

**Safety data sheet**  
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024



Version number 3 (replaces version 2)

Revision: 16.08.2024

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

- **1.1 Product identifier**
- **Trade name: GRADIA DIRECT Anterior**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Auxillary for dental technology
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
GC EUROPE N.V.  
Interleuvenlaan 33  
B-3001 Leuven  
Tel. +32/(0)16/74.10.00  
Fax +32/(0)16/40.26.84  
msds@gc.dental
- **Further information obtainable from:** Regulatory affairs
- **1.4 Emergency telephone number:** International: +01-813-248-0585 (ChemTel Inc.)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Skin Sens. 1 H317 May cause an allergic skin reaction.  
Aquatic Chronic 2 H411 Toxic 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 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**  
  
GHS07 GHS09
- **Signal word** Warning
- **Hazard-determining components of labelling:**  
Urethane Dimethacrylate (UDMA)  
1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde
- **Hazard statements**  
H317 May cause an allergic skin reaction.  
H411 Toxic to aquatic life with long lasting effects.
- **Precautionary statements**  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P272 Contaminated work clothing should not be allowed out of the workplace.

(Contd. on page 2)

**Safety data sheet**  
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

**Trade name: GRADIA\_DIRECT\_Anterior**

(Contd. of page 1)

- P273 Avoid release to the environment.  
 P280 Wear protective gloves.  
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Additional information:**  
 28 % of the mixture consists of component(s) of unknown toxicity.  
 Contains 28 % 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 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	Urethane Dimethacrylate (UDMA) Aquatic Chronic 2, H411; Skin Sens. 1B, H317	25-<50%
1985-51-9	2,2-dimethyl-1,3-propanediyl bismethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319	5-<10%
3290-92-4	Propylidynetrimehyl trimethacrylate Aquatic Chronic 2, H411	5-<10%
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%
13463-67-7	titanium dioxide Carc. 2, H351	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:**

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.

(Contd. on page 3)

**Safety data sheet**  
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: **GRADIA\_DIRECT\_Anterior**

(Contd. of page 2)

- **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:** CO<sub>2</sub>, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents:** Water
- **5.2 Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.  
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**  
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Remove persons from danger area.  
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:** Protect against electrostatic charges.
- **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.

(Contd. on page 4)

**Safety data sheet**  
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: **GRADIA\_DIRECT\_Anterior**

(Contd. of page 3)

· 7.3 **Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**· **Ingredients with limit values that require monitoring at the workplace:**

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 <sup>3</sup> (man)
------------	-----------------	----------------------------

· **PNECs****3290-92-4 Propylidynetrimethyl trimethacrylate**

PNEC Aqua	2.76 µg/L (freshwater) 20 µg/L (intermittent releases) 0.276 µg/L (marine water)
PNEC STP	10 mg/L (Sewage Treatment Plants)
PNEC Sediment	0.4951 mg/kg sed dw (freshwater) 0.04951 mg/kg sed dw (marine water)
PNEC Air	mg/L (air)
PNEC Soil	0.0974 mg/kg soil dw (soil)
PNEC Predator	mg/kg (Predator)

· **Additional information:** The lists valid during the making were used as basis.· **8.2 Exposure controls**· **Appropriate engineering controls** No further data; see section 7.· **Individual protection measures, such as personal protective equipment**· **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

· **Respiratory protection:** Suitable respiratory protective device recommended.· **Hand protection**

Protective gloves

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 5)

**Safety data sheet**  
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: GRADIA\_DIRECT\_Anterior

(Contd. of page 4)

· 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:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	Undetermined.
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
· 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:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.
· Particle characteristics	SiO <sub>2</sub> : Diameter particle structure = 2.5 - 50 nm (TEM, d <sub>50</sub> , number-based) Diameter agglomerate = 5 - 50 μm (laser diffraction dry module, d <sub>50</sub> , volume based)

#### · 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.

(Contd. on page 6)

**Safety data sheet**  
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: GRADIA\_DIRECT\_Anterior

(Contd. of page 5)

- **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
- **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)
------	------	--------------------------------------

**13463-67-7 titanium dioxide**

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

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

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **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.

