

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

Printing date 20.10.2016

Version number 1

Revision: 19.10.2016



SECTION 1: Identification

- **1.1 Product identifier**
- **Trade name: GC Acrylic 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@gceurope.com
- **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.
Skin Irrit. 2	H315	Causes skin irritation.
Eye Irrit. 2	H319	Causes serious eye irritation.
Skin Sens. 1	H317	May cause an allergic skin reaction.
STOT SE 3	H335-H336	May cause respiratory irritation. 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**
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 GHS07
- **Signal word** Danger
- **Hazard-determining components of labeling:**
Methyl methacrylate
acetone
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate

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Hazard statements

- H225 Highly flammable liquid and vapour.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H317 May cause an allergic skin reaction.
- H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.
- H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

- P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
- P280 Wear protective gloves / eye protection / face protection.
- P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/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.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional information:

- 8 % of the mixture consists of component(s) of unknown toxicity.
- Contains 8 % of components with unknown hazards to the aquatic environment.

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:

67-64-1	acetone Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	25-<50%
80-62-6	Methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	25-<50%
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate Skin Sens. 1, H317	10-<25%
128-37-0	2,6-di-tert-butyl-p-cresol Aquatic Acute 1, H400; Aquatic Chronic 1, H410	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.

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- **After inhalation:**
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
Take affected persons into fresh air and keep quiet.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
Seek medical treatment.
If skin irritation continues, consult a doctor.
- **After eye contact:**
Protect unharmed eye.
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** Allergic reactions
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: 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
- **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.
- **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.
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.

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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 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.

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:**

67-64-1 acetone		
IOELV	Long-term value: 1210 mg/m ³ , 500 ppm	
80-62-6 Methyl methacrylate		
IOELV	Short-term value: 100 ppm	
	Long-term value: 50 ppm	
DNELs		
80-62-6 Methyl methacrylate		
Dermal	DNEL dermal	13,67 mg/kg bw/day (man) (worker, l. te., syst.)
Inhalative	DNEL inhalation	208 mg/m ³ (air) (worker, l. te., syst.)
128-37-0 2,6-di-tert-butyl-p-cresol		
Dermal	DNEL dermal	0,5 mg/kg bw/day (man)
Inhalative	DNEL inhalation	3,5 mg/m ³ (man)

- **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.

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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:** Liquid

· **Color:** Clear

· **Odor:** Characteristic

· **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· **Melting point/Melting range:** Undetermined.

· **Boiling point/Boiling range:** 55 °C

· **Flash point:** -17 °C

· **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:** 2,1 Vol %

· **Upper:** 13,0 Vol %

· **Vapor pressure:** Not determined.

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· Density at 20 °C:	0,9 g/cm ³
· Relative density	Not determined.
· Vapor density	Not determined.
· 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:	
Organic solvents:	48,5 %
VOC (EC)	436,7 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 that are relevant for classification:**

67-64-1 acetone

Oral	LD50	5800 mg/kg (rat (f+m))
Dermal	LD50	20000 mg/kg (rabbit)

80-62-6 Methyl methacrylate

Oral	LD50	6000 mg/kg (rabbit)
Dermal	LD50	> 5000 mg/kg (rab)
Inhalative	LC50/4 h	29,8 mg/l (rat (f+m))

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

Oral	LD50	> 5000 mg/kg (rat female) (OECD 401)
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128-37-0 2,6-di-tert-butyl-p-cresol

Oral	LD50	> 6000 mg/kg (rat (f+m)) (OECD 401)
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- **Primary irritant effect:**
- **on the skin:**
Causes skin irritation.

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· **on the eye:**

Causes serious eye irritation.

· **Sensitization:**

May cause an allergic skin reaction.

· **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 (carcinogenicity, mutagenicity and toxicity for reproduction)**

No further relevant information available.

· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.· **Carcinogenicity** Based on available data, the classification criteria are not met.· **Reproductive toxicity** Based on available data, the classification criteria are not met.· **STOT-single exposure**

May cause respiratory irritation. May cause drowsiness or dizziness.

· **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 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

EC50/48h (static) > 1,2 mg/l (daphnia magna) (OECD 202)

128-37-0 2,6-di-tert-butyl-p-cresol

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.· **Ecotoxicological effects:**· **Remark:** Harmful to fish· **Additional ecological information:**· **General notes:**

Harmful to aquatic organisms

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

· **12.5 Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.· **12.6 Other adverse effects** No further relevant information available.**SECTION 13: Disposal considerations**· **13.1 Waste treatment methods**· **Recommendation:**

Must not be disposed 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 information

· 14.1 UN-Number · ADR, IMDG, IATA	UN1993
· 14.2 UN proper shipping name · DOT · ADR · IMDG, IATA	Flammable liquids, n.o.s. (Acetone, Methyl methacrylate monomer, stabilized) 1993 FLAMMABLE LIQUID, N.O.S. (ACETONE, METHYL METHACRYLATE MONOMER, STABILIZED), special provision 640D FLAMMABLE LIQUID, N.O.S. (ACETONE, METHYL METHACRYLATE MONOMER, STABILIZED)
· 14.3 Transport hazard class(es) · ADR	
	
· Class · Label	3 (F1) Flammable liquids 3
· IMDG, IATA	
	
· Class · Label	3 Flammable liquids 3
· 14.4 Packing group · ADR, IMDG, IATA	II
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user · Danger code (Kemler): · EMS Number: · Stowage Category	Warning: Flammable liquids 33 F-E,S-E B
· 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

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· 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 1993 FLAMMABLE LIQUID, N.O.S., SPECIAL PROVISION 640D (ACETONE, METHYL METHACRYLATE MONOMER, STABILIZED), 3, II

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 ingredients is listed.

· Section 313 (Specific toxic chemical listings):

80-62-6 Methyl methacrylate

· 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:

None of the ingredients is listed.

