

SAFETY DATA SHEETS

This SDS packet was issued with item:

070358234

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

070358242 070358259

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 12.03.2014

Version number 3



Revision: 12.03.2014

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** **VivaStyle 10% / 16%**
- **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** Tooth whitening gel
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35
Fax: +423 235 33 60
- **Further information obtainable from:**
Regulatory Affairs
msds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
C; Corrosive
R34: Causes burns.
.....
O; Oxidising
R7: May cause fire.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
- **Hazard pictograms**
 
GHS03 GHS05
- **Signal word** Danger
- **Hazard-determining components of labelling:**
hydrogen peroxide--urea
sodium hydroxide
- **Hazard statements**
H272 May intensify fire; oxidiser.
H314 Causes severe skin burns and eye damage.
- **Precautionary statements**
P102 Keep out of reach of children.

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P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

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

P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P310 Immediately call a POISON CENTER/doctor.

· **Additional information:**

Cosmetics which fall under Regulation (EC) 1223/2009 are exempt from the labeling requirements of Directive 1999/45/EC and Regulation (EC) 1272/2008.

· **Regulation (EC) No 1223/2009 on cosmetic products**

Contains carbamide peroxide. Avoid contact with eyes. Rinse immediately if product comes into contact with them. Not to be used on a person under 18 years of age. To be only sold to dental practitioners. For each cycle of use, the first use to be only done by dental practitioners or under their direct supervision if an equivalent level of safety is ensured. Afterwards to be provided to the consumer to complete the cycle of use. Keep out of the reach of children.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterization: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 56-81-5 EINECS: 200-289-5	glycerol substance with a Community workplace exposure limit	50-100%
CAS: 124-43-6 EINECS: 204-701-4	hydrogen peroxide--urea C R34; O R8 Ox. Sol. 2, H272; Skin Corr. 1B, H314	10-<25%
CAS: 9003-01-4	carbomer Xi R36 Eye Irrit. 2, H319	3-<10%
CAS: 7757-79-1 EINECS: 231-818-8	potassium nitrate O R8 Ox. Sol. 2, H272	3-<10%
CAS: 1310-73-2 EINECS: 215-185-5	sodium hydroxide C R35 Skin Corr. 1A, H314	3-<5%

· **Additional information:** For the wording of the listed risk phrases refer to section 16.

SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **General information:** Immediately remove any clothing soiled by the product.

· **After inhalation:** In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

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- **After swallowing:**
Rinse out mouth and then drink plenty of water.
Do not induce vomiting; call for medical help immediately.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
- **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**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep container tightly sealed.
Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

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· 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

56-81-5 glycerol

WEL () Long-term value: 10 mg/m³

1310-73-2 sodium hydroxide

WEL () Short-term value: 2 mg/m³

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

· 8.2 Exposure controls

· Personal protective equipment:

· General protective and hygienic measures:

Usual hygienic measures for dental practice.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Immediately remove all soiled and contaminated clothing

Avoid contact with the eyes and skin.

Do not inhale gases / fumes / aerosols.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form:

Viscous

Colour:

Colourless

· Odour:

like peppermint

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· pH-value at 20 °C:	6.0 - 7.5
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	Undetermined.
· Flammability (solid, gaseous):	Not applicable.
· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	Not determined.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density at 20 °C:	1.23 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Fully miscible.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions**
 - Reacts with certain metals.
 - Reacts with alkali (lyes).
 - Reacts with organic substances.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**

· LD/LC50 values relevant for classification:
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1310-73-2 sodium hydroxide

Oral	LD50	2000 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** Caustic effect on skin and mucous membranes.

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- **on the eye:** Strong caustic effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Corrosive

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
 - **Recommendation**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
 - **European waste catalogue**
- | | |
|-----------|--|
| 18 01 06* | chemicals consisting of or containing dangerous substances |
|-----------|--|
- **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---------------------------------------|--|
| · 14.1 UN-Number | UN3093 |
| · ADR, IMDG, IATA | |
| · 14.2 UN proper shipping name | 3093 CORROSIVE LIQUID, OXIDIZING, N.O.S.
(SODIUM HYDROXIDE, UREA HYDROGEN PEROXIDE) |
| · ADR | |
| · IMDG, IATA | |

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· **14.3 Transport hazard class(es)**

· **ADR**



· **Class**

8 (C01) Corrosive substances.

· **Label**

8+5.1

· **IMDG, IATA**



· **Class**

8 Corrosive substances.

· **Label**

8+5.1

· **14.4 Packing group**

· **ADR, IMDG, IATA**

II

· **14.5 Environmental hazards:**

· **Marine pollutant:**

No

· **14.6 Special precautions for user**

Warning: Corrosive substances.

· **Danger code (Kemler):**

85

· **EMS Number:**

F-A,S-Q

· **Segregation groups**

Alkalis

· **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable.

· **Transport/Additional information:**

· **ADR**

· **Limited quantities (LQ)**

1L

· **Transport category**

2

· **Tunnel restriction code**

E

· **UN "Model Regulation":**

UN3093, CORROSIVE LIQUID, OXIDIZING, N.O.S.
(SODIUM HYDROXIDE, UREA HYDROGEN
PEROXIDE), 8 (5.1), II

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a cosmetic according to Regulation (EC) 1223/2009.

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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· **Relevant phrases**

H272 May intensify fire; oxidiser.

H314 Causes severe skin burns and eye damage.

H319 Causes serious eye irritation.

R34 Causes burns.

R35 Causes severe burns.

R36 Irritating to eyes.

R8 Contact with combustible material may cause fire.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Ox. Liq. 2: Oxidising Liquids, Hazard Category 2

Ox. Sol. 2: Oxidising Solids, Hazard Category 2

Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A

Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

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