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# Safety Data Sheet acc. to OSHA HCS

Printing date 04/29/2015

Version number 4

Reviewed on 04/16/2015

## **1 Identification**

· Product identifier

Trade name: SR Adoro Incisal, Dentin, Deep Dentin, Neck, Transpa Incisal, Special Incisal, Inter Incisal, Occlusal Dentin, Mamelon, Effect, Opal Effect, Incisal Edge, Transpa, Transpa Clear, Add-On

• 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 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: urethane dimethacrylate 1,10-decandiol dimethacrylate* 

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Hazard statements	(00000000000000000000000000000000000000
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)	
$ \begin{array}{c} \textbf{Health} = 1\\ Fire = 0\\ Reactivity = 0\end{array} $	
HMIS-ratings (scale 0 - 4)	
HEALTH1Health = 1FIRE $\odot$ Fire = 0REACTIVITY $\odot$ Reactivity = 0	
Other hazards	
Results of PBT and vPvB assessment	
<b>PBT</b> : Not applicable.	
<b>vPvB:</b> Not applicable.	

### 3 Composition/information on ingredients

· Chemical characterization: Mixtures

· Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:			
72869-86-4	urethane dimethacrylate	10-<20%	
6701-13-9	1,10-decandiol dimethacrylate	2.5-<10%	
43048-08-4	tricyclodocane dimethanol dimethacrylate	1-<2.5%	

# 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. If symptoms persist, 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. (Contd. on page 3)

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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
- 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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·	Exposure	controls
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- · 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 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	
· Odour threshold:	Not determined.	
· pH-value:	Not applicable.	
· Change in condition		
Melting point/Melting range:	Undetermined.	
<b>Boiling point/Boiling range:</b>	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:		
<i>Lower:</i>	Not determined.	
Upper:	Not determined.	
· Vapor pressure:	Not determined.	
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		(Contd. of page
· Density:	Not determined.	
· Relative density	Not determined.	
· Vapour density	Not determined.	
· Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
Water:	Nearly insoluble.	
· Partition coefficient (n-octanol/w	ater): Not determined.	
· Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
• 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.

- 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.
- $\cdot$  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.

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### **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
- Do not allow product 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.

### **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, 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
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
• Transport in bulk according to Annex I MARPOL73/78 and the IBC Code	I of Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
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· 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

*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 1,10-decandiol dimethacrylate* 

· Hazard statements

Causes serious eye irritation.

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(Contd. of page 7) 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

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 / 3

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)
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.