

# EU Safety Data Sheet

VivaStyle



Date of issue / Reference

05.04.2005 hot

Replaces version of

25.02.2005

Date of printing

05.04.2005 **Sheet No. 1460**

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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**
- 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 glycerine > 80% (CAS No. 56-81-5), carbamide peroxide, polycarboxylic acid and peppermit oil
- 2.2 Hazardous components  
CAS No. 124-43-6 10 - 16 % Carbamide peroxide  
Xi: Irritant. R36/38: Irritating to eyes and skin.
- 2.3 Further information None.

## 3 Hazards identification

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.
- 5.3 Further information None.

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## 6 Accidental release measures

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

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## 7 Handling and storage

### 7.1 Handling

Only adequately trained personnel should handle this product.

### 7.2 Industrial hygiene

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

### 7.3 Storage

Store at 5-22 °C / 41-72 °F.

### 7.4 Place of storage

### 7.5 Fire- and explosion-protection

Keep away from heat source.

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## 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.

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## 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

not applicable

Test method:

### 9.5 Density

1.25 g/cm<sup>3</sup> (20°C)

### 9.6 Vapour pressure

not applicable

### 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 - 6.5

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.  
No decomposition below 30 °C.

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

Risk of serious damage to eyes.  
Oral LD50 for rats: > 5'000 mg/kg  
The VivaStyle gel is irritant. Avoid contact with skin, mucosal tissues and eyes.

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

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## 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.

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## 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

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15.2 National regulations

15.3 EU number

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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/m<sup>3</sup> (ppm)

15.9 BVD classification (CH)

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15.10 VbF (D)

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15.11 Further information

None.

## 16 Other information

Version: 2

Changes: 13.1/8.3.3.

*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.*