

Safety Data Sheet
acc. to OSHA HCS

Printing date 01/14/2019



Version number 11

Reviewed on 01/14/2019

1 Identification

- **Product identifier**
- **Trade name:** Syntac Primer
- **Application of the substance / the mixture** Enamel-Dentin Bonding Agent
- **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. 2 H225 Highly 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.
- STOT SE 3 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.
-
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**
-  
- GHS02 GHS07
- **Signal word** Danger
- **Hazard-determining components of labeling:**
triethylene glycol dimethacrylate
acetone
maleic acid

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polyethylene glycol dimethacrylate

· **Hazard statements**

Highly flammable liquid and vapor.

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause respiratory irritation. May cause drowsiness or dizziness.

· **Precautionary statements**

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

Keep container tightly closed.

Avoid breathing mist/vapours/spray.

Wear protective gloves / eye 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)**



· **HMIS-ratings (scale 0 - 4)**

HEALTH	1	Health = 1
FIRE	3	Fire = 3
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: 67-64-1	acetone	25-50%
CAS: 109-16-0	triethylene glycol dimethacrylate	10-25%
CAS: 25852-47-5	polyethylene glycol dimethacrylate	2.5-<10%
CAS: 110-16-7	maleic acid	2.5-<10%

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.

· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

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- **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.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.
- **Additional information**
Fumes are heavier than air.
Cool endangered receptacles with water spray.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
Dilute with plenty of water.
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:**
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 in a cool location.
Store only in the original receptacle.

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- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
- **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: 67-64-1 acetone

PEL	Long-term value: 2400 mg/m ³ , 1000 ppm
REL	Long-term value: 590 mg/m ³ , 250 ppm
TLV	Short-term value: (1782) NIC-1187 mg/m ³ , (750) NIC-500 ppm
	Long-term value: (1188) NIC-594 mg/m ³ , (500) NIC-250 ppm
BEI	

- **Ingredients with biological limit values:**

CAS: 67-64-1 acetone

BEI	50 mg/L
	Medium: urine
	Time: end of shift
	Parameter: Acetone (nonspecific)

- **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.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
Avoid contact with the eyes and skin.
Do not inhale dust / smoke / mist.

- **Breathing equipment:**

Not necessary if room is well-ventilated.

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.

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· Eye protection:



Tightly sealed goggles

· Body protection: Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	Fluid
· Color:	Colorless
· Odor:	Acetone-like
· Odor threshold:	Not determined.

· pH-value: Not determined.

· Change in condition

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

· Flash point: < 21 °C (< 70 °F)

· Flammability (solid, gaseous): Not applicable.

· Auto igniting: Product is not selfigniting.

· Danger of explosion: Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

· Explosion limits:

· Lower:	2.6 Vol %
· Upper:	13.0 Vol %

· Vapor pressure: Not determined.

· Density at 20 °C (68 °F): 0.957 g/cm³ (7.986 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.

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- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **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:** 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

· **UN-Number**
 · **DOT, ADR/RID/ADN, IMDG, IATA** *UN1090*

· **UN proper shipping name**
 · **ADR/RID/ADN** *1090 ACETONE*
 · **IMDG, IATA** *ACETONE*

· **Transport hazard class(es)**

· **DOT**



· **Class** *3 Flammable liquids*
 · **Label** *3*

· **ADR/RID/ADN**



· **Class** *3 (F1) Flammable liquids*
 · **Label** *3*

· **IMDG, IATA**



· **Class** *3 Flammable liquids*
 · **Label** *3*

· **Packing group**

· **DOT, ADR/RID/ADN, IMDG, IATA** *II*

· **Environmental hazards:**

· **Marine pollutant:** *No*

· **Special precautions for user** *Warning: Flammable liquids*

· **Danger code (Kemler):** *33*

· **EMS Number:** *F-E, S-E*

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** *Not applicable.*

· **Transport/Additional information:**

· **ADR/RID/ADN**

· **Excepted quantities (EQ)** *Code: E2*
 Maximum net quantity per inner packaging: 30 ml
 Maximum net quantity per outer packaging: 500 ml

· **IMDG**

· **Limited quantities (LQ)** *1L*

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· **Exempted quantities (EQ)**

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

· **UN "Model Regulation":**

UN1090, Acetone, 3, II

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)**

CAS: 67-64-1 | acetone

I

· **TLV (Threshold Limit Value established by ACGIH)**

CAS: 67-64-1 | acetone

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**

GHS02 GHS07

· **Signal word** Danger· **Hazard-determining components of labeling:**

triethylene glycol dimethacrylate

acetone

maleic acid

polyethylene glycol dimethacrylate

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· **Hazard statements**

Highly flammable liquid and vapor.
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause respiratory irritation. May cause drowsiness or dizziness.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. No smoking.
Keep container tightly closed.
Avoid breathing mist/vapours/spray.
Wear protective gloves / eye 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.

· **Date of preparation / last revision** 01/14/2019 / 10

· **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)
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
BEI: Biological Exposure Limit
Flam. Liq. 2: Flammable liquids – Category 2
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
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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

US