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

· **1.1 Product identifier**

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

· **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**
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 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

· **Signal word** Danger

· **Hazard-determining components of labelling:**
phosphoric acid

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· **Hazard statements**
H314 Causes severe skin burns and eye damage.
· **Precautionary statements**
P260 Do not breathe dusts or mists.
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 [or 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 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: 7664-38-2 EINECS: 231-633-2 Index number: 015-011-00-6	phosphoric acid Skin Corr. 1B, H314 Specific concentration limits: Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 10 % ≤ C < 25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 % substance with a Community workplace exposure limit	25-<50%
CAS: 7631-86-9 EINECS: 231-545-4	silicon dioxide Nanoform: set including amorphous nanoforms non-surface-treated nanoforms Shape: Spheroidal Structure: amorphous forms Crystallinity: amorphous nanoform	5-<10%
CAS: 1344-28-1 EINECS: 215-691-6	aluminium oxide Nanoform: non-surface-treated nanoforms Shape: Spheroidal Structure: crystalline forms Crystallinity: crystalline nanoform	2.5-<5%

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

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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.
· ***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, 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.

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· **6.3 Methods and material for containment and cleaning up:**
Use neutralising agent.
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.

· **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 container tightly sealed.
· **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:**	
7664-38-2 phosphoric acid	
WEL	Short-term value: 2 mg/m³ Long-term value: 1 mg/m³

· **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.

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· ***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:***	*Blue*
· ***Odour:***	*Odourless*
· ***Odour threshold:***	*Not determined.*
· ***Melting point/freezing point:***	*Undetermined.*
· ***Boiling point or initial boiling point and boiling range***	*100 °C*
· ***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 at 20 °C***	*<1.6*
· ***Viscosity:***	
· ***Kinematic viscosity***	*Not determined.*
· ***Dynamic:***	*Not determined.*
· ***Solubility***	
· ***water:***	*Fully miscible.*
· ***Partition coefficient n-octanol/water (log value)***	*Not determined.*
· ***Vapour pressure:***	*Not determined.*
· ***Density and/or relative density***	
· ***Density at 20 °C:***	*1.33 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)* *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*
· ***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:***	
· ***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*

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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:**		
7631-86-9 silicon dioxide		
Oral	LD50	10,000 mg/kg (rat (f+m))

· **Skin corrosion/irritation** Causes severe skin burns and eye damage.
· **Serious eye damage/irritation** Causes serious eye damage.
· **Additional toxicological information:**
· **Repeated dose toxicity** No further relevant information available.
· **CMR effects (carcinogenity, 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**
· **Additional ecological information:**
· **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Must not reach sewage water or drainage ditch undiluted or unneutralised.

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

· ***Uncleaned packaging:***
· ***Recommendation:*** *Disposal must be made according to official regulations.*
· ***Recommended cleansing agents:*** *Water, if necessary together with cleansing agents.*

SECTION 14: Transport information

· ***14.1 UN number or ID number***	
· ***ADR, IMDG, IATA***	*UN1805*
· ***14.2 UN proper shipping name***	
· ***ADR***	*1805 PHOSPHORIC ACID, SOLUTION*
· ***IMDG, IATA***	*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*

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· **Stowage Category**	A
· **Segregation Code**	SG36 Stow "separated from" SGG18-alkalis. SG49 Stow "separated from" SGG6-cyanides
· **14.7 Maritime transport in bulk according to IMO instruments**	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**	3
· **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**
· **Poisons Act**

· **Regulated explosives precursors**

7664-38-2	phosphoric acid	30%

· **Regulated poisons**
None of the ingredients is listed.

· **Reportable explosives precursors**
None of the ingredients is listed.

· **Reportable poisons**
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**
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

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· **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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
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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