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Material Safety Data Sheet acc. to ISO 11014

Printing date 04/29/2015

Version number 5

Reviewed on 04/16/2015

1 Identification

- · Product identifier
- Trade name: SR Adoro Opaquer, Gingiva Opaquer, Intensiv Opaquer
- *Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.*
- Application of the substance / the mixture Crowns- and bridges material
- · 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 USA - Injoirac: 1-800-353-5055 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

Eye Irrit. 2A H319 Causes serious eye irritation.

Skin Sens. 1 H317 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-determining components of labeling:* 1,10-decandiol dimethacrylate
- Hazard statements Causes serious eye irritation. May cause an allergic skin reaction.

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· Precautionary statements Wear protective gloves/protective clothing/eye protection/face protection. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. · Hazard description: · WHMIS-symbols: D2B - Toxic material causing other toxic effects · Classification system: · NFPA ratings (scale 0 - 4) Health = 10 Fire = 0Reactivity = 0· HMIS-ratings (scale 0 - 4) HEALTH 1 Health = 1FIRE 0 Fire = 0**REACTIVITY O** *Reactivity* = 0· Other hazards · Results of PBT and vPvB assessment · PBT: Not applicable. · vPvB: Not applicable. **3** Composition/information on ingredients · Chemical characterization: Mixtures · Description: Mixture of the substances listed below with nonhazardous additions. · Dangerous components: 6701-13-9 1,10-decandiol dimethacrylate 10-13% *≤1%* 10373-78-1 camphorquinone

4 First-aid measures

· Description of first aid measures

• After inhalation:

Supply fresh air and to be sure call for a doctor.

- In case of unconsciousness place patient stably in side position for transportation.
- · After skin contact: Rinse with water.
- 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

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- 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: 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.
- 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:
- Protect from exposure to the light.
- Protect from heat and direct sunlight.
- 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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(Contd. of page 3) · Exposure controls · Personal protective equipment: • General protective and hygienic measures: Usual hygienic measures for dental practice. Wash hands before breaks and at the end of work. *Keep away from foodstuffs, beverages and feed.* Avoid contact with the eyes and skin. · Breathing equipment: Not required. · Protection of hands: Protective gloves 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. · Not suitable are gloves made of the following materials: *Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.* · Eye protection: Safety glasses 9 Physical and chemical properties · Information on basic physical and chemical properties · General Information · Appearance: Form: Pasty Color: According to product specification · Odor: **Characteristic** Not determined. · Odour threshold: · 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. · Auto igniting: Product is not selfigniting. · Danger of explosion: Product does not present an explosion hazard. · Explosion limits:

 Upper:
 Not determined.

 · Vapor pressure:
 Not determined.

 · Density:
 Not determined.

 · Relative density
 Not determined.

 · Vapour density
 Not determined.

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Not determined. Not determined.

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• Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
Water:	Nearly insoluble.	
 Partition coefficient (n-octanol) Viscosity: 	waler): Not determined.	
Dynamic:	Not determined.	
Dynamic: Kinematic:	Not determined. Not determined.	

10 Stability and reactivity

· Reactivity No further relevant information available.

· Chemical stability

Stable under normal handling and storage conditions.

- Photoreactive (Danger of polymerization).
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid
- Protect from exposure to the light.
- Keep away from heat and direct sunlight.
- · 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.
- on the eye: Irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- 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.

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:

Water hazard class 2 (Self-assessment): hazardous for water

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Do not allow product to reach ground water, water course or sewage system. Danger to drinking water if even small quantities leak into the ground.

· 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

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· UN-Number · DOT, TDG, ADN, IMDG, IATA	Void
· UN proper shipping name · DOT, TDG, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, TDG, ADN, IMDG, IATA · Class	Void
· Packing group · DOT, TDG, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
• Transport in bulk according to Annex II oj 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":	-

15 Regulatory information

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

· Sara

 \cdot Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

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• TSCA (Toxic Substances Control Act):

All ingredients are listed.

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

 \cdot 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-determining components of labeling:* 1,10-decandiol dimethacrylate
- · Hazard statements
- Causes serious eye irritation. May cause an allergic skin reaction.

Precautionary statements
Wear protective gloves/protective clothing/eye protection/face protection.
Wash contaminated clothing before reuse.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.

· 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.

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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 / 4
Abbreviations and acronyms: 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 Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA) WHMIS: Workplace Hazardous Materials Information System (Canada) Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
* Data compared to the previous version altered.