**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@ivoclarvivadent.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. 1 H314 Causes severe skin burns and eye damage.

2.2 Label elements

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
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.

(Contd. on page 2)
Trade name: Ivoclean

- 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
    - EINECS: 215-185-5
    - Reg.nr.: 01-2119457892-27-xxxx
    - sodium hydroxide Skin Corr. 1A, H314 1-<2%
  - 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: CO2, 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.
Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: Ivoclean

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.

7.2 Conditions for safe storage, including any incompatibilities

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.2 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.
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)

Protection of hands:

Protective gloves (EN 374)

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 (EN 166)

**Body protection:** Protective work clothing

### SECTION 9: Physical and chemical properties

<table>
<thead>
<tr>
<th>9.1 Information on basic physical and chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Information</td>
</tr>
<tr>
<td>Appearance:</td>
</tr>
<tr>
<td>Form: Fluid</td>
</tr>
<tr>
<td>Colour: Violet</td>
</tr>
<tr>
<td>Odour: Characteristic</td>
</tr>
<tr>
<td>Odour threshold: Not determined.</td>
</tr>
</tbody>
</table>

| pH-value at 20 °C: 13                                   |

<table>
<thead>
<tr>
<th>Change in condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting point/freezing point: Undetermined.</td>
</tr>
<tr>
<td>Initial boiling point and boiling range: Undetermined.</td>
</tr>
</tbody>
</table>

| Flash point: Not applicable.                          |

| Auto-ignition temperature: Product is not selfigniting.|

| Explosive properties: Product does not present an explosion hazard. |

<table>
<thead>
<tr>
<th>Explosion limits:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower: Not determined.</td>
</tr>
<tr>
<td>Upper: Not determined.</td>
</tr>
</tbody>
</table>

| Vapour pressure: Not determined.                       |

<table>
<thead>
<tr>
<th>Density at 20 °C: 1.0344 g/cm³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative density: Not determined.</td>
</tr>
<tr>
<td>Vapour density: Not determined.</td>
</tr>
<tr>
<td>Evaporation rate: Not determined.</td>
</tr>
</tbody>
</table>

| Solubility in / Miscibility with water: Fully miscible. |

| Partition coefficient: n-octanol/water: Not determined. |

| Viscosity:                                             |
| Dynamic: Not determined.                               |
| Kinematic: Not determined.                             |

| 9.2 Other information No further relevant information available. |
SECTION 10: Stability and reactivity

10.1 Reactivity
No further relevant information available.

10.2 Chemical stability
Stable under normal handling and storage conditions.

10.3 Thermal decomposition / conditions to be avoided
No decomposition if used according to specifications.

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
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 severe skin burns and eye damage.

Respiratory or skin sensitisation
Based on available data, the classification criteria are not met.

Additional toxicological information:
The classification as „corrosive“ is due to the pH-value.

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.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

<table>
<thead>
<tr>
<th>CAS: 1310-73-2 sodium hydroxide</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50/96 h</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 1310-73-2 sodium hydroxide</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50/48 h</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

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:
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.

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/RID/ADN, IMDG, IATA UN1824

14.2 UN proper shipping name
ADR/RID/ADN 1824 SODIUM HYDROXIDE SOLUTION, mixture
IMDG, IATA SODIUM HYDROXIDE SOLUTION mixture

14.3 Transport hazard class(es)
ADR/RID/ADN

- Class 8 (C5) Corrosive substances.
- 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.
Danger code (Kemler): 80
EMS Number: F-A,S-B
Segregation groups Alkalis
SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

- 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.

- 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.
The classification as „corrosive“ is due to the pH-value.

- 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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Skin Corr. 1: Skin corrosion/irritation – Category 1
Skin Corr. 1A: Skin corrosion/irritation – Category 1A

* Data compared to the previous version altered.