

SAFETY DATA SHEETS

This SDS packet was issued with item:

071415884

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071415892

1 Identification

- **Product identifier**
- **Trade name:** ***Adhese Universal DC***
- **Application of the substance / the mixture** *Self-curing primer for Cention*
- **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**
Flam. Liq. 3 H226 Flammable liquid and vapor.
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.

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


GHS02 GHS07
- **Signal word** *Warning*
 - **Hazard-determining components of labeling:**
2-hydroxyethyl methacrylate
Bis-GMA
methacrylated phosphoric acid ester
1,10-decandiol dimethacrylate

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/02/2021

Version number 1

Reviewed on 03/17/2021

Trade name: Adhese Universal DC

(Contd. of page 1)

methacrylate modified polyacrylic acid
2-dimethylaminoethyl methacrylate

· **Hazard statements**

Flammable liquid and vapor.
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Avoid breathing dust/fume/gas/mist/vapors/spray
Wear protective gloves/protective clothing/eye protection/face protection.
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 = 2
Fire = 3
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = *2
Fire = 3
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: 868-77-9	2-hydroxyethyl methacrylate	10-25%
CAS: 36425-15-7	Bis-GMA	10-25%
CAS: 64-17-5	ethanol	10-25%
CAS: 85590-00-7	methacrylated phosphoric acid ester	10-25%
CAS: 6701-13-9	1,10-decandiol dimethacrylate	2.5-10%
CAS: 54351-53-0	methacrylate modified polyacrylic acid	2.5-10%
CAS: 10373-78-1	camphorquinone	<2.5%
CAS: 2867-47-2	2-dimethylaminoethyl methacrylate	<2.5%

US

(Contd. on page 3)

Safety Data Sheet acc. to OSHA HCS

Printing date 09/02/2021

Version number 1

Reviewed on 03/17/2021

Trade name: Adhese Universal DC

(Contd. of page 2)

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:**
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:** Wear self-contained respiratory protective device.

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).
- **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.
- **Protective Action Criteria for Chemicals**

· **PAC-1:**

CAS: 868-77-9	2-hydroxyethyl methacrylate	1.9 mg/m ³
CAS: 64-17-5	ethanol	1,800 ppm

· **PAC-2:**

CAS: 868-77-9	2-hydroxyethyl methacrylate	21 mg/m ³
CAS: 64-17-5	ethanol	3300* ppm

· **PAC-3:**

CAS: 868-77-9	2-hydroxyethyl methacrylate	1,000 mg/m ³
CAS: 64-17-5	ethanol	15000* ppm

US

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/02/2021

Version number 1

Reviewed on 03/17/2021

Trade name: **Adhese Universal DC**

(Contd. of page 3)

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:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **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:** 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:**

CAS: 64-17-5 ethanol

PEL	Long-term value: 1900 mg/m ³ , 1000 ppm
REL	Long-term value: 1900 mg/m ³ , 1000 ppm
TLV	Short-term value: 1880 mg/m ³ , 1000 ppm

- **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.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and 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.
- **Not suitable are gloves made of the following materials:**
Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

(Contd. on page 5)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/02/2021

Version number 1

Reviewed on 03/17/2021

Trade name: **Adhese Universal DC**

(Contd. of page 4)

· Eye protection:



Tightly sealed goggles

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	Liquid
· Color:	Yellow
· Odor:	Characteristic
· Odor threshold:	Not determined.

· pH-value: Not applicable.

· Change in condition

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.

· Flash point: 33.5 °C (92.3 °F) (ISO 13736)

· 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 (68 °F): 1.06 g/cm³ (8.846 lbs/gal)

· Relative density: Not determined.

· Vapor density: Not determined.

· Evaporation rate: Not determined.

· Solubility in / Miscibility with

Water: Fully miscible.

· 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.

· Conditions to avoid: No further relevant information available.

· Incompatible materials: No further relevant information available.

(Contd. on page 6)

Safety Data Sheet acc. to OSHA HCS

Printing date 09/02/2021

Version number 1

Reviewed on 03/17/2021

Trade name: Adhese Universal DC

(Contd. of page 5)

· **Hazardous decomposition products:** None under normal conditions of storage and use.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Specific symptoms in biological assay:**
 - **on the skin:** Irritant to skin and mucous membranes.
 - **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**

The substance ethanol is listed by IARC as carcinogen in alcoholic beverages (Group 1). This product contains ethanol but is not a consumable alcoholic beverage. Therefore it is not classified and labelled as carcinogenic.
- **Carcinogenic categories**

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

CAS: 64-17-5	ethanol	1
--------------	---------	---

· **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 2 (Self-assessment): hazardous for water
 - Do not allow product 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.

US

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/02/2021

Version number 1

Reviewed on 03/17/2021

Trade name: **Adhese Universal DC**

(Contd. of page 6)

14 Transport information

<ul style="list-style-type: none"> · UN-Number · DOT, ADR/RID/ADN, IMDG, IATA 	<p>UN1170</p>
<ul style="list-style-type: none"> · UN proper shipping name · DOT · ADR/RID/ADN · IMDG · IATA 	<p>Flammable liquids, n.o.s. (Ethanol) 1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL)) ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) ETHANOL SOLUTION</p>
<ul style="list-style-type: none"> · Transport hazard class(es) · DOT 	<p></p>
<ul style="list-style-type: none"> · Class · Label 	<p>3 Flammable liquids 3</p>
<ul style="list-style-type: none"> · ADR/RID/ADN 	<p></p>
<ul style="list-style-type: none"> · Class · Label 	<p>3 (F1) Flammable liquids 3</p>
<ul style="list-style-type: none"> · IMDG, IATA 	<p></p>
<ul style="list-style-type: none"> · Class · Label 	<p>3 Flammable liquids 3</p>
<ul style="list-style-type: none"> · Packing group · DOT, ADR/RID/ADN, IMDG, IATA 	<p>III</p>
<ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: 	<p>No</p>
<ul style="list-style-type: none"> · Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category 	<p>Warning: Flammable liquids 30 F-E,S-D A</p>
<ul style="list-style-type: none"> · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code 	<p>Not applicable.</p>
<ul style="list-style-type: none"> · Transport/Additional information: 	<p>-----</p>
<ul style="list-style-type: none"> · ADR/RID/ADN · Excepted quantities (EQ) 	<p>Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml</p>

(Contd. on page 8)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/02/2021

Version number 1

Reviewed on 03/17/2021

Trade name: Adhese Universal DC

(Contd. of page 7)

· IMDG	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· UN "Model Regulation":	UN 1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL)), 3, III

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 components have the value ACTIVE.

· **Hazardous Air Pollutants**

None of the ingredients is 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:**

CAS: 64-17-5 | ethanol

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

CAS: 64-17-5 | ethanol

A3

· **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**



GHS02

GHS07

(Contd. on page 9)

Safety Data Sheet acc. to OSHA HCS

Printing date 09/02/2021

Version number 1

Reviewed on 03/17/2021

Trade name: Adhese Universal DC

(Contd. of page 8)

· **Signal word** *Warning*

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

2-hydroxyethyl methacrylate

Bis-GMA

methacrylated phosphoric acid ester

1,10-decandiol dimethacrylate

methacrylate modified polyacrylic acid

2-dimethylaminoethyl methacrylate

· **Hazard statements**

Flammable liquid and vapor.

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Avoid breathing dust/fume/gas/mist/vapors/spray

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

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.

· **Contact:**

· **Date of preparation / last revision** 09/02/2021 / -

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Flam. Liq. 3: Flammable liquids – Category 3

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1