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1 Identification

- · Product identifier
- · Trade name: Fluor Protector
- $\cdot \textit{Relevant identified uses of the substance or mixture and uses advised against}$
- No further relevant information available.
- · Application of the substance / the preparation Protective varnish for desensitisation and caries prophylaxis
- · 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 Hazard(s) identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC

Irritant

Irritating to eyes. May cause sensitisation by skin contact.

Highly flammable

Highly flammable.

Repeated exposure may cause skin dryness or cracking. Vapours may cause drowsiness and dizziness.

Information concerning particular hazards for human and environment:

The product has to be labeled due to the calculation procedure of international guidelines.

At long or repeated contact with skin it may cause dermatitis due to the degreasing effect of the solvent.

· 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:

The product has been classified and marked in accordance with directives on hazardous materials.

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Trade name: Fluor Protector

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· Code letter and hazard designation of product:

Irritant Highly flammable

· Hazard-determining components of labeling:

polyisocyanate

· Risk phrases:

Highly flammable.

Irritating to eyes.

May cause sensitisation by skin contact.

Repeated exposure may cause skin dryness or cracking.

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.

· Special labeling of certain preparations:

Contains isocyanates. See information supplied by the manufacturer.

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



Health = 2

Fire = 3

Reactivity = 1

· HMIS-ratings (scale 0 - 4)



2 Health = 2

Fire = 3

REACTIVITY 1 Reactivity = 1

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- \cdot **Description:** Mixture of the substances listed below with nonhazardous additions.

	· Dangerous o	components:	
Ī	141-78-6	ethyl acetate	50-100%
	105-68-0	isopentyl propionate	10-25%
	53317-61-6	polyisocyanate	10-25%

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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 wash with water and soap and rinse thoroughly.
- · After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, 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.

- · 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: 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).

Ensure adequate ventilation.

Do not flush with water or aqueous cleansing agents

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.

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.

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- · 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.

Store receptacle in a well ventilated area.

· 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:

141-78-6 ethyl acetate

	1400 mg/m^3 ,	
REL	$1400 \ mg/m^3$,	400 ppm

TLV 1440 mg/m³, 400 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.

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.

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

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

Butyl rubber, BR

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.

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· 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.

· Eye protection:

Tightly sealed goggles

Physical and chemical propert	ties
Information on basic physical and c	hemical properties
General Information	• •
Appearance:	
Form:	Fluid
Color:	Clear
Odor:	Fruit-like
Odour threshold:	Not determined.
pH-value:	Not determined.
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
Flash point:	9 °C (48 °F)
Ignition temperature:	460 °C (860 °F)
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:	2.1 Vol %
Upper:	11.5 Vol %
Vapor pressure at 20 °C (68 °F):	97 hPa (73 mm Hg)
Density at 20 °C (68 °F):	0.869 g/cm³ (7.252 lbs/gal)
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Not miscible or difficult to mix.
Partition coefficient (n-octanol/wate	e r): Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
Solvent content:	
VOC content:	67.7 %
Other information	No further relevant information available.

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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:

· LD/LC50 values that are relevant for classification:

141-78-6 ethyl acetate

Oral	LD50	5620 mg/kg (rabbit)
Inhalative	LC50/4 h	1600 mg/l (rat)

- · Primary irritant effect:
- · on the skin: No irritant effect.
- · 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:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.

UN-Number		
DOT	UN1173	
ADR, IMDG, IATA	1173	
UN proper shipping name		
ADR	1173 ETHYL ACETATE	
IMDG, IATA	ETHYL ACETATE	
Transport hazard class(es)		
DOT		
Class	3 Flammable liquids.	
Label	3	
Class Lahel	3 (F1) Flammable liquids	
Class Label IMDG, IATA	3 (F1) Flammable liquids 3	
Label		
Label IMDG, IATA Class Label Packing group	3 Flammable liquids.	
Label IMDG, IATA Class Label Packing group DOT, ADR, IMDG, IATA	3 3 Flammable liquids.	
Label IMDG, IATA Class Label Packing group	3 Flammable liquids.	
Label IMDG, IATA Class Label Packing group DOT, ADR, IMDG, IATA Environmental hazards: Marine pollutant: Special precautions for user	3 Flammable liquids. 3	
Label IMDG, IATA Class Label Packing group DOT, ADR, IMDG, IATA Environmental hazards: Marine pollutant:	3 3 Flammable liquids. 3 II No	

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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):

141-78-6 ethyl acetate

105-68-0 isopentyl propionate

53317-61-6 polyisocyanate

- · 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)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· 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:

The product has been classified and marked in accordance with directives on hazardous materials.

· Hazard symbols:





Irritant Highly flammable

· Hazard-determining components of labeling: polyisocyanate

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· Risk phrases:

Highly flammable.

Irritating to eyes.

May cause sensitisation by skin contact.

Repeated exposure may cause skin dryness or cracking.

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.

· Special labeling of certain preparations:

Contains isocyanates. See information supplied by the manufacturer.

· National regulations:

· Other regulations, limitations and prohibitive regulations

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.

The product is a medical device according to the Directive 93/42/EEC.

· 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.

USA ·