

**Material Safety Data Sheet**  
acc. to ISO 11014

Printing date 04/20/2015

Version number 7

Reviewed on 02/25/2015



**1 Identification**

- **Product identifier**
- **Trade name: AdheSE Primer**
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Light-curing, self-etching dental adhesive
- **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 Corr. 1B H314 Causes severe skin burns and eye damage.  
Eye Dam. 1 H318 Causes serious eye damage.  
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**
- 


GHS05    GHS07
- **Signal word** Danger
  - **Hazard-determining components of labeling:**  
phosphonic acid acrylate  
bis-acrylamide derivative

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- **Hazard statements**

Causes severe skin burns and eye damage.  
May cause an allergic skin reaction.  
May cause respiratory irritation.

- **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.  
If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.  
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
If swallowed: Rinse mouth. Do NOT induce vomiting.  
Wash contaminated clothing before reuse.  
If skin irritation or rash occurs: Get medical advice/attention.

- **Additional information:**

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

- **Hazard description:**

- **WHMIS-symbols:**

D2B - Toxic material causing other toxic effects  
B2 - Flammable liquid



- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 3  
Fire = 0  
Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = 3  
Fire = 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:**

223681-84-3	phosphonic acid acrylate	25-40%
442200-41-1	bis-acrylamide derivative	20-<25%

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### 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:**  
Immediately rinse with water.  
If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then 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.

### 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**  
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Ensure adequate ventilation.
- **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.  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **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.

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- **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.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
  - Usual hygienic measures for dental practice.
  - Keep away from foodstuffs, beverages and feed.
  - Immediately remove all soiled and contaminated clothing.
  - Wash hands before breaks and at the end of work.
  - Avoid contact with the eyes and skin.
  - Do not inhale gases / fumes / aerosols.
- **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
  - 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.
- **Not suitable are gloves made of the following materials:**
  - Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

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· Eye protection:



Tightly sealed goggles

## 9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Fluid
Color:	Yellowish
Odor:	Characteristic
Odour threshold:	Not determined.

· 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 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.

Density at 20 °C:	1.125 g/cm <sup>3</sup>
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.

· Solubility in / Miscibility with

Water:	Fully miscible.
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· Partition coefficient (n-octanol/water): 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.

· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

· Possibility of hazardous reactions: No dangerous reactions known.

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- **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:** Irritant to skin and mucous membranes.
  - **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:** No further relevant information available.

- **Carcinogenic categories**

- **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.

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### 14 Transport information

· <b>UN-Number</b> · <b>DOT, TDG, ADN, IMDG, IATA</b>	Void
· <b>UN proper shipping name</b> · <b>DOT, TDG, ADN, IMDG, IATA</b>	Void
· <b>Transport hazard class(es)</b> · <b>DOT, TDG, ADN, IMDG, IATA</b> · <b>Class</b>	Void
· <b>Packing group</b> · <b>DOT, TDG, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b> · <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>	-

### 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.

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- **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**



GHS05 GHS07

- **Signal word** *Danger*

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

phosphonic acid acrylate

bis-acrylamide derivative

- **Hazard statements**

Causes severe skin burns and eye damage.

May cause an allergic skin reaction.

May cause respiratory irritation.

- **Precautionary statements**

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

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

If swallowed: Rinse mouth. Do NOT induce vomiting.

Wash contaminated clothing before reuse.

If skin irritation or rash occurs: 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** 04/20/2015 / 6

- **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 Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

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

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

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

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