

Oral Care
Cosmetic Product

Uses advised against

No other uses are advised.

1.3. Details of the supplier of the safety data sheet

Company name

GlaxoSmithKline UK

Address:

980 Great West Road
Brentford, Middlesex TW8 9GS UK
+44-20-8047-5000 (General Inquiries)

Telephone:

Email:

msds@gsk.com

Website:

www.gsk.com

EMERGENCY CONTACTS

Telephone:

CHEMTREC EMERGENCY NUMBERS
+(44)-870-8200418 (In country)
+(1) 703 527 3887 (International)
24/7; multi-language response
CCN9484

Contract Number:

Telephone:

VERISK 3E GLOBAL INCIDENT RESPONSE
+(44) 20 35147487 or 0 800 680 0425 (In country)
+(1) 760 476 3961 (International)
24/7; multi-language response
334878

Contract Number:

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.

2.3. Other hazards

This product will support combustion at elevated temperatures.

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
Propylene glycol	0 - 10	57-55-6 200-338-0	-	-	
Classification:	-				
Glycerol	0 - 5	56-81-5 200-289-5	-	-	
Classification:	-				
CHLORHEXIDINE DIGLUCONATE	0.06 - 1.1	18472-51-0 242-354-0	-	-	M=10
Classification:	Aquatic Acute 1;H400, Aquatic Chronic 1;H410				
509033 T CORSOLYPTUS FLAVOR	0 - 0.5	Unassigned -	-	-	
Classification:	Flam. Liq. 3;H226, Skin Irrit. 2;H315, Skin Sens. 1;H317, Aquatic Chronic 2;H411				
EUCALYPTUS FLAVOR	0 - 0.5	Unassigned -	-	-	
Classification:	Skin Irrit. 2;H315, Skin Sens. 1;H317, Eye Irrit. 2;H319, Aquatic Chronic 3;H412				
FLAVOUR TP 10886	0 - 0.5	Unassigned -	-	-	
Classification:	Skin Irrit. 2;H315, Skin Sens. 1B;H317, Eye Irrit. 2;H319, Aquatic Chronic 2;H411				
FLAVOUR TP 9150	0 - 0.5	Unassigned -	-	-	
Classification:	Skin Irrit. 2;H315, Skin Sens. 1B;H317, Eye Irrit. 2;H319, Aquatic Chronic 3;H412				
PROPYL PARABEN	0 - 0.1	94-13-3 202-307-7	-	-	
Classification:	-				
Sodium fluoride	< 0.1	7681-49-4 231-667-8	-	009-004-00-7	#
Classification:	Acute Tox. 3;H301, Skin Irrit. 2;H315, Eye Irrit. 2;H319				

Other components below reportable levels >90

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. If you feel unwell, seek medical advice (show the label where possible).

4.1. Description of first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. 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 advice/attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed None known. Direct contact with eyes may cause temporary irritation.

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

SECTION 5: Firefighting measures

General fire hazards This product will support combustion at elevated temperatures.

5.1. Extinguishing media

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
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	Wear suitable protective equipment.
Special fire fighting procedures	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. Wear appropriate protective equipment and clothing during clean-up.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions No special environmental precautions required.

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. Cover with plastic sheet to prevent spreading. 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 in 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	Keep away from heat and sources of ignition. Avoid prolonged exposure. Use care in handling/storage.
7.2. Conditions for safe storage, including any incompatibilities	Keep away from heat, sparks and open flame. Store in original tightly closed container. Use care in handling/storage. Store in accordance with local/regional/national/international regulation.
7.3. Specific end use(s)	Oral Care Cosmetic 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/m ³
	OHC	3

GSK Components	Type	Value
PROPYL PARABEN (CAS 94-13-3)	8 HR TWA	5000 mcg/m3
	OHC	1

UK. EH40 Workplace Exposure Limits (WELs)			
Components	Type	Value	Form
Glycerol (CAS 56-81-5)	TWA	10 mg/m3	Mist.
Propylene glycol (CAS 57-55-6)	TWA	474 mg/m3	Total vapour and particulates.
		10 mg/m3	Particulate.
		150 ppm	Total vapour and particulates.
Sodium fluoride (CAS 7681-49-4)	TWA	2.5 mg/m3	

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU		
Components	Type	Value
Sodium fluoride (CAS 7681-49-4)	TWA	2.5 mg/m3

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 No special ventilation requirements.

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 Not normally needed. Wear approved safety glasses with side shields or cover goggles if eye contact is possible. (eg. EN 166)

Skin protection

- Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other Not normally needed. Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust)

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Handle in accordance with good industrial hygiene and safety practices.

Environmental exposure controls

Hazard guidance and control recommendations Not available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state Liquid.

Form Solution

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	> 95 °C (> 203 °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.
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	Not available.
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	None under normal conditions.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Irritants.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact	Avoid contact with the skin.
Eye contact	May be irritating to eyes.
Ingestion	May be harmful if swallowed.

Symptoms None known. Direct contact with eyes may cause temporary irritation.

