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

Printing date 14.05.2019 Version number 8 Revision: 14.05.2019

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

· 1.1 Product identifier
  · Trade name: IPS Neutralizing Powder

· 1.2 Relevant identified uses of the substance or mixture and uses advised against
  · Application of the substance / the mixture Neutralizing powder
  · No further relevant information available.
  
· 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
  
· 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
    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.
  
· 2.3 Other hazards
  · Dust generation
    Particular danger of slipping on leaked/spilled product.

· Results of PBT and vPvB assessment
  · PBT: Not applicable.
  · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures
  · Description: Mixture of substances listed below with nonhazardous additions.
SECTION 4: First aid measures

4.1 Description of first aid measures
- After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Rinse with water. Generally the product does not irritate the skin.
- After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- After swallowing: Rinse out mouth and then drink plenty of water. If symptoms persist consult doctor.

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: The product is not flammable. 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
- Avoid formation of dust. Ensure adequate ventilation. Particular danger of slipping on leaked/spilled product.
- Environmental precautions: Do not allow to enter sewers/surface or ground water.
- Methods and material for containment and cleaning up: Pick up mechanically.

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. Prevent formation of dust.
**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:
  The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- 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 and dental laboratories.
    Keep away from foodstuffs, beverages and feed.
    Wash hands before breaks and at the end of work.
    Avoid contact with the eyes.
  - 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)
Trade name: **IPS Neutralizing Powder**

- **Body protection:** Protective work clothing

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties
- **General Information**
- **Appearance:**
  - **Form:** Powder
  - **Colour:** White
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **pH-value (10 g/l) at 20 °C:** 10.7
- **Change in condition**
  - **Melting point/freezing point:** Undetermined.
  - **Initial boiling point and boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not determined.
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**
  - **Lower:** Not determined.
  - **Upper:** Not determined.
- **Vapour pressure:** Not applicable.
- **Density:**
  - **Relative density:** Not determined.
  - **Vapour density:** Not applicable.
  - **Evaporation rate:** Not applicable.
- **Solubility in / Miscibility with**
  - **water:** Partly soluble.
- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**
  - **Dynamic:** Not applicable.
  - **Kinematic:** Not applicable.
- **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.
- **Thermal decomposition / conditions to be avoided** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** Reacts with acids.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials** No further relevant information available.
- **10.6 Hazardous decomposition products** Carbon dioxide (CO2)
SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity: Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification:

- **CAS: 497-19-8 sodium carbonate**
  - Oral LD50: 4090 mg/kg (rat)
- **CAS: 497-34-1 calcium carbonate**
  - Oral LD50: 6450 mg/kg (rat)

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Causes serious eye irritation.

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

Additional toxicological information: No further relevant information available.

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:

- **CAS: 497-19-8 sodium carbonate**
  - LC50/96 h: 300 mg/l (fish) (Min.), 300 mg/l (fish) (Max.), 300 mg/l (fish) (Median)
- **CAS: 497-19-8 sodium carbonate**
  - LC50/48 h: 176 mg/l (crustaceans) (Min.), 1640 mg/l (crustaceans) (Max.), 565 mg/l (crustaceans) (Median)
- **CAS: 497-19-8 sodium carbonate**
  - EC50/48 h: 200 mg/l (crustaceans) (Min.), 200 mg/l (crustaceans) (Min.), 200 mg/l (crustaceans) (Median)

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.

- **12.5 Results of PBT and vPvB assessment**
  - PBT: Not applicable.
  - vPvB: Not applicable.
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, ADN, IMDG, IATA Void

14.2 UN proper shipping name
ADR/RID/ADN, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)
ADR/RID/ADN, ADN, IMDG, IATA Class Void

14.4 Packing group
ADR/RID/ADN, IMDG, IATA Void

14.5 Environmental hazards:
Marine pollutant: No

14.6 Special precautions for user
Not applicable.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Not applicable.

Transport/Additional information: Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

UN "Model Regulation": Void

SECTION 15: Regulatory information

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
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.

(Contd. on page 7)
### 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
- **PBT**: Persistent, Bioaccumulative and Toxic
- **vPvB**: very Persistent and very Bioaccumulative
- **Eye Irrit. 2**: Serious eye damage/eye irritation – Category 2

*Data compared to the previous version altered.*