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

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Version number 2

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## **SECTION 1: Identification**

- · 1.1 Product identifier
- · Trade name: G-Premio BOND DCA
- 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
- $\cdot$  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

• Information department: Regulatory affairs • 1.4 Emergency telephone number: International: +01-813-248-0585 (ChemTel Inc.)

#### SECTION 2: Hazard(s) 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.

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

#### · 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 labeled according to the CLP regulation. • Hazard pictograms



GHS02

· Signal word Dange	21
· Hazard statements	
H225 Highly flamn	nable liquid and vapour.
· Precautionary stat	ements
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233	Keep container tightly closed.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P403+P235	Store in a well-ventilated place. Keep cool.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

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· 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 characterization: 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:		
64-17-5	ethyl alcohol	25-<50%
	Flam. Liq. 2, H225	
3077-12-1	2,2'-[(4-methylphenyl)imino]bisethanol	5-<10%
	Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
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. Do not use mouth to mouth or mouth to nose resuscitation.

- Take affected persons into fresh air and keep quiet.
- After skin contact: 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:

Do not induce vomiting; immediately call for medical help.

- Rinse out mouth and then drink plenty of water.
- · 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: Fire-fighting measures**

- · 5.1 Extinguishing media
- Suitable extinguishing agents: CO2, sand, extinguishing powder. Do not use water.
- · For safety reasons unsuitable extinguishing agents: Water
- $\cdot$  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.
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.
$\cdot$ 6.3 Methods and material for containment and cleaning up:
Ensure adequate ventilation.
Absorb liquid components with liquid-binding material.
Dispose of the collected material 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 aerosols. Avoid contact with the eyes and skin. · Information about protection against explosions and fires: Keep ignition sources away - Do not smoke. Protect against electrostatic charges. Do not spray on 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 in one common storage facility: Store away from foodstuffs. • Further information about storage conditions: Keep receptacle tightly sealed. Store in cool, dry conditions in well sealed receptacles. Protect from heat and direct sunlight. Store in a cool place. · 7.3 Specific end use(s) No further relevant information available. EU

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#### SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · 8.1 Control parameters
- · Components 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 that were valid during the creation were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed. 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.
- · Breathing equipment: 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: Color: · Odor:
- Odor threshold:

• pH-value at 20 °C:

Not determined. 8.1 Not determined.

Liquid

Colorless Alcohol-like

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Change in condition Melting point/Melting range: Boiling point/Boiling range:	Undetermined. 100 °C Undetermined.	
Flash point:	13 °C Not applicable.	
Flammability (solid, gaseous):	Not applicable.	
Ignition temperature:	Undetermined.	
Decomposition temperature:	Not determined.	
Auto igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits: Lower:	3.5 Vol % Not determined.	
Upper:	15 Vol % Not determined.	
Vapor pressure:	Not determined.	
Density at 20 °C:	0.96 g/cm <sup>3</sup> Not determined.	
Relative density	Not determined.	
Vapor density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with Water:	Insoluble.	
Partition coefficient (n-octanol/wa	uter): Not determined.	
Viscosity: Dynamic: Kinematic:	Not determined. Not determined.	
Solvent content:		
Organic solvents:	30.0 %	
Water:	56.0 %	
VOC (EC)	622.8 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.

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· 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 that are relevant for classification:

#### 64-17-5 ethyl alcohol

Oral LD50 7,060 mg/kg (rat (f+m))

Inhalative LC50/4 h 20,000 mg/l (rat (f+m))

#### • Primary irritant effect:

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

- on the eye: Based on available data, the classification criteria are not met.
- · Sensitization: Based on available data, the classification criteria are not met.
- Additional toxicological information:

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

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

- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- 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.*
- $\cdot$  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
- $\cdot$  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 2 (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.

- · 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 of together with household garbage. Do not allow product to reach sewage system.

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· Uncleaned packagings:

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

SECTION 14: Transport informat	
14.1 UN-Number	
ADR, IMDG, IATA	UN1170
14.2 UN proper shipping name	
DOT	Ethanol mixture
ADR	1170 ETHANOL SOLUTION mixture
IMDG, IATA	ETHANOL SOLUTION mixture
14.3 Transport hazard class(es)	
ADR	
3	
Class	3 (F1) Flammable liquids
Label	3
IMDG, IATA	
Class	3 Flammable liquids
Label	3
14.4 Packing group	
ADR, IMDĞ, IATA	II
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	Warning: Flammable liquids
Danger code (Kemler):	33
EMS Number:	F-E,S-D
Stowage Category	A
14.7 Transport in bulk according to Anne	pr II of
MARPOL73/78 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	D/E
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·IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities ( $\widetilde{E}Q$ )	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	not regulated

#### **SECTION 15: Regulatory information**

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture · Sara

• Section 355 (extremely hazardous substances):

None of the ingredient is listed.

• Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· Proposition 65

• Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

64-17-5 ethyl alcohol

#### · Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

64-17-5 ethyl alcohol

· MAK (German Maximum Workplace Concentration)

64-17-5 ethyl alcohol

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

· Seveso category P5c FLAMMABLE LIQUIDS

 $\cdot$  Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t

 $\cdot$  Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 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.

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,	SECTION 16: Other information
•	Relevant phrases
	H225 Highly flammable liquid and vapour.
	H302 Harmful if swallowed.
	H315 Causes skin irritation.
	H319 Causes serious eye irritation.
	H335 May cause respiratory 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 Internationa
	Carriage of Dangerous Goods by Road)
	IMDG: International Maritime Code for Dangerous Goods
	DOT: US Department of Transportation IATA: International Air Transport Association
	GHS: Globally Harmonised System of Classification and Labelling of Chemicals
	ACGIH: American Conference of Governmental Industrial Hygienists
	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
	VIOSH: National Institute for Occupational Safety
	OSHA: Occupational Safety & Health
	Flam. Liq. 2: Flammable liquids – Category 2
4	Acute Tox. 4: Acute toxicity – Category 4
,	Skin Irrit. 2: Skin corrosion/irritation – Category 2
	Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
	STOT SE 3: Specific target organ toxicity (single exposure) – 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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