

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 02.08.2018



Version number 4

Revision: 26.04.2018

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

- **1.1 Product identifier**
- **Trade name: GC Freegenol Accelerator**
- **1.2 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
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
GC EUROPE N.V.
Interleuvenlaan 33
B-3001 Leuven
Tel. +32/(0)16/74.10.00
Fax +32/(0)16/40.26.84
msds@gc.dental
- **Further information obtainable from:** Regulatory affairs
- **1.4 Emergency telephone number:**
National poison center for United Kingdom of Great Britain and Northern Ireland:
Belfast: +44 28 90 63 2032
Birmingham: +44 121 507 4123
Edinburgh: +44 131 242 1383
Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180
Penarth: +44 292 071 55 54

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.
Skin Corr. 1C H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
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 CLP regulation.
- **Hazard pictograms**
 
GHS05 GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**
octanoic acid
Rosin

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· Hazard statements*H314 Causes severe skin burns and eye damage.**H317 May cause an allergic skin reaction.***· Precautionary statements***P260 Do not breathe dusts or mists.**P280 Wear protective gloves / eye protection / face protection.**P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].**P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.**P310 Immediately call a POISON CENTER/doctor.**P321 Specific treatment (see on this label).**P362+P364 Take off contaminated clothing and wash it before reuse.**P405 Store locked up.**P501 Dispose of contents/container in accordance with local/regional/national/international regulations.***· Additional information:***1 % of the mixture consists of component(s) of unknown toxicity.**Contains 1 % of components with unknown hazards to the aquatic environment.***· 2.3 Other hazards****· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients****· 3.2 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:**

CAS: 8050-09-7 EINECS: 232-475-7 Index number: 650-015-00-7	Rosin ----- Skin Sens. 1, H317	25-<50%
CAS: 124-07-2 EINECS: 204-677-5 Index number: 607-708-00-4	octanoic acid ----- Skin Corr. 1C, H314; Aquatic Chronic 3, H412	10-<25%
CAS: 123-76-2 EINECS: 204-649-2	Levulinic acid ----- Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	1-<2.5%
CAS: 594-61-6 EINECS: 209-848-8	2-hydroxy-2-methylpropionic acid ----- Acute Tox. 4, H312; Acute Tox. 4, H332	0.5-<1%

· Additional information: For the wording of the listed hazard phrases refer to section 16.**SECTION 4: First aid measures****· 4.1 Description of first aid measures****· General information:***Immediately remove any clothing soiled by the product.*

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*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:***Protect unharmed eye.**Rinse opened eye for several minutes under running water.**Call a doctor immediately.***· After swallowing:***Rinse out mouth and then drink plenty of water.**If symptoms persist consult doctor.***· 4.2 Most important symptoms and effects, both acute and delayed Allergic reactions****· 4.3 Indication of any immediate medical attention and special treatment needed***No further relevant information available.***SECTION 5: Firefighting measures****· 5.1 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****· 5.2 Special hazards arising from the substance or mixture***Formation of toxic gases is possible during heating or in case of fire.***· 5.3 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.***SECTION 6: Accidental release measures****· 6.1 Personal precautions, protective equipment and emergency procedures***Remove persons from danger area.**Avoid contact with the eyes and skin.**Wear protective clothing.***· 6.2 Environmental precautions:***Do not allow product to reach sewage system or any water course.**Do not allow to penetrate the ground/soil.***· 6.3 Methods and material for containment and cleaning up:***Use neutralising agent.**Absorb liquid components with liquid-binding material.**Dispose of the material collected according to regulations.***· 6.4 Reference to other sections***See Section 7 for information on safe handling.**See Section 8 for information on personal protection equipment.*

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See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Avoid contact with the eyes and skin.

· **Information about fire - and explosion protection:** No special measures required.

· 7.2 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:** Keep container tightly sealed.

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

SECTION 8: Exposure controls/personal protection

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

· 8.1 Control parameters

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

8050-09-7 Rosin

WEL	Short-term value: 0.15 mg/m ³
	Long-term value: 0.05 mg/m ³
Sen	

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

· 8.2 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.

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· Eye protection:



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Pasty
Colour:	Brown
· Odour:	Characteristic
· Odour threshold:	Not determined.

· pH-value: Not determined.

· Change in condition

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.

· Flash point: Not applicable.

· 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.

· 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:

VOC (EC) 0.0 g/l

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- **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

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

124-07-2 octanoic acid

Oral	LD50	10,080 mg/kg (rat (f+m))
Dermal	LD50	>5,000 mg/kg (kan)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**
Causes serious eye damage.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish

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- **Additional ecological information:**
- **General notes:**
Must not reach sewage water or drainage ditch undiluted or unneutralised.
Harmful to aquatic organisms
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations


- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 06*	chemicals consisting of or containing dangerous substances

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN-Number**
· **ADR, IMDG, IATA** UN3265
- **14.2 UN proper shipping name**
· **ADR** 3265 CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (octanoic acid)
· **IMDG, IATA** CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (octanoic acid)
- **14.3 Transport hazard class(es)**
· **ADR**

· **Class** 8 (C3) Corrosive substances.
· **Label** 8

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· **IMDG, IATA**

· **Class** 8 Corrosive substances.
· **Label** 8

· **14.4 Packing group**
· **ADR, IMDG, IATA** II

· **14.5 Environmental hazards:**
· **Marine pollutant:** No

· **14.6 Special precautions for user** Warning: Corrosive substances.
· **Danger code (Kemler):** 80
· **EMS Number:** F-A,S-B
· **Stowage Category** B
· **Stowage Code** SW2 Clear of living quarters.

· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.

· **Transport/Additional information:**

· **ADR**
· **Limited quantities (LQ)** 1L
· **Excepted quantities (EQ)** Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml
· **Transport category** 2
· **Tunnel restriction code** E

· **IMDG**
· **Limited quantities (LQ)** 1L
· **Excepted quantities (EQ)** Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml

· **UN "Model Regulation":** UN 3265 CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (OCTANOIC ACID), 8, II

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

- **Relevant phrases**
H302 Harmful if swallowed.
H312 Harmful in contact with skin.

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H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H412 Harmful to aquatic life with long lasting effects.

· **Classification according to Regulation (EC) No 1272/2008** Calculation method

· **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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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

Acute Tox. 4: Acute toxicity – Category 4

Skin Corr. 1C: Skin corrosion/irritation – Category 1C

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

· **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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Version number 3

Revision: 22.06.2017

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

- **1.1 Product identifier**
- **Trade name: GC Freegenol Base**
- **1.2 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
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
GC EUROPE N.V.
Interleuvenlaan 33
B-3001 Leuven
Tel. +32/(0)16/74.10.00
Fax +32/(0)16/40.26.84
msds@gc.dental
- **Further information obtainable from:** Regulatory affairs
- **1.4 Emergency telephone number:**
National poison center for United Kingdom of Great Britain and Northern Ireland:
Belfast: +44 28 90 63 2032
Birmingham: +44 121 507 4123
Edinburgh: +44 131 242 1383
Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180
Penarth: +44 292 071 55 54

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.
Aquatic Acute 1 H400 Very toxic to aquatic life.
Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
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 CLP regulation.
- **Hazard pictograms**

GHS09
- **Signal word** Warning
- **Hazard statements**
H410 Very toxic to aquatic life with long lasting effects.
- **Precautionary statements**
P273 Avoid release to the environment.
P391 Collect spillage.

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Trade name: GC Freegenol Base

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P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 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:**

CAS: 1314-13-2 EINECS: 215-222-5 Index number: 030-013-00-7	zinc oxide Aquatic Acute 1, H400; Aquatic Chronic 1, H410	75-<90%
CAS: 9003-29-6 NLP: 500-004-7	Butene, homopolymer Asp. Tox. 1, H304; Skin Irrit. 2, H315	0.5-<1%

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

SECTION 4: First aid measures

- **4.1 Description of first aid measures**

- **General information:** 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:** If skin irritation continues, consult a doctor.

- **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- **After swallowing:**

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

- **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 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

- **5.2 Special hazards arising from the substance or mixture**

Formation of toxic gases is possible during heating or in case of fire.

- **5.3 Advice for firefighters**

- **Protective equipment:** Wear self-contained respiratory protective device.

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· **Additional information**

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**

Remove persons from danger area.

Wear protective clothing.

· **6.2 Environmental precautions:**

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to penetrate the ground/soil.

In case of seepage into the ground inform responsible authorities.

· **6.3 Methods and material for containment and cleaning up:**

Absorb liquid components with liquid-binding material.

Dispose of the material collected according to regulations.

· **6.4 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.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling** *No special precautions are necessary if used correctly.*

· **Information about fire - and explosion protection:** *No special measures required.*

· **7.2 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.*

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

SECTION 8: Exposure controls/personal protection

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

· **8.1 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.*

· **8.2 Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

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

Wash hands before breaks and at the end of work.

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

· **Protection of hands:** *Protective gloves*

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Trade name: GC Freegenol Base

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- **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: Safety glasses**

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form: Pasty

Colour: White

- **Odour:** Characteristic

- **Odour threshold:** Not determined.

- **pH-value:** Not determined.

- **Change in condition**

Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: Undetermined.

- **Flash point:** Not applicable.

- **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.

- **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: 0.0 %

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VOC (EC)	0.0 g/l
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:** No further relevant information available.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Very toxic for fish
- **Additional ecological information:**
- **General notes:**
Also poisonous for fish and plankton in water bodies.
Very toxic for aquatic organisms
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.

