

EU Safety Data Sheet

VivaStyle 30 %



Date of issue / Reference

15.04.2005 hot

Replaces version of

31.03.2004

Date of printing

15.04.2005 **Sheet No. 1545**

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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 **VivaStyle 30 %**
- 1.2 Application / Use Tooth whitening gel
- 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 Mixture of water, propylene glycol, carbamide peroxide,
polycarboxylic acid, sodium pyrophosphate and peppermint oil
- 2.2 Hazardous components
- CAS No. 124-43-6 30 % Carbamide peroxide
Xi: Irritant. R36/38: Irritating to eyes and skin.
- 2.3 Further information None.

3 Hazards identification

Irritating to eyes and skin.
Irritating to eyes, skin and mucous membrans.

4 First aid measures

- 4.1 Eye contact Flush eyes with plenty of water (10-15 min.). Call a physician.
- 4.2 Skin contact Wash thoroughly with soap and water.
- 4.3 Ingestion Give large amounts of water. No hazards anticipated from
swallowing small amounts incidentally to normal handling. If you
feel unwell, seek medical advice (show this safety data sheet).
- 4.4 Inhalation Take into fresh air.
- 4.5 Further information Remove contaminated clothing.

5 Fire-fighting measures

- 5.1 Suitable extinguishing media Water fog, carbon dioxide, foam
- 5.2 Extinguishing media to avoid None.

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5.3 Further information None.

6 Accidental release measures Clean up with absorbent material.
Clean area with large amounts of water.
Prevent skin and eye contact.

7 Handling and storage

- 7.1 Handling Only adequately trained personnel should handle this product.
- 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 Store at 2-8 °C / 36-46 °F.
- 7.4 Place of storage Do not freeze.
Avoid exposure to direct sunlight.
- 7.5 Fire- and explosion-protection Keep away from heat source.
-

8 Exposure controls / Personal protection

- 8.1 Technical measures Good general ventilation should be sufficient.
- 8.2 Control of threshold limits None established.
- 8.3 Personal protective equipment
- 8.3.1 Respiratory protection Not required.
- 8.3.2 Hand protection Gloves.
- 8.3.3 Eye protection Where contact with liquid is likely, safety glasses are recommended.
- 8.3.4 Other None.
-

9 Physical and chemical properties

- 9.1 Appearance Gel
- 9.2 Colour colourless to light yellow
- 9.3 Odour practically odourless
- 9.4 Change of physical state Test method:
not applicable
- 9.5 Density 1.1 g/cm³ (20°C)
- 9.6 Vapour pressure not determined
- 9.7 Viscosity 2.0 - 2.5 mPa·s (20°C)

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9.8 Solubility

Solubility in

soluble

9.9 pH

5.0

9.10 Flash point

> 150 °C

9.11 Ignition temperature

> 200 °C

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

Product may decompose at elevated temperatures generating vapours which could be irritating.

10.3 Hazardous reactions

Avoid excessive heat and direct sunlight.

10.4 Further information

None.

11 Toxicological information

11.1 Acute toxicity

Oral LD50 for rats: > 5'000 mg/kg
VivaStyle 30 % is irritant. Avoid contact with skin, mucosal tissues and eyes.
Risk of serious damage to eyes.
Prevent from accidental ingestion.
Ingestion: larger amounts may cause gastrointestinal irritation.

11.2 Subacute / Chronic toxicity

Carbamide peroxide
- Cytotoxicity: slightly positive (MTT Assay)
- Mutagenicity: slightly positive (Ames Test)

11.3 Further information

None.

12 Ecological information

No ecological problems to be anticipated if properly handled and used.

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13 Disposal considerations

Take to a waste incineration plant, under conditions approved by the local authority.

13.1 EU waste key

18 01 06

14 Transport information

14.1 Transport at land

ADR

RID

UN Number

Kemler Number

Packing Group

Proper shipping name

14.2 Transport at sea

ADNR

IMDG

UN Number

EMS

MFAG

Packing Group

Proper shipping name

14.3 Air transport

ICAO / IATA-DGR

UN Number

Proper shipping name

Subsidiary Risk

Labels

Packing Group

Passenger airplane

Packing Instructions

max.

Cargo Airplane

Packing Instructions

max.

14.4 Further information

Product is not classified for any mode of transportation.

15 Regulatory information

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

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

15.1 UN number

15.2 National regulations

15.3 EU number

15.4 Hazard symbols

Xi

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15.5 Hazard designation

Xi: Irritant. Contains Carbamide peroxide.

15.6 Risk phrases

R: 36/38

36/38 Irritating to eyes and skin.

15.7 Safety phrases

S: 2-26-28-24/25-37/39

2 Keep out of the reach of children.

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

28 After contact with skin, wash immediately with plenty of water and soap.

24/25 Avoid contact with skin and eyes.

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

15.8 MAK value

--- ml/m³ (ppm)

15.9 BVD classification (CH)

15.10 VbF (D)

15.11 Further information

None.

16 Other information

Version: 2

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.