· Carcinogenic categories**· EPA (Environmental Protection Agency)**

67-64-1	acetone	I
80-62-6	Methyl methacrylate	E, NL

· TLV (Threshold Limit Value established by ACGIH)

67-64-1	acetone	A4
80-62-6	Methyl methacrylate	A4
128-37-0	2,6-di-tert-butyl-p-cresol	A4

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· **MAK (German Maximum Workplace Concentration)**

128-37-0 2,6-di-tert-butyl-p-cresol

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· **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**· **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.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

· **Classification according to Regulation (EC) No 1272/2008** Calculation method· **Department issuing SDS:** Regulatory affairs· **Contact:** msds@gceurope.com· **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

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)

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

Flam. Liq. 2: Flammable liquids – Category 2

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

Skin Sens. 1: Skin sensitisation – Category 1

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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*** Data compared to the previous version altered.***This version replaces all previous versions.***Disclaimer:**

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Version number 1

Revision: 02.06.2016

SECTION 1: Identification

- **1.1 Product identifier**
- **Trade name: GRADIA PLUS Air Barrier Agent**
- **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@gceurope.com
- **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**
The product is not classified according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Precautionary statements**
P260 Do not breathe mist/vapours/spray.
P280 Wear protective gloves / eye protection / face protection.
P272 Contaminated work clothing should not be allowed out of the workplace.
P270 Do not eat, drink or smoke when using this product.
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
- **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.

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- **Dangerous components:** Void
- **Additional information:** For the wording of the listed risk phrases refer to section 16.

SECTION 4: First-aid measures

- **4.1 Description of first aid measures**
- **General information:**
No special measures required.
If symptoms persist consult doctor.
- **After inhalation:** Take affected persons into fresh air and keep quiet.
- **After skin contact:** Immediately rinse with water.
- **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** 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, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **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.
- **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.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to penetrate the ground/soil.
In case of seepage into the ground inform responsible authorities.
- **6.3 Methods and material for containment and cleaning up:**
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.

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See Section 13 for disposal information.

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SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:** 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 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.
Wash hands before breaks and at the end of work.
- **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:** Safety glasses

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
- **Form:** Liquid
- **Color:** Transparent
- **Odor:** Odorless
- **Odor threshold:** Not determined.
- **pH-value:** Not determined.

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Trade name: GRADIA PLUS Air Barrier Agent

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· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	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:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density:	Not determined.
· Relative density	Not determined.
· Vapor density	Not determined.
· 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:	
Organic solvents:	0.0 %
· 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 that are relevant for classification:** No further relevant information available.

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Trade name: GRADIA PLUS Air Barrier Agent

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- **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:**

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

79-06-1 | acrylamide

2A

- **NTP (National Toxicology Program)**

79-06-1 | acrylamide

R

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **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.
- **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:** 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 3 (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:** Smaller quantities can be disposed of with household waste.

- **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

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Trade name: **GRADIA PLUS Air Barrier Agent**

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18 01 06* | chemicals consisting of or containing hazardous substances

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

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, ADN, IMDG, IATA** not regulated
- **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 MARPOL73/78 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**
- **Sara**

- **Section 355 (extremely hazardous substances):**

79-06-1 | acrylamide

- **Section 313 (Specific toxic chemical listings):**

79-06-1 | acrylamide

- **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

79-06-1 | acrylamide

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

79-06-1 | acrylamide

- **Chemicals known to cause developmental toxicity:**

79-06-1 | acrylamide

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· **Carcinogenic categories**· **EPA (Environmental Protection Agency)**

79-06-1	acrylamide	L
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· **TLV (Threshold Limit Value established by ACGIH)**

79-06-1	acrylamide	A3
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· **MAK (German Maximum Workplace Concentration)**

79-06-1	acrylamide	2
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· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

79-06-1	acrylamide	
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· **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

· **Classification according to Regulation (EC) No 1272/2008** Calculation method· **Department issuing MSDS:** Regulatory affairs· **Contact:** msds@gceurope.com· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

· **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

- **1.1 Product identifier**
- **Trade name: GRADIA PLUS DIE HARDNER**
- **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@gceurope.com
- **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**
Flam. Liq. 2 H225 Highly flammable liquid and vapour.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labeled according to the CLP regulation.
- **Hazard pictograms**



GHS02

- **Signal word** Danger
- **Hazard statements**
H225 Highly flammable liquid and vapour.
- **Precautionary statements**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P233 Keep container tightly closed.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P403+P235 Store in a well-ventilated place. Keep cool.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Additional information:**
19 % of the mixture consists of component(s) of unknown toxicity.

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Contains 19 % of components with unknown hazards to the aquatic environment.

- **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	Flam. Liq. 2, H225	60-80%
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- **Additional information:** For the wording of the listed risk 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** 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
- **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.
- **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

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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 clothing.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to penetrate the ground/soil.
In case of seepage into the ground inform responsible authorities.
- **6.3 Methods and material for containment and cleaning up:**
Ensure adequate ventilation.
Absorb liquid components with liquid-binding material.
Dispose of the 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** No special precautions are necessary if used correctly.
- **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.

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.

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· **8.2 Exposure controls**· **Personal protective equipment:**· **General protective and hygienic measures:**

The usual precautionary measures for handling chemicals should be followed.

Wash hands before breaks and at the end of work.

· **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:	Liquid
· Color:	Clear
· Odor:	Characteristic
· Odor threshold:	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.

· **Flash point:** 13 °C

· **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 %
· Upper:	15.0 Vol %

· **Vapor pressure:** Not determined.

· **Density:** Not determined.

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· Relative density	Not determined.
· Vapor density	Not determined.
· 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:	
Organic solvents:	76.0 %
VOC (EC)	760,0 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 that are relevant for classification:**

64-17-5 ethyl alcohol

Oral	LD50	7060 mg/kg (rat (f+m))
Inhalative	LC50/4 h	20000 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:**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

64-17-5 ethyl alcohol	I
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· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **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.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** 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 3 (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 of 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 packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, IMDG, IATA** UN1170
- **14.2 UN proper shipping name**
- **DOT, IATA** Ethanol mixture
- **ADR** 1170 ETHANOL SOLUTION mixture

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· IMDG	<i>ETHANOL SOLUTION mixture</i>
· 14.3 Transport hazard class(es)	
· ADR	
	
· Class	3 (F1) Flammable liquids
· Label	3
<hr/>	
· 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
· Danger code (Kemler):	33
· EMS Number:	F-E,S-D
· Stowage Category	A
· 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
<hr/>	
· 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
<hr/>	
· 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 1170 ETHANOL SOLUTION MIXTURE, 3, II

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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 ingredients is listed.

- Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

- TSCA (Toxic Substances Control Act):

64-17-5 ethyl alcohol

- 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

A3

- MAK (German Maximum Workplace Concentration)

64-17-5 ethyl alcohol

5

- 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

- 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.

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

- Department issuing MSDS: Regulatory affairs

- Contact: msds@gceurope.com

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· **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

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

Flam. Liq. 2: Flammable liquids, 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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Revision: 31.05.2016

SECTION 1: Identification

- **1.1 Product identifier**
- **Trade name: GRADIA PLUS GUM LB**
- **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@gceurope.com
- **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.
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 labeled according to the CLP regulation.
- **Hazard pictograms**

GHS07
- **Signal word** Warning
- **Hazard-determining components of labeling:**
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate
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**
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.

