

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

Printing date 18.02.2019

Version number 1

Revision: 20.09.2018

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

- **1.1 Product identifier**
- **Trade name: G-CEM Veneer**
- **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)16/40.26.84
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**
Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate
1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde
Urethane Dimethacrylate (UDMA)

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2,2'-ethylenedioxydiethyl dimethacrylate
2-(2H-benzotriazol-2-yl)-p-cresol

· 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.

· Dangerous components:

CAS: 41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid. Aquatic Chronic 4, H413	10-<25%
CAS: 43048-08-4 EINECS: 256-062-6	(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	5-<10%
CAS: 1985-51-9 EINECS: 217-856-8	2,2-dimethyl-1,3-propanediyl bismethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319	2.5-<5%
CAS: 9003-08-1	1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde Eye Dam. 1, H318; Skin Sens. 1, H317; STOT SE 3, H335	0.2-<0.5%
CAS: 75980-60-8 EINECS: 278-355-8 Index number: 015-203-00-X	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f	0.2-<0.5%
CAS: 72869-86-4 EINECS: 276-957-5	Urethane Dimethacrylate (UDMA) Aquatic Chronic 2, H411; Skin Sens. 1B, H317	≥0.25-<0.5%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	0.2-<0.5%
CAS: 128-37-0 EINECS: 204-881-4	Butylated hydroxytoluene Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥0.25-<0.5%
CAS: 2440-22-4 EINECS: 219-470-5	2-(2H-benzotriazol-2-yl)-p-cresol Aquatic Chronic 1, H410; Skin Sens. 1, H317	≥0.25-<0.5%
CAS: 1879-09-0 EINECS: 217-533-1	6-tert-butyl-2,4-xylenol Acute Tox. 2, H310; STOT RE 2, H373; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	≥0.25-<0.5%

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· **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:**

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:**

Do not induce vomiting; call for medical help immediately.

Rinse out mouth and then drink plenty of water.

· **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.

Inform respective authorities in case of seepage into water course or sewage system.

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- 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:**
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.
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:** 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:** 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.
- **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.

- **DNELs**

128-37-0 Butylated hydroxytoluene

Dermal	DNEL dermal	0.5 mg/kg bw/day (man)
Inhalative	DNEL inhalation	3.5 mg/m ³ (man)

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

Inhalative	DNEL inhalation	0.14 mg/m ³ (man)
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- **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.
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.

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· 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 determined.

· Change in condition

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

· Flash point: Not applicable.

· Flammability (solid, gas): Not applicable.

· 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 determined.

· Density: Not determined.

· Relative density Not determined.

· Vapour density Not determined.

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· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
VOC (EC)	0.0 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.
- **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 relevant for classification:**

72869-86-4 Urethane Dimethacrylate (UDMA)		
Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)
128-37-0 Butylated hydroxytoluene		
Oral	LD50	>6,000 mg/kg (rat (f+m)) (OECD 401)
2440-22-4 2-(2H-benzotriazol-2-yl)-p-cresol		
Oral	LD50	10,000 mg/kg (rat (f+m))
Inhalative	LC50/4 h	0.59 mg/l (rat (f+m))
1879-09-0 6-tert-butyl-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 (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

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- **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)
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128-37-0 Butylated hydroxytoluene

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

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.

European waste catalogue

18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 06*	chemicals consisting of or containing hazardous substances

Uncleaned packaging:

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

SECTION 14: Transport information

14.1 UN-Number

- **ADR, ADN, IMDG, IATA** not regulated

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- | | |
|---|-----------------|
| · 14.2 UN proper shipping name
· ADR, ADN, 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:
· Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | 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.
- **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.

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.
H318 Causes serious eye damage.
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
- **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

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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 (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 – Category 4
 Acute Tox. 2: Acute toxicity – Category 2
 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
 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

Sources

- ECHA (<http://echa.europa.eu/>)
- EnviChem (www.echemportal.org)

*** Data compared to the previous version altered.**

This version replaces all previous versions.

