**SAFETY DATA SHEET (GHS)**

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE/PRODUCT AND MANUFACTURER/IMPORTER

**1.1 Product identifier:-**

| | |
|---|---|
| **Product name:** | **Ivoclean** |
| **Product number:** | 637568AN / 641156AN |

**1.2 Other means of identification:-**
Not applicable.

**1.3 Recommended use of the chemical and restrictions on use:-**
Not applicable.

| | |
|---|---|
| **Identified uses:** | Extraoral cleaning paste for indirect restorations. |

**1.4 Details of the manufacturer and importer:-**

| | |
|---|---|
| **Manufacturer:** | Ivoclar Vivadent AG<br>Bendererstrasse 2 FL-9494 Schaan<br>Principality of Liechtenstein<br>Tel: + 423 235 35 35 Fax: + 423 235 33 60 |
| **Importer:** | Ivoclar Vivadent Pty Ltd<br>1- 5 Overseas Drive Noble Park North VIC 3174<br>Tel: + 61 3 9795 9599 Fax: + 61 3 9795 9645<br>Email: info@ivoclarvivadent.com |
| **1.5 Emergency phone number:** | 13 11 26<br>Poisons Hotline (24 hours / 7 days) |

## 2. HAZARD(S) IDENTIFICATION

**2.1 GHS Classification:-**
Skin Corr. 1A H314 Causes severe skin burns and eye damage.
Eye Irrit. 2 H319 Causes serious eye irritation.

**2.2 GHS Label elements, including precautionary statements:-**

**Hazard Pictogram:**

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.<br>P260 Do not breathe dust/fume/gas/mist/vapours/spray.<br>P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.<br>P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P310 Immediately call a POISON CENTER/doctor.<br>P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting. |

**Additional information:-**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

**2.3 Other hazards:-**

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

## 3 COMPOSITION/INFORMATION ON INGREDIENTS

| Ingredient name | CAS No. | Classification | Concentration |
|---|---|---|---|
| Sodium Hydroxide | 1310-73-2 | Skin Corr. 1A - H314 | 1-<2% |
| Non-hazardous ingredients | N/A | N/A | to 100% |

For the full text of the H-Statements mentioned in this Section, refer to Section 16.

## 4. FIRST AID MEASURES

**4.1 Description of necessary first aid measures:-**

| | |
|---|---|
| **General advice:** | Remove contaminated clothing and shoes immediately and launder thoroughly before reusing.<br>First aid facilities include first aid rooms and medical centres.<br>If a risk assessment determines that a first aid room or medical centre is not needed, a rest area within the workplace may be suitable to assist an injured or ill person. |
| **If inhaled:** | Ensure supply of fresh air.<br>Remove affected person from the immediate area.<br>Keep patient warm. Consult doctor if symptoms persist.<br>In case of unconsciousness place patient stably in side position for transportation. |
| **In case of skin contact:** | Wash off immediately with water.<br>If skin irritation continues, consult a doctor. |
| **In case of eye contact:** | Remove contact lenses, irrigate copiously with clean, fresh water for at least 15 minutes holding the eyelids apart and seek medical advice. |
| **If swallowed:** | Do not induce vomiting.<br>Rinse mouth thoroughly with water.<br>Let plenty of water be drunk in small gulps.<br>Never give anything by mouth to an unconscious person.<br>Call a doctor immediately**.** |
| **4.2 Symptoms caused by exposure:-** | Please refer to section 2.2 and section 11. |
| **4.3 Medical attention and special treatment:-** | No further relevant information available. |

## 5. FIRE FIGHTING MEASURES

**5.1 Suitable extinguishing equipment:-**

| | |
|---|---|
| **Suitable extinguishing media:** | $CO_2$, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. |
| **Unsuitable extinguishing media:** | No further relevant information available. |
| **5.2 Specific hazards arising from the substance/mixture/product:-** | No further relevant information available. |

**5.3 Special protective equipment and precautions for fire fighters:-**

| | |
|---|---|
| **Special personal protective equipment:** | Wear self-contained respiratory protective device. |
| **Precautions:** | Cool endangered receptacles with water spray. |
| **Hazchem code:** | 8 Corrosive substances. |

## 6. ACCIDENTAL RELEASE MEASURES

**6.1 Personal precautions, protective equipment and emergency procedures:-**

Wear protective equipment. Keep unprotected persons away.
Use of suitable equipment (incl PPE) to prevent contamination of skin, eyes, clothing, removal of ignition sources, ventilation, emergency procedures (eg. evacuate, consult expert).

**6.2 Environmental precautions:-**

Do not allow to enter sewers/surface or ground water.