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

P302+P352 IF ON SKIN: Wash with plenty of water.

P321 Specific treatment (see on this label).

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 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:**

41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid. Aquatic Chronic 4, H413	10-25%
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate Skin Sens. 1, H317	5-10%
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	1-5%
128-37-0	2,6-di-tert-butyl-p-cresol Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0,1-0,5%
1879-09-0	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	0,1-0,5%
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol Acute Tox. 2, H330; Aquatic Chronic 1, H410; Skin Sens. 1, H317	0,1-0,5%

· **Additional information:** For the wording of the listed risk phrases refer to section 16.

SECTION 4: First-aid measures

· **4.1 Description of first aid measures**

· **General information:**

Immediately remove any clothing soiled by the product.

If symptoms persist consult doctor.

· **After inhalation:**

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

Take affected persons into fresh air and keep quiet.

· **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment.

If skin irritation continues, consult a doctor.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

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- **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: Fire-fighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **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.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Remove persons from danger area.
Avoid contact with the eyes and skin.
Wear protective clothing.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to penetrate the ground/soil.
In case of seepage into the ground inform responsible authorities.
- **6.3 Methods and material for containment and cleaning up:**
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:** 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.

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- **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 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.

· DNELs		
128-37-0 2,6-di-tert-butyl-p-cresol		
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)

- **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.
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

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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:** Pasty
· **Color:** According to product specification

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· **Melting point/Melting range:** Undetermined.

· **Boiling point/Boiling range:** Undetermined.

· **Flash point:** > 150 °C

· **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:** Not determined.

· **Upper:** Not determined.

· **Vapor pressure:** Not determined.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapor density** Not determined.

· **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:**

· **Organic solvents:** 0,0 %

· **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.

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- **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 that are relevant for classification:**

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate		
Oral	LD50	> 5000 mg/kg (rat female) (OECD 401)
128-37-0 2,6-di-tert-butyl-p-cresol		
Oral	LD50	> 6000 mg/kg (rat (f+m)) (OECD 401)
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)
2440-22-4 2-(2H-benzotriazol-2-yl)-p-cresol		
Oral	LD50	10000 mg/kg (rat (f+m))
Inhalative	LC50/4 h	0,59 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:**
May cause an allergic skin reaction.
- **Additional toxicological information:**

- **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)		
128-37-0	2,6-di-tert-butyl-p-cresol	3
13463-67-7	titanium dioxide	2B
1309-37-1	Iron(III)oxide	3

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **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.
- **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.

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SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
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EC50/48h (static)	> 1,2 mg/l (daphnia magna) (OECD 202)
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128-37-0	2,6-di-tert-butyl-p-cresol
----------	----------------------------

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.

· Ecotoxicological effects:

· Remark: Harmful to fish

· Additional ecological information:

· General notes:

Harmful to aquatic organisms

Water hazard class 3 (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 of 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)
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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 packagings:

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

SECTION 14: Transport information

· 14.1 UN-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 Transport in bulk according to Annex II of MARPOL73/78 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**
· Sara

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

65997-17-3	Glass, oxide, chemicals
41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid.
2530-85-0	3-trimethoxysilylpropyl methacrylate
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate
10287-53-3	ethyl 4-dimethylaminobenzoate
128-37-0	2,6-di-tert-butyl-p-cresol
13463-67-7	titanium dioxide
1309-37-1	Iron(III)oxide
1317-61-9	triiron tetraoxide
5870-38-2	Diethyl 2,5-dihydroxyterephthalate
1879-09-0	6-tert-butyl-2,4-xylenol
10373-78-1	Camphorquinone
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol

- **Proposition 65**

- **Chemicals known to cause cancer:**

13463-67-7 titanium dioxide

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

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· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

128-37-0	2,6-di-tert-butyl-p-cresol	A4
13463-67-7	titanium dioxide	A4
1309-37-1	Iron(III)oxide	A4

· **MAK (German Maximum Workplace Concentration)**

128-37-0	2,6-di-tert-butyl-p-cresol	4
13463-67-7	titanium dioxide	3A

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

13463-67-7	titanium dioxide	
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· **Directive 2012/18/EU**

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

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· **Relevant phrases**

H302 Harmful if swallowed.

H310 Fatal in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H330 Fatal if inhaled.

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 MSDS:** Regulatory affairs

· **Contact:** msds@gceurope.com

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

DNEL: Derived No-Effect Level (REACH)

LC50: Lethal concentration, 50 percent

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*LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**NIOSH: National Institute for Occupational Safety**OSHA: Occupational Safety & Health**Acute Tox. 4: Acute toxicity, Hazard Category 4**Acute Tox. 2: Acute toxicity, Hazard Category 2**Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2**Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2**Skin Sens. 1: Sensitisation - Skin, Hazard Category 1**STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2**Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1**Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1**Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2**Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3**Aquatic Chronic 4: Hazardous to the aquatic environment - Chronic 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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SECTION 1: Identification

- **1.1 Product identifier**
- **Trade name: GRADIA PLUS LUSTRE PAINT (stain)**
- **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@gceurope.com
- **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.
Skin Sens. 1 H317 May cause an allergic skin reaction.
Repr. 2 H361f Suspected of damaging fertility.
- **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**

GHS07 GHS08
- **Signal word** Warning
- **Hazard-determining components of labeling:**
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
Methyl methacrylate
- **Hazard statements**
H317 May cause an allergic skin reaction.
H361f Suspected of damaging fertility.
- **Precautionary statements**
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P272 Contaminated work clothing should not be allowed out of the workplace.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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P308+P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:**

82,1 % of the mixture consists of component(s) of unknown toxicity.

Contains 82,1 % of components with unknown hazards to the aquatic environment.

· **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:**

75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f	1-5%
80-62-6	Methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	1-5%

· **Additional information:** For the wording of the listed risk phrases refer to section 16.

SECTION 4: First-aid measures

· **4.1 Description of first aid measures**· **General information:**

Immediately remove any clothing soiled by the product.

If symptoms persist consult doctor.

· **After inhalation:**

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

Take affected persons into fresh air and keep quiet.

· **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment.

