

Safety Data Sheet according to WHS Regulations

Printing date 21.01.2021

Version number 4



Revision: 21.01.2021

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- **Product identifier**
- **Trade name: GC Freegenol Cleaner**
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Auxillary for dental technology
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
GC Australasia Dental Pty Ltd
1753 Botany Road
Banksmeadow, NSW 2019
Tel: +61 2 9301 8200
- **Further information obtainable from:** Regulatory affairs
- **Emergency telephone number:** 24 hours Emergency: 13 11 26.

2 Hazard(s) Identification

- **Classification of the substance or mixture**
Skin Irrit. 2 H315 Causes skin irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
Asp. Tox. 1 H304 May be fatal if swallowed and enters airways.
- **Label elements**
- **GHS label elements**
Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Exemptions**
The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).
- **Hazard pictograms**


GHS07 GHS08
- **Signal word** Danger
- **Hazard-determining components of labelling:**
Butene, homopolymer
(R)-p-mentha-1,8-diene
- **Hazard statements**
Causes skin irritation.
May cause an allergic skin reaction.

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May be fatal if swallowed and enters airways.

· **Precautionary statements**

IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

Specific treatment (see on this label).

Do NOT induce vomiting.

Take off contaminated clothing and wash it before reuse.

Store locked up.

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

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition and Information on Ingredients

· **Chemical characterisation: Mixtures**

· **Description:**

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

· **Dangerous components:**

9003-29-6	Butene, homopolymer	Asp. Tox. 1, H304; Skin Irrit. 2, H315	90-<100%
112-80-1	oleic acid	Skin Irrit. 2, H315; Eye Irrit. 2A, H319	5-<10%
5989-27-5	(R)-p-mentha-1,8-diene	Flam. Liq. 3, H226; Skin Irrit. 2, H315; Skin Sens. 1, H317	2.5-<5%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

· **Description of first aid measures**

· **General information:**

Immediately remove any clothing soiled by the product.

If symptoms persist consult doctor.

· **After inhalation:**

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

Take affected persons into fresh air and keep quiet.

· **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment.

If skin irritation continues, consult a doctor.

· **After eye contact:**

Rinse opened eye for several minutes under running water.

If symptoms persist consult doctor.

· **After swallowing:**

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed** Allergic reactions

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- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**
Remove persons from danger area.
Avoid contact with the eyes and skin.
Wear protective clothing.
- **Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Do not allow to penetrate the ground/soil.
- **Methods and material for containment and cleaning up:**
Ensure adequate ventilation.
Absorb liquid components with liquid-binding material.
Dispose of the material collected according to regulations.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and Storage

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Do not inhale dust / smoke / mist.
Prevent formation of aerosols.
Avoid contact with the eyes and skin.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in unopened original receptacles.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** None.

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· **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· **Additional information:** The lists valid during the making were used as basis.

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

· **Respiratory protection:** Suitable respiratory protective device recommended.

· **Protection of hands:**



Protective gloves

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

9 Physical and Chemical Properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Liquid

Colour: Light yellow

· **Odour:** Characteristic

· **Odour threshold:** Not determined.

· **pH-value:** Not determined.

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· Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	360 °C (680 °F)
· Flash point:	189 °C (372.2 °F)
· Flammability (solid, gas):	Not applicable.
· Ignition temperature:	Undetermined.
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density:	Not determined. 2,56 g/cm ³ 1,18g/ml
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	3.5 %
VOC (EC)	35.0 g/l
· Other information	No further relevant information available.

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

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11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**

- **LD/LC50 values relevant for classification:**

112-80-1 oleic acid		
Oral	LD50	74,000 mg/kg (rat (f+m))

- **Primary irritant effect:**
- **Skin corrosion/irritation** Irritant to skin and mucous membranes.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** Sensitisation possible through skin contact.
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.

12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Toxic for fish
- **Additional ecological information:**
- **General notes:**
Also poisonous for fish and plankton in water bodies.
Toxic for aquatic organisms
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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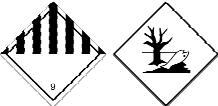
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14 Transport information

· UN-Number · ADG, IMDG, IATA	UN3082
· UN proper shipping name · ADG · IMDG · IATA	not regulated ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (DIPENTENE), MARINE POLLUTANT ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (DIPENTENE)
· Transport hazard class(es) · ADG	
	
· Class · Label	9 (M6) Miscellaneous dangerous substances and articles. 9
· IMDG, IATA	
	
· Class · Label	9 Miscellaneous dangerous substances and articles. 9
· Packing group · ADG, IMDG, IATA	III
· Environmental hazards: · Marine pollutant:	No Symbol (fish and tree)
· Special marking (ADG): · Special marking (IATA):	Symbol (fish and tree) Symbol (fish and tree)
· Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category	Warning: Miscellaneous dangerous substances and articles. 90 F-A,S-F A
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADG · Limited quantities (LQ) · Excepted quantities (EQ)	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· Transport category · Tunnel restriction code	3 -

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- | | |
|--|---|
| <ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) | <p style="margin: 0;">5L</p> <p style="margin: 0;">Code: E1</p> <p style="margin: 0;">Maximum net quantity per inner packaging: 30 ml</p> <p style="margin: 0;">Maximum net quantity per outer packaging: 1000 ml</p> |
| <ul style="list-style-type: none"> · UN "Model Regulation": | <p style="margin: 0;">not regulated</p> |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**

- **Australian Inventory of Chemical Substances**

9003-29-6	Butene, homopolymer
112-80-1	oleic acid
8008-57-9	Orange oil

- **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

- **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Danger

- **Hazard-determining components of labelling:**

Butene, homopolymer
(R)-p-mentha-1,8-diene

- **Hazard statements**

Causes skin irritation.
May cause an allergic skin reaction.
May be fatal if swallowed and enters airways.

- **Precautionary statements**

IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
Specific treatment (see on this label).
Do NOT induce vomiting.
Take off contaminated clothing and wash it before reuse.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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16 Other information

· **Relevant phrases**

H226 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.

· **Department issuing SDS:** Regulatory affairs

· **Contact:** msds@gc.dental

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods
 IATA: International Air Transport Association
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 VOC: Volatile Organic Compounds (USA, EU)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 Flam. Liq. 3: Flammable liquids – Category 3
 Skin Irrit. 2: Skin corrosion/irritation – Category 2
 Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
 Skin Sens. 1: Skin sensitisation – Category 1
 Asp. Tox. 1: Aspiration hazard – Category 1

· **Sources**

- ECHA (<http://echa.europa.eu/>)
- EnviChem (www.echemportal.org)

· *** Data compared to the previous version altered.**

This version replaces all previous versions.

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