SAFETY DATA SHEETS

This SDS packet was issued with item: 071316496

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071316488

ivoclar vivadent

Safety Data Sheet acc. to OSHA HCS

Printing date 11/26/2020

Version number 1

Reviewed on 11/26/2020

1 Identification

- · Product identifier
- · Trade name: ZirCAD Cement

· Application of the substance / the mixture Resin reinforced glass ionomer luting cement

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

Skin Irrit. 2H315 Causes skin irritation.Eye Irrit. 2AH319 Causes serious eye irritation.Skin Sens. 1H317 May cause an allergic skin reaction.

- · 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 skin irritation.
- *Causes serious eye irritation. May cause an allergic skin reaction.*
- **Precautionary statements**
- Avoid breathing dust/fume/gas/mist/vapors/spray Wear protective gloves / eye protection / face protection.

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If on skin: Wash with plenty of water.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If skin irritation or rash occurs: Get medical advice/attention.

Dispose of contents/container in accordance with local/regional/national/international regulations. • Additional information:

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

• Classification system:

· NFPA ratings (scale 0 - 4)

 $\begin{array}{c} \textbf{Health} = 2\\ Fire = 0\\ Reactivity = 0 \end{array}$

· HMIS-ratings (scale 0 - 4)

| HEALTH 2 | Health = 2 |
|--------------|--------------|
| | Fire = 0 |
| REACTIVITY 0 | Reactivity = |

· Other hazards

· Results of PBT and vPvB assessment

· **PBT:** Not applicable.

• **vPvB:** Not applicable.

3 Composition/information on ingredients

0

· Chemical characterization: Mixtures

• Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:

| Fluoro-aluminosilicate glass 50-10 | | 50-100% |
|------------------------------------|---|---------|
| CAS: 27813-02-1 | methacrylic acid, monoester with propane-1,2-diol | 10-25% |
| CAS: 1830-78-0 | glycerin-1.3-dimethacrylate | 2.5-10% |

4 First-aid measures

· Description of first aid measures

• After inhalation:

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

• After skin contact:

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.

If symptoms persist consult doctor.

• Information for doctor:

• *Most important symptoms and effects, both acute and delayed* No further relevant information available.

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• Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 *Fire-fighting measures*

- · Extinguishing media
- Suitable extinguishing agents:
- CO2, extinguishing powder or water spray. Fight larger fire with alcohol resistant foam.
- Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures Wear protective clothing.

- 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.
- Protective Action Criteria for Chemicals

• PAC-1:

None of the ingredients is listed.

· PAC-2:

None of the ingredients is listed.

· PAC-3:

None of the ingredients is listed.

7 Handling and storage

- · Handling:
- · Precautions for safe handling For use in dentistry only.
- · 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: No special requirements.
- · 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:
- 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 that were valid during the creation were used as basis.

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| • Exposure | controls |
|------------|----------|
|------------|----------|

- · Personal protective equipment:
- General protective and hygienic measures:
- Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin.
- · Breathing equipment: Not required.
- Protection of hands:



Protective gloves

· Material of gloves

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 can not be calculated in advance and has therefore to be checked prior to the application.

· 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

9 Physical and chemical properties

| General Information | | |
|--------------------------------|--|--|
| Appearance: Form: | Dastu | |
| Form: Color: | Pasty | |
| Odor: | According to product specification Characteristic | |
| Odor threshold: | Not determined. | |
| pH-value: | Not applicable. | |
| Change in condition | | |
| Melting point/Melting range: | Undetermined. | |
| Boiling point/Boiling range: | Undetermined. | |
| Flash point: | Not applicable. | |
| Flammability (solid, gaseous): | Not applicable. | |
| Decomposition temperature: | 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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|------------------------------------|--|-------------------|
| · Vapor pressure: | Not determined. | |
| Density: | Not determined. | |
| · Relative density | Not determined. | |
| Vapor density | Not determined. | |
| · Evaporation rate | Not determined. | |
| · Solubility in / Miscibility with | | |
| Water: | Not miscible or difficult to mix. | |
| · Partition coefficient (n-octano | l/water): Not determined. | |
| · Viscosity: | | |
| Dynamic: | Not determined. | |
| Kinematic: | Not determined. | |
| · Solvent content: | | |
| VOC content: | 0.00 % | |
| • 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.
- Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological information

· Information on toxicological effects

- Acute toxicity:
- on the skin: Irritant to skin and mucous membranes.
- on the eye: Irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- Additional toxicological information:

· Carcinogenic categories

·NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

· Toxicity

- Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- *Mobility in soil* No further relevant information available.

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- 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.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

· Waste treatment methods

· Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

· Uncleaned packagings:

· Recommendation: Disposal must be made according to official regulations.

14 Transport information

| · UN-Number · DOT, ADR/RID/ADN, IMDG, IATA | Void |
|--|--|
| · UN proper shipping name · DOT, ADR/RID/ADN, IMDG, IATA | Void |
| • Transport hazard class(es) | |
| · DOT, ADR/RID/ADN, ADN, IMDG, IATA · Class | 4 Void |
| · Packing group · DOT, ADR/RID/ADN, IMDG, IATA | Void |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |
| • Transport in bulk according to Annex II of MARPOL73/78 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 |

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.

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• Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

• TSCA (Toxic Substances Control Act):

All components have the value ACTIVE.

• *Hazardous Air Pollutants* None of the ingredients is listed.

· 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.

· GHS label elements

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



· Signal word Warning

· Hazard statements

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

Precautionary statements

Avoid breathing dust/fume/gas/mist/vapors/spray

Wear protective gloves / eye protection / face protection.

If on skin: Wash with plenty of water.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If skin irritation or rash occurs: Get medical advice/attention.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· 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.

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· 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 11/26/2020 / -• 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) VOC: Volatile Organic Compounds (USA, EU) 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 Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Irrit. 2A: Serious eye damage/eye irritation - Category 2A Skin Sens. 1: Skin sensitisation – Category 1