If skin irritation continues, consult a doctor.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:**

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

· **4.2 Most important symptoms and effects, both acute and delayed Allergic reactions**· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

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SECTION 5: Fire-fighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire fighting measures that suit the environment.
- **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.
- **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 equipment. Keep unprotected persons away.
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.
- **6.3 Methods and material for containment and cleaning up:**
Allow to evaporate.
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:** 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

· **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:**

80-62-6 Methyl methacrylate

IOELV	Short-term value: 100 ppm Long-term value: 50 ppm
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· **DNELs**

80-62-6 Methyl methacrylate

Dermal	DNEL dermal	13,67 mg/kg bw/day (man) (worker, l. te., syst.)
Inhalative	DNEL inhalation	208 mg/m ³ (air) (worker, l. te., syst.)

· **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.

Avoid contact with the skin.

Immediately remove all soiled and contaminated clothing.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

Suitable respiratory protective device recommended.

· **Protection of hands:**

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.



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

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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· Form:	Pasty
· Color:	Different according to coloring
· Odor:	Odorless
· Odor threshold:	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.

· **Flash point:** 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:	Not determined.
· Upper:	Not determined.

· **Vapor pressure:** Not determined.

· Density at 20 °C:	1 g/cm ³
· Relative density	Not determined.
· Vapor density	Not determined.
· 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:**

· **Organic solvents:** 0.0 %

· **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.

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- **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 that are relevant for classification:

80-62-6 Methyl methacrylate

Oral	LD50	6000 mg/kg (rabbit)
Dermal	LD50	>5000 mg/kg (rab)
Inhalative	LC50/4 h	29,8 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:**
May cause an allergic skin reaction.
- **Additional toxicological information:**

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

80-62-6	Methyl methacrylate	3
13463-67-7	titanium dioxide	2B

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

- **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.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity**
Suspected of damaging fertility.
- **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:** 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 1 (Self-assessment): slightly hazardous for water

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Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

· **12.5 Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**

· **Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

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

SECTION 14: Transport information

· **14.1 UN-Number**

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

· **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**

MARPOL73/78 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**

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

80-62-6 Methyl methacrylate

· **TSCA (Toxic Substances Control Act):**

29570-58-9 2-[[3-[(1-oxoallyl)oxy]-2,2-bis[[[(1-oxoallyl)oxy]methyl]propoxy]methyl]-2-[[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl diacrylate

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75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
80-62-6	Methyl methacrylate
82799-44-8	2,4-Diethyl-9H-thioxanthen-9-one
13463-67-7	titanium dioxide
5580-57-4	C.I. Pigment Yellow 93
5280-78-4	CI Pigment Red 144
81-77-6	C.I. Pigment Blue 60

· **Proposition 65**· **Chemicals known to cause cancer:**

13463-67-7 titanium dioxide

· **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:**

None of the ingredients is listed.

· **Carcinogenic categories**· **EPA (Environmental Protection Agency)**

80-62-6 Methyl methacrylate

E, NL

· **TLV (Threshold Limit Value established by ACGIH)**

80-62-6 Methyl methacrylate

A4

13463-67-7 titanium dioxide

A4

· **MAK (German Maximum Workplace Concentration)**

13463-67-7 titanium dioxide

3A

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

13463-67-7 titanium dioxide

· **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**

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

H361f Suspected of damaging fertility.

· **Classification according to Regulation (EC) No 1272/2008** Calculation method· **Department issuing MSDS:** Regulatory affairs· **Contact:** msds@gceurope.com· **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)

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ICAO: International Civil Aviation Organisation

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

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

Flam. Liq. 2: Flammable liquids, Hazard Category 2

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Repr. 2: Reproductive toxicity, Hazard Category 2

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard 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.

Disclaimer:

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SECTION 1: Identification

- **1.1 Product identifier**
 - **Trade name:** GRADIA PLUS LUSTRE PAINT DILUTING LIQUID
 - **CAS Number:**
80-62-6
 - **EC number:**
201-297-1
 - **Index number:**
607-035-00-6
- **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@gceurope.com
- **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.
Skin Irrit. 2 H315 Causes skin irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H335 May cause respiratory irritation.
- **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 substance is classified and labeled according to the CLP regulation.
 - **Hazard pictograms**
 
GHS02 GHS07
 - **Signal word** Danger
 - **Hazard-determining components of labeling:**
Methyl methacrylate

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- **Hazard statements**

- H225 Highly flammable liquid and vapour.*

- H315 Causes skin irritation.*

- H317 May cause an allergic skin reaction.*

- H335 May cause respiratory irritation.*

- **Precautionary statements**

- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.*

- P280 Wear protective gloves/protective clothing/eye protection/face protection.*

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

- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.*

- P405 Store locked up.*

- 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

- **3.1 Chemical characterization: Substances**

- **CAS No. Description**

- 80-62-6 Methyl methacrylate*

- **Identification number(s)**

- **EC number:** 201-297-1

- **Index number:** 607-035-00-6

SECTION 4: First-aid measures

- **4.1 Description of first aid measures**

- **General information:**

- Immediately remove any clothing soiled by the product.*

- If symptoms persist consult doctor.*

- **After inhalation:**

- Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.*

- Take affected persons into fresh air and keep quiet.*

- **After skin contact:**

- Immediately wash with water and soap and rinse thoroughly.*

- Seek medical treatment.*

- If skin irritation continues, consult a doctor.*

- **After eye contact:**

- Rinse opened eye for several minutes under running water.*

- If symptoms persist consult 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: 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
- **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.
- **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.
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.

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- **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.

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:**

80-62-6 Methyl methacrylate

IOELV	Short-term value: 100 ppm Long-term value: 50 ppm
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- **DNELs**

80-62-6 Methyl methacrylate

Dermal	DNEL dermal	13,67 mg/kg bw/day (man) (worker, l. te., syst.)
Inhalative	DNEL inhalation	208 mg/m ³ (air) (worker, l. te., syst.)

- **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.

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.

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· Eye protection:



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	Liquid
· Color:	Colorless
· Odor:	Pungent, makes eyes water
· Odor threshold:	Not determined.

· pH-value: Not determined.

· Change in condition

· Melting point/Melting range:	-48 °C
· Boiling point/Boiling range:	101 °C

· Flash point: 10 °C

· Flammability (solid, gaseous): Not applicable.

· Ignition temperature: 430 °C

· Decomposition temperature: Not determined.

· Auto igniting: Not determined.

· Danger of explosion: Product does not present an explosion hazard.

· Explosion limits:

· Lower:	2,1 Vol %
· Upper:	12,5 Vol %

· Vapor pressure at 20 °C: 47 hPa

· Density at 20 °C:	0,94 g/cm ³
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.