Disclaimer:

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according to 1907/2006/EC, Article 31

Printing date 05.02.2024

Version number 2 (replaces version 1)

Revision: 05.02.2024

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

- **1.1 Product identifier**
- **Trade name: G-CEM Try-In Paste**
- **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)16/40.26.84
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**
The product is not classified, according to the GB CLP regulation.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **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** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**
Contains Urethane Dimethacrylate (UDMA). May produce an allergic reaction.
Safety data sheet available on request.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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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:

CAS: 56-81-5 EINECS: 200-289-5	glycerol substance with a Community workplace exposure limit	90-<100%
CAS: 7631-86-9 EINECS: 231-545-4	silicon dioxide Nanoform: set including amorphous nanoforms non-surface-treated nanoforms Shape: Spheroidal Structure: amorphous forms Crystallinity: amorphous nanoform	5-<10%
CAS: 1344-28-1 EINECS: 215-691-6	aluminium oxide Nanoform: non-surface-treated nanoforms Shape: Spheroidal Structure: crystalline forms Crystallinity: crystalline nanoform	1-<2.5%
CAS: 13463-67-7 EINECS: 236-675-5 Index number: 022-006-00-2	titanium dioxide Carc. 2, H351 substance with a Community workplace exposure limit	0.5-<1%
CAS: 68611-44-9 EINECS: 271-893-4	Silane, dichlorodimethyl-, reaction products with silica Nanoform: set including amorphous nanoforms surface-treated nanoforms Shape: Spheroidal Structure: amorphous forms Crystallinity: amorphous nanoform	0.2-<0.5%
CAS: 72869-86-4 EINECS: 276-957-5	Urethane Dimethacrylate (UDMA) Aquatic Chronic 2, H411; Skin Sens. 1B, H317	≥0.25-<0.5%

· **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:** 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:** 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

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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, 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.
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:**
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.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **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:** None.
- **7.3 Specific end use(s)** No further relevant information available.

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SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

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

56-81-5 glycerol

WEL Long-term value: 10 mg/m³

13463-67-7 titanium dioxide

WEL Long-term value: 10* 4** mg/m³
*total inhalable **respirable

· DNELs

13463-67-7 titanium dioxide

Inhalative DNEL inhalation 10 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.

Wash hands before breaks and at the end of work.

· **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** Safety glasses

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· **Physical state**

Fluid

· **Colour:**

Yellow

· **Odour:**

Alcohol-like

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **Boiling point or initial boiling point and boiling range** 290 °C

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**

· **Lower:**

0.9 Vol %

· **Upper:**

0.0 Vol %

· **Flash point:**

160 °C

· **Auto-ignition temperature:**

Undetermined.

· **Decomposition temperature:**

Not determined.

· **pH**

Not determined.

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· Viscosity:	<i>Not determined.</i>
· Kinematic viscosity	<i>Not determined.</i>
· Dynamic:	<i>Not determined.</i>
· Solubility	
· water:	<i>Insoluble.</i>
· Partition coefficient n-octanol/water (log value)	<i>Not determined.</i>
· Vapour pressure:	<i>Not determined.</i>
· Density and/or relative density	
· Density at 20 °C:	<i>1.3 g/cm³</i>
· Relative density	<i>Not determined.</i>
· Vapour density	<i>Not determined.</i>
· Particle characteristics	<p><i>SiO₂: Diameter particle structure = 2.5 - 50 nm (TEM, d50, number-based)</i> <i>Diameter agglomerate = 5 - 50 nm (laser diffraction dry module, d50, volume based)</i> <i>Al₂O₃: Diameter particle structure = 2 - 100 nm (d50, number-based)</i> <i>7631-86-9 silicon dioxide:</i> <i>set including amorphous nanoforms</i> <i>non-surface-treated nanoforms</i> <i>Shape: Spheroidal</i> <i>Structure: amorphous forms</i> <i>Crystallinity: amorphous nanoform</i></p> <p><i>1344-28-1 aluminium oxide:</i> <i>non-surface-treated nanoforms</i> <i>Shape: Spheroidal</i> <i>Structure: crystalline forms</i> <i>Crystallinity: crystalline nanoform</i></p> <p><i>68611-44-9 Silane, dichlorodimethyl-, reaction products with silica:</i> <i>set including amorphous nanoforms</i> <i>surface-treated nanoforms</i> <i>Shape: Spheroidal</i> <i>Structure: amorphous forms</i> <i>Crystallinity: amorphous nanoform</i></p>

