

1 Identification

- **Product identifier**
- **Trade name:** **Ivoclean**
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the preparation** Extraoral cleaning paste for indirect restorations
- **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**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Corrosive
Causes burns.
- **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
The classification as „corrosive“ is due to the pH-value.
- **Label elements**
- **Labelling according to EU guidelines:**
The product has been classified and marked in accordance with directives on hazardous materials.
- **Code letter and hazard designation of product:**



Corrosive

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

· **Risk phrases:**
Causes burns.

· **Safety phrases:**
When using do not eat or drink.
Do not breathe vapour/spray.
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Wear suitable protective clothing, gloves and eye/face protection.
In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
This material and its container must be disposed of as hazardous waste.

· **Classification system:**
· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**



· **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:**

25322-68-3	Polyethylene glycol	2.5-10%
1310-73-2	sodium hydroxide	≤ 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.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:**
Immediately rinse with water.
If skin irritation continues, consult a doctor.
· **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.
Call a doctor immediately.

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- **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 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:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **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.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **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.
- **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.

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- Control parameters

- Components with limit values that require monitoring at the workplace:

25322-68-3 Polyethylene glycol	
WEEL	10 mg/m ³ aerosol
1310-73-2 sodium hydroxide	
PEL	2 mg/m ³
REL	Short-term value: C 2 mg/m ³
TLV	Short-term value: C 2 mg/m ³

- 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.

Immediately remove all soiled and contaminated clothing.

Do not inhale gases / fumes / aerosols.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

- 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.

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:



Tightly sealed goggles

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9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Fluid
Color:	Violet
Odor:	Characteristic
Odour threshold:	Not determined.

· pH-value at 20 °C (68 °F): 13

· Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

· Flash point: Not applicable.

· Auto igniting: Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

· Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· Vapor pressure: Not determined.

· Density at 20 °C (68 °F): 1.0344 g/cm³ (8.632 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.

· 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: 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.

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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:

Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

- Carcinogenic categories

- IARC (International Agency for Research on Cancer)

1345-16-0 Pigment blue 28

2B

- 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.

- 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

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Must not reach bodies of water or drainage ditch undiluted or unneutralized.

Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values. A high pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

- 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.

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- Uncleaned packagings:
- Recommendation: Disposal must be made according to official regulations.

14 Transport information

- | | |
|---|---|
| · UN-Number | UN1824 |
| · DOT | 1824 |
| · ADR, IMDG, IATA | 1824 |
| · UN proper shipping name | 1824 SODIUM HYDROXIDE SOLUTION, mixture |
| · ADR | SODIUM HYDROXIDE SOLUTION, mixture |
| · IMDG, IATA | SODIUM HYDROXIDE SOLUTION, mixture |
| · Transport hazard class(es) | |
| · DOT | |
|  | |
| · Class | 8 Corrosive substances. |
| · Label | 8 |
| · ADR | |
|  | |
| · Class | 8 (C5) Corrosive substances |
| · Label | 8 |
| · IMDG, IATA | |
|  | |
| · Class | 8 Corrosive substances. |
| · Label | 8 |
| · Packing group | III |
| · DOT, ADR, IMDG, IATA | III |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Warning: Corrosive substances |
| · Danger code (Kemler): | 80 |
| · EMS Number: | F-A, S-B |
| · Segregation groups | Alkalis |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |

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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.

· 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.

· Product related hazard informations:

The product has been classified and marked in accordance with directives on hazardous materials.

· Hazard symbols:



Corrosive

· Hazard-determining components of labeling:

sodium hydroxide

· Risk phrases:

Causes burns.

· Safety phrases:

When using do not eat or drink.

Do not breathe vapour/spray.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Wear suitable protective clothing, gloves and eye/face protection.

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*In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
This material and its container must be disposed of as hazardous waste.*

· **National regulations:**

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

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.

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