ivoclar vivadeni:

Safety Data Sheet acc. to OSHA HCS

Printing date 05/14/2019

Version number 8

Reviewed on 05/14/2019

1 Identification

· Product identifier

• Trade name: IPS Ceramic Neutralizing powder

· Application of the substance / the mixture Neutralizing powder

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(s) identification

- \cdot Classification of the substance or mixture
- Eye Irrit. 2A H319 Causes serious eye irritation.
- · Label elements
- · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



- · Signal word Warning
- · Hazard statements
- Causes serious eye irritation.
- · Precautionary statements
- Wear protective gloves/protective clothing/eye protection/face protection.

If eye irritation persists: Get medical advice/attention.

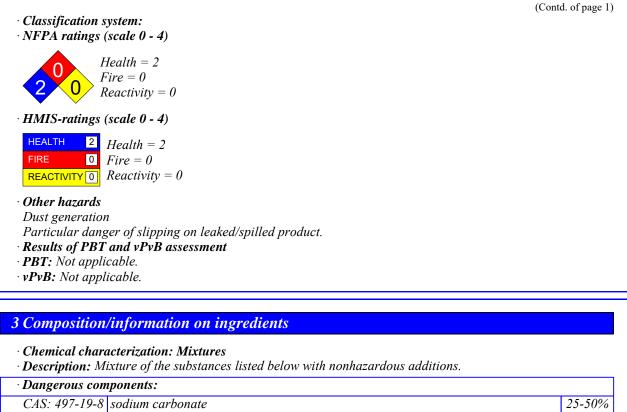
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Trade name: IPS Ceramic Neutralizing powder



CAS: 471-34-1 calcium carbonate

4 First-aid measures

· 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.
- · 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 Fire-fighting measures

- · Extinguishing media
- Suitable extinguishing agents:
- The product is not flammable.
- Use fire fighting measures that suit the environment.

• Special hazards arising from the substance or mixture No further relevant information available.

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25-50%

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• Advice for firefighters

· Protective equipment: No special measures required.

6 Accidental release measures

· 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.

· 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.

Prevent formation of dust.

• 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: 471-34-1 calcium carbonate

PEL 15* 5** mg/m³

*total dust **respirable fraction

REL 10* 5** mg/m³ *total dust **respirable fraction

TLV TLV withdrawn

• 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.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

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• 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:

· Protection of nanas

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

Information on basic physical and ch General Information	nemical properties	
Appearance:		
Form:	Powder	
Color:	White	
Odor:	Odorless	
Odor threshold:	Not determined.	
<i>pH-value</i> (10 g/l) at 20 °C (68 °F):	10.7	
Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined.	
Flash point:	Not applicable.	
Flammability (solid, gaseous):	Not determined.	
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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		(Contd. of page 4
· Vapor pressure:	Not applicable.	
· Density:	Not determined.	
Relative density	Not determined.	
Vapor density	Not applicable.	
Evaporation rate	Not applicable.	
· Solubility in / Miscibility with		
Water:	Partly soluble.	
Partition coefficient (n-octan	ol/water): Not determined.	
Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
• 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.
- \cdot Possibility of hazardous reactions Reacts with acids.
- Conditions to avoid No further relevant information available.
- $\cdot \textit{Incompatible materials: } No further relevant information available.$
- · Hazardous decomposition products: Carbon dioxide (CO2)

11 Toxicological information

· Information on toxicological effects

• Acute toxicity:

· LD/LC50 values that are relevant for classification:

CAS: 497-19-8 sodium carbonate

Oral LD50 4090 mg/kg (rat)

CAS: 471-34-1 calcium carbonate

Oral LD50 6450 mg/kg (rat)

• on the skin: No irritant effect.

• on the eye: Irritating effect.

- Sensitization: No sensitizing effects known.
- · Additional toxicological information: No further relevant information available.

· Carcinogenic categories

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

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Trade name: IPS Ceramic Neutralizing powder

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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) CAS: 497-19-8 sodium carbonate EC50/48 h 200 mg/l (crustaceans) (Min.) 200 mg/l (crustaceans) (Median) Persistence and degradability No further relevant information available. Bioaccumulative potential No further relevant information available. Mobility in soil No further relevant information available. Additional ecological information: General notes: 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: •PWB: Not applicable. •PWB: Not applicable. •PWB: Not applicable. •PWB: Not applicable. •PWB: Not applica	· Toxicity	
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· DOT, ADR/RID/ADN, ADN, IMDG, IATA Void

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

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Reviewed on 05/14/2019

Trade name: IPS Ceramic Neutralizing powder

	(Contd. of page
· Transport hazard class(es)	
· DOT, ADR/RID/ADN, ADN, IMDG, IA · Class	TA Void
· Packing group · DOT, ADR/RID/ADN, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
• Transport in bulk according to Annex I MARPOL73/78 and the IBC Code	I of Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN ''Model Regulation'':	Void

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.
TSCA (Toxic Substances Control Act): CAS: 497-19-8 sodium carbonate CAS: 471-34-1 calcium carbonate

· Proposition 65

• Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

• TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

·NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

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US ·

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Trade name: IPS Ceramic Neutralizing powder

(Contd. of page 7) · GHS label elements The product is classified and labeled according to the Globally Harmonized System (GHS). Hazard pictograms · Signal word Warning · Hazard statements Causes serious eye irritation. · Precautionary statements Wear protective gloves/protective clothing/eye protection/face protection. If eye irritation persists: Get medical advice/attention. · 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 preparation / last revision 05/14/2019 / 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 DOT: US Department of Transportation IATA: International Air Transport Association ACGIH: American Conference of Governmental Industrial Hygienists 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) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit Eye Irrit. 2A: Serious eye damage/eye irritation - Category 2A • * Data compared to the previous version altered.