

**Safety Data Sheet**  
according to HPR, Schedule 1

Printing date 03/25/2019

Version number 7

Reviewed on 01/31/2019


**1 Identification**

- **Product identifier**
- **Trade name: AdheSE Bonding**
- **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 identification**

- **Classification of the substance or mixture**  
*Skin Irritation - Category 2 H315 Causes skin irritation.*  
*Eye Irritation - Category 2A H319 Causes serious eye irritation.*  
*Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.*

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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:**  
*Bis-GMA*  
*2-hydroxyethyl methacrylate*
  - **Hazard statements**  
*Causes skin irritation.*  
*Causes serious eye irritation.*

(Contd. on page 2)

## Safety Data Sheet according to HPR, Schedule 1

Printing date 03/25/2019

Version number 7

Reviewed on 01/31/2019

**Trade name: AdheSE Bonding**

(Contd. of page 1)

May cause an allergic skin reaction.

· **Precautionary statements**

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

Wash thoroughly after handling.

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

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

If on skin: Wash with plenty of water.

Specific treatment (see on this label).

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

Take off contaminated clothing and wash it before reuse.

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

If eye irritation persists: Get medical advice/attention.

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 = 2

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

HEALTH	2	Health = 2
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

### \* 3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 36425-15-7	Bis-GMA	15-40% w/w *
CAS: 868-77-9	2-hydroxyethyl methacrylate	10-30% w/w *

\* Actual concentration ranges are withheld as a trade secret.

### 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.

(Contd. on page 3)

## Safety Data Sheet according to HPR, Schedule 1

Printing date 03/25/2019

Version number 7

Reviewed on 01/31/2019

**Trade name: AdheSE Bonding**

(Contd. of page 2)

- **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:**  
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.
- **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.
- **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.

(Contd. on page 4)

CA

## Safety Data Sheet according to HPR, Schedule 1

Printing date 03/25/2019

Version number 7

Reviewed on 01/31/2019

**Trade name: AdheSE Bonding**

(Contd. of page 3)

- **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 and dental laboratories.  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing.  
Wash hands before breaks and at the end of work.  
Do not inhale gases / fumes / aerosols.
- **Breathing equipment:** Not necessary if room is well-ventilated.
- **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.
- **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
Odor threshold:	Not determined.
- **pH-value:** Not determined.
- **Change in condition**

Melting point/Melting range:	Undetermined.
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(Contd. on page 5)

CA

## Safety Data Sheet

### according to HPR, Schedule 1

Printing date 03/25/2019

Version number 7

Reviewed on 01/31/2019

Trade name: **AdheSE Bonding**

(Contd. of page 4)

<b>Boiling point/Boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Undetermined. Not applicable.
· <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 determined.
· <b>Density at 20 °C:</b>	1.135 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapor density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water:</b>	Fully miscible.
· <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:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**  
The product shows the following dangers according to internally approved calculation methods for preparations:  
Irritant

(Contd. on page 6)

CA

## Safety Data Sheet

### according to HPR, Schedule 1

Printing date 03/25/2019

Version number 7

Reviewed on 01/31/2019

**Trade name: AdheSE Bonding**

(Contd. of page 5)

· **Carcinogenic categories**

· **NTP (National Toxicology Program)**

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.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**  
 Harmful to aquatic organisms  
 Water hazard class 2 (Self-assessment): hazardous for water  
 Do not allow product to reach ground water, water course or sewage system.  
 Danger to drinking water if even small quantities leak into the ground.
- **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>· <b>DOT, TDG, ADN, IMDG, IATA</b>                                    | Void |
| · <b>UN proper shipping name</b><br>· <b>DOT, TDG, ADN, IMDG, IATA</b>                      | Void |
| · <b>Transport hazard class(es)</b><br>· <b>DOT, TDG, ADN, IMDG, IATA</b><br>· <b>Class</b> | Void |
| · <b>Packing group</b><br>· <b>DOT, TDG, IMDG, IATA</b>                                     | Void |
| · <b>Environmental hazards:</b><br>· <b>Marine pollutant:</b>                               | No   |

(Contd. on page 7)

CA

## Safety Data Sheet

### according to HPR, Schedule 1

Printing date 03/25/2019

Version number 7

Reviewed on 01/31/2019

**Trade name: AdheSE Bonding**

(Contd. of page 6)

· <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>	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):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

All ingredients are 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:**

Bis-GMA

2-hydroxyethyl methacrylate

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

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

Wash thoroughly after handling.

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

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

If on skin: Wash with plenty of water.

Specific treatment (see on this label).

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

Take off contaminated clothing and wash it before reuse.

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

(Contd. on page 8)

CA

## Safety Data Sheet according to HPR, Schedule 1

Printing date 03/25/2019

Version number 7

Reviewed on 01/31/2019

**Trade name: AdheSE Bonding**

(Contd. of page 7)

- **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 the latest revision of the safety data sheet** 03/25/2019 / 6
- **Abbreviations and acronyms:**  
IMDG: International Maritime Code for Dangerous Goods  
DOT: US Department of Transportation  
IATA: International Air Transport Association  
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)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative
- **\* Data compared to the previous version altered.**

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