

Printing date 04/29/2015 Version number 5 Reviewed on 04/17/2015

1 Identification

- · Product identifier
- · Trade name: SR Chromasit Opaquer, Intensive 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 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 Sens. 1 H317 May cause an allergic skin reaction.

Carc. 2 H351 Suspected of causing cancer.

- · Label elements
- · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms





GHS07

GHSU8

- · Signal word Warning
- · Hazard-determining components of labeling:

titanium dioxide dibenzoyl peroxide

· Hazard statements

May cause an allergic skin reaction.

Suspected of causing cancer.

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· Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection. Wash contaminated clothing before reuse.

- · Hazard description:
- · WHMIS-symbols:

D2B - Toxic material causing other toxic effects



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



Health = 0 Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



· Other hazards

Dust generation

Particular danger of slipping on leaked/spilled product.

- · 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:			
7727-43-7	barium sulphate, natural	25-40%	
1344-28-1	aluminium oxide	25-30%	
13463-67-7	titanium dioxide	1-1.5%	
94-36-0	dibenzoyl peroxide	≤1%	

4 First-aid measures

- · Description of first aid measures
- · After inhalation:

 $Supply fresh\ air;\ consult\ doctor\ in\ case\ of\ complaints.$

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Rinse with water.

If skin irritation continues, consult a doctor.

· 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.

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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.

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

Avoid formation of dust.

Particular danger of slipping on leaked/spilled product.

- · Environmental precautions: No special measures required.
- · 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 heat and direct sunlight.
- · 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:

7727-43-7 barium sulphate, natural

EL Long-term value: 10* 3** mg/m³ *total dust, **respirable fraction

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EV Long-term value: 10 mg/m³

total dust

1344-28-1 aluminium oxide

EL Long-term value: 1.0 mg/m³

respirable, as Al

EV Long-term value: 10 mg/m³

total dust

13463-67-7 titanium dioxide

EL Long-term value: 10* 3** mg/m³

*total dust; **respirable fraction; IARC 2B

EV Long-term value: 10 mg/m³

total dust

94-36-0 dibenzoyl peroxide

EL Long-term value: 5 mg/m³

EV Long-term value: 5 mg/m³

- · 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.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the skin.

· Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· 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.

· Eye protection: Safety glasses

9 Physical and chemical properties

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

Form: Powder

Color: According to product specification

Odor:OdorlessOdour threshold:Not determined.

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· 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.				
· Solubility in / Miscibility with				
Water:	Nearly insoluble.			
· Partition coefficient (n-octanol/wat	ter): Not determined.			
· Viscosity:				
Dynamic: Not applicable.				
Kinematic:	Not applicable.			
· 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.
- · on the eye: No irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information: No further relevant information available.

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Carcinogenic categories

IARC (International Agency for Research on Cancer)

9011-14-7 polymethylmethacrylate 3

94-36-0 dibenzoyl peroxide

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.

· 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	

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Special precautions for user

Not applicable.

Transport in bulk according to Annex II of 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
- · Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

1344-28-1 aluminium oxide 94-36-0 dibenzoyl peroxide

· 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)

1344-28-1 aluminium oxide 94-36-0 dibenzoyl peroxide A4

· 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





GHS07

GHS08

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· Signal word Warning

· Hazard-determining components of labeling:

titanium dioxide

dibenzoyl peroxide

· Hazard statements

May cause an allergic skin reaction.

Suspected of causing cancer.

· Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

Wash contaminated clothing before reuse.

· 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 / 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 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)

WHMIS: Workplace Hazardous Materials Information System (Canada)

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Carc. 2: Carcinogenicity, Hazard Category 2

 \cdot * Data compared to the previous version altered.

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