

# Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/30/2011

Version number 7

Reviewed on 06/30/2011


## 1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** **Proxyt**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Paste for professional tooth cleaning
- **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.  
2785 Skyview Avenue, Unit 1, Mississauga, Ontario L4W4Y3  
CANADA  
Tel. +1 800 263 8182  
Fax +1 905 238 5711
- **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 Composition/information on ingredients

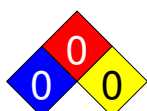
- **Chemical characterization:** Mixtures
- **Description:** Mixture of the substances listed below with nonhazardous additions.

### · **Dangerous components:**

56-81-5	glycerol		10-25%
7681-49-4	sodium fluoride	 H301; H315; H319	≤ 2.5%

## 3 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
- **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- **Label elements**
- **Labelling according to EU guidelines:**  
Observe the general safety regulations when handling chemicals.  
The product is not subject to identification regulations according to directives on hazardous materials.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



Health = 0  
Fire = 0  
Reactivity = 0

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## · HMIS-ratings (scale 0 - 4)

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

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

## 4 First aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:**  
Rinse opened eye for several minutes under running water.  
Mechanical effects only.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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:** No special measures required.

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**  
No dangerous substances are released.  
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.
- **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:** No special requirements.
- **Information about storage in one common storage facility:** Not required.

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- **Further information about storage conditions:** None.
- **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	15* 5** mg/m <sup>3</sup> *total dust **respirable fraction
TLV	10* ppm *Mist

- **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.

- **Breathing equipment:** Not required.

- **Protection of hands:**

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

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **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:** Not required.

## 9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

<b>Form:</b>	Pasty
<b>Color:</b>	According to product specification
<b>Odor:</b>	like peppermint
<b>Odour threshold:</b>	Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Not determined.

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

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· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapor pressure at 20°C (68°F):</b>	23 hPa (17 mm Hg)
· <b>Density at 20°C (68°F):</b>	1.43-1.53 g/cm <sup>3</sup> (35-12.768 lbs/gal)
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with Water:</b>	Insoluble.
· <b>Segregation coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Other information</b>	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** No dangerous reactions known.
- **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:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**  
The product is not subject to classification according to internally approved calculation methods for preparations:  
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

## 12 Ecological information

- **Toxicity**
- **Acquatic 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 1 (Self-assessment): slightly hazardous for water

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- **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:** Smaller quantities can be disposed of with household waste.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- **DOT regulations:**
- **Hazard class:** -
- **Land transport ADR/RID (cross-border):**
- **ADR/RID class:** -
- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** No
- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

### 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):**

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.

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· **Carcinogenic categories**· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

7631-86-9 silicon dioxide, chemically prepared

3

13463-67-7 titanium dioxide

2B

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

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

13463-67-7 titanium dioxide

A4

7681-49-4 sodium fluoride

A4

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

13463-67-7 titanium dioxide

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

None of the ingredients is listed.

· **Product related hazard informations:**

Observe the general safety regulations when handling chemicals.

The product is not subject to identification regulations according to directives on hazardous materials.

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

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

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.

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

—USA—