

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

Printing date 23.01.2024

Version number 3 (replaces version 2)

Revision: 23.01.2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:****GC Ortho Etching Gel**

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 Orthodontics Europe GmbH
Straße/Postfach :Harkortstraße 2
Nat.-PLZ/Ort :D-58339 Breckerfeld
Deutschland / Germany
++49-2338/8010

· **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**

Skin Corr. 1B H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.

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

GHS05

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

phosphoric acid

Hazard statements

H314 Causes severe skin burns and eye damage.

Precautionary statements

P260 Do not breathe dusts or mists.

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- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- 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.
- P310 Immediately call a poison center/doctor.
- P321 Specific treatment (see on this label).
- 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

- **3.2 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:**

7664-38-2	phosphoric acid Skin Corr. 1B, H314 Specific concentration limits: Skin Corr. 1B; H314: $C \geq 25 \%$ Skin Irrit. 2; H315: $10 \% \leq C < 25 \%$ Eye Irrit. 2; H319: $10 \% \leq C < 25 \%$	25-<50%
7631-86-9	silicon dioxide	5-<10%
1344-28-1	aluminium oxide	2.5-<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** 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.
- **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:**
Use neutralizing agent.
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:** Keep receptacle tightly sealed.
- 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:**

7664-38-2 phosphoric acid

IOELV	Short-term value: 2 mg/m ³
	Long-term value: 1 mg/m ³

- **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.

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

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state

Fluid

· Color:

Blue

· Odor:

Odorless

· Odor threshold:

Not determined.

· Melting point/Melting range:

Undetermined.

· Boiling point/Boiling range:

100 °C

· Flammability (solid, gaseous):

Not applicable.

· Explosion limits:

· Lower:

Not determined.

· Upper:

Not determined.

· Flash point:

Not applicable.

· Auto igniting:

Undetermined.

· Decomposition temperature:

Not determined.

· pH-value at 20 °C:

<1.6

· Viscosity:

· Kinematic:

Not determined.

· Dynamic:

Not determined.

· Solubility in / Miscibility with

· Water:

Fully miscible.

· Partition coefficient (n-octanol/water):

Not determined.

· Vapor pressure:

Not determined.

· Density and/or relative density

· Density at 20 °C:

1.33 g/cm³

· Relative density

Not determined.

· Vapor density

Not determined.

· Particle characteristics

SiO₂: Diameter particle structure = 2.5 - 50 nm (TEM, d₅₀, number-based)Diameter agglomerate = 5 - 50 μm (laser diffraction dry module, d₅₀, volume based)Al₂O₃: Diameter particle structure = 2 - 100 nm (d₅₀, number-based)

7631-86-9 silicon dioxide:

set including amorphous nanoforms

non-surface-treated nanoforms

Shape: Spheroidal

Structure: amorphous forms

Crystallinity: amorphous nanoform

1344-28-1 aluminium oxide:

non-surface-treated nanoforms

Shape: Spheroidal

Structure: crystalline forms

Crystallinity: crystalline nanoform

· 9.2 Other information

· Appearance:

· Form:

Highly viscous

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|--|---|
| · 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. |
| · Solvent content: | |
| · Water: | 54.7 % |
| · 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 |
| · 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:** Causes severe skin burns and eye damage.
- **on the eye:** Causes serious eye damage.
- **Sensitization:** Based on available data, the classification criteria are not met.

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- **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)
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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
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None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Must not reach bodies of water or drainage ditch undiluted or unneutralized.
Danger to drinking water if even small quantities leak into the ground.
Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

SECTION 13: Disposal considerations

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

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· **Recommended cleansing agent:** Water, if necessary with cleansing agents.**SECTION 14: Transport information**· **14.1 UN-Number**· **ADR, IMDG, IATA**

UN1805

· **14.2 UN proper shipping name**· **DOT**· **ADR**· **IMDG, IATA**

Phosphoric acid solution

1805 PHOSPHORIC ACID, SOLUTION

PHOSPHORIC ACID, SOLUTION

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

8 (C1) Corrosive substances

· **Label**

8

· **IMDG, IATA**· **Class**

8 Corrosive substances

· **Label**

8

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

III

· **14.5 Environmental hazards:**· **Marine pollutant:**

No

· **14.6 Special precautions for user**

Warning: Corrosive substances

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

80

· **EMS Number:**

F-A,S-B

· **Segregation groups**

(SGG1) Acids

· **Stowage Category**

A

· **Segregation Code**

SG36 Stow "separated from" SGG18-alkalis.

SG49 Stow "separated from" SGG6-cyanides

· **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)**

5L

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

· **Transport category**

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· Tunnel restriction code	E
· IMDG	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· UN "Model Regulation":	UN 1805 PHOSPHORIC ACID, SOLUTION, 8, 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):**

7664-38-2 phosphoric acid

1344-28-1 aluminium oxide

1345-16-0 Cobalt aluminate blue spinel

· **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)**

1344-28-1 aluminium oxide

A4

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

1344-28-1 aluminium oxide

2

· **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.· **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.

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· **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**

H314 Causes severe skin burns and eye damage.

· **Classification according to Regulation (EC) No 1272/2008 Calculation method**· **Department issuing SDS:** Regulatory affairs· **Contact:** msds@gc.dental· **Date of previous version** 22.01.2024· **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

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)

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

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

· **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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