

SAFETY DATA SHEETS

This SDS packet was issued with item:

070358226

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

077107105 077107113 077107204 077107923 077107931 077107949 077107956 077108186 077108194 077108202


1 Identification

- **Product identifier**
- **Trade name:** **VivaStyle 10% / 16%**
- **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 SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Dam. 1 H318 Causes serious eye damage.
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**

GHS05
- **Signal word** Danger
- **Hazard-determining components of labeling:**
hydrogen peroxide--urea
- **Hazard statements**
Causes skin irritation.
Causes serious eye damage.
- **Precautionary statements**
Keep away from heat/sparks/open flames/hot surfaces. No smoking.

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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.

Immediately call a POISON CENTER/doctor.

If swallowed: Rinse mouth. Do NOT induce vomiting.

· **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 = 2

Fire = 0

Reactivity = 0

The substance possesses oxidizing properties.

· **HMIS-ratings (scale 0 - 4)**



Health = 2

Fire = 0

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.

· **Dangerous components:**

CAS: 56-81-5	glycerol	50-100%
CAS: 124-43-6	hydrogen peroxide--urea	10-<25%
CAS: 9003-01-4	carbomer	0.1-<2.5%
CAS: 7757-79-1	potassium nitrate	0.1-<2.5%
CAS: 7758-16-9	disodium dihydrogenpyrophosphate	0.1-<2.5%

4 First-aid measures

· **Description of first aid measures**

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

· **After inhalation:**

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:** Immediately rinse with water.

· **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.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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- **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

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **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:**
The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

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CAS: 56-81-5 glycerol

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

TLV TLV withdrawn-insufficient data human occup. exp.

· **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 and dental laboratories.

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.

· **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):** ~ 6.9

· **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

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· 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:	Not determined.
· Relative density	Not determined.
· Vapor 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.
· Other information	No further relevant information available.

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.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

11 Toxicological information

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

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· **Carcinogenic categories**· **IARC (International Agency for Research on Cancer)**

CAS: 9003-01-4 carbomer

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· **NTP (National Toxicology Program)**

None of the ingredients is listed.

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

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.· **Behavior in environmental systems:**· **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.

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**· **DOT, ADR, RID, ADN, ADN, IMDG, IATA** Void· **UN proper shipping name**· **DOT, ADR, RID, ADN, ADN, IMDG, IATA** Void· **Transport hazard class(es)**· **DOT, ADR, RID, ADN, ADN, IMDG, IATA**· **Class** Void· **Packing group**· **DOT, ADR, RID, ADN, IMDG, IATA** Void· **Environmental hazards:**· **Marine pollutant:** No

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- | | |
|--|--|
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN "Model Regulation": | Void |

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):**

CAS: 7757-79-1 | potassium nitrate

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

All ingredients are listed.

· **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.

· **GHS label elements**

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

· **Hazard pictograms**



GHS05

· **Signal word Danger**

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

hydrogen peroxide--urea

· **Hazard statements**

Causes skin irritation.

Causes serious eye damage.

· **Precautionary statements**

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.

Immediately call a POISON CENTER/doctor.

If swallowed: Rinse mouth. Do NOT induce vomiting.

· **National regulations:**

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

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

This product is classified as cosmetic.

· **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** 10/19/2017 / 3

· **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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

· *** Data compared to the previous version altered.**

US