# 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

CORSODYL DENTAL GEL

Registration number

**Synonyms** 

CORSODYL DENTAL GEL (UK) \* CORSODYL DENTAL GEL 1.0% \* MFC 1383 \*

CHLORHEXIDINE GLUCONATE, FORMULATED PRODUCT

Issue date 25-May-2018

Version number

**Revision date** 25-May-2018 Supersedes 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

Company name GlaxoSmithKline UK Address: 980 Great West Road

Brentford, Middlesex TW8 9GS UK

Telephone: +44-20-8047-5000 (General Inquiries)

Email: msds@gsk.com Website: www.gsk.com

#### **EMERGENCY CONTACTS**

CHEMTREC EMERGENCY NUMBERS

Telephone: +(44)-870-8200418 (In country)

+(1) 703 527 3887 (International) 24/7; multi-language response

**Contract Number:** CCN9484

VERISK 3E GLOBAL INCIDENT RESPONSE

Telephone: +(44) 20 35147487 or 0 800 680 0425 (In country)

> +(1) 760 476 3961 (International) 24/7; multi-language response

**Contract Number:** 334878

### **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 See section 11 for additional information on health hazards.

### **SECTION 3: Composition/information on ingredients**

#### 3.2. Mixtures

Material name: CORSODYL DENTAL GEL 4216 Version #: 07 Revision date: 25-May-2018 Issue date: 25-May-2018

#### **General information**

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
sopropyl alcohol	4	67-63-0 200-661-7	-	603-117-00-0	
Classification: Flam.	Liq. 2;H225, Ey	e Irrit. 2;H319, STO	T SE 3;H336		
CHLORHEXIDINE DIGLUCONA	ATE 1	18472-51-0 242-354-0	-	-	M=10
Classification: Aquat	ic Acute 1;H400	, Aquatic Chronic 1	;H410		
PEPPERMINT OIL	< 0.2	8006-90-4	-	-	
	Гох. 1;Н304, Ski iic 2;Н411	r Irrit. 2;H315, Skin	Sens. 1;H317, Eye Irrit. 2;H3	19, Aquatic	

Other components below reportable levels

#### 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).

The full text for all R- and H-phrases is displayed in section 16. **Composition comments** 

#### **SECTION 4: First aid measures**

Take off all contaminated clothing immediately. Wash contaminated clothing before reuse. **General information** 

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.

Immediately flush eyes with plenty of water for at least 15 minutes. Rinse thoroughly with plenty of Eye contact

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 unconsious 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

Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing

media

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 In case of fire and/or explosion do not breathe fumes. Use standard firefighting procedures and consider the hazards of other involved materials. procedures

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. 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 of the SDS.

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 of the SDS. For waste disposal, see section 13 of the SDS.

## **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).

Medicinal Product 7.3. Specific end use(s)

#### **SECTION 8: Exposure controls/personal protection**

### 8.1. Control parameters

# Occupational exposure limits

cupational exposure limits  GSK			
Components	Туре	Value	
CHLORHEXIDINE DIGLUCONATE (CAS 18472-51-0)	8 HR TWA	100 mcg/m3	
·	OHC	3	
HYDROXYPROPYL CELLULOSE (CAS 9004-64-2)	OHC	1	
UK. EH40 Workplace Expo	osure Limits (WELs)		
Components	Туре	Value	
Isopropyl alcohol (CAS 67-63-0)	STEL	1250 mg/m3	
		500 ppm	
	TWA	999 mg/m3	
		400 ppm	
logical limit values	No biological exposure limits noted for the ingredient(s).		
commended monitoring cedures	Follow standard monitoring procedures.		
rived no effect levels IELs)	Not available.		

concentrations (PNECs) 8.2. Exposure controls

Predicted no effect

Not available.

# 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 Not available.

range

Flash point 58 - 59 °C (136.4 - 138.2 °F) Closed cup (Estimation based on components).

Evaporation rateNot available.Flammability (solid, gas)Not available.Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

(%)

Vapour pressureNot available.Vapour densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water)

Not available.

Partition coefficient

Not available.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.Explosive propertiesNot available.Oxidising propertiesNot 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

Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

decomposition products

# **SECTION 11: Toxicological information**

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

Information on likely routes of exposure

InhalationHealth injuries are not known or expected under normal use.Skin contactHealth injuries are not known or expected under normal use.

Eye contact Avoid contact with eyes. Direct contact with eyes may cause temporary irritation.

