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

Printing date 19.07.2023

Version number 6 (replaces version 5)

Revision: 19.07.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier · Trade name: G-aenial Bond · 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

Flam. Liq. 2	H225 Highly flammable liquid and vapour.
Skin Irrit. 2	H315 Causes skin irritation.
Eye Irrit. 2	H319 Causes serious eye irritation.
Skin Sens. 1	H317 May cause an allergic skin reaction.
STOT SE 3	H336 May cause drowsiness or dizziness.
Aquatic Chronic 3	H412 Harmful to aquatic life with long lasting

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 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



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⁻ GB

GB

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Trade name: G-aenial_Bond

Image: Components of labelling: Cetone .2'-ethylenedioxydiethyl dimethacrylate Image: Components of labelling: .2'-ethylenedioxydiethyl dimethacrylate .225 .225 .2'-ethylenedioxydiethyl dimethacrylate .225 .225 .226 .2305 .2412 .2412 .2412 .2412 .210 .210 .210 .210 .210 .210 .2280 .2280 .2280 .2280 .2280 .2305+P351+P333 .2305+P351+P338	Signal word I	(Contd. of page 1)
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	P501	Dispose of contents/container in accordance with local/regional/national/international
dditional information:	Additional in	formation:
Product contains: Reportable explosives precursors. Making available, introduction, possession and use ccording to Regulation (EU) 2019/1148, Article 9.	Product cont according to 1	tains: Reportable explosives precursors. Making available, introduction, possession and use Regulation (EU) 2019/1148, Article 9.
.3 Other hazards		

- · 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.

CAS: 67-64-1	acetone	25-<50%
EINECS: 200-662-2 Index number: 606-001-00-8	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336, EUH066 substance with a Community workplace exposure limit	
CAS: 1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane	≥10-<20%
EINECS: 217-388-4	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 85590-00-7	methacryloyloxydecyl dihydrogen phosphate	5-<10%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	5-<10%
EINECS: 203-652-6	Skin Sens. 1, H317	
CAS: 68611-44-9	Silane, dichlorodimethyl-, reaction products with silica	2.5-<5%
EINECS: 271-893-4	Nanoform: Spheroidal, amorphous nanoform, set including	
	amorphous nanoforms, amorphous forms, surface-treated	
	nanoforms	

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CAS: 75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	1-<2.5%
EINECS: 278-355-8 Index number: 015-203-00-X	Repr. 2, H361f	
CAS: 128-37-0	Butylated hydroxytoluene	0.5-<1%
EINECS: 204-881-4	Aquatic Acute 1, H400; Aquatic Chronic 1, H410 Substance identified as having endocrine disrupting properties (II)	
CAS: 1344-28-1	aluminium oxide	0.5-<1%
EINECS: 215-691-6	Nanoform: Spheroidal, crystalline nanoform, crystalline forms, non- surface-treated nanoforms	

• 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. Then 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.

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 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: Keep ignition sources away - Do not smoke. Protect against electrostatic charges. Do not spray onto a naked flame or any incandescent material. 7.2 Conditions for safe storage, including any incompatibilities Storage: Requirements to be met by storerooms and receptacles: Store in a cool location. Store only in unopened original receptacles. Information about storage conditions: Keep container tightly sealed. Store in cool, dry conditions in well sealed receptacles. Store in a cool place.	SECTION 6: Accidental release measures	
Storage: Requirements to be met by storerooms and receptacles: Store in a cool location. 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. Store in cool, dry conditions in well sealed receptacles. Protect from heat and direct sunlight. Store in a cool place.	 6.1 Personal precautions, protective equipment and emergency procedures Remove persons from danger area. Keep away from ignition sources. 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: 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. 	
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7.5 Specific end use(s) no further relevant information available.	Storage: Requirements to be met by storerooms and receptacles: Store in a cool location. 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. Store in cool, dry conditions in well sealed receptacles.	

