



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

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

- **1.1 Product identifier**
 - **Trade name: Gluma Etch 35 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** Dental bonding material
- **1.3 Details of the supplier of the safety data sheet**
 - **Manufacturer/Supplier:**
Kulzer GmbH
Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522
 - **Informing department:** E-Mail: msds@kulzer-dental.com
- **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

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 CLP regulation.

 - **Hazard pictograms**



GHS05

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

orthophosphoric acid
- **Hazard statements**

H314 Causes severe skin burns and eye damage.
- **Precautionary statements**

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P303+P361+P353 IF ON SKIN (or hair): Remove/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.
- **2.3 Other hazards -**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.

(Contd. on page 2)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Gluma Etch 35 Gel

· **vPvB:** Not applicable.

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** -

· **Dangerous components:**

CAS: 7664-38-2	orthophosphoric acid	Skin Corr. 1B, H314	25-50%
EINECS: 231-633-2			

· **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** Instantly remove any clothing soiled by the product.

· **After skin contact** Instantly wash with water and soap and rinse thoroughly.

· **After eye contact** Rinse opened eye for several minutes under running water. Then consult doctor.

· **After swallowing**

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms 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 jet. Fight larger fires with water jet or alcohol-resistant foam.

· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

· **5.3 Advice for firefighters**

· **Protective equipment:** No special measures required.

· **Additional information** -

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep unprotected persons away.

· **6.2 Environmental precautions:** Dilute with much water.

· **6.3 Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

Use neutralising agent.

Dispose of contaminated material as waste according to item 13.

Send for recovery or disposal in suitable containers.

· **6.4 Reference to other sections**

See Section 13 for information on disposal.

(Contd. on page 3)

GB



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Gluma Etch 35 Gel

See Section 8 for information on personal protection equipment.

(Contd. of page 2)

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Keep containers tightly sealed.
 - **Information about protection against explosions and fires:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and containers:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **8.1 Control parameters**
 - **Components with critical values that require monitoring at the workplace:**

7664-38-2 orthophosphoric acid	
WEL	Short-term value: 2 mg/m ³ Long-term value: 1 mg/m ³

 - **Additional information:** The lists that were valid during the compilation were used as basis.

- **8.2 Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures**

Keep away from foodstuffs, beverages and food.
Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.
Avoid contact with the eyes and skin.
 - **Breathing equipment:** Not required.
 - **Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
Check protective gloves prior to each use for their proper condition.
recommended

 - **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 4)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Gluma Etch 35 Gel

(Contd. of page 3)

- **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**
 - Butyl rubber, BR
 - Nitrile rubber, NBR
- **Eye protection:** Safety glasses
- **Body protection:** Light weight protective clothing

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

- **Form:** Pasty
- **Colour:** Blue
- **Smell:** Odourless
- **Odour threshold:** Not determined.

· **pH-value at 20 °C:** 0.3

· **Change in condition**

- **Melting point/Melting range:** Not determined
- **Boiling point/Boiling range:** > 100 °C

· **Flash point:** Not applicable

· **Inflammability (solid, gaseous)** Not applicable.

· **Ignition temperature:**

- **Decomposition temperature:** Not determined.

· **Self-inflammability:** Product is not selfigniting.

· **Danger of explosion:** Product is not explosive.

· **Critical values for explosion:**

- **Lower:** Not determined.
- **Upper:** Not determined.

· **Steam pressure at 20 °C:** 23 hPa

· **Density at 20 °C** 1.2 g/cm³

- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**

- **Water:** Fully miscible

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

- **dynamic:** Not determined.
- **kinematic:** Not determined.

(Contd. on page 5)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Gluma Etch 35 Gel

(Contd. of page 4)

- **Solvent content:**
 - **Water:** 53.1 %
 - **VOC USA** 0.0 g/l / 0.00 lb/gl
- **Solids content:** 11.7 %
- **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
 - **Conditions to be avoided:** No decomposition if used and stored 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:** None

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:**

7664-38-2 orthophosphoric acid

Oral	LD50	1530 mg/kg (rat)
Dermal	LD50	2740 mg/kg (can)
Inhalative	LC50/4 h	>850 mg/l (rat)

7631-86-9 silicon dioxide, chemically prepared

Oral	LD50	> 5000 mg/kg (rat)
Dermal	LD50	> 5000 mg/kg (rabbit)

- **Primary irritant effect:**
 - **Skin corrosion/irritation** Causes severe skin burns and eye damage.
 - **Serious eye damage/irritation** Causes serious eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - **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.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

GB

(Contd. on page 6)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Gluma Etch 35 Gel

(Contd. of page 5)

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.
 - **Additional ecological information:**
 - **General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
Must not reach sewage water or drainage ditch undiluted or unneutralised.
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.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

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 01 06*	chemicals consisting of or containing hazardous substances
-----------	--
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.
 - **Recommended cleaning agent:** Water, if necessary with cleaning agent.

SECTION 14: Transport information

- **14.1 UN-Number**
 - **ADR, IMDG, IATA** UN1805
- **14.2 UN proper shipping name**
 - **ADR** 1805 PHOSPHORIC ACID, SOLUTION
 - **IMDG** PHOSPHORIC ACID, SOLUTION
 - **IATA** Phosphoric acid solution

(Contd. on page 7)

GB



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Gluma Etch 35 Gel

(Contd. of page 6)

· 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.

· Kemler Number: 80
· EMS Number: F-A,S-B
· Segregation groups Acids
· Stowage Category A

· 14.7 Transport in bulk according to Annex II of Marpol 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 3
· Tunnel restriction code E

· IMDG

· Limited quantities (LQ) 5L

(Contd. on page 8)



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: Gluma Etch 35 Gel

(Contd. of page 7)

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

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H314 Causes severe skin burns and eye damage.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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

· *** Data compared to the previous version altered.**