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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: CAVITY CONDITIONER · 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

Eye Dam. 1 H318 Causes serious eye damage.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

· 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 statements
H318 Causes serious eye damage.
H411 Toxic to aquatic life with long lasting effects.

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· Precautiona	ry statements
P273	Avoid release to the environment.
P280	Wear eye protection / face protection.
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.
P391	Collect spillage.
P501	Dispose of contents/container in accordance with local/regional/national/international
	regulations.
· 2.3 Other ho	azards

· Results of PBT and vPvB assessment

• **PBT:** Not applicable.

• **vPvB:** Not applicable.

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.

· Dangerous components:			
9003-01-4 Polyacrylic acid	10-<25%		
Eye Irrit. 2, H319			
7784-13-6 aluminum chloride hexahydrate	2.5-<5%		
Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Irrit. 2, H315			
• 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:

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 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, sand, extinguishing powder. Do not use water.
- · For safety reasons unsuitable extinguishing agents: Water
- 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. 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: 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 7 for information on safe nanaling. 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. Prevent formation of aerosols. Avoid contact with the eyes and skin.

· Information about fire - and explosion protection: Protect against electrostatic charges.

· 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.

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• 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:
- 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
- · Appropriate engineering controls No further data; see section 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



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/face protection



Tightly sealed goggles

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
- General Information
 Physical state
 Colour:
 Odour:
 Odour threshold:
 Melting point/freezing point: and boiling range
 Boiling point or initial boiling point and boiling range
 Flammability

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Lower and upper explosion limit	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	Not applicable.
Auto-ignition temperature:	Undetermined.
Decomposition temperature:	Not determined.
pH at 20 °C	1.9
Viscosity:	
Kinematic viscosity	Not determined.
Dynamic:	Not determined.
Solubility	
water:	Fully miscible.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not determined.
Density and/or relative density	
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
	1101 40101 111104.
9.2 Other information	
Appearance:	
Form:	Liquid
Important information on protection of health a environment, and on safety.	ind
Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Solvent content:	
Water:	77.0 %
VOC (EC)	$0.0 \ { m g/l}$
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard classes	
Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
	Void
Gases under pressure	
Flammable liquids Elammable solids	Void Void
Flammable solids	Void Void
Self-reactive substances and mixtures	Void Void
Pyrophoric liquids	Void Void
Pyrophoric solids	Void Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammable ga	
in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void
Desensitised explosives	Void

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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 Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

7784-13-6 aluminum chloride hexahydrate

Oral LD50 3,311 mg/kg (rat (f+m))

- · Serious eye damage/irritation Causes serious eye damage.
- · 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.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

7784-13-6 aluminum chloride hexahydrate

LC50/96h 0.671 mg/L (fish)

- · 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:** Toxic for fish
- Additional ecological information:
- · General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water Do not allow product to reach ground water, water course or sewage system, even in small quantities. Must not reach sewage water or drainage ditch undiluted or unneutralised. Danger to drinking water if even extremely small quantities leak into the ground.

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Also poisonous for fish and plankton in water bodies.

Toxic for aquatic organisms

Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

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.*
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information	
• 14.1 UN number or ID number • ADR, IMDG, IATA	UN3082
· 14.2 UN proper shipping name · ADR	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE,
·IMDG	LIQUID, N.O.S. (Aluminium chloride, hexahydrate) ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Aluminium chloride, hexahydrate),
·IATA	MARINE POLLUTANT ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Aluminium chloride, hexahydrate)
· 14.3 Transport hazard class(es)	
·ADR	
· Class · Label	9 (M6) Miscellaneous dangerous substances and articles. 9
· IMDG, IATA	
· Class · Label	9 Miscellaneous dangerous substances and articles. 9
· 14.4 Packing group · ADR, IMDG, IATA	III
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14.5 Environmental hazards:	
Marine pollutant:	Yes
	Symbol (fish and tree)
Special marking (ADR):	Symbol (fish and tree)
Special marking (IATA):	Symbol (fish and tree)
14.6 Special precautions for user	Warning: Miscellaneous dangerous substances and articles.
Hazard identification number (Kemler code):	90
EMS Number:	F-A,S-F
Stowage Category	A
14.7 Maritime transport in bulk according to IM	10
instruments	Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: El
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml
Transport category	3
Tunnel restriction code	(-)
IMDG	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: El
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml
UN "Model Regulation":	UN 3082 ENVIRONMENTALLY HAZARDOU
-	SUBSTANCE, LIQUID, N.O.S. (ALUMINIUM CHLORIDI
	HEXAHYDRATE), 9, III

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.
- Seveso category E2 Hazardous to the Aquatic Environment
- Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· Relevant phrases

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

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

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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
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
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
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
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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