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Safety Data Sheet acc. to OSHA HCS

Printing date 04/29/2015

Version number 3

Reviewed on 04/20/2015

1 Identification

· Product identifier

• Trade name: <u>SR Phonares NHC, SR Phonares Typ NHC, SR Phonares Lingual</u> NHC

• Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.

· 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 LST 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:
- · NFPÅ ratings (scale 0 4)



· HMIS-ratings (scale 0 - 4)



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- · Other hazards Avoid breathing sanding dust /swarf.
- · 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 methacrylates
- · Dangerous components: Void

4 First-aid measures

- · Description of first aid measures
- · General information: No special measures required.
- After skin contact: 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. Mechanical effects only.*
- · After swallowing: Seek medical treatment.
- · Information for doctor:
- Most important symptoms and effects, both acute and delayed No further relevant information available.
- \cdot 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:
- \cdot 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.
- · Breathing equipment: Use respiratory protective device against the effects of dust.
- · Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· 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:

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: Color:

Solid According to product specification

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· Odor:	Odorless		
· Odour 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.		
· Vapour density	Not applicable.		
· Evaporation rate	Not applicable.		
\cdot Solubility in / Miscibility with			
Water:	Insoluble.		
· Partition coefficient (n-octanol/way	t er): 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:
- · Primary irritant effect:
- 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)

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

1 9			
· UN-Number · DOT, ADR, ADN, IMDG, IATA	Void		
· UN proper shipping name · DOT, ADR, ADN, IMDG, IATA	Void		
· Transport hazard class(es)			
· DOT, ADR, ADN, IMDG, IATA · Class	Void		
· Packing group · DOT, ADR, 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'':		

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 04/29/2015 / 2

• 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)

 \cdot * Data compared to the previous version altered.