

SECTION 1. Product identification/preparation/company undertaking

1.1. Product identifier:

Product no.: 82090, 82091

Product name: BISICO Etch

Trade number: 75280, 75282

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 etching gel

1.3. Details of the supplier of the safety data sheet:

BISICO Bielefelder Dentalsilicone GmbH & Co. KG

D-33611 Bielefeld Tel.: +49 521 8016800 Fax: +49 521 8016801 Email: info@Bisico.de

Johanneswerkstraße 3

responsible for the Safety Data Sheet: Sebastian Zimmermann

1.4. Emergency telephone number:

BISICO Bielefelder Dentalsilicone GmbH & Co. KG

Tel.: +49 521 8016800 (08:00-16:00 PM)

Fax: +49 521 8016801 S. Zimmermann

SECTION 2. <u>Hazards identification</u>

2.1 Classification of the substance or mixture:

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments:

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

2.1.2. 67/548/EEC and 1999/45/EC Directives and following amendments and adjustments: The product has to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

2.2 Label elements: Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and

subsequent amendments and supplements:

Hazard pictograms:



Signal words: 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.

2.3. Other hazards: Results of PBT and vPvB assessment

> PBT: not applicable vPvB: not applicable

SECTION 3. Composition/Information of Ingredients

3.1. Substances: 37% phosphoric acid based on thixotropic gel

3.2. Mixtures: **Hazardous components:**

> CAS 7664-38-2 Phosphoric acid GHS05, H314

SECTION 4. First-aid measures

4.1. Description of 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 vomitting.

Do not attempt to neutralize. Seek medical advice

4.2. Most important symptoms and effects, both

acute and delayed:

needed:

For symptoms and effects caused by the contained substances, see

chap. 11.

4.3. Indication of any immediate medical attention and special treatment

Information not available



SECTION 5. Fire fighting measures

5.1. Extinguishing media: Non combustible. In case of fire use extinguishing method and media

suitable to surrounding fire.

5.2. Special hazards arising from the substance or

mixture:

Fire may cause evolution of oxides of phosphorus. Suppress vapors

with water spray.

5.3. Advice for firefighters: Protective equipment: Wear self-contained respiratory protective

equipment

SECTION 6. <u>Accidental release measures</u>

6.1. Personal precautions, protective equipment and emergency procedures:

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

adequate ventilation.

6.2. Environmental

precautions:

6.3. Methods and material for containment and cleaning up:

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

Absorb with liquid binding and neutralizing material. Forward for diposal. Clean up affected area. Ensure adequate ventilation.

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:

This product should only be supplied or handled to dentists or dental

technicians or upon their instructions.

Observe normal care for working with chemicals.

7.2. Conditions for safe storage, including any incompatibilities:

Store at a dry place. Store tightly closed. Storage temperature 15-

25°C.

Information about fire and explosion protection: none

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

7.3. Specific end use(s): No further relevant information available



SECTION 8. Exposure controls/personal protection

8.1. Control parameters: 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 2 mg/cm²

type of exposure: inhalable fraction

Additional information: The lists valid during the making were used

as basis

8.2. Exposure controls: 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

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical

properties:

Appearance: thixotropic gel

Colour: blue Odour: odourless pH.: approx.. 1

Melting point / freezing point: -1 °C Initial boiling point/Boiling range: >100 °C

Flash point: n.a.

Ignition temperature: no information available

Danger of Explosion: none

Density: 1.33 g/cm³

Vapour pressure: non volatile

Solubility:

Solubility in Water: 95% Content of solvents: none Organic solvents: none

9.2. Other information: no information available



SECTION 10. Stability and reactivity

no information available 10.1. Reactivity:

10.2. Chemical stability: no information available

10.3. Possibility of

hazardous reactions:

10.4. 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.

10.5. Incompatible

materials:

Incompatible with iron/iron-containing compounds, steel, aluminium

and their compounds.

no information available

10.6. Hazardous

decomposition products:

Fire may cause evolution of oxides of phosphorus.

SECTION 11. Toxicological information

Acute toxicity: LD₅₀ (oral, rat) 1530 mg/kg 11.1. Information on

toxicological effects: **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.

SECTION 12. Ecological information

General information: Anorganic substance. Does not cause biological oxigen deficit. Harmful effect on aquatic organisms. Harmful effect due to pH shift.

12.1. Toxicity: Information not available.

12.2. Persistence and

degradability:

Information not available.

12.3. Bioaccumulative

potential:

Information not available.

Information not available. 12.4. Mobility in soil:

12.5. Results of PBT and

vPvB assessment:

PBT: not applicable

vPvB: not applicable

Classification of water endangerment: WGK=1 (slightly polluting 12.6. Other adverse effects:

substance).



SECTION 13. <u>Disposal consideration</u>

13.1. Waste treatment methods:

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

SECTION 14. Transport information

14.1 UN-Number ADR, ADN, IMDG, IATA: UN 1804

14.2 UN proper shipping name ADR, ADN, IMDG, IATA: Void

14.3 Transport hazard class(es) ADR, ADN, IMDG, IATA

Class:

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

UN 1805 PHOSPHORSÄURE, LÖSUNG, 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 Germany. Possible national deviations in other countries are not considered.

14.4 Packing group ADR, IMDG, IATA: Void

14.5 Environmental hazards Marine pollutant: No

14.6 Special precautions for user: Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

UN "Model Regulation": -



SECTION 15. Regulatory information

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

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

15.2. Chemical safety

assessment:

No chemical safety assessment has been processed for the mixture

and the substances it contains.

SECTION 16. Other information:

Changes compared with the

previous version:

Adaptation according to 1907/2006/EG, Article 31

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product. This document must not be regarded as a guarantee on any specific product property. The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses. Provide appointed staff with adequate training on how to use chemical products.

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