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SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

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

67-64-1 acetone

WEL Short-term value: 3620 mg/m³, 1500 ppm Long-term value: 1210 mg/m³, 500 ppm

· DNELs

128-37-0 Butylated hydroxytoluene

Dermal DNEL dermal 0.5 mg/kg bw/day (man)

Inhalative DNEL inhalation 3.5 mg/m3 (man)

• 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:

Fluid Light yellow Ester-like

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	(Contd. of page
Odour threshold:	Not determined.
Melting point/freezing point:	-95 °C
Boiling point or initial boiling point and boiling range	ge 56 °C
Flammability	Highly flammable.
Lower and upper explosion limit	
Lower:	2.6 Vol %
Upper:	13 Vol %
Flash point:	-17 °C
Auto-ignition temperature:	Undetermined.
Decomposition temperature:	Not determined.
pH	Not determined.
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.
Particle characteristics	SiO2: Diameter particle structure = $2.5 - 50$ nm (TEM)
	d50, number-based)
	Diameter agglomerate = 5 - 50 mm (laser diffraction dr
	module, d50, volume based)
	Al2O3: Diameter particle structure = $2 - 100 \text{ nm} (d50)$
	number-based)
	68611-44-9 Silane, dichlorodimethyl-, reaction product
	with silica: Spheroidal, amorphous nanoform, se
	including amorphous nanoforms, amorphous forms
	surface-treated nanoforms
	1344-28-1 aluminium oxide: Spheroidal, crystallin
	nanoform, crystalline forms, non-surface-treate
	nanoforms
9.2 Other information	
Appearance:	T····1
Form:	Liquid
Important information on protection of health and	nd
environment, and on safety.	
Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Solvent content:	
Organic solvents:	39.0 %
Water:	20.0 %
VOC (EC)	487.5 g/l
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard classes	
Explosives	Void
Flammable gases	Void

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·Aerosols	Void	
· Oxidising gases	Void	
· Gases under pressure	Void	
· Flammable liquids	Highly flammable liquid and vapour.	
· 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 Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

67-64-1 acetone

Oral LD50 5,800 mg/kg (rat (f+m))

Dermal LD50 20,000 mg/kg (rabbit)

128-37-0 Butylated hydroxytoluene

Oral LD50 >6,000 mg/kg (rat (f+m)) (OECD 401)

· Skin corrosion/irritation Causes skin irritation.

· Serious eye damage/irritation Causes serious eye irritation.

• Respiratory or skin sensitisation May cause an allergic skin reaction.

• STOT-single exposure May cause drowsiness or dizziness.

• Additional toxicological information:

• *Repeated dose toxicity No further relevant information available.*

• CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) No further relevant information available.

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List II

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· 11.2 Information on other hazards

· Endocrine disrupting properties

128-37-0 Butylated hydroxytoluene

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

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.

12.5 Results of PBT and vPvB assessment

• **PBT:** Not applicable.

· vPvB: Not applicable.

· 12.6 Endocrine disrupting properties For information on endocrine disrupting properties see section 11.

· 12.7 Other adverse effects

· Remark: Harmful to 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. Danger to drinking water if even extremely small quantities leak into the ground. 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.

- Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

· 14.1 UN number or ID number		
· ADR, IMDG, IATA	UN1090	
· 14.2 UN proper shipping name		
ADR	1090 ACETONE	
· IMDG, IATA	ACETONE	

[•] Uncleaned packaging:

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14.3 Transport hazard class(es)	
ADR	
Class	3 (F1) Flammable liquids.
Label	3
IMDG, IATA	
Class Label	3 Flammable liquids. 3
	5
14.4 Packing group ADR, IMDG, IATA	II
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user Hazard identification number (Kemler code): EMS Number: Stowage Category	Warning: Flammable liquids. 33 F-E,S-D E
14.7 Maritime transport in bulk according to L instruments	
	Not applicable.
Transport/Additional information:	
ADR Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2 Marimum nat quantity par inner packaging: 30 ml
	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
Transport category	2
Tunnel restriction code	<i>D/E</i>
IMDG Limited quantities (LQ)	
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 1090 ACETONE, 3, II

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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 P5c FLAMMABLE LIQUIDS
- Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· Relevant phrases

- H225 Highly flammable liquid and vapour.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H336 May cause drowsiness or dizziness.
- H361f Suspected of damaging fertility.
- H400 Very toxic to aquatic life.
- *H410 Very toxic to aquatic life with long lasting effects.*
- EUH066 Repeated exposure may cause skin dryness or cracking.

· 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) DNEL: Derived No-Effect Level (UK REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids – 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 Repr. 2: Reproductive toxicity – Category 2 STOT SE 3: Specific target organ toxicity (single exposure) - Category 3 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 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3 Sources • ECHA (http://echa.europa.eu/)

• EnviChem (www.echemportal.org)

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Trade name: G-aenial_Bond

• * Data compared to the previous version altered.

This version replaces all previous versions.

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