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

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SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier · Trade name: 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)16/40.26.84msds@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
- 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
- The product is classified and labelled according to the GB CLP regulation.
- · 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



· Signal word Danger

• Hazard-determining components of labelling: octanoic acid

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Rosin	
 Hazard statemen 	ts
H314 Causes seve	ere skin burns and eye damage.
H317 May cause	an allergic skin reaction.
· Precautionary sta	atements
P260	Do not breathe dusts or mists.
P280	<i>Wear protective gloves / eye protection / face protection.</i>
P303+P361+P35	53 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P33	88 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.
· Additional inform	nation:
1 % of the mixtur	e consists of component(s) of unknown toxicity.
	components with unknown hazards to the aquatic environment.
· 2.3 Other hazard	S
· Results of PBT a	nd vPvB assessment
• PBT: Not applica	
• vPvB: Not applic	

SECTION 3: Composition/information on ingredients

· 3.2 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.

Rosin Skin Sens. 1, H317	25-<50%
octanoic acid Skin Corr. 1C, H314; Aquatic Chronic 3, H412	10-<25%
Levulinic acid Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	1-<2.5%
2-hydroxy-2-methylpropionic acid Acute Tox. 4, H312; Acute Tox. 4, H332	1-<2.5%
	Skin Sens. 1, H317 octanoic acid Skin Corr. 1C, H314; Aquatic Chronic 3, H412 Levulinic acid Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 2-hydroxy-2-methylpropionic acid

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.

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• After inhalation:

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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. No further relevant information available.
- 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.

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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

· 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/m³ Long-term value: 0.05 mg/m³ Sen

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

- · 8.2 Exposure controls
- Appropriate engineering controls No further data; see item 7.
- · Individual protection measures, such as 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.
- · Hand protection



• 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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(Contd. of page 4) · Eye/face protection Tightly sealed goggles **SECTION 9: Physical and chemical properties** · 9.1 Information on basic physical and chemical properties · General Information · Physical state Fluid Brown · Colour: Characteristic · Odour: Not determined. • Odour threshold: • Melting point/freezing point: Undetermined. · Boiling point or initial boiling point and boiling range Undetermined. · Flammability Not applicable. · Lower and upper explosion limit Not determined. · Lower: · Upper: Not determined. *Not applicable.* · Flash point: Undetermined. · Ignition temperature: Not determined. • Decomposition temperature: Not determined. · pH · Viscosity: · Kinematic viscosity Not determined. · Dynamic: Not determined. · Solubility Insoluble. · water: · Partition coefficient n-octanol/water (log value) Not determined. Not determined. · Vapour pressure: · Density and/or relative density · Density: Not determined. · Relative density Not determined. · Vapour density Not determined. • 9.2 Other information · Appearance: · Form: Pastv · Important information on protection of health and environment, and on safety. · Auto-ignition temperature: Product is not selfigniting. · Explosive properties: Product does not present an explosion hazard. · Solvent content: $0.0 \, g/l$ \cdot VOC (EC) · Change in condition Not determined. · Evaporation rate · Information with regard to physical hazard classes · Explosives Void · Flammable gases Void Void

· Aerosols

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Oxidising gases	Void	
Gases under pressure	Void	
Flammable liquids	Void	
Flammable solids	Void	
Self-reactive substances and mixtures	Void	
Pyrophoric liquids	Void	
Pyrophoric solids	Void	
Self-heating substances and mixtures	Void	
Substances and mixtures, which emit flammal	ble gases	
in contact with water	Void	
Oxidising liquids	Void	
Oxidising solids	Void	
Organic peroxides	Void	
Corrosive to metals	Void	
Desensitised explosives	Void	

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 hazard classes as defined in Regulation (EC) No 1272/2008

• Acute toxicity

· 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)

· 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.

- Additional toxicological information:
- *Repeated dose toxicity No further relevant information available.*
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

No further relevant information available.

· 11.2 Information on other hazards

· Endocrine disrupting properties

None of the ingredients is listed.

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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.
- · 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties
- The product does not contain substances with endocrine disrupting properties.
- · 12.7 Other adverse effects
- Remark: Harmful to fish
- 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. Must not reach sewage water or drainage ditch undiluted or unneutralised. Harmful to aquatic organisms

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.

· Uncleaned packaging:

• Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

· 14.1 UN number or ID number · ADR, IMDG, IATA	UN1760
14.2 UN proper shipping name ADR IMDG, IATA	1760 CORROSIVE LIQUID, N.O.S. (octanoic acid, glutario acid) CORROSIVE LIQUID, N.O.S. (octanoic acid, glutaric acid)
14.3 Transport hazard class(es)	
ADR	
Class	8 (C9) Corrosive substances.
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Label	8
IMDG, IATA	
8	
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.
Hazard identification number (Kemler code):	80 E 4 C D
EMS Number: Stowage Category	F-A,S-B B
Stowage Code	SW2 Clear of living quarters.
14.7 Maritime transport in bulk according to IM	10
instruments	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	Ε
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
TRUBELLE LA "	1 /1 1 0 0
UN "Model Regulation":	UN 1760 CORROSIVE LIQUID, N.O.S. (OCTANOIC ACII GLUTARIC ACID), 8, 11

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.

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SECTION 16: Other information · Relevant phrases H302 Harmful if swallowed. H312 Harmful in contact with skin. 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 relatif au transport international 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. Disclaimer: The information contained herein is believed to be true and accurate. However, all statements, recommendations

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