

**Safety Data Sheet**  
acc. to OSHA HCS

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.

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  - **Label elements**
  - **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
  - **Hazard pictograms**
- 

GHS07



GHS08
- **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.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

· **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	25-50%
1344-28-1	aluminium oxide	25-50%
13463-67-7	titanium dioxide	1-<2.5%
94-36-0	dibenzoyl peroxide	1-<2.5%

### 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.  
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.

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### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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**

PEL	Long-term value: 15* 5** mg/m <sup>3</sup> *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m <sup>3</sup> *total dust **respirable fraction
TLV	Long-term value: 5* mg/m <sup>3</sup> *inhalable fraction; E

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### 1344-28-1 aluminium oxide

PEL	Long-term value: 15*; 15** mg/m <sup>3</sup> *Total dust; ** Respirable fraction
REL	Long-term value: 10* 5** mg/m <sup>3</sup> as Al*Total dust**Respirable/pyro powd./welding f.
TLV	Long-term value: 1* mg/m <sup>3</sup> as Al; *as respirable fraction

### 13463-67-7 titanium dioxide

PEL	Long-term value: 15* mg/m <sup>3</sup> *total dust
REL	See Pocket Guide App. A
TLV	Long-term value: 10 mg/m <sup>3</sup> withdrawn from NIC

### 94-36-0 dibenzoyl peroxide

PEL	Long-term value: 5 mg/m <sup>3</sup>
REL	Long-term value: 5 mg/m <sup>3</sup>
TLV	Long-term value: 5 mg/m <sup>3</sup>

· **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

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· <b>Odor:</b>	Odorless
· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	Not applicable.
· <b>Change in condition</b>	
<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gaseous):</b>	Not determined.
· <b>Auto igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapor pressure:</b>	Not applicable.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with</b>	
<b>Water:</b>	Nearly insoluble.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Other information</b>	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.

### 14 Transport information

- |                                     |      |
|-------------------------------------|------|
| · <b>UN-Number</b>                  |      |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>  | Void |
| · <b>UN proper shipping name</b>    |      |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>  | Void |
| · <b>Transport hazard class(es)</b> |      |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>  |      |
| · <b>Class</b>                      | Void |
| · <b>Packing group</b>              |      |
| · <b>DOT, ADR, IMDG, IATA</b>       | Void |
| · <b>Environmental hazards:</b>     |      |
| · <b>Marine pollutant:</b>          | No   |

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- |  |  |
|--|--|
| <b>· Special precautions for user</b>  | Not applicable.  |
| <b>· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable.  |
| <b>· Transport/Additional information:</b>                                       | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| <b>· UN "Model Regulation":</b>  | -  |

### 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
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94-36-0	dibenzoyl peroxide
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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.

**· 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	
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94-36-0	dibenzoyl peroxide	
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**· 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**



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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:**  
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)  
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1  
Carc. 2: Carcinogenicity, Hazard Category 2
- **\* Data compared to the previous version altered.**

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