

Safety Data Sheet (SDS)

according to Regulation (EC) No 1907/2006, article 31*

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: **Pluraetch**

Product type: Etching gel

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

Use of the substance or mixture: Etching gel with 37% phosphoric acid for conditioning of enamel and dentine as part of the adhesive filling therapy.

Uses advised against: Restricted to professional users.

1.3* Details of the supplier of the safety data sheet

Company name: Pluradent AG & Co KG
Street/Mailbox: Kaiserleistr. 3
Place: D-63067 Offenbach a.M.
Contact for technical information: Pluradent Vertrieb
Phone / Telefax / E-Mail: +49 (0) 69-82983-0 / +49 (0) 69-82983-271 / regulatory.affairs@pluradent.de

1.4* Emergency telephone number

Germany: Giftnotruf Mainz - 24 Hour Service - Tel.: +49 (0) 6131/19240

2. * Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:



Skin Corr. 1A - H314 Causes severe skin burns and eye damage.
Eye Dam. 1 - H318 Causes serious eye damage.

Classification according to Directive 67/548/EEC or 1999/45/EC:



C - Corrosive

R34 Causes burns.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008:

The product is classified and labelled according to the CLP regulation.

Hazard-determining components of labelling:

- phosphoric acid

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Hazard pictograms:



GHS05

Signal word : Danger

Hazard statements

H314 Causes severe skin burns and eye damage.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P303+PP361+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.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

Additional information:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

2.3 Other hazards

Results of PBT and vPvB assessment:

PBT: Not applicable.
vPvB: Not applicable.

3. Composition/information on ingredients

3.2 Mixtures

Description: Mixture of substances listed below with non-hazardous additions.

Dangerous components:

Chemical Name	Index-No. CAS-No. EC-No. Registr. No.	Classification according (67/548/EEC)	Classification according to Regulation EC No. 1272/2008)	Concen- tration (%)
phosphoric acid	CAS-Nr.: 7664-38-2 EINECS : 231-633-2	C – R34	Skin Corr.1B – H314	25 - 50 %

Additional information: For the wording of the listed risk phrases refer to section 16.

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4. First aid measures



4.1 Description of first aid measures

General information

Immediately remove any clothing soiled by the product.

After inhalation

Supply fresh air; consult doctor in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

After skin contact

Immediately rinse with water.

If skin irritation continues, consult a doctor.

After eye contact

Rinse opened eye for several minutes under running water. Call a doctor immediately.

After swallowing

Rinse out mouth and then drink plenty of water.

Do not induce vomiting; call for medical help immediately.

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.

5. Firefighting measures

5.1 Extinguishing media

The product is not flammable.

Use fire extinguishing methods suitable to surrounding conditions.

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

5.3 Advice for firefighters

Protective equipment: No special measures required.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions

Do not allow product to reach ground water, water course or sewage system.

6.3 Methods and material for containment and cleaning up

Dilute with plenty water.

Use neutralising agent.

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

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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.

7. Handling and storage

7.1 Precautions for safe handling

No special precautions are necessary if used correctly.

Information about fire- and explosion-protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage: -

Requirements for storage rooms and vessels: Store only in the original receptacle.

Advice on storage compatibility: Not required.

Further information about storage conditions:

Protect from heat and direct sunlight.
Keep container tightly sealed.

7.3 Specific end use(s)

No further relevant information available.

8. Exposure controls/personal protection

8.1 Control parameters

8.1.1 Ingredients with limit values that require monitoring at the workplace:

7664-38-2 phosphoric acid	
AGW (Germany)	Long-term value: 2 E mg/m ³ 2(l);DFG, EU, AGS, Y
MAK (Austria)	Short-term value: 2 mg/m ³ Long-term value: 1 mg/m ³
MAK (Schweizerland)	Short-term value: 2 mg/m ³ Long-term value: 1 mg/m ³ SSc;
WEL	Short-term value: 2 mg/m ³ Long-term value: 1 mg/m ³

Additional information: The lists that were valid during the making were used as basis.

8.1.2. DNEL/PNEC-values

No further relevant information available.

8.1.3. Control-Banding

No further relevant information available.

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8.2 Exposure controls

8.2.1 Appropriate engineering controls

No further relevant information available.

8.2.2 Individual protection measures - Personal protective equipment

General protective and hygienic measures:

Usual hygienic measures for dental practice.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.

Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Protection of hands



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
After each cleaning use treatment creams, for very dry skin greasy ointments.

Material of gloves

Butyl rubber, BR
Fluorocarbon rubber (Viton)
Nitrile rubber, NBR
Natural rubber, NR
Chloroprene rubber, CR

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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.

Not suitable are gloves made of the following materials:

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

Eye protection



Tightly sealed goggles

8.2.3 Environmental exposure controls:

General notes:

Do not allow product to reach ground water, water course or sewage system.

