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

Printing date 08.11.2018

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Version number 1

Revision: 08.11.2018

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

· 1.1 Product identifier

· Trade name: SR Vivodent CAD Multi

• 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 DCL tooth material for the CAD/CAM technology

• 1.3 Details of the supplier of the safety data sheet • Manufacturer/Supplier: Ivoclar Vivadent AG Bendererstrasse 2 FL-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, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

• 2.1 Classification of the substance or mixture • Classification according to Regulation (EC) No 1272/2008 The product is not classified according to the CLP regulation.

· 2.2 Label elements

· Labelling according to Regulation (EC) No 1272/2008 Void

· Hazard pictograms Void

· Signal word Void

· Hazard statements Void

· 2.3 Other hazards Avoid breathing sanding dust /swarf.

· 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.

· Dangerous components: Void

• 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: No special measures required.

- After inhalation: Grinding dust: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin.

• After eye contact:

Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

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Mechanical effects only.

- After swallowing: Rinse out mouth and then drink plenty of water.
- 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 Not required.
- · 6.2 Environmental precautions: No special measures required.
- 6.3 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.

- Information about fire and explosion protection: No special measures required.
- · 7.2 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: Protect from heat and direct sunlight.
- 7.3 Specific end use(s) No further relevant information available.

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.

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Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work.

• **Respiratory protection:** Mechanical processing:

Use respiratory protective device against the effects of dust.

- Recommended filter device for short term use: Filter Pl
- Protection of hands:

Protective gloves should always be worn during mechanical and thermal processing. After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

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:

Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

SECTION 9: Physical and chemical prope	rties
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General Information		
Appearance:	G 1:1	
Form:	Solid	
Colour:	According to product specification	
Odour:	Odourless N. () ()	
Odour threshold:	Not determined.	
pH-value:	Not applicable.	
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.	
Vapour pressure:	Not applicable.	
Density:	Not determined.	
Relative density	Not determined.	
Vapour density	Not applicable.	
Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
water:	Insoluble.	
Partition coefficient: n-octanol/water:	Not determined.	
Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	

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· Solvent content:

Solids content:

• 9.2 Other information

100.0 % 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 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.

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 Based on available data, the classification criteria are not met.
- Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- 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.*
- \cdot **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: No further relevant information available.
- 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: Generally not hazardous for water
- · 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

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.

\cdot European waste catalogue

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· 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 I Marpol and the IBC Code	I of Not applicable.
• Transport/Additional information:	Product is not classified as a dangerous good for transpor (ADR, IMDG, IATA).
· UN ''Model Regulation'':	Void

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

· National regulations:

 \cdot Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

· 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.

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 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