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- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 06*	chemicals consisting of or containing dangerous substances

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

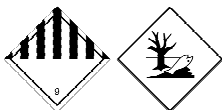
SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, IMDG, IATA** UN3082

- **14.2 UN proper shipping name**
- **ADR** 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (zinc oxide)
- **IMDG** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (zinc oxide), MARINE POLLUTANT
- **IATA** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (zinc oxide)

- **14.3 Transport hazard class(es)**

- **ADR**



- **Class** 9 (M6) Miscellaneous dangerous substances and articles.
- **Label** 9

- **IMDG, IATA**



- **Class** 9 Miscellaneous dangerous substances and articles.
- **Label** 9

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· 14.4 Packing group · ADR, IMDG, IATA	III
· 14.5 Environmental hazards: · Marine pollutant:	Product contains environmentally hazardous substances: zinc oxide Yes Symbol (fish and tree)
· Special marking (ADR): · Special marking (IATA):	Symbol (fish and tree) Symbol (fish and tree)
· 14.6 Special precautions for user · Danger code (Kemler): · EMS Number: · Stowage Category	Warning: Miscellaneous dangerous substances and articles. 90 F-A,S-F A
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR · 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 E
· IMDG · 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
· UN "Model Regulation":	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ZINC OXIDE), 9, III

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Directive 2012/18/EU
- Qualifying quantity (tonnes) for the application of lower-tier requirements 100 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

- Relevant phrases
H304 May be fatal if swallowed and enters airways.
H315 Causes skin irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

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· **Classification according to Regulation (EC) No 1272/2008 Calculation method**

· **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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Asp. Tox. 1: Aspiration hazard – Category 1

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic 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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SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
 - **Trade name: GC Freegenol Cleaner**
- **1.2 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
- **1.3 Details of the supplier of the safety data sheet**
 - **Manufacturer/Supplier:**
GC EUROPE N.V.
Interleuvenlaan 33
B-3001 Leuven
Tel. +32/(0)16/74.10.00
Fax +32/(0)16/40.26.84
msds@gc.dental
- **Further information obtainable from:** Regulatory affairs
- **1.4 Emergency telephone number:**

National poison center for United Kingdom of Great Britain and Northern Ireland:
Belfast: +44 28 90 63 2032
Birmingham: +44 121 507 4123
Edinburgh: +44 131 242 1383
Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180
Penarth: +44 292 071 55 54

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
 - **Classification according to Regulation (EC) No 1272/2008**

Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.

Skin Irrit. 2 H315 Causes skin irritation.

Asp. Tox. 1 H304 May be fatal if swallowed and enters airways.

- **2.2 Label elements**
 - **Labelling according to Regulation (EC) No 1272/2008**

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 CLP regulation.
 - **Hazard pictograms**



GHS07 GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**

Butene, homopolymer
- **Hazard statements**

H315 Causes skin irritation.

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*H304 May be fatal if swallowed and enters airways.***· Precautionary statements***P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.**P321 Specific treatment (see on this label).**P331 Do NOT induce vomiting.**P362+P364 Take off contaminated clothing and wash it before reuse.**P405 Store locked up.**P501 Dispose of contents/container in accordance with local/regional/national/international regulations.***· 2.3 Other hazards****· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients****· 3.2 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:**

CAS: 9003-29-6 NLP: 500-004-7	Butene, homopolymer	Asp. Tox. 1, H304; Skin Irrit. 2, H315	75-<90%
CAS: 112-80-1 EINECS: 204-007-1	oleic acid	Skin Irrit. 2, H315; Eye Irrit. 2, H319	5-<10%
CAS: 8008-57-9 EC number: 307-891-8	Orange oil	Flam. Liq. 3, H226	2.5-<5%

· Additional information: For the wording of the listed hazard phrases refer to section 16.**SECTION 4: First aid measures****· 4.1 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.***· 4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

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

SECTION 5: Firefighting measures

- **5.1 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
- **5.2 Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
- **5.3 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.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Remove persons from danger area.
Avoid contact with the eyes and skin.
Wear protective clothing.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Do not allow to penetrate the ground/soil.
- **6.3 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.
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 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.
- **7.2 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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· 7.3 **Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

· **8.1 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.

· **8.2 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

SECTION 9: Physical and chemical properties

· **9.1 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
· Flash point:	189 °C
· 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.
· 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:	0.0 %
VOC (EC)	0.0 g/l
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

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

112-80-1 oleic acid

Oral	LD50	74000 mg/kg (rat (f+m))
------	------	-------------------------

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard**
May be fatal if swallowed and enters airways.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**

18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 06*	chemicals consisting of or containing hazardous substances

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN-Number
· ADR, ADN, IMDG, IATA | not regulated |
| · 14.2 UN proper shipping name
· ADR, ADN, IMDG, IATA | not regulated |
| · 14.3 Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | not regulated |
| · 14.4 Packing group
· ADR, IMDG, IATA | not regulated |
| · 14.5 Environmental hazards:
· Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | not regulated |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

- **Relevant phrases**
H226 Flammable liquid and vapour.
H304 May be fatal if swallowed and enters airways.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
- **Classification according to Regulation (EC) No 1272/2008 Calculation method**
- **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
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances

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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. 2: Serious eye damage/eye irritation – Category 2
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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