· Solubility in / Miscibility with

· Water at 20 °C:	1,6 g/l Insoluble.
-------------------	-----------------------

· Partition coefficient (n-octanol/water): Not determined.

· Viscosity:

· Dynamic:	Not determined.
· Kinematic:	Not determined.
· Organic solvents:	0,0 %

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· **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 that are relevant for classification:**

80-62-6 Methyl methacrylate

Oral	LD50	6000 mg/kg (rabbit)
Dermal	LD50	>5000 mg/kg (rab)
Inhalative	LC50/4 h	29,8 mg/l (rat (f+m))

- **Primary irritant effect:**
- **on the skin:**
Causes skin irritation.
- **on the eye:** Based on available data, the classification criteria are not met.
- **Sensitization:**
May cause an allergic skin reaction.
- **Additional toxicological information:**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

112926-00-8	silicon dioxide, amorphous	3
13463-67-7	titanium dioxide	2B

· **NTP (National Toxicology Program)**

Substance is not listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

Substance is not listed.

- **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.
- **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**
May cause respiratory irritation.
- **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.


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.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (Assessment by list): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---|--|
| · 14.1 UN-Number | UN1247 |
| · ADR, IMDG, IATA | |
| · 14.2 UN proper shipping name | Methyl methacrylate monomer, stabilized |
| · DOT, IATA | 1247 METHYL METHACRYLATE MONOMER, STABILIZED |
| · ADR | METHYL METHACRYLATE MONOMER, STABILIZED |
| · IMDG | METHYL METHACRYLATE MONOMER, STABILIZED |
| · 14.3 Transport hazard class(es) | |
| · ADR | |
|  | |
| · Class | 3 (F1) Flammable liquids |
| · Label | 3 |

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· **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
· **Danger code (Kemler):** 339
· **EMS Number:** F-E,S-D
· **Stowage Category** B
· **Stowage Code** SW2 Clear of living quarters.

· **14.7 Transport in bulk according to Annex 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

· **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 1247 METHYL METHACRYLATE MONOMER, STABILIZED, 3, II

SECTION 15: Regulatory information

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

· **Section 355 (extremely hazardous substances):**

Substance is not listed.

· **Section 313 (Specific toxic chemical listings):**

Substance is not listed.

· **TSCA (Toxic Substances Control Act):**

68083-19-2 Vinyl dimethyl polysiloxane

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13463-67-7 titanium dioxide

· **Proposition 65**

· **Chemicals known to cause cancer:**

13463-67-7 titanium dioxide

· **Chemicals known to cause reproductive toxicity for females:**

Substance is not listed.

· **Chemicals known to cause reproductive toxicity for males:**

Substance is not listed.

· **Chemicals known to cause developmental toxicity:**

Substance is not listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

Substance is not listed.

· **TLV (Threshold Limit Value established by ACGIH)**

13463-67-7 titanium dioxide

A4

· **MAK (German Maximum Workplace Concentration)**

13463-67-7 titanium dioxide

3A

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

13463-67-7 titanium dioxide

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** Substance is not 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

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

· **Department issuing MSDS:** Regulatory affairs

· **Contact:** msds@gceurope.com

· **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

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

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

Flam. Liq. 2: Flammable liquids, Hazard Category 2

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Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard 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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SECTION 1: Identification



- **1.1 Product identifier**
 - **Trade name: GRADIA PLUS MODELLING LIQUID**
- **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@gceurope.com
- **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.
 - Eye Dam. 1 H318 Causes serious eye damage.
 - 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 labeled according to the CLP regulation.
 - **Hazard pictograms**

GHS05 GHS07
 - **Signal word** Danger
 - **Hazard-determining components of labeling:**

(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate
2,2'-ethylenedioxydiethyl dimethacrylate
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
2-(2H-benzotriazol-2-yl)-p-cresol
 - **Hazard statements**

H318 Causes serious eye damage.
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

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· Precautionary statements

- P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P272 Contaminated work clothing should not be allowed out of the workplace.
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 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.
 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 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:

41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid. Aquatic Chronic 4, H413	50-70%
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	10-25%
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazaheptadecane-1,16-diyl bismethacrylate Skin Sens. 1, H317	5-10%
1565-94-2	(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate Eye Dam. 1, H318; Skin Sens. 1, H317	5-10%
128-37-0	2,6-di-tert-butyl-p-cresol Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0,5-1%
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol Acute Tox. 2, H330; Aquatic Chronic 1, H410; Skin Sens. 1, H317	0,1-0,5%

· **Additional information:** For the wording of the listed risk 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.

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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: Fire-fighting measures

· 5.1 Extinguishing media

· Suitable extinguishing agents:

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire fighting measures that suit the environment.

· 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.

· 5.3 Advice for firefighters

· Protective equipment: Wear self-contained respiratory protective device.

· Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Remove persons from danger area.

Avoid contact with the eyes and skin.

Wear protective clothing.

· 6.2 Environmental precautions:

Do not allow product to reach sewage system or any water course.

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

Do not allow to penetrate the ground/soil.

In case of seepage into the ground inform responsible authorities.

· 6.3 Methods and material for containment and cleaning up:

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.

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Prevent formation of aerosols.

Avoid contact with the eyes and skin.

· **Information about protection against explosions and fires:** 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 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.

· **DNELs**

128-37-0 2,6-di-tert-butyl-p-cresol

Dermal	DNEL dermal	0,5 mg/kg bw/day (man)
Inhalative	DNEL inhalation	3,5 mg/m ³ (man)

· **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.

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.

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· Eye protection:



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	Liquid
· Color:	Light yellow
· Odor:	Odorless
· Odor threshold:	Not determined.

· pH-value: Not determined.

· Change in condition

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	283 °C

· Flash point: 123 °C

· 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:	Not determined.
· Upper:	Not determined.

· Vapor pressure: Not determined.

