

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/12/2014

Version number 3

Reviewed on 03/12/2014

1 Identification

- **Product identifier**
- **Trade name:** VivaStyle 10% / 16%
- **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*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

- Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102
- **Information department:** *Quality Assurance / Regulatory Affairs*
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

- General MSDS Assistance:*
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
Ox. Liq. 2 H272 May intensify fire; oxidizer.
Skin Corr. 1B H314 Causes severe skin burns and eye damage.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Corrosive
Causes burns.

- Oxidizing*
May cause fire.
- **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

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- **Label elements**
- **GHS label elements**
- **Hazard pictograms**



GHS03 GHS05

- **Signal word** *Danger*
- **Hazard-determining components of labeling:**
hydrogen peroxide--urea
sodium hydroxide

- **Hazard statements**

May intensify fire; oxidizer.
Causes severe skin burns and eye damage.

- **Precautionary statements**

Keep out of reach of children.
Keep away from heat/sparks/open flames/hot surfaces. No smoking.
If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
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.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 3
Fire = 3
Reactivity = 0

The substance possesses oxidizing properties.

- **HMIS-ratings (scale 0 - 4)**



Health = 3
Fire = 3
Reactivity = 0

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** *Mixture of the substances listed below with nonhazardous additions.*

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· Dangerous components:		
56-81-5	glycerol	50-100%
124-43-6	hydrogen peroxide--urea	10-<25%
9003-01-4	carbomer	2.5-<10%
7757-79-1	potassium nitrate	2.5-<10%
1310-73-2	sodium hydroxide	2.5-<5%

4 First-aid measures

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

5 Fire-fighting measures

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

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
- **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.

7 Handling and storage

- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.

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- **Information about protection against explosions and fires:** No special measures required.
- **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 receptacle tightly sealed.
 - Protect from heat and direct sunlight.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

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

· **Components with limit values that require monitoring at the workplace:**

56-81-5 glycerol

PEL () Long-term value: 15* 5** mg/m³
*total dust **respirable fraction

TLV () TLV withdrawn-insufficient data human occup. exp.

1310-73-2 sodium hydroxide

PEL () Long-term value: 2 mg/m³

REL () Ceiling limit value: 2 mg/m³

TLV () Ceiling limit value: 2 mg/m³

- **Additional information:** The lists that were valid during the creation were used as basis.

- **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.

- **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

- **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.

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· **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

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· Form:	Viscous
· Color:	Colorless
· Odor:	like peppermint

· **pH-value at 20 °C (68 °F):** 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.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Not determined.

· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapor pressure:** Not determined.

· **Density at 20 °C (68 °F):** 1.23 g/cm³ (10.264 lbs/gal)

· **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.

· **Solvent content:**

· **VOC content:** 10.0 %

· **Other information** No further relevant information available.

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10 Stability and reactivity

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

11 Toxicological information

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

- **LD/LC50 values that are relevant for classification:**

1310-73-2 sodium hydroxide

Oral LD50 2000 mg/kg (rat)

- **Primary irritant effect:**
 - **on the skin:** Caustic effect on skin and mucous membranes.
 - **on the eye:** Strong caustic effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Corrosive

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

9003-01-4 carbomer

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- **NTP (National Toxicology Program)**

None of the ingredients is listed.

12 Ecological information

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

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|---------------------------------------|--|
| · UN-Number | UN3093 |
| · DOT, ADR, IMDG, IATA | |
| · UN proper shipping name | Corrosive liquids, oxidizing, n.o.s. (Sodium hydroxide, Urea hydrogen peroxide) |
| · DOT | |
| · ADR | 3093 Corrosive liquids, oxidizing, n.o.s. (Sodium hydroxide, Urea hydrogen peroxide) |
| · IMDG, IATA | CORROSIVE LIQUID, OXIDIZING, N.O.S. (SODIUM HYDROXIDE, UREA HYDROGEN PEROXIDE) |
| · Transport hazard class(es) | |
| · DOT | |
| |  |
| · Class | 8 Corrosive substances. |
| · Label | 8+5.1 |
| · ADR | |
| |  |
| · Class | 8 (CO1) Corrosive substances |
| · Label | 8+5.1 |
| · IMDG, IATA | |
| |  |
| · Class | 8 Corrosive substances. |
| · Label | 8+5.1 |
| · Packing group | II |
| · DOT, ADR, IMDG, IATA | |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Warning: Corrosive substances |

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· Danger code (Kemler):	85
· EMS Number:	F-A,S-Q
· Segregation groups	Alkalis
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	UN3093, Corrosive liquids, oxidizing, n.o.s. (Sodium hydroxide, Urea hydrogen peroxide), 8 (5.1), II

15 Regulatory information

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

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

56-81-5 glycerol

124-43-6 hydrogen peroxide--urea

9003-01-4 carbomer

7757-79-1 potassium nitrate

1310-73-2 sodium hydroxide

8006-90-4 peppermint oil

7732-18-5 water, distilled, conductivity or of similar purity

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

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- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS03 GHS05

- **Signal word** Danger

- **Hazard-determining components of labeling:**

hydrogen peroxide--urea
sodium hydroxide

- **Hazard statements**

May intensify fire; oxidizer.
Causes severe skin burns and eye damage.

- **Precautionary statements**

Keep out of reach of children.
Keep away from heat/sparks/open flames/hot surfaces. No smoking.
If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
Immediately call a POISON CENTER/doctor.

- **National regulations:**

- **Other regulations, limitations and prohibitive regulations**

The product is a cosmetic according to Regulation (EC) 1223/2009.
This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

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

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.

- **Date of preparation / last revision** 03/12/2014 / 2

- **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
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
Ox. Liq. 2: Oxidising Liquids, Hazard Category 2
Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B