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Safety Data Sheet acc. to OSHA HCS

Printing date 05/12/2016

Version number 6

Reviewed on 05/12/2016

1 Identification

· Product identifier

• Trade name: SR Chromasit Dentin, Creative Dentin, Incisal, Creative Incisal, Transparent

· 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 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
Skin Irrit. 2 H315 Causes skin irritation.
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: urethane dimethacrylate
 1,4-butanediol dimethacrylate
 Hazard statements Causes skin irritation.

(Contd. on page 2)

US

Trade name: SR Chromasit Dentin, Creative Dentin, Incisal, Creative Incisal, **Transparent**

(Contd. of page 1)

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. · Classification system: · NFPA ratings (scale 0 - 4)



Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



- · 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:

CAS: 72869-86-4	urethane dimethacrylate	50-100%
CAS: 2082-81-7	1,4-butanediol dimethacrylate	10-<20%

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

(Contd. on page 3)

Printing date 05/12/2016

Version number 6

Trade name: SR Chromasit Dentin, Creative Dentin, Incisal, Creative Incisal, Transparent

(Contd. of page 2)

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: 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.
- \cdot Further information about storage conditions:

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.
- · Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures: Usual hygienic measures for dental practice and dental laboratories. Wash hands before breaks and at the end of work. Keep away from foodstuffs, beverages and feed. Avoid contact with the eyes and skin.

Printing date 05/12/2016

(Contd. of page 3)

Trade name: SR Chromasit Dentin, Creative Dentin, Incisal, Creative Incisal, Transparent

· Breathing equipment: Not required.

• Protection of hands:



Protective gloves

After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of 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.

· 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

General Information		
Appearance:		
Form:	Pasty	
Color:	According to product specification	
Odor:	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.	
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 determined.	
Density:	Not determined.	
Relative density	Not determined.	
Vapor density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
Water:	Nearly insoluble.	
Partition coefficient (n-octanol/wat	er): Not determined.	
Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	

US

Printing date 05/12/2016

Version number 6

Reviewed on 05/12/2016

Trade name: SR Chromasit Dentin, Creative Dentin, Incisal, Creative Incisal, Transparent

(Contd. of page 4)

· 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 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:
- on the skin: Irritant to skin and mucous membranes.
- · 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 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.

(Contd. on page 6)

Version number 6

Trade name: SR Chromasit Dentin, Creative Dentin, Incisal, Creative Incisal, Transparent

(Contd. of page 5)

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.

UN-Number	
DOT, ADR,RID,ADN, ADN, IMDG, IATA	Void
UN proper shipping name DOT, ADR,RID,ADN, ADN, IMDG, IATA	Void
Transport hazard class(es)	
DOT, ADR,RID,ADN, ADN, IMDG, IATA	
Class	Void
Packing group DOT, ADR,RID,ADN, IMDG, IATA	Void
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Not applicable.
Transport in bulk according to Annex II of	f
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 haza	urdous substances):
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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.

(Contd. on page 7)

Printing date 05/12/2016

Version number 6

Reviewed on 05/12/2016

Trade name: SR Chromasit Dentin, Creative Dentin, Incisal, Creative Incisal, Transparent

(Contd. of page 6)

A4

· 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)

CAS: 13760-80-0 ytterbium trifluoride

· 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: urethane dimethacrylate
 1,4-butanediol dimethacrylate
 Hazard statements
 Causes skin irritation.
 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.

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 05/12/2016 / 5

(Contd. on page 8)

US

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Trade name: SR Chromasit Dentin, Creative Dentin, Incisal, Creative Incisal, Transparent

(Contd. of page 7)

· 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 Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2 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. US