vivadent

Printing date 03/20/2017

Version number 10

Reviewed on 03/17/2017

1 Identification

· Product identifier

Trade name: SR Vivodent DCL, SR Vivodent Plus DCL, SR Orthotyp DCL, SR Postaris DCL, SR Ortholingual DCL, SR Orthoplane DCL

· Application of the substance / the mixture Manufacture of dental prothesis

· 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

Classification of the substance or mixture The product is not classified according to the Globally Harmonized System (GHS).

- · Label elements · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Classification system:
- · NFPA ratings (scale 0 4)



Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)

HEALTH • Health = 00 FIRE Fire = 0**REACTIVITY** O *Reactivity* = 0

· Other hazards Avoid breathing sanding dust /swarf.

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

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · Description: Resin teeth based on polymethylmethacrylate
- · Dangerous components: Void

4 First-aid measures

- · 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.
- Mechanical effects only.
- After swallowing: Grinding dust: Rinse out mouth and then drink plenty of water.
- 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:
- CO2, extinguishing powder or water spray. Fight larger fires with water spray or 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 Not required.
- · Environmental precautions: No special measures required.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- · Reference to other sections
- No dangerous substances are released.
- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

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7 Handling and storage

- · Handling:
- · Precautions for safe handling
- Only adequately trained personnel should handle this product. 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: None.

• 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. · 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. Breathing equipment: Mechanical processing: Use respiratory protective device against the effects of dust. • 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 Mechanical processing: Leather gloves Strong gloves · 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).

9 Physical and chemical properties

- · Information on basic physical and chemical properties
- General Information
- · Appearance: Form:

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Solid

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Color:	According to product specification	
· Odor:	Odorless	
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 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.	
Vapor pressure:	Not applicable.	
Density:	Not determined.	
Relative density	Not determined.	
· Vapor density	Not applicable.	
Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
Water:	Insoluble.	
Partition coefficient (n-octanol/wa	ter): Not determined.	
Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
Solvent content:		
Solids content:	100.0 %	
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: No irritant effect.

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• on the eye: No irritating effect.

· Sensitization: No sensitizing effects known.

• Additional toxicological information:

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

CAS: 9011-14-7 polymethylmethacrylate

· 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.
- · Additional ecological information:
- · General notes: Generally not hazardous for water
- · 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:

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	
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· DOT, A	DR,RID,ADN, ADN, IMDG, IATA Void	
	7 • •	

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

• Transport hazard class(es)

· DOT, ADR, RID, ADN, ADN, IMDG, IATA Void

· Class

· Packing group · DOT, ADR, RID, ADN, IMDG, IATA Void

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• Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
• Transport in bulk according to Annex . MARPOL73/78 and the IBC Code	II 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):

All ingredients are 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 Void

· Hazard pictograms Void

· Signal word Void

· Hazard statements Void

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- National regulations:
 Other regulations, limitations and prohibitive regulations
 The product is a medical device according to the Directive 93/42/EEC.
 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 03/20/2017 / 9

• 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) 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 • * Data compared to the previous version altered.