11.1. Information on toxicological effects

Acute toxicity May be harmful if swallowed.

Components	Species	Test results
CHLORHEXIDINE DIGLUCONATE (CAS 18472-51-0)		
<u>Acute</u>		
Inhalation		
LC50	Rat	0.3 - 0.43 mg/l chlorhexidine diacetate
Oral		
LD50	Rat	2000 mg/kg
<u>Subchronic</u>		
Dermal		
LOEL	Rabbit	250 mg/kg/day minimal irritation-chlorhexidine diacetate

Components	Species	Test results
NOAEL	Rabbit	500 mg/kg/day liver- chlorhexidine diacetate
PROPYL PARABEN (CAS 94-13-3)		
Acute		
Oral		
LD50	Rat	> 2000 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
Serious eye damage/eye irritation	May be irritating to eyes.	
Eye		
CHLORHEXIDINE DIGLUCONATE		OECD 405, chlorhexidine diacetate Result: Severe Species: Rabbit
Respiratory sensitisation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
Skin sensitisation	Symptoms of hypersensitivity may include skin rash, hives, itching, and/or difficulty breathing.	
Sensitisation		
CHLORHEXIDINE DIGLUCONATE		Occupational exposure, Sensitive individuals Result: Positive Species: Human
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
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 in vivo cytogenetics assay, chlorhexidine digluconate Result: negative Species: Hamster Micronucleus Test, chlorhexidine digluconate Result: negative Species: Mouse
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Sodium fluoride (CAS 7681-49-4)	3 Not classifiable as to carcinogenicity to humans.	
Reproductive toxicity	Contains no ingredient listed as toxic to reproduction	
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
Specific target organ toxicity - single exposure	None known.	
Specific target organ toxicity - repeated exposure	None known.	
Aspiration hazard	Due to lack of data the classification is not possible.	
Mixture versus substance information	Not available.	
Other information	Occupational exposure to the substance or mixture may cause adverse effects.	

SECTION 12: Ecological information

12.1. Toxicity

No data available for this product. Contains a substance which causes risk of hazardous effects to 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
Propylene glycol (CAS 57-55-6)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Selenastrum capricornutum)	19000 mg/l, 14 days
	NOEC	Green algae (Selenastrum capricornutum)	15000 mg/l, 14 days
Crustacea	EC50	Daphnia	43500 mg/l, 48 hours
	NOEC	Daphnia	28500 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	51400 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhynchus mykiss)	51600 mg/l, 96 hours Static test
	NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhynchus mykiss)	42000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	51400 mg/l, 30 minutes
Sodium fluoride (CAS 7681-49-4)			
<i>Acute</i>			
	IC50	Activated sludge	2930 mg/l, 3 hours
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Selenastrum capricornutum)	272 mg/l, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	340 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	180 mg/l, 96 hours Static renewal test
		Mosquito fish (Adult Gambusia affinis)	418 mg/l, 96 hours Static test
		Rainbow trout (Juvenile Oncorhynchus mykiss)	108 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-aqueous)

Propylene glycol 1.3 - 2.3 years Estimated

Half-life (Photolysis-atmospheric)

Propylene glycol 32 Hours Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

Propylene glycol 62 %, 5 days BOD5, Activated sludge
79 %, 20 Days BOD20, Activated sludge

Percent degradation (Anaerobic biodegradation)

Propylene glycol 100 %, 9 days

12.3. Bioaccumulative potential

Not available.

**Partition coefficient
n-octanol/water (log Kow)**

Glycerol	-1.76
PROPYL PARABEN	3.04
Propylene glycol	-1.35

Bioconcentration factor (BCF)

Propylene glycol	< 1 Estimated
Sodium fluoride	2.3 Measured

12.4. Mobility in soil No data available.

Mobility in general Not available.

Volatility

Henry's law

Propylene glycol	0 atm m ³ /mol Estimated
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Distribution

Octanol/water distribution coefficient log DOW

PROPYL PARABEN	3.04
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12.5. Results of PBT Not available.

**and vPvB
assessment**

12.6. Other adverse effects Not available.

12.7. Additional information 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.
EU waste code	Not available.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. 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 Not applicable.

**according to Annex II of
MARPOL73/78 and the IBC Code**

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.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

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

Not available.

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

Not available.

Full text of any H-statements not written out in full under Sections 2 to 15

H226 Flammable liquid and vapour.
H301 Toxic if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

Revision information

Product and Company Identification: Synonyms
SECTION 2: Hazards identification: Main symptoms
SECTION 4: First aid measures: 4.2. Most important symptoms and effects, both acute and delayed
SECTION 5: Firefighting measures: Suitable extinguishing media
SECTION 7: Handling and storage: 7.3. Specific end use(s)
SECTION 9: Physical and chemical properties: Form
SECTION 11: Toxicological information: Other information
SECTION 11: Toxicological information: Symptoms
Transport Information: Agency Name and Packaging Type/Transport Mode Selection

Training information

Not available.

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.