· Density at 20 °C:	1.2 g/cm ³
· Relative density	Not determined.
· Vapor density	Not determined.
· 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:

Organic solvents: 0.0 %

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· **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 that are relevant for classification:**

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate		
Oral	LD50	> 5000 mg/kg (rat female) (OECD 401)
128-37-0 2,6-di-tert-butyl-p-cresol		
Oral	LD50	> 6000 mg/kg (rat (f+m)) (OECD 401)
2440-22-4 2-(2H-benzotriazol-2-yl)-p-cresol		
Oral	LD50	10000 mg/kg (rat (f+m))
Inhalative	LC50/4 h	0,59 mg/l (rat (f+m))

- **Primary irritant effect:**
- **on the skin:** Based on available data, the classification criteria are not met.
- **on the eye:**
Causes serious eye damage.
- **Sensitization:**
May cause an allergic skin reaction.
- **Additional toxicological information:**

· **Carcinogenic categories**

IARC (International Agency for Research on Cancer)		
9011-14-7	Polymethylmethacrylate	3

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **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.
- **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.**SECTION 12: Ecological information**· **12.1 Toxicity**· **Aquatic toxicity:**

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahehexadecane-1,16-diyl bismethacrylate

EC50/48h (static) > 1,2 mg/l (daphnia magna) (OECD 202)

128-37-0 2,6-di-tert-butyl-p-cresol

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.· **Ecotoxicological effects:**· **Remark:** Harmful to fish· **Additional ecological information:**· **General notes:**

Harmful to aquatic organisms

Water hazard class 3 (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 of 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 packagings:**· **Recommendation:** Disposal must be made according to official regulations.**SECTION 14: Transport information**· **14.1 UN-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 Transport in bulk according to Annex II of MARPOL73/78 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**
· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

1565-94-2	(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate
65997-17-3	Glass, oxide, chemicals
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate
2530-85-0	3-trimethoxysilylpropyl methacrylate
9011-14-7	Polymethylmethacrylate
10373-78-1	Camphorquinone
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
10287-53-3	ethyl 4-dimethylaminobenzoate
1879-09-0	6-tert-butyl-2,4-xylenol

· **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:**

None of the ingredients is listed.

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· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **MAK (German Maximum Workplace Concentration)**

None of the ingredients is listed.

· **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.

· **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.

H318 Causes serious eye damage.

H330 Fatal if inhaled.

H400 Very toxic to aquatic life.

H410 Very 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 MSDS:** Regulatory affairs

· **Contact:** msds@gceurope.com

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

Acute Tox. 2: Acute toxicity, Hazard Category 2

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

Aquatic Chronic 4: Hazardous to the aquatic environment - Chronic Hazard, Category 4

· **Sources**

• ECHA (<http://echa.europa.eu/>)

• EnviChem (www.echemportal.org)

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

This version replaces all previous versions.

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Revision: 01.06.2016

SECTION 1: Identification

- **1.1 Product identifier**
- **Trade name: GRADIA PLUS OPAQUE**
- **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@gceurope.com
- **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.
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **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**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labeling:**
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate
2,2'-ethylenedioxydiethyl dimethacrylate
- **Hazard statements**
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P302+P352 IF ON SKIN: Wash with plenty of water.
P321 Specific treatment (see on this label).
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:

72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate Skin Sens. 1, H317	10-25%
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	10-25%
13760-80-0	Ytterbium trifluoride Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331	1-5%
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f	0,1-0,5%

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

SECTION 4: First-aid measures

· 4.1 Description of first aid measures

· General information:

Immediately remove any clothing soiled by the product.

If symptoms persist consult doctor.

· After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

Take affected persons into fresh air and keep quiet.

· After skin contact:

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment.

If skin irritation continues, consult a doctor.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· After swallowing:

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

· 4.2 Most important symptoms and effects, both acute and delayed Allergic reactions

· 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

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SECTION 5: Fire-fighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire fighting measures that suit the environment.
- **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.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Remove persons from danger area.
Avoid contact with the eyes and skin.
Wear protective clothing.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to penetrate the ground/soil.
In case of seepage into the ground inform responsible authorities.
- **6.3 Methods and material for containment and cleaning up:**
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:** 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

· **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.

· **DNELs**

13463-67-7 titanium dioxide

Inhalative	DNEL inhalation	10 mg/m ³ (man)
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· **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.

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: Pasty

Color: According to product specification

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value:** Not determined.

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· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	283 °C
· Flash point:	> 150 °C
· 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:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density at 20 °C:	2 g/cm ³
· Relative density	Not determined.
· Vapor density	Not determined.
· 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:	
Organic solvents:	0.0 %
· 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.

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· LD/LC50 values that are relevant for classification:**72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate**

Oral LD50 > 5000 mg/kg (rat female) (OECD 401)

13463-67-7 titanium dioxide

Oral LD50 > 5000 mg/kg (mouse) (OECD 420)

Inhalative LC50/4 h > 6,82 mg/l (rat male)

· 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:**

May cause an allergic skin reaction.

· Additional toxicological information:**· Carcinogenic categories****· IARC (International Agency for Research on Cancer)**

128-37-0 2,6-di-tert-butyl-p-cresol

3

13463-67-7 titanium dioxide

2B

1309-37-1 Iron(III)oxide

3

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· 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.**· 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 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate**

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.**· Additional ecological information:****· General notes:**

Water hazard class 3 (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.

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- **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.

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

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, ADN, IMDG, IATA** not regulated
- **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 MARPOL73/78 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**
- **Sara**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

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· TSCA (Toxic Substances Control Act):	
65997-17-3	Glass, oxide, chemicals
41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid.
2530-85-0	3-trimethoxysilylpropyl methacrylate
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate
10287-53-3	ethyl 4-dimethylaminobenzoate
128-37-0	2,6-di-tert-butyl-p-cresol
13463-67-7	titanium dioxide
1309-37-1	Iron(III)oxide
1317-61-9	triiron tetraoxide
5870-38-2	Diethyl 2,5-dihydroxyterephthalate
1879-09-0	6-tert-butyl-2,4-xylenol
10373-78-1	Camphorquinone
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol

· Proposition 65

· Chemicals known to cause cancer:	
13463-67-7	titanium dioxide

· 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:	
None of the ingredients is listed.	

· Carcinogenic categories

· EPA (Environmental Protection Agency)	
None of the ingredients is listed.	

· TLV (Threshold Limit Value established by ACGIH)		
128-37-0	2,6-di-tert-butyl-p-cresol	A4
13463-67-7	titanium dioxide	A4
1309-37-1	Iron(III)oxide	A4

· MAK (German Maximum Workplace Concentration)		
128-37-0	2,6-di-tert-butyl-p-cresol	4
13463-67-7	titanium dioxide	3A

· NIOSH-Ca (National Institute for Occupational Safety and Health)	
13463-67-7	titanium dioxide

· 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.

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Trade name: **GRADIA PLUS OPAQUE**

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SECTION 16: Other information

- **Relevant phrases**

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H317 May cause an allergic skin reaction.

H331 Toxic if inhaled.

H361f Suspected of damaging fertility.

