

Safety Data Sheet
according to HPR, Schedule 1

Printing date 01/12/2016

Version number 4

Reviewed on 03/12/2015

1 Identification

- **Product identifier**
- **Trade name:** ***SpeedCEM (Catalyst)***
- **Application of the substance / the mixture**
Self-adhesive self-curing dental resin cement with light-curing option
- **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 identification

- **Classification of the substance or mixture**

<i>Skin Irritation - Category 2</i>	<i>H315 Causes skin irritation.</i>
<i>Eye Irritation - Category 2A</i>	<i>H319 Causes serious eye irritation.</i>
<i>Skin Sensitizer - Category 1</i>	<i>H317 May cause an allergic skin reaction.</i>
<i>Specific Target Organ Toxicity - Single Exposure - Category 3</i>	<i>H335 May cause respiratory irritation.</i>

- **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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triethylene glycol dimethacrylate

Methacrylated phosphoric acid ester

- **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

- **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.

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

Wash thoroughly after handling.

Use only outdoors or in a well-ventilated area.

Contaminated work clothing should not be allowed out of the workplace.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label).

IF ON SKIN: Wash with plenty of water.

Call a POISON CENTER/doctor if you feel unwell.

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

Store locked up.

Store in a well-ventilated place. Keep container tightly closed.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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:**

CAS: 13760-80-0	ytterbium trifluoride	30-60% w/w
CAS: 72869-86-4	urethane dimethacrylate	10-<20% w/w
CAS: 109-16-0	triethylene glycol dimethacrylate	≤10% w/w

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CAS: 85590-00-7	Methacrylated phosphoric acid ester	3-5% w/w
CAS: 25852-47-5	polyethylene glycol dimethacrylate	1-<3% w/w
CAS: 94-36-0	dibenzoyl peroxide	0.3-<1% w/w

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:** 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 Firefighting 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:** No special requirements.
- **Information about storage in one common storage facility:** Not required.

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- **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.
- **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.
- **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
- **Odor threshold:** Not determined.

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· pH-value:	<i>Not determined.</i>
· Change in condition	
Melting point/Melting range:	<i>Undetermined.</i>
Boiling point/Boiling range:	<i>Undetermined.</i>
· Flash point:	<i>Not applicable.</i>
· Auto igniting:	<i>Product is not selfigniting.</i>
· Danger of explosion:	<i>Product does not present an explosion hazard.</i>
· Explosion limits:	
Lower:	<i>Not determined.</i>
Upper:	<i>Not determined.</i>
· Vapor pressure:	<i>Not determined.</i>
· Density:	<i>Not determined.</i>
· Relative density	<i>Not determined.</i>
· Vapor density	<i>Not determined.</i>
· Evaporation rate	<i>Not determined.</i>
· Solubility in / Miscibility with	
Water:	<i>Nearly insoluble.</i>
· Partition coefficient (n-octanol/water):	<i>Not determined.</i>
· Viscosity:	
Dynamic:	<i>Not determined.</i>
Kinematic:	<i>Not determined.</i>
· Other information	<i>No further relevant information available.</i>

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:**
- **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.*

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· **Carcinogenic categories**

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

CAS: 7631-86-9	silicon dioxide, chemically prepared	3
CAS: 94-36-0	dibenzoyl peroxide	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.
- **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.

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

- **UN-Number**
- **DOT, TDG, ADN, IMDG, IATA** Void
- **UN proper shipping name**
- **DOT, ADN, IMDG, IATA** Void
- **ADR/RID/ADN** Void
- **Transport hazard class(es)**
- **DOT, TDG, ADN, IMDG, IATA**
- **Class** Void

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· Packing group	Void
· DOT, TDG, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· 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":	Void

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):**

CAS: 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)**

CAS: 13760-80-0 | ytterbium trifluoride

A4

CAS: 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).

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· **Hazard pictograms**



GHS07

· **Signal word** Warning

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

urethane dimethacrylate
ytterbium trifluoride
triethylene glycol dimethacrylate
Methacrylated phosphoric acid ester

· **Hazard statements**

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

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.
Wear protective gloves/protective clothing/eye protection/face protection.
Wash thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Contaminated work clothing should not be allowed out of the workplace.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Specific treatment (see on this label).
IF ON SKIN: Wash with plenty of water.
Call a POISON CENTER/doctor if you feel unwell.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
Take off contaminated clothing and wash it before reuse.
Store locked up.
Store in a well-ventilated place. Keep container tightly closed.
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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** 01/12/2016 / 3

· **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

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CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Irritation - Category 2: Skin corrosion/irritation, Hazard Category 2

Eye Irritation - Category 2A: Serious eye damage/eye irritation, Hazard Category 2A

Skin Sensitizer - Category 1: Sensitisation - Skin, Hazard Category 1

Specific Target Organ Toxicity - Single Exposure - Category 3: Specific target organ toxicity - Single exposure, Hazard Category 3

· * Data compared to the previous version altered.

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