· 9.2 Other information	
· Appearance:	
· Form:	<i>Pasty</i>
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	<i>Product is not selfigniting.</i>
· Explosive properties:	<i>Product does not present an explosion hazard.</i>
· Solvent content:	
· Organic solvents:	<i>90.0 %</i>
· VOC (EC)	<i>0.0 g/l</i>
· Change in condition	
· Evaporation rate	<i>Not determined.</i>

· Information with regard to physical hazard classes	
· Explosives	<i>Void</i>

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· Flammable gases	Void
· Aerosols	Void
· 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 flammable 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:**

7631-86-9 silicon dioxide

Oral	LD50	10,000 mg/kg (rat (f+m))
------	------	--------------------------

13463-67-7 titanium dioxide

Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)
------	------	---------------------------------

Inhalative	LC50/4 h	>6.82 mg/l (rat male)
------------	----------	-----------------------

72869-86-4 Urethane Dimethacrylate (UDMA)

Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)
------	------	--------------------------------------

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

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- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, 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:

72869-86-4 Urethane Dimethacrylate (UDMA)

EC50/48h (static) >1.2 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**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **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.

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, ADN, IMDG, IATA | not regulated |
| · 14.2 UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | not regulated |

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· 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:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk according to IMO instruments	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**
- **Poisons Act**

- **Regulated explosives precursors**

None of the ingredients is listed.

- **Regulated poisons**

None of the ingredients is listed.

- **Reportable explosives precursors**

None of the ingredients is listed.

- **Reportable poisons**

None of the ingredients is listed.

- **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**

H317 May cause an allergic skin reaction.

H351 Suspected of causing cancer.

H411 Toxic 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

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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

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

Carc. 2: Carcinogenicity – Category 2

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

- **1.1 Product identifier**
 - **Trade name: G-Multi PRIMER**
- **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:**

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**

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



GHS02 GHS07

- **Signal word** Danger
- **Hazard-determining components of labelling:**

2,2'-ethylenedioxydiethyl dimethacrylate
2-Propenoic acid, 2-methyl-, polymer with (chloromethyl)oxirane and 4,4-(1-methylethylidene)bisphenol

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· Hazard statements*H225 Highly flammable liquid and vapour.**H317 May cause an allergic skin reaction.***· Precautionary statements***P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.**P261 Avoid breathing dust/fume/gas/mist/vapours/spray.**P272 Contaminated work clothing should not be allowed out of the workplace.**P280 Wear protective gloves / eye protection / face protection.**P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].**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 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:

CAS: 64-17-5 EINECS: 200-578-6 Index number: 603-002-00-5	ethyl alcohol Flam. Liq. 2, H225 substance with a Community workplace exposure limit	90-<100%
CAS: 85590-00-7	methacryloyloxydecyl dihydrogen phosphate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	1-<2.5%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	1-<2.5%
CAS: 36425-15-7 NLP: 500-089-0	2-Propenoic acid, 2-methyl-, polymer with (chloromethyl)oxirane and 4,4-(1-methylethylidene)bisphenol Eye Dam. 1, H318; Skin Sens. 1, H317	0.5-<1%

· 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:***Generally the product does not irritate the skin.**Immediately wash with water and soap and rinse thoroughly.*

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*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, 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.**Keep away from ignition sources.**Wear protective equipment. Keep unprotected persons away.**Use respiratory protective device against the effects of fumes/dust/aerosol.**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.**Do not allow to enter sewers/ surface or ground water.**Prevent seepage into sewage system, workpits and cellars.**Dilute with plenty of water.***· 6.3 Methods and material for containment and cleaning up:***Ensure adequate ventilation.**Allow to evaporate.**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.**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:**
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 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.
- **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:**

64-17-5 ethyl alcohol
WEL Long-term value: 1920 mg/m ³ , 1000 ppm

- **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.
Immediately remove all soiled and contaminated clothing
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
Suitable respiratory protective device recommended.
- **Hand protection**
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.