(Contd. on page 7)

**Safety data sheet**  
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: **GRADIA\_DIRECT\_Anterior**

(Contd. of page 6)

- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
No further relevant information available.
- **11.2 Information on other hazards**

· <b>Endocrine disrupting properties</b>	
128-37-0	Butylated hydroxytoluene
List II	

## SECTION 12: Ecological information

### · 12.1 Toxicity

#### · **Aquatic toxicity:**

<b>72869-86-4 Urethane Dimethacrylate (UDMA)</b>	
EC50/48h (static)	>1.2 mg/l (daphnia magna) (OECD 202)
<b>3290-92-4 Propylidynetrimethyl trimethacrylate</b>	
LC50/96h (dynamic)	>1 mg/L (Oncorhynchus mykiss) (OECD Guideline 203 (Fish, Acute Toxicity Test))

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

## SECTION 13: Disposal considerations

### · 13.1 Waste treatment methods

#### · **Recommendation**

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

#### · **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

(Contd. on page 8)

**Safety data sheet**  
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: GRADIA\_DIRECT\_Anterior

(Contd. of page 7)

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

**SECTION 14: Transport information**

· **14.1 UN number or ID number**

· **ADR, IMDG, IATA**

UN3082

· **14.2 UN proper shipping name**

· **ADR**

3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA), Propylidynetrimethyl trimethacrylate)

· **IMDG**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA), Propylidynetrimethyl trimethacrylate), MARINE POLLUTANT

· **IATA**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA), Propylidynetrimethyl trimethacrylate)

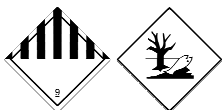
· **14.3 Transport hazard class(es)**

· **ADR**· **Class**

9 (M6) Miscellaneous dangerous substances and articles.

· **Label**

9

· **IMDG, IATA**· **Class**

9 Miscellaneous dangerous substances and articles.

· **Label**

9

· **14.4 Packing group**

· **ADR, IMDG, IATA**

III

· **14.5 Environmental hazards:**

· **Marine pollutant:**

No

Symbol (fish and tree)

· **Special marking (ADR):**

Symbol (fish and tree)

· **Special marking (IATA):**

Symbol (fish and tree)

· **14.6 Special precautions for user**

Warning: Miscellaneous dangerous substances and articles.

· **Hazard identification number (Kemler code):**

90

· **EMS Number:**

F-A,S-F

· **Stowage Category**

A

(Contd. on page 9)



**Safety data sheet**  
according to Regulation (EC) No 1907/2006, Article 31

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: GRADIA\_DIRECT\_Anterior

(Contd. of page 8)

· <b>14.7 Maritime transport in bulk according to IMO instruments</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b>	
· <b>Limited quantities (LQ)</b>	5L
· <b>Excepted quantities (EQ)</b>	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· <b>Transport category</b>	3
· <b>Tunnel restriction code</b>	(-)
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	5L
· <b>Excepted quantities (EQ)</b>	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· <b>UN "Model Regulation":</b>	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (URETHANE DIMETHACRYLATE (UDMA), PROPYLIDYNETRIMETHYL TRIMETHACRYLATE), 9, III

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category E2** Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

(Contd. on page 10)

**Safety data sheet**  
**according to Regulation (EC) No 1907/2006, Article 31**

Printing date 16.08.2024

Version number 3 (replaces version 2)

Revision: 16.08.2024

Trade name: **GRADIA\_DIRECT\_Anterior**

(Contd. of page 9)

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

### SECTION 16: Other information

- **Relevant phrases**

H315 Causes skin irritation.  
 H317 May cause an allergic skin reaction.  
 H318 Causes serious eye damage.  
 H319 Causes serious eye irritation.  
 H335 May cause respiratory irritation.  
 H351 Suspected of causing cancer.  
 H411 Toxic to aquatic life with long lasting effects.

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

- **Department issuing SDS:** Regulatory affairs

- **Contact:** msds@gc.dental

- **Date of previous version:** 16.08.2024

- **Version number of previous version:** 2

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

VOC: Volatile Organic Compounds (USA, EU)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

- **Sources**

- ECHA (<http://echa.europa.eu/>)

- EnviChem ([www.echemportal.org](http://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.*