

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

Printing date 05/07/2015

Version number 6

Reviewed on 03/20/2015


**1 Identification**

- **Product identifier**
- **Trade name: *Dual Cement (Catalyst)***
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** *Dual-curing resin-based dental luting 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.*  
*STOT SE 3 H335 May cause respiratory irritation.*

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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
- **Signal word** *Warning*
  - **Hazard-determining components of labeling:**  
*urethane dimethacrylate*  
*ytterbium trifluoride*

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**Trade name: Dual Cement (Catalyst)**

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1,10-decandiol dimethacrylate  
dibenzoyl peroxide

· **Hazard statements**

Causes skin irritation.  
Causes serious eye irritation.  
May cause an allergic skin reaction.  
May cause respiratory irritation.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.  
Avoid release to the environment.  
Wash contaminated clothing before reuse.  
If skin irritation or rash occurs: Get medical advice/attention.  
If eye irritation persists: Get medical advice/attention.

· **Additional information:**

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 1  
Fire = 0  
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



HEALTH 1 Health = 1  
FIRE 0 Fire = 0  
REACTIVITY 0 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:**

72869-86-4	urethane dimethacrylate	25-50%
13760-80-0	ytterbium trifluoride	20-<25%
6701-13-9	1,10-decandiol dimethacrylate	2.5-<10%
94-36-0	dibenzoyl peroxide	0.1-<1%

### 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.

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- **After swallowing:** 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:**  
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** 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:**  
Store in a cool place.  
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.

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· **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.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Keep away from foodstuffs, beverages and feed.

· **Breathing equipment:** Not required.

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **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: Pasty

Color: According to product specification

· **Odor:** Characteristic

· **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

· **Flash point:** 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.

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· <b>Density at 20 °C (68 °F):</b>	1.7 g/cm <sup>3</sup> (14.187 lbs/gal)
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water:</b>	Nearly insoluble.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
· <b>Dynamic:</b>	Not determined.
· <b>Kinematic:</b>	Not determined.
· <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**  
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**

· **IARC (International Agency for Research on Cancer)**

7631-86-9	silicon dioxide, chemically prepared	3
94-36-0	dibenzoyl peroxide	3
128-37-0	2,6-di-tert-butyl-p-cresol	3

· **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.

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- **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 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.

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

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### 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):**

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)**

13760-80-0 ytterbium trifluoride

A4

94-36-0 dibenzoyl peroxide

A4

128-37-0 2,6-di-tert-butyl-p-cresol

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

· **Signal word** Warning

· **Hazard-determining components of labeling:**

urethane dimethacrylate

ytterbium trifluoride

1,10-decandiol dimethacrylate

dibenzoyl peroxide

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

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*May cause respiratory irritation.*

· **Precautionary statements**

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

*Avoid release to the environment.*

*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** 05/07/2015 / 5

· **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 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*

*STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3*

· **\* Data compared to the previous version altered.**

US