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

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)

<u>Acute</u>

Inhalation

LC50 Rat 0.3 - 0.43 mg/l chlorhexidine diacetate

Oral

LD50 Rat 2000 mg/kg

Subchronic

**Dermal** 

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** 

**Dermal** 

LD50 Rabbit 12.8 g/kg

Inhalation

LC50 Rat 39 mg/l 8-hr

Oral

LD50 Rat 5045 mg/kg

**Subchronic** 

Inhalation

LOEL Mouse 1500 ppm

Rat 1500 ppm

NOEL Mouse 500 ppm, 13 weeks

Rat 500 ppm, 13 weeks

PEPPERMINT OIL (CAS 8006-90-4)

Acute Oral

LD50 Rat 2426 mg/kg

<sup>\*</sup> 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

PEPPERMINT OIL Literature search

Result: Positive

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.

PEPPERMINT OIL Literature search

Result: Mild/moderate Irritant

**OECD 405** Isopropyl alcohol

Result: Mild irritant Species: Rabbit

Notes: UN SIDS evaluation: 2-Propanol OECD 405, chlorhexidine diaceate

CHLORHEXIDINE DIGLUCONATE Result: Severe

Species: Rabbit

Respiratory sensitisation

No data recorded.

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

Sensitisation

PEPPERMINT OIL Literature search

Result: Positive

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

CHI ORHEXIDINE DIGI UCONATE 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 In vivo Micronucleus

Isopropyl alcohol Result: negative

Species: Mouse

mammalian cell mutation assay (CHO/HGPRT forward

mutation assay) Result: negative

Micronucleus Test, chlorhexidine digluconate CHLORHEXIDINE DIGLUCONATE

Result: negative Species: Mouse

SA7 - Sister Chromatid Exchange Isopropyl alcohol

Result: negative

Sister Chromatid Exchange, V79 cells

Result: negative

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

Isopropyl alcohol 0, Inhalation study Result: negative

Species: Mouse

Notes: UN SIDS evaluation: 2-Propanol 2 year bioassay, Inhalation study

Result: negative Species: Rat

Notes: UN SIDS evaluation: 2-Propanol

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

Reproductivity

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

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

CHLORHEXIDINE DIGLUCONATE

Result: Narcosis

Organ: Central nervous system.

Specific target organ toxicity -

repeated exposure

None known.

None known.

**Aspiration hazard** Not an aspiration hazard. Mixture versus substance

Isopropyl alcohol

information

No information available.

Not available. Other information

#### **SECTION 12: Ecological information**

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

Components Species restres	Components	Species	Test results
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CHLORHEXIDINE DIGLUCONATE (CAS 18472-51-0)

Aquatic

Acute

Fish EC50 Brown trout (Adult Salmo trutta) 3.2 mg/l, 96 hours Static test

Isopropyl alcohol (CAS 67-63-0)

Aquatic

Acute

Activated Sludge IC50 > 1000 mg/l, 3 hours Industrial sludge

Respiration

EC50 Algae Green algae (Scenedesmus > 1000 mg/l, 72 hours

subspicatus)

Crustacea EC50 Water flea (Daphnia magna) 13299 mg/l, 48 hours Static test

Fish EC50 Bluegill sunfish (Juvenile Lepomis

macrochirus)

Fathead minnow (Juvenile Pimephales 6550 - 10400 mg/l, 96 hours

> 1400 mg/l, 96 hours Static test

> 1400 mg/l, 96 hours Static test

Flow-through test promelas)

Mosquito fish (Juvenile Gambusia

No data is available on the degradability of this product.

affinis)

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

degradability

12.2. Persistence and

Material name: CORSODYL DENTAL GEL

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**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

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

No data available. 12.4. Mobility in soil Mobility in general Not available.

Volatility

Henry's law

Isopropyl alcohol 0.000008 atm m^3/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).

Empty containers should be taken to an approved waste handling site for recycling or disposal. Contaminated packaging

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.

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material Disposal methods/information

and its container must be disposed of as hazardous waste. 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

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.

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

14.7. Transport in bulk according to Annex II of 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.

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

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

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

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 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, as amended.

Not listed.

### Other EU regulations

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

Isopropyl alcohol (CAS 67-63-0)

The product is classified and labelled in accordance with EC directives or respective national laws. Other regulations

This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

Follow national regulation for work with chemical agents. National regulations No Chemical Safety Assessment has been carried out. 15.2. Chemical safety

assessment

### **SECTION 16: Other information**

Not available. List of abbreviations

References **GSK Hazard Determination** 

Information on evaluation method leading to the classification of mixture

**Revision information** 

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 H225 Highly flammable liquid and vapour.

H304 May be fatal if swallowed and enters airways.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness.

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. Product and Company Identification: Synonyms

Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Multiple Properties

Regulatory Information: United States SECTION 16: Other information: References

GHS: Classification

Training information Follow training instructions when handling this material.

The information and recommendations in this safety data sheet are, to the best of our knowledge, Disclaimer

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.

Material name: CORSODYL DENTAL GEL

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