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

· **1.1 Product identifier**

· **Trade name: GRADIA_PLUS_PASTE_LB,_ONE_BODY**

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** Auxillary for dental technology

· **1.3 Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**
GC EUROPE N.V.
Interleuvenlaan 33
B-3001 Leuven
Tel. +32/(0)16/74.10.00
Fax +32/(0)16/40.26.84
msds@gc.dental

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

· **1.4 Emergency telephone number:**
National poison center for United Kingdom of Great Britain and Northern Ireland:
Belfast: +44 28 90 63 2032
Birmingham: +44 121 507 4123
Edinburgh: +44 131 242 1383
Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180
Penarth: +44 292 071 55 54

*
SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

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

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**
The product is classified and labelled according to the GB CLP regulation.

· **Exemptions**
The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).

· **Hazard pictograms**

GHS05 GHS07

· **Signal word** Danger

· **Hazard-determining components of labelling:**
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate

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2,2'-ethylenedioxydiethyl dimethacrylate
Urethane Dimethacrylate (UDMA)
1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde
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.

· **Precautionary statements**

P272	*Contaminated work clothing should not be allowed out of the workplace.*
P305+P351+P338	*IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*
P310	*Immediately call a POISON CENTER/doctor.*
P321	*Specific treatment (see on this label).*
P362+P364	*Take off contaminated clothing and wash it before reuse.*
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.*

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SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**
· **Description:**

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

· **Dangerous components:**

CAS: 41637-38-1	*Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid.* *Aquatic Chronic 4, H413*	*10-<25%*
CAS: 109-16-0 *EINECS: 203-652-6*	*2,2'-ethylenedioxydiethyl dimethacrylate* *Skin Sens. 1, H317*	*5-<10%*
CAS: 1565-94-2 *EINECS: 216-367-7*	*(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate* *Eye Dam. 1, H318; Skin Sens. 1, H317*	*≥3-<5%*
CAS: 72869-86-4 *EINECS: 276-957-5*	*Urethane Dimethacrylate (UDMA)* *Aquatic Chronic 2, H411; Skin Sens. 1B, H317*	*2.5-<5%*
CAS: 1309-37-1 *EINECS: 215-168-2*	*Iron(III)oxide* *substance with a Community workplace exposure limit*	*0.5-<1%*
CAS: 9003-08-1	*1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde* *Eye Dam. 1, H318; Skin Sens. 1, H317; STOT SE 3, H335*	*0.5-<1%*

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CAS: 13463-67-7 EINECS: 236-675-5 Index number: 022-006-00-2	titanium dioxide Carc. 2, H351 substance with a Community workplace exposure limit	0.5-<1%
CAS: 13463-67-7 EINECS: 236-675-5 Index number: 022-006-00-2	titanium dioxide Carc. 2, H351 Substance with a Community workplace exposure limit. Nanoform: Spheroidal, crystalline nanoform, set including crystalline nanoforms with precise crystal structure, crystalline forms, non-surface-treated nanoforms.	0.5-<1%
CAS: 68611-44-9 EINECS: 271-893-4	Silane, dichlorodimethyl-, reaction products with silica Nanoform: Spheroidal, amorphous nanoform, set including amorphous nanoforms, amorphous forms, surface-treated nanoforms	0.5-<1%
CAS: 68909-20-6 EINECS: 272-697-1	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica STOT RE 2, H373, EUH066 Nanoform: Spheroidal, amorphous nanoform, set including amorphous nanoforms, amorphous forms, surface-treated nanoforms	1-<2.5%
CAS: 128-37-0 EINECS: 204-881-4	Butylated hydroxytoluene Aquatic Acute 1, H400; Aquatic Chronic 1, H410 Substance identified as having endocrine disrupting properties (II)	≥0.25-<0.5%
CAS: 1879-09-0 EINECS: 217-533-1	6-tert-butyl-2,4-xylenol Acute Tox. 2, H310; STOT RE 2, H373; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	≥0.25-<0.5%
CAS: 2440-22-4 EINECS: 219-470-5	2-(2H-benzotriazol-2-yl)-p-cresol Acute Tox. 3, H331; Aquatic Chronic 1, H410; Skin Sens. 1, H317	≥0.25-<0.5%
CAS: 75980-60-8 EINECS: 278-355-8 Index number: 015-203-00-X	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f	0.2-<0.5%

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

SECTION 4: First aid measures

· ***4.1 Description of first aid measures***
· ***General information:***
Immediately remove any clothing soiled by the product.
If symptoms persist consult doctor.
· ***After inhalation:***
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
Take affected persons into fresh air and keep quiet.
· ***After skin contact:***
Immediately wash with water and soap and rinse thoroughly.
Seek medical treatment.
If skin irritation continues, consult a doctor.
· ***After eye contact:***
Protect unharmed eye.
Rinse opened eye for several minutes under running water.
Call a doctor immediately.

