

According to Regulation (EC) No.1907/2006, Art.31

Printing date: 20.05.2015

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

Product details :

1.1. Trade name

ETCHING GEL

1.2. Application of the substance / the preparation Filler/ Extender

Dental product

1.3. Manufacturer/Supplier

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1.4. Information in case of emergency

Ospedale Niguarda di Milano-Centro antiveneni numero di emergenza +39 02 66101029

2. Hazards identification

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

Information concerning particular hazards for human and environment: The product has to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

Label elements

Labeling according to Regulation (EC) 1272/2008:

Hazard pictograms

Signal word :

Danger

Hazard statements

H314 Causes severe skin burns and eye damage

Precautionary statements

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P280 Wear protective gloves/protective clothing/eye protection/face protection

Labeling according to EU guidelines:

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.

Other hazards Results of PBT and vPvB assessment

PBT: not applicable

vPvB: not applicable

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3. Composition/information on ingredients

Chemical characterization:

Description: 37% phosphoric acid based on thixotropic gel

Hazardous components:

CAS 7664-38-2 Phosphoric acid GHS05, H314

4. First aid measures

General information: Seek medical advice, if symptoms occur, which can be caused by the product after skin contact: Wash with plenty of water. Immediately remove contaminated clothing.

after inhalation: Fresh air. Consult a doctor.

after eye contact: Rinse opened eye for several minutes under running water and consult a doctor

after swallowing: Make victim drink plenty of water. Avoid vomiting. . Do not attempt to neutralize.

Seek medical advice.

5. Fire-fighting measures

Extinguishing media:

Non combustible. In case of fire use extinguishing method and media suitable to surrounding fire.

Special hazards arising from the substance or mixture :

Fire may cause evolution of oxides of phosphorus. Suppress vapors with water spray.

Protective equipment :

Wear self-contained respiratory protective equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Avoid substance contact.. Do not inhale vapours/aerosols. Ensure adequate ventilation.

Environmental precautions:

Do not allow to enter drains/surface water/ ground-water.

Methods for cleaning up:

Absorb with liquid binding and neutralizing material. Forward for disposal. Clean up affected area.

Ensure adequate ventilation.

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

Handling:

This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

Precautions for safe handling: Observe normal care for working with chemicals

Information about fire and explosion protection: none

Storage: Store at a dry place. Store tightly closed. Storage temperature 15-25°C.

Requirements at storerooms and containers: Store only in the original containers

Further information on storage conditions: Store away from food stuffs. Avoid contact with alkalis, heavy-metal-containing components and combustibles

Specific end uses: No further relevant information available .

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8. Exposure controls and personal protection gear

Components with limits of values to be supervised at the workplace:

CAS-No.	name	art	Value	unit
[7664-38-2]	Phosphoric acid	TRGS 900 AGW type of exposure: inhalable fraction	2	mg/cm ³

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

Personal protective equipment:

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals. Keep away from foodstuffs and beverages. Avoid contact with eyes or skin

Hand protection : Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection: Safety glasses

Respiratory protection: Required, when aerosols are generated.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance

Form: thixotropic gel

Color: blue

Odor: odourless

Safety relevant basic data

Melting point/melting range: -1 °C

Boiling point/boiling range: > 100 °C

Flash point: n.a.

Autoignition temperature: No information available

Danger of explosion: none

Density: 1.33 g/cm³

Vapor pressure: Non volatile

pH: approx. 1

Solubility in/miscibility with:

Water: 95%

Content of solvents: none

Organic solvents: none

10. Thermal decomposition / conditions to be avoided

Thermal decomposition / conditions to be avoided

Conditions to avoid:

Bases, metallic oxides most metals and metal alloys: Formation of hydrogen. Incompatible with iron/iron-containing compounds, steel, aluminium and their compounds.

Hazardous decomposition products:

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Fire may cause evolution of oxides of phosphorus.

11.Toxicological information

Acute toxicity:

LD50 (oral) Rat: 1530 mg/kg

Primary irritation:

skin: Caustic effect on skin and mucous membranes

eye: Strong caustic effect. after inhalation: Irritation symptoms in the respiratory tract. after

ingestion: Strong caustic effect on mouth and throat.

Sensitization: not observed

Additional toxicological information: When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12.Ecological information

General information:

Anorganic substance. Does not cause biological oxygen deficit. Harmful effect on aquatic organisms. Harmful effect due to pH shift.

Water pollution class: WGK = 1 (slightly polluting substance).

13. Disposal considerations

Product:

Recommendation: Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

14. Transport information

Land transport ADR/RID and GGVS/GGVE (EU):

UN 1805 PHOSPHORIC ACID, SOLUTION, 8, III

Sea transport IMDG:

UN 1805 PHOSPHORIC ACID, SOLUTION, 8, III EmS: F-A S-B

Air transport ICAO-TI and IATA-DGR: UN 1805 PHOSPHORIC ACID, SOLUTION, 8, III

The transport regulations are cited according to international regulations and in the form applicable in EU. Possible national deviations in other countries are not considered.

15.Regulations

Classification according to EC-guidelines:

The product is a medical device according to EC-directive 93/42 EEC.

Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16.Other informations

Changes compared with the previous version: Adaptation according to 1907/2006/EG, Article 31

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.

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