**6.3 Methods and materials 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.

## 7. HANDLING AND STORAGE

**7.1 Precautions for safe handling:-**

No special measures necessary if stored and handled as prescribed.
Only adequately trained personnel should handle this product – for use in dentistry only.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
Keep ignition sources away – do not smoke.
Wash hands before breaks and after work.
Do not eat, drink or smoke during work time.
Remove soiled or soaked clothing immediately.
Keep away from foodstuffs and beverages.

**7.2 Conditions for safe storage, including any incompatibilities:-**

Keep only in the original container.
Containers which are opened must be carefully closed and kept upright to prevent leakage.
Keep container tightly sealed.
Store in cool, dry conditions in well-sealed receptacles.
Store receptacle in a well ventilated area.
Recommended storage temperature for storage rooms and vessels is 20 - 30°C.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**8.1 Exposure control measures:-**

**Occupational exposure limits:**

| Component | CAS No. | Value | Parameters | Basis |
|---|---|---|---|---|
| Sodium Hydroxide | 1310-73-2 | Short-term value: 2 mg/m³, | | The lists valid during the making were used as basis. |

**Ingredients with biological limit values:**

Exposure should be kept to as low as practicable and below the AOES.

**8.2 Biological monitoring:-**

Assess in accordance with exposure limits – please refer to section 8.1.

**Exposure controls / Personal protective equipment / General protective and hygienic measures:**

Usual hygienic measures for dental practice.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Do not inhale gases / fumes / aerosols.
Avoid contact with the eyes and skin.

**8.3 Control banding:-**

Use good industrial hygiene practice and general ventilation**.**

**8.4 Engineering controls:-**

In case of intensive contact, wear protective gloves (EN 374).
Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties).
Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves.
Protective gloves shall be replaced immediately when physically damaged or worn.

**8.5 Individual protection measures include PPE:-**

| | |
|---|---|
| **Eye/face protection:**  | **Safety glasses**<br>Use tightly fitting safety glasses as per Australian Standard AS 1336 and AS/NZS 1337. |
| **Skin protection:**  | **Protective gloves**<br>The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.<br>Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.<br>Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.<br>**Material of gloves**<br>Butyl rubber, BR.<br>Fluorocarbon rubber (Viton).<br>PVA gloves.<br>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 cannot be calculated in advance and has therefore to be checked prior to the application.<br>**Penetration time of glove material**<br>The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed. |
| **Respiratory protection:** | Provide for good ventilation of working area (local exhaust ventilation, if necessary).<br>In case of brief exposure or low pollution use respiratory filter device.<br>In case of intensive or longer exposure use self-contained respiratory protective device. |

## 9. PHYSICAL/CHEMICAL PROPERTIES

**9.1 Information on physical/chemical properties:-**

| | | |
|---|---|---|
| a) | **Appearance/Form:** | Fluid. |
| b) | **Colour:** | Violet. |
| c) | **Odour:** | Characteristic. |
| d) | **Odour threshold:** | Not determined. |
| e) | **pH value at 20°C:** | 13. |
| f) | **Melting point/melting range:** | Undetermined. |
| g) | **Boiling point/boiling range:** | Undetermined. |
| h) | **Flash point:** | Not applicable. |

| | | |
|---|---|---|
| i) | **Ignition temperature:** | Not applicable. |
| j) | **Self-igniting:** | Product is not self-igniting. |
| k) | **Danger of explosion:** | Product does not present an explosion hazard. |
| l) | **Upper/lower flammability or explosive limits:** | Lower: Not determined.<br>Upper: Not determined. |
| m) | **Vapour pressure:** | Not determined. |
| n) | **Density at 20ºC:** | 1.0344 g/cm$^3$. |
| o) | **Relative density:** | Not determined. |
| p) | **Vapour density:** | Not determined. |
| q) | **Evaporation rate:** | Not determined. |
| r) | **Solubility in/miscibility with water:** | Fully miscible. |
| s) | **Partition coefficient: n- octanol/water:** | Not determined. |
| t) | **Viscosity:** | Dynamic: Not determined.<br>Kinematic: Not determined. |

## 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.

## 11. TOXICOLOGICAL INFORMATION

**11.1 Information on toxicological effects:-**

**Acute toxicity / Values relevant for classification:**

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

| | | | |
|---|---|---|---|
| Sodium Hydroxide | Oral | LD50 | 2000mg/kg (rat) |

No further relevant information available.

