

Printing date 04.06.2021 Version number 1 Revision: 04.06.2021

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

- · 1.1 Product identifier
- · Trade name: GC G-aenial A'CHORD
- · 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 Auxiliary for dental technology
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Manujacturer/Suppuer: 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 Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 3 H412 Harmful 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 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 Warning
- · Hazard-determining components of labelling:

Urethane Dimethacrylate (UDMA)

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2,2'-ethylenedioxydiethyl dimethacrylate

(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate

· Hazard statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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.

	· 1	
· Dangerous components:		
CAS: 41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid.	10-<25%
	Aquatic Chronic 4, H413	
CAS: 72869-86-4	Urethane Dimethacrylate (UDMA)	2.5-<5%
EINECS: 276-957-5	Aquatic Chronic 2, H411; Skin Sens. 1B, H317	
CAS: 109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	2.5-<5%
EINECS: 203-652-6	Skin Sens. 1, H317	
CAS: 1985-51-9	2,2-dimethyl-1,3-propanediyl bismethacrylate	1-<2.5%
EINECS: 217-856-8	Skin Irrit. 2, H315; Eye Irrit. 2, H319	
CAS: 43048-08-4 EINECS: 256-062-6	(octahydro-4,7-methano-1H-indenediyl)bis(methylene)	1-<2.5%
EINECS. 230-002-0	bismethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	
CAS: 1309-37-1	Iron(III)oxide	1-<2.5%
EINECS: 215-168-2	substance with a Community workplace exposure limit	
CAS: 5870-38-2	Diethyl 2,5-dihydroxyterephthalate	1-<2.5%
EINECS: 227-522-3	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 13463-67-7	titanium dioxide	1-<2.5%
EINECS: 236-675-5	substance with a Community workplace exposure limit	
CAS: 128-37-0	Butylated hydroxytoluene	≥0.25-<0.5%
EINECS: 204-881-4	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	
CAS: 1879-09-0	6-tert-butyl-2,4-xylenol	0.1-<0.2%
EINECS: 217-533-1	Acute Tox. 2, H310; STOT RE 2, H373; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	
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CAS: 75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	0.1-<0.2%
EINECS: 278-355-8	Repr. 2, H361f	
Index number: 015-203-00-X		

[·] 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 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 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 formation of dust.

Avoid contact with the eyes and skin.

Wear protective clothing.

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· 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:

Pick up mechanically.

Prevent formation of dust.

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.

Prevent formation of dust.

Any unavoidable deposit of dust must be regularly removed.

Avoid contact with the eyes and skin.

- · Information about fire and explosion protection: Dust can combine with air to form an explosive mixture.
- · 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.

- Ingredien	ts with limit values	that require monitoring at the workplace:
1309-37-1	Iron(III)oxide	
Lon	rt-term value: 10* i g-term value: 5* 10 ne (as Fe),**total r	
13463-67-	7 titanium dioxide	
	g-term value: 10* 4 al inhalable **resp	
128-37-0	Butylated hydroxyt	oluene
WEL Lon	g-term value: 10 m	g/m^3
DNELs		
13463-67-	7 titanium dioxide	
Inhalative	DNEL inhalation	10 mg/m3 (man)
128-37-0	Butylated hydroxyt	oluene
Dermal	DNEL dermal	0.5 mg/kg bw/day (man)

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Inhalative | DNEL inhalation | 3.5 mg/m3 (man)

1879-09-0 6-tert-butyl-2,4-xylenol

Inhalative DNEL inhalation 0.14 mg/m3 (man)

- · 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.

Do not inhale dust / smoke / mist.

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: Pasty

Colour: According to product specification

• Odour: Odourless
• Odour threshold: Not determined.

• pH-value: Not applicable.

· Change in condition

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

• Flash point: Not applicable.

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Flammability (solid, gas):	Not determined.
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 applicable.
Density at 20 °C:	1.9 g/cm³
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
water:	Insoluble.
Partition coefficient: n-octanol/water:	Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
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 rel	evant for classification:
72869-86	6-4 Urethar	ne Dimethacrylate (UDMA)
Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)
1309-37-	1 Iron(III)	oxide
Oral	LD50	>5,000 mg/kg (rat (f+m))
13463-67	7-7 titaniun	n dioxide
Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)

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Inhalati	ve $ LC50/4 h$	>6.82 mg/l (rat male)
128-37-	0 Butylated I	nydroxytoluene
Oral	LD50	>6,000 mg/kg (rat (f+m)) (OECD 401)
1879-09	9-0 6-tert-but	yl-2,4-xylenol
Oral	LD50	910 mg/kg (rat (f+m)) (OECD 401)
Dermal	LD50	<200 mg/kg (rabbit) (OECD 402)

- 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

May cause an allergic skin reaction.

- Repeated dose toxicity No further relevant information available.
- · CMR effects (carcinogenity, 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:

72869-86-4 Urethane Dimethacrylate (UDMA)

EC50/48h (static) >1.2 mg/l (daphnia magna) (OECD 202)

128-37-0 Butylated hydroxytoluene

EC50/48h (static) 0.48 mg/l (daphnia magna) (OECD 202)

- · 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.

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

14 1 UNI November		
14.1 UN-Number ADR, IMDG, IATA	not regulated	
14.2 UN proper shipping name ADR, 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:	Not applicable.	
14.6 Special precautions for user	Not applicable.	
14.7 Transport in bulk according to Ann Marpol and the IBC Code	vex II of 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
- H302 Harmful if swallowed.
- H310 Fatal in contact with skin.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H361f Suspected of damaging fertility.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.
- H411 Toxic to aquatic life with long lasting effects.
- H413 May cause long lasting harmful effects to aquatic life.
- · Classification according to Regulation (EC) No 1272/2008 Calculation method
- · Department issuing SDS: Regulatory affairs

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· 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)

DNEL: Derived No-Effect Level (REACH) 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 - oral - Category 4

Acute Tox. 2: Acute toxicity - dermal - Category 2 Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

Skin Sens. 1: Skin sensitisation - Category 1 Skin Sens. 1B: Skin sensitisation - Category 1B

Repr. 2: Reproductive toxicity - Category 2

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

STOT RE 2: Specific target organ toxicity (repeated exposure) – 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

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

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard - Category 4

- 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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