Protective gloves

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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	Fluid
· Colour:	Colourless
· Odour:	Alcohol-like
· Odour threshold:	Not determined.
· Melting point/freezing point:	-114,5 °C
· Boiling point or initial boiling point and boiling range	78 °C
· Flammability	Highly flammable.
· Lower and upper explosion limit	
· Lower:	3.5 Vol %
· Upper:	15 Vol %
· Flash point:	13 °C
· Auto-ignition temperature:	425 °C
· Decomposition temperature:	Not determined.
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water at 20 °C:	1.000 g/l Insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure at 20 °C:	59 hPa
· Density and/or relative density	
· Density at 20 °C:	0.8 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.

9.2 Other information**Appearance:**

· **Form:** Liquid

Important information on protection of health and environment, and on safety.

· **Ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

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· Solvent content:	
· Organic solvents:	94.0 %
· VOC (EC)	752.0 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
· 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 flammable 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:

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))

- **Skin corrosion/irritation** No further relevant information available
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Additional toxicological information:**
- **Repeated dose toxicity** No further relevant information available.

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- **CMR effects (carcinogenicity, 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:** 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**

- **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.

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**

UN1170

- **14.2 UN proper shipping name**

- **ADR**

1170 ETHANOL SOLUTION mixture

- **IMDG, IATA**

ETHANOL SOLUTION mixture

- **14.3 Transport hazard class(es)**

- **ADR**



- **Class**

3 (F1) Flammable liquids.

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· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids.
· Label	3
· 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 A
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category · Tunnel restriction code	2 D/E
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1170 ETHANOL SOLUTION MIXTURE, 3, II

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **Poisons Act**

· **Regulated explosives precursors**

None of the ingredients is listed.

· **Regulated poisons**

None of the ingredients is listed.

· **Reportable explosives precursors**

None of the ingredients is listed.

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· Reportable poisons

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**· 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.

H318 Causes serious eye damage.

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:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

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

Flam. Liq. 2: Flammable liquids – Category 2

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

· 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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referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.

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

· **1.1 Product identifier**

· **Trade name: G-Premio 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)16/40.26.84

msds@gc.dental

· **Further information obtainable from:** Regulatory affairs

· **1.4 Emergency telephone number:**

International: +01-813-248-0585 (ChemTel Inc.)

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 Corr. 1 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.

STOT SE 3 H336 May cause drowsiness or dizziness.

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).

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Hazard pictograms

GHS02 GHS05 GHS07

Signal word *Danger***Hazard-determining components of labelling:***acetone**2,2'-ethylenedioxydiethyl dimethacrylate***Hazard statements***H225 Highly flammable liquid and vapour.**H314 Causes severe skin burns and eye damage.**H317 May cause an allergic skin reaction.**H336 May cause drowsiness or dizziness.**H412 Harmful to aquatic life with long lasting effects.***Precautionary statements***P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.**P260 Do not breathe dusts or mists.**P280 Wear protective gloves / eye protection / face protection.**P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].**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.**P321 Specific treatment (see on this label).**P362+P364 Take off contaminated clothing and wash it before reuse.**P405 Store locked up.**P501 Dispose of contents/container in accordance with local/regional/national/international regulations.***Additional information:***Product contains: Reportable explosives precursors. Making available, introduction, possession and use according to Regulation (EU) 2019/1148, Article 9.***2.3 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.***Dangerous components:**

CAS: 67-64-1	acetone	25-<50%
EINECS: 200-662-2	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336, EUH066	
Index number: 606-001-00-8	substance with a Community workplace exposure limit	