| | |
|---|---|
| **Skin corrosion/irritation:** | Caustic effect on skin and mucous membranes. |
| **Serious eye damage/eye irritation:** | Strong caustic effect. |
| **Respiratory or skin sensitization:** | No sensitizing effects known. |
| **Germ cell mutagenicity:** | No further relevant information available |
| **Carcinogenicity:** | No further relevant information available |
| **Reproductive toxicity:** | No further relevant information available |
| **Specific target organ toxicity - single exposure:** | No further relevant information available |
| **Specific target organ toxicity - repeated exposure:** | No further relevant information available |
| **Aspiration hazard:** | No further relevant information available |
| **Additional information:** | Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of oesophagus and stomach. |

| | | |
|---|---|---|
| **11.2** | **Information on possible routes of exposure:-** | |
| | **Short Term (Acute) Exposure:** | No further relevant information available. |
| | **Swallowed:** | No further relevant information available. |
| | **Eyes:** | Strong caustic effect. |
| | **Skin:** | Caustic effect on skin and mucous membranes. |
| | **Inhaled:** | No further relevant information available. |
| | **Long Term (Chronic) Exposure:** | No further relevant information available. |
| | **Swallowed:** | No further relevant information available. |
| | **Eyes:** | Strong caustic effect. |
| | **Skin:** | Caustic effect on skin and mucous membranes. |
| | **Inhaled:** | No further relevant information available. |
| **11.3** | **Early onset symptoms related to exposure:-** | No further relevant information available. |
| **11.4** | **Delayed health effects from exposure:-** | No further relevant information available. |
| **11.5** | **Exposure levels and health effects:-** | No further relevant information available. |
| **11.6** | **Interactive effects:-** | No further relevant information available. |
| **11.7** | **Other:-** | No further relevant information available. |

## 12. ECOLOGICAL INFORMATION

**12.1 Ecotoxicity:-**
No further relevant information available.

**12.2 Persistence/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 Other adverse effects:-**
No further relevant information available.

**Additional ecological information / General notes:**
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 un-neutralised.
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.

**12.6 Other adverse effects:-**
No further relevant information available.

## 13. DISPOSAL CONSIDERATIONS

**13.1 Disposal methods:-**
Must not be disposed together with household garbage.
Do not allow product to reach sewage system.
Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal.
Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.
Disposal must be made according to official regulations.
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

## 14. TRANSPORT INFORMATION

| | |
|---|---|
| **UN number ADR / IMDG / IATA:-** | UN1824 |
| **UN proper shipping name or technical name:-** | |
| **ADR:** | *1824 SODIUM HYDROXIDE SOLUTION, mixture* |
| **IMDG, IATA:** | *SODIUM HYDROXIDE SOLUTION mixture* |
| **Transport hazard class(es):** | |
|  | |
| | 8 (C5) Corrosive substances. |
| **Label:** | 8 |
| **Packaging group:** | III |
| **Environmental hazards:** | Not applicable. |
| **Special precautions for user:** | Warning: Corrosive substances. |
| **Danger code:** | 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. |
| **Additional information – ADR:-** | |
| **Limited quantities:** | 5L |
| **Excepted quantities:** | Code: E1<br>Maximum net quantity per inner packaging: 30 ml<br>Maximum net quantity per outer packaging: 1000 ml |
| **Transport category:** | 3 |
| **Tunnel restriction code:** | E |
| **Additional information – IMDG:-** | |
| **Limited quantities:** | 5L |
| **Excepted quantities:** | Code: E1<br>Maximum net quantity per inner packaging: 30 ml<br>Maximum net quantity per outer packaging: 1000 ml |
| **Hazchem or emergency action code:** | 8 (C5) Corrosive substances. |

## 15. REGULATORY INFORMATION

**15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture/product:-**

Classified as Hazardous according to the criteria of the National Occupational Health and Safety Commission (NOHSC) approved criteria for the classifying hazardous substances [NOHSC: 1008] 3rd edition.
Standard for the Uniform Scheduling of Medicines and Poisons.
Carcinogen classification under WHS Regulation 2011, Schedule 10.
Notification status in accordance with section 3 and current national legislation.

## 16. OTHER INFORMATION

| | |
|---|---|
| **Key to abbreviations/acronyms used in SDS:-** | H314 Causes severe skin burns and eye damage. |

**Key literature references/data sources used to compile SDS:-**

Standard EN420:2003 General requirements for protective gloves: disposable gloves, e.g. nitrile rubber, material thickness 0.1 mm (Australian Standard 2161).
Long-term exposure (Level 6: < 480 min): protective gloves, e.g. nitrile rubber, material thickness 0.7 mm (Australian Standard 2161).
Personal eye protection - Eye and face protectors for occupational applications: safety glasses (Australian Standard AS 1336 and AS/NZS 1337.1:2010).

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**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.
Flam. Liq. 2: Flammable liquids, Hazard Category 2.
Flam. Liq. 3: Flammable liquids, Hazard Category 3.
Acute Tox. 4: Acute toxicity, Hazard Category 4.
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2.
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2.
Repr. 2: Reproductive toxicity, Hazard Category 2.
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3.
STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2.
Asp. Tox. 1: Aspiration hazard, Hazard Category 1.
*** Data compared to the previous version altered**

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