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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: Firefighting measures

· ***5.1 Extinguishing media***
· ***Suitable extinguishing agents:***
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.
· ***For safety reasons unsuitable extinguishing agents:*** *Water with full jet*
· ***5.2 Special hazards arising from the substance or mixture***
Formation of toxic gases is possible during heating or in case of fire.
No further relevant information available.
· ***5.3 Advice for firefighters***
· ***Protective equipment:*** *Wear self-contained respiratory protective device.*
· ***Additional information***
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

· ***6.1 Personal precautions, protective equipment and emergency procedures***
Remove persons from danger area.
Avoid contact with the eyes and skin.
Wear protective clothing.
· ***6.2 Environmental precautions:***
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to penetrate the ground/soil.
In case of seepage into the ground inform responsible authorities.
· ***6.3 Methods and material for containment and cleaning up:***
Absorb liquid components with liquid-binding material.
Dispose of the material collected according to regulations.
· ***6.4 Reference to other sections***
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· ***7.1 Precautions for safe handling***
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
Avoid contact with the eyes and skin.
· ***Information about fire - and explosion protection:*** *No special measures required.*

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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.

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SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**	
1309-37-1 Iron(III)oxide	
WEL	Short-term value: 10* mg/m³ Long-term value: 5* 10** 4*** mg/m³ *fume (as Fe),**total respirable,***respirable
13463-67-7 titanium dioxide	
WEL	Long-term value: 10* 4** mg/m³ *total inhalable **respirable
13463-67-7 titanium dioxide	
WEL	Long-term value: 10* 4** mg/m³ *total inhalable **respirable

· **DNELs**		
13463-67-7 titanium dioxide		
Inhalative	DNEL inhalation	10 mg/m3 (man)
13463-67-7 titanium dioxide		
Inhalative	DNEL inhalation	10 mg/m3 (man)
128-37-0 Butylated hydroxytoluene		
Dermal	DNEL dermal	0.5 mg/kg bw/day (man)
Inhalative	DNEL inhalation	3.5 mg/m3 (man)
1879-09-0 6-tert-butyl-2,4-xylenol		
Inhalative	DNEL inhalation	0.14 mg/m3 (man)

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**
· **Appropriate engineering controls** No further data; see section 7.
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
Avoid contact with the eyes and skin.
Wash hands before breaks and at the end of work.
Immediately remove all soiled and contaminated clothing
· **Respiratory protection:** Suitable respiratory protective device recommended.
· **Hand protection**

Protective gloves

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· ***Material of gloves***
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· ***Penetration time of glove material***
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· ***Eye/face protection***

Tightly sealed goggles

*
SECTION 9: Physical and chemical properties

· ***9.1 Information on basic physical and chemical properties***	
· ***General Information***	
· ***Physical state***	*Fluid*
· ***Colour:***	*According to product specification*
· ***Odour:***	*Odourless*
· ***Odour threshold:***	*Not determined.*
· ***Melting point/freezing point:***	*Undetermined.*
· ***Boiling point or initial boiling point and boiling range***	*190 °C*
· ***Flammability***	*Not applicable.*
· ***Lower and upper explosion limit***	
· ***Lower:***	*Not determined.*
· ***Upper:***	*Not determined.*
· ***Flash point:***	*>150 °C*
· ***Auto-ignition temperature:***	*Undetermined.*
· ***Decomposition temperature:***	*Not determined.*
· ***pH***	*Not determined.*
· ***Viscosity:***	
· ***Kinematic viscosity***	*Not determined.*
· ***Dynamic:***	*Not determined.*
· ***Solubility***	
· ***water:***	*Insoluble.*
· ***Partition coefficient n-octanol/water (log value)***	*Not determined.*
· ***Vapour pressure:***	*Not determined.*
· ***Density and/or relative density***	
· ***Density at 20 °C:***	*2 g/cm³*
· ***Relative density***	*Not determined.*

