

EU Safety Data Sheet

PhosphaCEM PL / PhosphaCEM IC



Date of issue / Reference

10.07.2006 hot

Replaces version of

12.04.2005

Date of printing

10.07.2006 **Sheet No. 1261**

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Company

Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan
Principality of Liechtenstein

1 Commercial product name and supplier

- 1.1 Commercial product name / Designation **PhosphaCEM PL / PhosphaCEM IC**
- 1.2 Application / Use Zinc phosphate-based luting cement
- 1.3 Producer Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan
Fürstentum Liechtenstein
- 1.4 Supplier
- 1.5 TOX emergency number Emergency-Call: +423 / 235 35 35 or 373 40 40
Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein

2 Composition

- 2.1 Chemical characterization Powder and Liquid
Paste aus zinc oxide, magnesium oxide, aluminium hydroxide,
phosphoric acid and pigments
- 2.2 Hazardous components
CAS No. 7664-38-2 44-56 % Phosphoric acid, Solution in Water
C: Corrosive. R34: Causes burns.
- 2.3 Further information None.

3 Hazards identification

Liquid and uncured material: corrosive
Powder: dust formation

4 First aid measures

- 4.1 Eye contact Consult a physician or transport to emergency facility immediately.
- 4.2 Skin contact Wash thoroughly with soap and water.
- 4.3 Ingestion After ingestion call a physician immediately and show this safety data sheet. Do not induce vomiting. Give large amounts of water.
- 4.4 Inhalation Remove to fresh air. If respiratory irritation is experienced, call a physician.
- 4.5 Further information Remove contaminated clothing.

5 Fire-fighting measures

- 5.1 Suitable extinguishing media Non-combustible product.
- 5.2 Extinguishing media to avoid Not required since not combustible.

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5.3 Further information Cool containers in the vicinity of the blaze using a water spray.

6 Accidental release measures Clean up with absorbent material.
Prevent skin and eye contact.
Dispose of according to local and national regulations.
Clean area with large amounts of water.

7 Handling and storage

7.1 Handling Only adequately trained personnel should handle this product.
Use only in a well ventilated area.
This product is intended for use in dentistry only.

7.2 Industrial hygiene Usual hygienic measures for dental practice.
Practice care and caution to avoid skin and eye contact.
Keep out of reach of children.

7.3 Storage Cool storage of (2-8°C / 36-46 °F) is indicated for larger stock.
Store at 2-28 °C / 36-82 °F

7.4 Place of storage

7.5 Fire- and explosion-protection Keep away from heat source.
Not combustible.

8 Exposure controls / Personal protection

8.1 Technical measures Use only with adequate ventilation.

8.2 Control of threshold limits None established for the mixture.

8.3 Personal protective equipment

8.3.1 Respiratory protection Respiratory Protection.

8.3.2 Hand protection Rubber gloves.

8.3.3 Eye protection Eye wash fountain should be located in immediate work area.
Safety goggles or face-shield.

8.3.4 Other Remove contaminated clothing immediately, wash skin area with
water, and launder clothing.

9 Physical and chemical properties

9.1 Appearance Powder and Liquid

9.2 Colour yellowish

9.3 Odour practically odourless

9.4 Change of physical state Test method:
not applicable

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9.5 Density

not determined

9.6 Vapour pressure

not applicable

9.7 Viscosity

not known

9.8 Solubility

Liquid soluble

Powder non soluble

9.9 pH

< 1.5
Liquid

9.10 Flash point

not flammable

9.11 Ignition temperature

not applicable

9.12 Explosion limits

Lower:
Upper:
not applicable

9.13 Further information

None.

10 Stability and reactivity

10.1 Thermal decomposition

None, if used in accordance to instructions.

10.2 Hazardous decomposition products

None under normal conditions of storage and use.

10.3 Hazardous reactions

Avoid excessive heat and direct sunlight.

10.4 Further information

None.

11 Toxicological information

11.1 Acute toxicity

May cause severe eye irritation. Eye Contact: (see 4.1., First aid measures).

Ingestion may cause burns of mouth and throat.

Liquid and uncured material

Due to the pH of this material, it is assumed that exposure will cause skin burns.

Oral LD50 for rats: > 2000 mg/kg

Avoid breathing dust.

11.2 Subacute / Chronic toxicity

not known

11.3 Further information

None.

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12 Ecological information

The product must not enter effluent, ground water, surface water or the soil.

German "Wassergefährdungs Klasse (WGK)": 1

13 Disposal considerations

Take to a special waste incineration plant, in line with local regulations.

13.1 EU waste key

18 01 06

14 Transport information

14.1 Transport at land

ADR 8 RID 8

UN Number 1805 Kemler Number ---

Packing Group III

Proper shipping name Phosphoric acid solution

14.2 Transport at sea

ADNR 8 IMDG 32-04

UN Number 1805

EMS F-A, S-D MFAG 700

Packing Group III

Proper shipping name Phosphorsäure, Lösung

14.3 Air transport

ICAO / IATA-DGR Class 8

UN Number 1805

Proper shipping name Phosphoric acid, solution

Subsidiary Risk ---

Labels Corrosive

Packing Group III

Passenger airplane Packing Instructions 819

max. 5 L

Cargo Airplane Packing Instructions 821

max. 60 L

14.4 Further information

Sample shipment not allowed by mail.

15 Regulatory information

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

This product requires classification according to the criteria of the EC.

15.1 UN number

1805

15.2 National regulations

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15.3 EU number

15.4 Hazard symbols

C



15.5 Hazard designation

C: Corrosive. Contains Phosphoric acid, Solution in Water.

15.6 Risk phrases

R: 34

34 Causes burns.

15.7 Safety phrases

S: 26-45-1/2-37/39

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advise.

45 In case of accident or if you feel unwell, seek medical advise immediately (show the label where possible).

1/2 Keep locked up and out of reach of children.

37/39 Wear suitable gloves and eye/face protection.

15.8 MAK value

not known

15.9 BVD classification (CH)

15.10 VbF (D)

15.11 Further information

None.

16 Other information

Version: 4

Changes: 14

The above mentioned data correspond to our present state of knowledge and experience. The safety data sheet serves as description of the products in regard to necessary safety measures. The indications do not have the meaning of guarantees on properties.