

Safety Data Sheet
according to HPR, Schedule 1

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 identification

- **Classification of the substance or mixture**

Flammable Liquids - Category 2	H225	Highly flammable liquid and vapour.
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.
Specific Target Organ Toxicity - Single Exposure - Category 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

(Contd. on page 2)

Safety Data Sheet

according to HPR, Schedule 1

Printing date 01/14/2019

Version number 11

Reviewed on 01/14/2019

Trade name: Syntac Primer

(Contd. of page 1)

maleic acid

polyethylene glycol dimethacrylate

· **Hazard statements**

Highly flammable liquid and vapour.

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, hot surfaces, sparks, open flames and other ignition sources. 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)**



Health = 1

Fire = 3

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 1

Fire = 3

Reactivity = 0

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	30-60% w/w
CAS: 109-16-0	triethylene glycol dimethacrylate	10-30% w/w
CAS: 25852-47-5	polyethylene glycol dimethacrylate	3-7% w/w
CAS: 110-16-7	maleic acid	1-5% 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:** Immediately rinse with water.

· **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)

CA

Safety Data Sheet according to HPR, Schedule 1

Printing date 01/14/2019

Version number 11

Reviewed on 01/14/2019

Trade name: Syntac Primer

(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:**
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.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.

(Contd. on page 4)

CA

Safety Data Sheet according to HPR, Schedule 1

Printing date 01/14/2019

Version number 11

Reviewed on 01/14/2019

Trade name: Syntac Primer

(Contd. of page 3)

- 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

EL	Short-term value: 500 ppm Long-term value: 250 ppm
EV	Short-term value: 750 ppm Long-term value: 500 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.
 - 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.
- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

(Contd. on page 5)

Safety Data Sheet

according to HPR, Schedule 1

Printing date 01/14/2019

Version number 11

Reviewed on 01/14/2019

Trade name: **Syntac Primer**

(Contd. of page 4)

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

· **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:	0.957 g/cm ³
· 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.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

(Contd. on page 6)

Safety Data Sheet

according to HPR, Schedule 1

Printing date 01/14/2019

Version number 11

Reviewed on 01/14/2019

Trade name: **Syntac Primer**

(Contd. of page 5)

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.

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, IMDG, IATA | UN1090 |
| · UN proper shipping name | |
| · DOT, IMDG, IATA | ACETONE |
| · TDG | 1090 ACETONE |

(Contd. on page 7)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 01/14/2019

Version number 11

Reviewed on 01/14/2019

Trade name: **Syntac Primer**

(Contd. of page 6)

· **Transport hazard class(es)**· **DOT**· **Class** 3 Flammable liquids· **Label** 3· **TDG (Transport dangerous goods):**· **Class** 3 (F1) Flammable liquids· **Label** 3· **IMDG, IATA**· **Class** 3 Flammable liquids· **Label** 3· **Packing group**· **DOT, TDG, 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:**· **TDG**

· **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

· **Excepted 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

(Contd. on page 8)

Safety Data Sheet according to HPR, Schedule 1

Printing date 01/14/2019

Version number 11

Reviewed on 01/14/2019

Trade name: **Syntac Primer**

(Contd. of page 7)

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**



GHS02 GHS07

· **Signal word** *Danger*

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

triethylene glycol dimethacrylate

acetone

maleic acid

polyethylene glycol dimethacrylate

· **Hazard statements**

Highly flammable liquid and vapour.

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, hot surfaces, sparks, open flames and other ignition sources. 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

(Contd. on page 9)

CA

Safety Data Sheet
according to HPR, Schedule 1

Printing date 01/14/2019

Version number 11

Reviewed on 01/14/2019

Trade name: Syntac Primer

(Contd. of page 8)

· 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.**

CA