

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

Printing date 24.08.2023

Version number 5 (replaces version 4)

Revision: 24.08.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:****GRADIA DIAPOLISHER**

Nanoform

1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

· **Application of the substance / the mixture** Auxiliary for dental technology**1.3 Details of the supplier of the safety data sheet****Manufacturer/Supplier:**

GC EUROPE N.V.

Interleuvenlaan 33

B-3001 Leuven

Tel. +32/(0)16/74.10.00

Fax +32/(0)16/40.26.84

msds@gc.dental

· **Information department:** 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**

Aquatic Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 1 H410 Very 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 labeled 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

GHS09

Signal word Warning**Hazard statements**

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.

P391 Collect spillage.

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

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 24.08.2023

Version number 5 (replaces version 4)

Revision: 24.08.2023

Trade name: GRADIA_DIAPOLISHER

(Contd. of page 1)

- **Additional information:**
20 % of the mixture consists of component(s) of unknown toxicity.
Contains 20 % 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:**

1314-13-2	zinc oxide	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	25-<50%
7631-86-9	silicon dioxide		10-<25%

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

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** If symptoms persist consult doctor.
- **After inhalation:**
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
Take affected persons into fresh air and keep quiet.
- **After skin contact:** If skin irritation continues, consult a doctor.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **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, 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.
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

(Contd. on page 3)

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

Printing date 24.08.2023

Version number 5 (replaces version 4)

Revision: 24.08.2023

Trade name: **GRADIA_DIAPOLISHER**

(Contd. of page 2)

· **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 formation of dust.

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:**

Pick up mechanically.

Prevent formation of dust.

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**

Prevent formation of dust.

Any deposit of dust which cannot be avoided must be regularly removed.

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

Dust can combine with air to form an explosive mixture.

· **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

· **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**

· **Additional information about design of technical systems:** *No further data; see section 7.*

· **Personal protective equipment:**· **General protective and hygienic measures:**

The usual precautionary measures for handling chemicals should be followed.

(Contd. on page 4)

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

Printing date 24.08.2023

Version number 5 (replaces version 4)

Revision: 24.08.2023

Trade name: GRADIA_DIAPOLISHER

(Contd. of page 3)

*Do not inhale dust / smoke / mist.**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

· **Physical state**

Solid

· **Color:**

White

· **Odor:**

Odorless

· **Odor threshold:**

Not determined.

· **Melting point/Melting range:**

Undetermined.

· **Boiling point/Boiling range:**

Undetermined.

· **Flammability (solid, gaseous):**

Not determined.

· **Explosion limits:**· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

Not applicable.

· **Auto igniting:**

Undetermined.

· **Decomposition temperature:**

Not determined.

· **pH-value:**

Not applicable.

· **Viscosity:**· **Kinematic:**

Not applicable.

· **Dynamic:**

Not applicable.

· **Solubility in / Miscibility with**· **Water:**

Insoluble.

· **Partition coefficient (n-octanol/water):**

Not determined.

· **Vapor pressure:**

Not applicable.

· **Density and/or relative density**· **Density:**

Not determined.

· **Relative density**

Not determined.

· **Vapor density**

Not applicable.

· **Particle characteristics**SiO₂: Diameter particle structure = 2.5 - 50 nm (TEM, d₅₀, number-based)Diameter agglomerate = 5 - 50 nm (laser diffraction dry module, d₅₀, volume based)

7631-86-9 silicon dioxide: Spheroidal, amorphous nanoform, set including amorphous nanoforms, amorphous forms, non-surface-treated nanoforms

(Contd. on page 5)

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

Printing date 24.08.2023

Version number 5 (replaces version 4)

Revision: 24.08.2023

Trade name: GRADIA_DIAPOLISHER

(Contd. of page 4)

- **9.2 Other information**
 - **Appearance:**
 - **Form:** Solid
 - **Important information on protection of health and environment, and on safety.**
 - **Ignition temperature:** Product is not selfigniting.
 - **Danger of explosion:** Product does not present an explosion hazard.
 - **Change in condition**
 - **Evaporation rate** Not applicable.
-
- **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 toxicological effects**
- **Acute toxicity:** Based on available data, the classification criteria are not met.

· **LD/LC50 values that are relevant for classification:**

7631-86-9 silicon dioxide

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

- **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.

(Contd. on page 6)

EU

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 24.08.2023

Version number 5 (replaces version 4)

Revision: 24.08.2023

Trade name: **GRADIA_DIAPOLISHER**

(Contd. of page 5)

- **Sensitization:** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **Specific target organ toxicity - single exposure** Based on available data, the classification criteria are not met.
- **Specific target organ toxicity - repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**

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

None of the ingredients is listed.

- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Remark:** Very toxic for fish
- **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.
Also poisonous for fish and plankton in water bodies.
Very toxic for aquatic organisms

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

(Contd. on page 7)

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

Printing date 24.08.2023

Version number 5 (replaces version 4)

Revision: 24.08.2023

Trade name: GRADIA_DIAPOLISHER

(Contd. of page 6)

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**

UN3077

- **14.2 UN proper shipping name**
- **DOT**
- **ADR**

not regulated

3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)

- **IMDG**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), MARINE POLLUTANT

- **IATA**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)

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

- **ADR**



- **Class**
- **Label**

9 (M7) Miscellaneous dangerous substances and articles

9

- **IMDG, IATA**



- **Class**
- **Label**

9 Miscellaneous dangerous substances and articles

9

- **14.4 Packing group**
- **ADR, IMDG, IATA**

III

- **14.5 Environmental hazards:**

- **Marine pollutant:**

Yes

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

- **Stowage Code**

SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.

(Contd. on page 8)

EU

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

Printing date 24.08.2023

Version number 5 (replaces version 4)

Revision: 24.08.2023

Trade name: GRADIA_DIAPOLISHER

(Contd. of page 7)

· **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)**

5 kg

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 g

Maximum net quantity per outer packaging: 1000 g

· **Transport category**

3

· **Tunnel restriction code**

(-)

· **IMDG**

· **Limited quantities (LQ)**

5 kg

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 g

Maximum net quantity per outer packaging: 1000 g

· **UN "Model Regulation":**

UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ZINC OXIDE), 9, III

SECTION 15: Regulatory information

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

· **Sara**

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

None of the ingredient is listed.

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

1314-13-2 | zinc oxide

· **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)**

1314-13-2 | zinc oxide

D, I, II

· **TLV (Threshold Limit Value)**

14807-96-6 | talc

A4

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

14807-96-6 | talc

3B

(Contd. on page 9)

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

Printing date 24.08.2023

Version number 5 (replaces version 4)

Revision: 24.08.2023

Trade name: GRADIA_DIAPOLISHER

(Contd. of page 8)

· **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 E1** Hazardous to the Aquatic Environment

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 100 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t

· **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.

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

SECTION 16: Other information

· **Relevant phrases**

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@gc.dental

· **Date of previous version** 24.08.2023

· **Version number of previous version:** 4

· **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

DOT: US Department of Transportation

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)

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

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

(Contd. on page 10)

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

Printing date 24.08.2023

Version number 5 (replaces version 4)

Revision: 24.08.2023

Trade name: GRADIA_DIAPOLISHER

(Contd. of page 9)

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.