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· **Vapour density**	Not determined.
· **Particle characteristics**	SiO2: Diameter particle structure = 2.5 - 50 nm (TEM, d50, number-based) Diameter agglomerate = 5 - 50 mm (laser diffraction dry module, d50, volume based) TiO2: Diameter particle structure = 72 nm (dynamic light scattering, d50, number-based) 13463-67-7 titanium dioxide: Spheroidal, crystalline nanoform, set including crystalline nanoforms with precise crystal structure, crystalline forms, non-surface-treated nanoforms 68611-44-9 Silane, dichlorodimethyl-, reaction products with silica: Spheroidal, amorphous nanoform, set including amorphous nanoforms, amorphous forms, surface-treated nanoforms 68909-20-6 Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica: Spheroidal, amorphous nanoform, set including amorphous nanoforms, amorphous forms, surface-treated nanoforms

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

· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void
· **Aerosols**	Void
· **Oxidising gases**	Void
· **Gases under pressure**	Void
· **Flammable liquids**	Void
· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **Self-heating substances and mixtures**	Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void
· **Oxidising liquids**	Void
· **Oxidising solids**	Void
· **Organic peroxides**	Void
· **Corrosive to metals**	Void

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· **Desensitised explosives** Void

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known.
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

*
SECTION 11: Toxicological information

· **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
· **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**		
72869-86-4 Urethane Dimethacrylate (UDMA)		
Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)
1309-37-1 Iron(III)oxide		
Oral	LD50	>5,000 mg/kg (rat (f+m))
13463-67-7 titanium dioxide		
Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)
Inhalative	LC50/4 h	>6.82 mg/l (rat male)
13463-67-7 titanium dioxide		
Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)
Inhalative	LC50/4 h	>6.82 mg/l (rat male)
128-37-0 Butylated hydroxytoluene		
Oral	LD50	>6,000 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	10,000 mg/kg (rat (f+m))
Inhalative	LC50/4 h	0.59 mg/l (rat (f+m))

· **Serious eye damage/irritation** Causes serious eye damage.
· **Respiratory or skin sensitisation** May cause an allergic skin reaction.
· **Additional toxicological information:**
· **Repeated dose toxicity** No further relevant information available.
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
No further relevant information available.

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· **11.2 Information on other hazards**

· **Endocrine disrupting properties**		
128-37-0	Butylated hydroxytoluene	List II

*
SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
72869-86-4 Urethane Dimethacrylate (UDMA)	
EC50/48h (static)	>1.2 mg/l (daphnia magna) (OECD 202)
128-37-0 Butylated hydroxytoluene	
EC50/48h (static)	0.48 mg/l (daphnia magna) (OECD 202)

· **12.2 Persistence and degradability** No further relevant information available.
· **12.3 Bioaccumulative potential** No further relevant information available.
· **12.4 Mobility in soil** No further relevant information available.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
· **12.7 Other adverse effects**
· **Remark:** Harmful to fish
· **Additional ecological information:**
· **General notes:**
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.
Harmful to aquatic organisms

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SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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

SECTION 14: Transport information

· **14.1 UN number or ID number**	
· **ADR, ADN, IMDG, IATA**	not regulated
· **14.2 UN proper shipping name**	
· **ADR, ADN, IMDG, IATA**	not regulated

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· **14.3 Transport hazard class(es)**	
· **ADR, ADN, IMDG, IATA**	
· **Class**	not regulated
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	not regulated
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	No
· **14.6 Special precautions for user**	Not applicable.
· **14.7 Maritime transport in bulk according to IMO instruments**	Not applicable.
· **UN "Model Regulation":**	not regulated

SECTION 15: Regulatory information

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

· **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.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H331 Toxic if inhaled.
H335 May cause respiratory irritation.
H351 Suspected of causing cancer.
H361f Suspected of damaging fertility.
H373 May cause damage to organs through prolonged or repeated exposure.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.
H413 May cause long lasting harmful effects to aquatic life.
EUH066 Repeated exposure may cause skin dryness or cracking.
· **Classification according to Regulation (EC) No 1272/2008** Calculation method

· **Department issuing SDS:** Regulatory affairs
· **Contact:** msds@gc.dental
· **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
DNEL: Derived No-Effect Level (UK REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity – Category 4
Acute Tox. 2: Acute toxicity – Category 2
Acute Tox. 3: Acute toxicity – Category 3
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1B: Skin sensitisation – Category 1B
Carc. 2: Carcinogenicity – Category 2
Repr. 2: Reproductive toxicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

· ***Sources***
• ECHA (http://echa.europa.eu/)
• EnviChem (www.echemportal.org)

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

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