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9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: - Form : - Colour : Odour : Odour threshold :	Vicous Blue Odourless Not determined
pH-value at 20 °C :	0,9
Change in condition Melting point/ freezing point : Boiling point/Boiling range :	undetermined undetermined
Flash point : Flammability (solid, gaseous) : Evaporation rate : Auto-ignition temperature : Danger of explosion : Explosion limits - lower : - upper :	Not applicable Not applicable Not applicable Product is not self igniting. Product does not present an explosion hazard. Not determined Not determined
Vapour pressure at 20°C : Vapour density :	Not determined Not determined
Density at 20 °C :	1,3 g/cm ³
Relative density :	Not determined
Solubility in / Miscibility with water :	Soluble
Partition coefficient (n-octanol/water) :	Not determined
Viscosity dynamic : cinematic :	Not determined Not determined

9.2 Other information

No further relevant information available.

10. Stability and reactivity

10.1 Reactivity

No further relevant information available.

10.2 Chemical Stability

Stable under normal handling and storage conditions.

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

None under normal conditions of storage and use.

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11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD/LC₅₀ values relevant for classification:

7664-38-2 phosphoric acid

oral	LD ₅₀	1530 mg/kg (rat)
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Primary irritant effect:

On the skin: Caustic effect on skin and mucous membranes.

On the eye: Strong irritant with the danger of severe eye injury.

Sensitization: No sensitising effects known.

Germ cell mutagenicity
No further relevant information available.

Carcinogenicity
No further relevant information available.

Reproductive toxicity
No further relevant information available.

Specific target organ toxicity - single exposure
No further relevant information available.

Specific target organ toxicity - repeated exposure
No further relevant information available.

Severe effects after repeated or prolonged exposure
No further relevant information available.

Aspiration hazard
No further relevant information available.

Additional toxicological information
Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

12. Ecological information

12.1 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.

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12.4 Mobility in soil

No further relevant information available.

General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow product to reach ground water, water course or sewage system.

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.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

12.6 Other adverse effects

No further relevant information available.

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.

Contaminated packaging:

Recommendation:

Disposal must be made according to official regulations.

Waste codes / waste designations according to EWC / AVV:

European waste catalogue

18 01 06* chemicals consisting of or containing dangerous substances

Packaging:

Disposal must be made according to official regulations.

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14. Transport information

14.1 UN-Number

ADR, ADN, IMDG, IATA UN1805

14.2 UN proper shipping name

ADR/RID, AND 1805 PHOSPHORIC ACID, SOLUTION
IMDG, IATA PHOSPHORIC ACID, SOLUTION

14.3 Transport hazard class(es)

ADR:



Class
Label

8 (C1) Corrosive substances
8

IMDG, IATA:



Class
Label

8 Corrosive substances
8

14.4 Packing group

ADR/RID, ADN, IMDG, IATA III

14.5 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

14.6 Environmental hazards:

Marine Pollutant: yes / no

14.7 Special precautions for user

· Danger code (Kemler): 80
· EMS Number: F-A,S-B
· Segregation groups: Acids

Warning: Corrosive substances.

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14.8 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

14.9 UN "Model Regulation"

UN1805, PHOSPHORIC ACID, SOLUTION, 8, III

15. Regulatory information

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

EU regulations:

The product is a medical device and classified and labelled according to the Directive 93/42/EEC. See Chapter 2.

National regulations:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16. Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. The receiver of our product is solely responsible for adhering to existing laws and regulations.

Changes compared to the previous version

* Data changed compared to the previous version are marked with *.

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)
RID	Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IATA-DGR	Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical Instructions by the "International Civil Aviation Organization" (ICAO)
IMDG	International Maritime Code for Dangerous Goods
IATA	International Air Transport Association
GHS	Globally Harmonized 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)
GefStoffV	Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
LC ₅₀	Lethal concentration, 50 percent
LD ₅₀	Lethal dose, 50 percent
EC ₅₀	half maximal effective concentration
NOEC	No Observed Effect Concentration

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Skin Corr.	Skin corrosion/irritation
Skin Sens.	Skin sensitisation
Eye Dam.	Serious eye damage/eye irritation
Eye Irrit.	Serious eye damage/eye irritation
Repr.	Reproductive toxicity
STOT SE	Specific target organ toxicity - single exposure

Relevant phrases

H314 Causes severe skin burns and eye damage.

R34 Causes burns.

Further information

Department issuing MSDS: Regulatory Affairs

The information contained in this security data sheet is based on our best knowledge and conscience on topically available information about the correct use of the product under normal conditions. The user is solely responsible for any other usage of this product in connection with other processes / procedures which is not described in this data sheet. This document does not show any explicit or implicit guarantee with regard to product quality or suitability for a certain purpose.