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

- **Department issuing MSDS: Regulatory affairs**

- **Contact:** *msds@gceurope.com*

- **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

Acute Tox. 3: Acute toxicity, Hazard Category 3

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Repr. 2: Reproductive toxicity, 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.

Disclaimer:

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SECTION 1: Identification

- **1.1 Product identifier**
- **Trade name: GRADIA PLUS PASTE HB & GRADIA PLUS GUM HB**
- **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@gceurope.com
- **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.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **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**



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- **Signal word** Warning
- **Hazard-determining components of labeling:**
2,2'-ethylenedioxydiethyl dimethacrylate
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
- **Hazard statements**
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P272 Contaminated work clothing should not be allowed out of the workplace.

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P280 Wear protective gloves.

P305+P351+P338 *IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*

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

P337+P313 *If eye irritation persists: 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 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:

41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid. Aquatic Chronic 4, H413	10-25%
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	1-5%
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate Skin Sens. 1, H317	1-5%
1565-94-2	(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate Eye Dam. 1, H318; Skin Sens. 1, H317	1-5%
128-37-0	2,6-di-tert-butyl-p-cresol Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0,1-0,5%

- **Additional information:** For the wording of the listed risk 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.

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Rinse opened eye for several minutes under running water. Then consult a doctor.

· **After swallowing:**

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

· **4.2 Most important symptoms and effects, both acute and delayed** *Allergic reactions*

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

SECTION 5: Fire-fighting measures

· **5.1 Extinguishing media**

· **Suitable extinguishing agents:**

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire fighting measures that suit the environment.

· **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.

· **5.3 Advice for firefighters**

· **Protective equipment:** *Wear self-contained respiratory protective device.*

· **Additional information**

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**

Remove persons from danger area.

Avoid contact with the eyes and skin.

Wear protective clothing.

· **6.2 Environmental precautions:**

Do not allow product to reach sewage system or any water course.

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

Do not allow to penetrate the ground/soil.

In case of seepage into the ground inform responsible authorities.

· **6.3 Methods and material for containment and cleaning up:**

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:** *No special measures required.*

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- **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 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.

- **DNELs**

128-37-0 2,6-di-tert-butyl-p-cresol

Dermal	DNEL dermal	0,5 mg/kg bw/day (man)
Inhalative	DNEL inhalation	3,5 mg/m ³ (man)

- **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.

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

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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:** Pasty
· **Color:** According to product specification

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· **Melting point/Melting range:** Undetermined.

· **Boiling point/Boiling range:** 190 °C

· **Flash point:** > 150 °C

· **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:** Not determined.

· **Upper:** Not determined.

· **Vapor pressure:** Not determined.

· **Density at 20 °C:** 2 g/cm³

· **Relative density** Not determined.

· **Vapor density** Not determined.

· **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:**

· **Organic solvents:** 0.0 %

· **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.

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- **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 that are relevant for classification:**

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate

Oral LD50 > 5000 mg/kg (rat female) (OECD 401)

128-37-0 2,6-di-tert-butyl-p-cresol

Oral LD50 > 6000 mg/kg (rat (f+m)) (OECD 401)

- **Primary irritant effect:**
- **on the skin:** Based on available data, the classification criteria are not met.
- **on the eye:**
Causes serious eye irritation.
- **Sensitization:**
May cause an allergic skin reaction.
- **Additional toxicological information:**

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

13760-80-0 Ytterbium trifluoride

3

1309-37-1 Iron(III)oxide

3

13463-67-7 titanium dioxide

2B

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **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.
- **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 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate

EC50/48h (static) > 1,2 mg/l (daphnia magna) (OECD 202)

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128-37-0 2,6-di-tert-butyl-p-cresol

EC50/48h (static) 0,48 mg/l (daphnia magna) (OECD 202)

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 3 (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 of 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 packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN-Number
· ADR, ADN, IMDG, IATA | not regulated |
| · 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 MARPOL73/78 and the IBC Code | Not applicable. |

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· 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 ingredients is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

65997-17-3 Glass, oxide, chemicals

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate

13760-80-0 Ytterbium trifluoride

1985-51-9 2,2-dimethyl-1,3-propanediyl bismethacrylate

2530-85-0 3-trimethoxysilylpropyl methacrylate

1309-37-1 Iron(III)oxide

21245-01-2 3-methylbutyl 4-(dimethylamino)benzoate

2440-22-4 2-(2H-benzotriazol-2-yl)-p-cresol

· 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:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

13760-80-0 Ytterbium trifluoride

A4

1309-37-1 Iron(III)oxide

A4

13463-67-7 titanium dioxide

A4

· MAK (German Maximum Workplace Concentration)

13463-67-7 titanium dioxide

3A

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

13463-67-7 titanium dioxide

· Directive 2012/18/EU

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

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· **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.

H318 Causes serious eye damage.

H400 Very toxic to aquatic life.

H410 Very 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 MSDS:** Regulatory affairs

· **Contact:** msds@gceurope.com

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

Aquatic Chronic 4: Hazardous to the aquatic environment - Chronic 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:

The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products 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.

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

Printing date 02.06.2016



Version number 1

Revision: 31.05.2016

SECTION 1: Identification

- **1.1 Product identifier**
- **Trade name: GRADIA PLUS PASTE LB**
- **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@gceurope.com
- **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.
Eye Dam. 1 H318 Causes serious eye damage.
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 labeled according to the CLP regulation.
- **Hazard pictograms**

GHS05 GHS07
- **Signal word** Danger
- **Hazard-determining components of labeling:**
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate
2,2'-ethylenedioxydiethyl dimethacrylate
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
- **Hazard statements**
H318 Causes serious eye damage.
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

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· Precautionary statements

- P272 Contaminated work clothing should not be allowed out of the workplace.
 P280 Wear protective gloves.
 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.
 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 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:

41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid. Aquatic Chronic 4, H413	10-25%
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	5-10%
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate Skin Sens. 1, H317	1-5%
1565-94-2	(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate Eye Dam. 1, H318; Skin Sens. 1, H317	1-5%
128-37-0	2,6-di-tert-butyl-p-cresol Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0,1-0,5%

· **Additional information:** For the wording of the listed risk 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.

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- **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: Fire-fighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **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.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Remove persons from danger area.
Avoid contact with the eyes and skin.
Wear protective clothing.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to penetrate the ground/soil.
In case of seepage into the ground inform responsible authorities.
- **6.3 Methods and material for containment and cleaning up:**
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.

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- **Information about protection against explosions and fires:** 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 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.

