

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

Printing date 07.03.2024

Version number 5 (replaces version 4)

Revision: 05.03.2024

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
9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35
Fax: +423 235 33 60
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclar.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 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 Dam. 1 H318 Causes serious eye damage.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB 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**
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or 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.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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Trade name: **Ivoclean**· **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**· **Description:** Mixture of substances listed below with nonhazardous additions.· **Dangerous components:**

CAS: 1310-73-2 EINECS: 215-185-5 Reg.nr.: 01-2119457892-27-xxxx	sodium hydroxide Skin Corr. 1A, H314 Specific concentration limits: Skin Corr. 1A; H314: $C \geq 5\%$ Skin Corr. 1B; H314: $2\% \leq C < 5\%$ Skin Irrit. 2; H315: $0.5\% \leq C < 2\%$ Eye Irrit. 2; H319: $0.5\% \leq C < 2\%$	1-<2%
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· **Additional information:** For the wording of the listed hazard 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:** Use fire extinguishing methods suitable to surrounding conditions.· **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).

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Dispose contaminated material as waste according to section 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.

See Section 13 for disposal information.

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

· **8.1 Control parameters**

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

CAS: 1310-73-2 sodium hydroxide
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WEL	Short-term value: 2 mg/m ³
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· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**

· **Appropriate engineering controls** No further data; see section 7.

· **Individual protection measures, such as 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.

Do not inhale gases / fumes / aerosols.

· **Respiratory protection:**

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 self-contained respiratory protective device.

· **Recommended filter device for short term use:** Filter P (EN 143)

· **Hand protection**



Protective gloves (EN 374)

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

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- **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**
Value for the permeation: Level 6 (> 480 Min.)
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye/face protection**



Tightly sealed goggles (EN 166)

- **Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

- | | |
|---|--------------------------|
| · Colour: | Violet |
| · Odour: | Characteristic |
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | Undetermined. |
| · Boiling point or initial boiling point and boiling range | Undetermined. |
| · Lower and upper explosion limit | |
| · Lower: | Not determined. |
| · Upper: | Not determined. |
| · Flash point: | Not applicable. |
| · pH at 20 °C | 13 |
| · Viscosity: | |
| · Kinematic viscosity | Not determined. |
| · Dynamic: | Not determined. |
| · Solubility | |
| · water: | Fully miscible. |
| · Partition coefficient n-octanol/water (log value) | Not determined. |
| · Vapour pressure: | Not determined. |
| · Density and/or relative density | |
| · Density at 20 °C: | 1.0344 g/cm ³ |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |

· 9.2 Other information

- | | |
|--|---|
| · Appearance: | No further relevant information available. |
| · Form: | Fluid |
| · Important information on protection of health and environment, and on safety. | |
| · Ignition temperature: | Product is not selfigniting. |
| · Explosive properties: | Product does not present an explosion hazard. |

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- | | |
|--|-----------------|
| · Change in condition | |
| · Evaporation rate | Not determined. |
| · Information with regard to physical hazard classes | |
| · Explosives | Void |
| · Flammable gases | Void |
| · Aerosols | Void |
| · Oxidising gases | Void |
| · Gases under pressure | Void |
| · Flammable liquids | Void |
| · Flammable solids | Void |
| · Self-reactive substances and mixtures | Void |
| · Pyrophoric liquids | Void |
| · Pyrophoric solids | Void |
| · Self-heating substances and mixtures | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids | Void |
| · Oxidising solids | Void |
| · Organic peroxides | Void |
| · Corrosive to metals | Void |
| · Desensitised explosives | Void |

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**
Causes serious eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Additional toxicological information:** The classification as „corrosive“ is due to the pH-value.

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· **11.2 Information on other hazards**· **Endocrine disrupting properties**

None of the ingredients is listed.

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.· **12.5 Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.· **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.· **12.7 Other adverse effects** No further relevant information available.· **Additional ecological information:**· **General notes:**

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.

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.

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.

· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.**SECTION 14: Transport information**· **14.1 UN number or ID number**· **ADR/RID/ADN, IMDG, IATA**

UN1824

· **14.2 UN proper shipping name**· **ADR/RID/ADN**· **IMDG, IATA**1824 SODIUM HYDROXIDE SOLUTION, mixture
SODIUM HYDROXIDE SOLUTION· **14.3 Transport hazard class(es)**· **ADR/RID/ADN**· **Class**

8 (C5) Corrosive substances.

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· Label	8
· IMDG, IATA	
	
· Class	8 Corrosive substances.
· Label	8
· 14.4 Packing group	
· ADR/RID/ADN, IMDG, IATA	III
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Warning: Corrosive substances.
· Hazard identification number (Kemler code):	80
· EMS Number:	F-A,S-B
· Segregation groups	(SGG18) Alkalis
· Stowage Category	A
· Segregation Code	SG35 Stow "separated from" SGG1-acids
· 14.7 Maritime transport in bulk according to IMO instruments	
Not applicable.	
· Transport/Additional information:	
· ADR/RID/ADN	
· 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	E
· 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

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.

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*H315 Causes skin irritation.**H319 Causes serious eye irritation.***· Classification according to Regulation (EC) No 1272/2008***The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.***· Abbreviations and acronyms:***IMO: International Maritime Organization**ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)**RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)**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)**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Skin Corr. 1A: Skin corrosion/irritation – Category 1A**Eye Dam. 1: Serious eye damage/eye irritation – Category 1***· * Data compared to the previous version altered.**

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