

Safety Data Sheet
according to HPR, Schedule 1

Printing date 05/14/2019

Version number 3

Reviewed on 05/14/2019

1 Identification


- **Product identifier**
- **Trade name: *Ivoclean***
- **Application of the substance / the mixture** *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 SDS Assistance:*
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard identification

- **Classification of the substance or mixture**
Skin Corrosion - Category 1A H314 Causes severe skin burns and 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:**
sodium hydroxide
 - **Hazard statements**
Causes severe skin burns and eye damage.
 - **Precautionary statements**
Do not breathe dust/fume/gas/mist/vapours/spray.
Wear protective gloves/protective clothing/eye protection/face protection.
IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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*IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or 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.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 3

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

HEALTH	3	Health = 3
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 1310-73-2	sodium hydroxide	≤1% w/w
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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.

· **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:**

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.

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- **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.

- **Control parameters**

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

CAS: 1310-73-2 sodium hydroxide

EL Ceiling limit value: 2 mg/m³EV 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 and dental laboratories.
Immediately remove all soiled and contaminated clothing.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.

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Do not inhale gases / fumes / aerosols.

· **Breathing equipment:**

Not necessary if room is well-ventilated.

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.

· **Recommended filter device for short term use: Filter P**

· **Protection of hands:**



Protective gloves

After use of gloves apply skin-cleaning agents and skin cosmetics.

· **Material of gloves**

Natural rubber, NR

Chloroprene rubber, CR

Nitrile rubber, NBR

Butyl rubber, BR

Fluorocarbon rubber (Viton)

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

· **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

· **Body protection: Protective work clothing**

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form: Fluid

Color: Violet

· **Odor:** Characteristic

· **Odor threshold:** Not determined.

· **pH-value at 20 °C:** 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.

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· Vapor pressure:	Not determined.
· Density at 20 °C:	1.0344 g/cm ³
· 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** 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:**
- **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.
The classification as „corrosive“ is due to the pH-value.
- **Carcinogenic categories**

- **NTP (National Toxicology Program)**
None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:**
- **CAS: 1310-73-2 sodium hydroxide**
- **LC50/96 h** 196 mg/l (fish) (Min.)
- 196 mg/l (fish) (Max.)
- 196 mg/l (fish) (Median)

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CAS: 1310-73-2 sodium hydroxide

EC50/48 h	40.4 mg/l (crustaceans) (Min.)
	40.4 mg/l (crustaceans) (Max.)
	40.4 mg/l (crustaceans) (Median)

- **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:**
 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.
 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.
- **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/TDG, ADR, IMDG, IATA | UN1824 |
| · UN proper shipping name | |
| · DOT/TDG | SODIUM HYDROXIDE SOLUTION, mixture |
| · ADR | 1824 SODIUM HYDROXIDE SOLUTION, mixture |
| · IMDG, IATA | SODIUM HYDROXIDE SOLUTION mixture |

- **Transport hazard class(es)**
- **DOT/TDG (Transport dangerous goods):**



- **Class** 8 Corrosive substances

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· Label	8
· ADR	
	
· Class	8 (C5) Corrosive substances
· Label	8
· IMDG, IATA	
	
· Class	8 Corrosive substances
· Label	8
· Packing group	
· DOT/TDG, 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.
· Transport/Additional information:	
· ADR	
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· IMDG	
· 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
· UN "Model Regulation":	UN1824, SODIUM HYDROXIDE SOLUTION, mixture, 8, III

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.

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

CAS: 7732-18-5	water, distilled, conductivity or of similar purity
CAS: 1314-23-4	zirconium oxide
CAS: 25322-68-3	Polyethylene glycol
CAS: 1310-73-2	sodium hydroxide
CAS: 1345-16-0	Pigment blue 28
CAS: 143-74-8	phenol red

· **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:**

sodium hydroxide

· **Hazard statements**

Causes severe skin burns and eye damage.

· **Precautionary statements**

Do not breathe dust/fume/gas/mist/vapours/spray.

Wear protective gloves/protective clothing/eye protection/face protection.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or 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.

· **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.

· **Date of the latest revision of the safety data sheet** 05/14/2019 / 2

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

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

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