· DNELs

128-37-0 2,6-di-tert-butyl-p-cresol

Dermal	DNEL dermal	0,5 mg/kg bw/day (man)
Inhalative	DNEL inhalation	3,5 mg/m ³ (man)

- **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.

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

EU

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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Pasty
 Color: According to product specification

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: 190 °C

· **Flash point:** > 150 °C

· **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: Not determined.

Upper: Not determined.

· **Vapor pressure:** Not determined.

· **Density at 20 °C:** 2 g/cm³

· **Relative density** Not determined.

· **Vapor density** Not determined.

· **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:**

Organic solvents: 0.0 %

· **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.

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Trade name: GRADIA PLUS PASTE LB

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- **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 that are relevant for classification:**

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

Oral LD50 > 5000 mg/kg (rat female) (OECD 401)

128-37-0 2,6-di-tert-butyl-p-cresol

Oral LD50 > 6000 mg/kg (rat (f+m)) (OECD 401)

- **Primary irritant effect:**
- **on the skin:** Based on available data, the classification criteria are not met.
- **on the eye:**
Causes serious eye damage.
- **Sensitization:**
May cause an allergic skin reaction.
- **Additional toxicological information:**

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

128-37-0	2,6-di-tert-butyl-p-cresol	3
13463-67-7	titanium dioxide	2B
1309-37-1	Iron(III)oxide	3

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **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.
- **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 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

EC50/48h (static) > 1,2 mg/l (daphnia magna) (OECD 202)

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128-37-0 2,6-di-tert-butyl-p-cresol

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.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**
Harmful to aquatic organisms
Water hazard class 3 (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 of 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 packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, ADN, IMDG, IATA** not regulated

- **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

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- | | |
|---|-----------------|
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of MARPOL73/78 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**
· **Sara**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

65997-17-3	Glass, oxide, chemicals
41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid.
2530-85-0	3-trimethoxysilylpropyl methacrylate
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate
1565-94-2	(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate
128-37-0	2,6-di-tert-butyl-p-cresol
13463-67-7	titanium dioxide
1309-37-1	Iron(III)oxide
1317-61-9	triiron tetraoxide
5870-38-2	Diethyl 2,5-dihydroxyterephthalate
10287-53-3	ethyl 4-dimethylaminobenzoate

- **Proposition 65**

- **Chemicals known to cause cancer:**

13463-67-7 titanium dioxide

- **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:**

None of the ingredients is listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value established by ACGIH)**

128-37-0	2,6-di-tert-butyl-p-cresol	A4
13463-67-7	titanium dioxide	A4

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1309-37-1	Iron(III)oxide	A4
· MAK (German Maximum Workplace Concentration)		
128-37-0	2,6-di-tert-butyl-p-cresol	4
13463-67-7	titanium dioxide	3A
· NIOSH-Ca (National Institute for Occupational Safety and Health)		
13463-67-7	titanium dioxide	

· **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.

H318 Causes serious eye damage.

H400 Very toxic to aquatic life.

H410 Very 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 MSDS:** Regulatory affairs· **Contact:** msds@gceurope.com· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

Aquatic Chronic 4: Hazardous to the aquatic environment - Chronic 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.

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SECTION 1: Identification

- **1.1 Product identifier**
- **Trade name: GRADIA PLUS SEPARATOR**
- **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@gceurope.com
- **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**
Flam. Liq. 2 H225 Highly flammable liquid and vapour.
Eye Irrit. 2 H319 Causes serious eye irritation.
STOT SE 3 H336 May cause drowsiness or dizziness.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labeled according to the CLP regulation.
- **Hazard pictograms**



GHS02 GHS07

- **Signal word** Danger
- **Hazard-determining components of labeling:**
isopropyl alcohol
- **Hazard statements**
H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
- **Precautionary statements**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 Wear protective gloves / eye protection.

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- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/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.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:**

23 % of the mixture consists of component(s) of unknown toxicity.
 Contains 23 % of components with unknown hazards to the aquatic environment.

· **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:**

67-63-0	isopropyl alcohol	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	60-80%
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· **Additional information:** For the wording of the listed risk 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:** If skin irritation continues, consult a doctor.· **After eye contact:**

Protect unharmed eye.

Rinse opened eye for several minutes under running water. Then consult a doctor.

· **After swallowing:**

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

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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
- **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.
- **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.
- **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.

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- **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.

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: Liquid

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· Color:	Clear
· Odor:	Characteristic
· Odor threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	13 °C
· 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:	2.0 Vol %
Upper:	12.0 Vol %
· Vapor pressure:	Not determined.
· Density:	Not determined.
· Relative density	Not determined.
· Vapor density	Not determined.
· 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:	
Organic solvents:	77.0 %
VOC (EC)	770,0 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.

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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:**

67-63-0 isopropyl alcohol

Oral	LD50	4570 mg/kg (rat (f+m))
Dermal	LD50	13400 mg/kg (rab)
Inhalative	LC50/4 h	30 mg/l (rat (f+m))

- **Primary irritant effect:**
- **on the skin:** Based on available data, the classification criteria are not met.
- **on the eye:**
Causes serious eye irritation.
- **Sensitization:** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

67-63-0 isopropyl alcohol	3
---------------------------	---

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **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.
- **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**
May cause drowsiness or dizziness.
- **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:** 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 3 (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.

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· **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.

· **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 packagings:**· **Recommendation:** Disposal must be made according to official regulations.**SECTION 14: Transport information**· **14.1 UN-Number**· **ADR, IMDG, IATA**

UNI219

· **14.2 UN proper shipping name**· **DOT**

Isopropanol

· **ADR**

1219 ISOPROPYL ALCOHOL

· **IMDG**

ISOPROPYL ALCOHOL mixture

· **IATA**

Isopropanol mixture

· **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

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· Danger code (Kemler):	33
· EMS Number:	F-E,S-D
· Stowage Category	B
· 14.7 Transport in bulk according to Annex 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
· 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 1219 ISOPROPYL ALCOHOL, 3, II

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 ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

67-63-0 isopropyl alcohol

- **TSCA (Toxic Substances Control Act):**

All ingredients are 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:**

None of the ingredients is listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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· **TLV (Threshold Limit Value established by ACGIH)**

67-63-0 isopropyl alcohol

A4

· **MAK (German Maximum Workplace Concentration)**

None of the ingredients is listed.

· **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· **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.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

· **Classification according to Regulation (EC) No 1272/2008** Calculation method· **Department issuing MSDS:** Regulatory affairs· **Contact:** msds@gceurope.com· **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

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

Flam. Liq. 2: Flammable liquids, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard 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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