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		(Contd. of page 2)
CAS: 1830-78-0 EINECS: 217-388-4	2-Hydroxy-1,3 dimethacryloxypropane Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≥10-<20%
CAS: 85590-00-7	methacryloyloxydecyl dihydrogen phosphate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	5-<10%
CAS: 68611-44-9 EINECS: 271-893-4	Silane, dichlorodimethyl-, reaction products with silica Nanoform: Spheroidal, amorphous nanoform, set including amorphous nanoforms, amorphous forms, surface-treated nanoforms	5-<10%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	2.5-<5%
CAS: 75980-60-8 EINECS: 278-355-8 Index number: 015-203-00-X	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f	1-<2.5%
CAS: 128-37-0 EINECS: 204-881-4	Butylated hydroxytoluene Aquatic Acute 1, H400; Aquatic Chronic 1, H410 Substance identified as having endocrine disrupting properties (II)	≥0.25-<0.5%
CAS: 1344-28-1 EINECS: 215-691-6	aluminium oxide Nanoform: Spheroidal, crystalline nanoform, crystalline forms, non-surface-treated nanoforms	0.2-<0.5%

· **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 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, sand, extinguishing powder. Do not use water.

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- **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.
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.
Do not allow to penetrate the ground/soil.
- **6.3 Methods and material for containment and cleaning up:**
Ensure adequate ventilation.
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.
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:**
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 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.

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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:****67-64-1 acetone**

WEL	Short-term value: 3620 mg/m ³ , 1500 ppm
	Long-term value: 1210 mg/m ³ , 500 ppm

· **DNELs****128-37-0 Butylated hydroxytoluene**

Dermal	DNEL dermal	0.5 mg/kg bw/day (man)
Inhalative	DNEL inhalation	3.5 mg/m ³ (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**

Fluid

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· Colour:	Yellow
· Odour:	Acetone-like
· Odour threshold:	Not determined.
· Melting point/freezing point:	-95 °C
· Boiling point or initial boiling point and boiling range	55 °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 at 20 °C	1.8
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	0.94 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Particle characteristics	SiO ₂ : Diameter particle structure = 2.5 - 50 nm (TEM, d ₅₀ , number-based) Diameter agglomerate = 5 - 50 nm (laser diffraction dry module, d ₅₀ , volume based) Al ₂ O ₃ : Diameter particle structure = 2 - 100 nm (d ₅₀ , number-based) 68611-44-9 Silane, dichlorodimethyl-, reaction products with silica: Spheroidal, amorphous nanoform, set including amorphous nanoforms, amorphous forms, surface-treated nanoforms 1344-28-1 aluminium oxide: Spheroidal, crystalline nanoform, crystalline forms, non-surface-treated nanoforms

· **9.2 Other information**

· Appearance:	
· Form:	Liquid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· Organic solvents:	33.0 %
· Water:	24.0 %
· VOC (EC)	400.6 g/l
· Change in condition	
· Evaporation rate	Not determined.

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· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· 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 flammable 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 severe skin burns and eye damage.
- **Serious eye damage/irritation** Causes serious eye damage.
- **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 (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.

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· 11.2 Information on other hazards

· Endocrine disrupting properties

128-37-0 Butylated hydroxytoluene

List II

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 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

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.

SECTION 14: Transport information

· 14.1 UN number or ID number

· ADR, IMDG, IATA

UN1090

· 14.2 UN proper shipping name

· ADR

1090 ACETONE

· IMDG, IATA

ACETONE

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· 14.3 Transport hazard class(es)

· ADR



· Class 3 (F1) Flammable liquids.
· Label 3

· IMDG, IATA



· Class 3 Flammable liquids.
· Label 3

· 14.4 Packing group

· ADR, IMDG, IATA II

· 14.5 Environmental hazards:

· Marine pollutant: No

· 14.6 Special precautions for user

Warning: Flammable liquids.

· Hazard identification number (Kemler code): 33

· EMS Number: F-E,S-D

· Stowage Category E

· 14.7 Maritime transport in bulk according to IMO 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

D/E

· 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

· 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 Corr. 1: Skin corrosion/irritation – Category 1
 - 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
 - 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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