

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

Printing date 20.05.2015

Version number 2

Revision: 12.03.2015

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

- **1.1 Product identifier**
- **Trade name: *Ivoclean***
- **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** Extraoral cleaning paste for indirect restorations
- **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  
sds@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 Regulation (EC) No 1272/2008**  
Skin Corr. 1A H314 Causes severe skin burns and eye damage.  
Eye Irrit. 2 H319 Causes serious eye irritation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.

- **Hazard pictograms**



GHS05

- **Signal word** *Danger*
- **Hazard-determining components of labelling:**  
*sodium hydroxide*
- **Hazard statements**  
H314 Causes severe skin burns and eye damage.
- **Precautionary statements**
  - P280 Wear protective gloves/protective clothing/eye protection/face protection.
  - P260 Do not breathe dust/fume/gas/mist/vapours/spray.
  - 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.
  - P310 Immediately call a POISON CENTER/doctor.
  - P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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· **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 1310-73-2	sodium hydroxide	Skin Corr. 1A, H314	1-<2%
EINECS: 215-185-5			

- **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:**  
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.
- **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:**  
CO<sub>2</sub>, 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:** No special measures required.

### 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:** Do not allow to enter sewers/ surface or ground water.
- **6.3 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.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

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### SECTION 7: Handling and storage

· **7.1 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 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.

· **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.

· **8.1 Control parameters**

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

**1310-73-2 sodium hydroxide**

WEL Short-term value: 2 mg/m<sup>3</sup>

· **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.

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.

· **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.

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**

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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:**

<b>Form:</b>	Fluid
<b>Colour:</b>	Violet
<b>Odour:</b>	Characteristic
<b>Odour threshold:</b>	Not determined.

· **pH-value at 20 °C:** 13

· **Change in condition**

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

· **Flash point:** Not applicable.

· **Self-igniting:** Product is not selfigniting.

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

· **Explosion limits:**

<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.

· **Vapour pressure:** Not determined.

<b>Density at 20 °C:</b>	1.0344 g/cm <sup>3</sup>
<b>Relative density</b>	Not determined.
<b>Vapour density</b>	Not determined.
<b>Evaporation rate</b>	Not determined.

· **Solubility in / Miscibility with water:** Fully miscible.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.

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

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**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** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

**SECTION 11: Toxicological information**

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

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

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.
- **on the eye:** Strong caustic effect.
- **Sensitisation:** No sensitising 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.

**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 1 (German Regulation) (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 sewage water or drainage ditch undiluted or unneutralised.  
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.
- **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.

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· **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**· **ADR, IMDG, IATA**

UN1824

· **14.2 UN proper shipping name**· **ADR**

1824 SODIUM HYDROXIDE SOLUTION, mixture

· **IMDG, IATA**

SODIUM HYDROXIDE SOLUTION mixture

· **14.3 Transport hazard class(es)**· **ADR**· **Class**

8 (C5) Corrosive substances.

· **Label**

8

· **IMDG, IATA**· **Class**

8 Corrosive substances.

· **Label**

8

· **14.4 Packing group**· **ADR, IMDG, IATA**

III

· **14.5 Environmental hazards:**· **Marine pollutant:**

No

· **14.6 Special precautions for user**

Warning: Corrosive substances.

· **Danger code (Kemler):**

80

· **EMS Number:**

F-A,S-B

· **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)**

5L

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

· **Transport category**

3

· **Tunnel restriction code**

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· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	5L
· <b>Excepted quantities (EQ)</b>	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· <b>UN "Model Regulation":</b>	UN1824, SODIUM HYDROXIDE SOLUTION mixture, 8, III

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.
- **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.*

- **Relevant phrases**  
H314 Causes severe skin burns and eye damage.
- **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  
GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
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  
Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A  
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
- **\* Data compared to the previous version altered.**

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