SAFETY DATA SHEETS

This SDS packet was issued with item: 077089576

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077089550

Printing date 02/27/2013

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Version number 9

Reviewed on 02/27/2013

1 Identification of the substance/mixture and of the company/undertaking

· Product identifier

· Trade name: Syntac Primer

• *Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.*

- · Application of the substance / the preparation 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 MSDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

2 Hazards identification

· Classification of the substance or mixture

• Classification according to Directive 67/548/EEC or Directive 1999/45/EC Irritant

Irritating to eyes, respiratory system and skin. May cause sensitisation by skin contact.

Highly flammable Highly flammable.

Vapours may cause drowsiness and dizziness.

· Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· Label elements

· Labelling according to EU guidelines:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Substance Directive 1999/45/ EWG usually if they are in the finished state and intended for the final user.

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· Code letter and hazard designation of product:



Irritant Highly flammable

• *Hazard-determining components of labelling:* triethyleneglycol dimethacrylate maleic acid

· Risk phrases:

Highly flammable. Irritating to eyes, respiratory system and skin. May cause sensitisation by skin contact. Vapours may cause drowsiness and dizziness.

· Safety phrases:

Keep container in a well-ventilated place. Keep away from sources of ignition - No smoking. Do not breathe vapour/spray. Avoid contact with skin. Wear suitable gloves. This material and its container must be disposed of as hazardous waste.

• Classification system: • NFPA ratings (scale 0 - 4)



Health = 1Fire = 3 Reactivity = 0

· HMIS-ratings (scale 0 - 4)

HEALTH1Health = 1FIRE3Fire = 3REACTIVITYReactivity = 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:		
67-64-1	acetone	25-50%
109-16-0	triethyleneglycol dimethacrylate	10-25%
25852-47-5	polyethylene glycol dimethacrylate	2.5-10%
110-16-7	maleic acid	2.5-10%
		USA

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Trade name: Syntac Primer

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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.
- 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.
- \cdot 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.

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- *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. 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:

67-64-1 acetone

PEL 2400 mg/m³, 1000 ppm

REL 590 mg/m³, 250 ppm

TLV Short-term value: (1782) NIC-1187 mg/m³, (750) NIC-500 ppm Long-term value: (1188) NIC-475 mg/m³, (500) NIC-200 ppm BEI

• Additional information: The lists that were valid during the creation were used as basis.

· Exposure controls

· Personal protective equipment:

 \cdot General protective and hygienic measures:

Usual hygienic measures for dental practice. 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:

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

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

• Material of gloves

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

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(Contd. of page 4) 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

General Information	
Appearance:	
Form:	Fluid
Color:	Colorless
Odor:	Acetone-like
Odour 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.
<i>Density at 20 °C (68 °F):</i>	1.39 g/cm ³ (11.6 lbs/gal)
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Fully miscible.
Partition coefficient (n-octanol/wate	e r): Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.

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Trade name: Syntac Primer

• 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.

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:
- The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

- · 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.

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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.

UN-Number		
DOT, ADR, IMDG, IATA	UN1090	
UN proper shipping name		
ADR MDC LATA	1090 ACETONE ACETONE	
IMDG, IATA	ACETONE	
Transport hazard class(es)		
DOT		
FLAMMABLE LIQUID		
3		
Class	3 Flammable liquids.	
Label	3	
ADR		
Class	3 (F1) Flammable liquids	
Label	3	
IMDG, IATA		
Class	3 Flammable liquids.	
Label	3	
Packing group DOT, ADR, IMDG, IATA	II	
Environmental hazards:		
Marine pollutant:	No	
Special precautions for user	Warning: Flammable liquids	
Danger code (Kemler):	33	
EMS Number:	<i>F-E</i> , <u><i>S-E</i></u>	

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

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.

 \cdot 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)

67-64-1 acetone • TLV (Threshold Limit Value established by ACGIH)

67-64-1 acetone

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

• Product related hazard informations:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Substance Directive 1999/45/ EWG usually if they are in the finished state and intended for the final user.

· Hazard symbols:



Highly flammable

• *Hazard-determining components of labelling: triethyleneglycol dimethacrylate*

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Trade name: Syntac Primer

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USA

• **Risk phrases:** Highly flammable. Irritating to eyes, respiratory system and skin. May cause sensitisation by skin contact. Vapours may cause drowsiness and dizziness.

· Safety phrases:

maleic acid

Keep container in a well-ventilated place. Keep away from sources of ignition - No smoking. Do not breathe vapour/spray. Avoid contact with skin. Wear suitable gloves. This material and its container must be disposed of as hazardous waste.

· National regulations:

• Other regulations, limitations and prohibitive regulations The product is a medical device according to the EC-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.

 \cdot * Data compared to the previous version altered.

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Safety Data Sheet acc. to OSHA HCS

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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



· 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) Health = 1Fire = 3Reactivity = 0· HMIS-ratings (scale 0 - 4) HEALTH 1 Health = lFIRE *Fire* = 3 3 **REACTIVITY O** *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.
- \cdot 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/m³, 1000 ppm
- *REL* Long-term value: 590 mg/m³, 250 ppm
- *TLV* Short-term value: (1782) NIC-1187 mg/m³, (750) NIC-500 ppm Long-term value: (1188) NIC-594 mg/m³, (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:

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Tightly sealed goggles

· Body protection: Protective work clothing

Information on basic physical and	chemical properties
General Information	enemieu propernes
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/vapo 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/wat	t er): 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:
- \cdot 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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Trade name: Syntac Primer

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Transport information	
UN-Number DOT, ADR/RID/ADN, IMDG, IATA	UN1090
UN proper shipping name ADR/RID/ADN IMDG, IATA	1090 ACETONE ACETONE
Transport hazard class(es)	
DOT	
Class	3 Flammable liquids
Label ADR/RID/ADN	3
Class Label	3 (F1) Flammable liquids 3
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): EMS Number:	33 F-E,S-E
	I of Not applicable.
Transport in bulk according to Annex L MARPOL73/78 and the IBC Code	
Transport in bulk according to Annex L	

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· 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

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

• TLV (Threshold Limit Value established by ACGIH)

CAS: 67-64-1 acetone

·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*



· Signal word Danger

• *Hazard-determining components of labeling:* triethylene glycol dimethacrylate acetone maleic acid polyethylene glycol dimethacrylate

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Trade name: Syntac Primer

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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.