Printing date 12/04/2013

Version number 2

Reviewed on 11/28/2013

1 Identification

vivadeni:

- · Product identifier
- Trade name: <u>Fluor</u> Protector N

• **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

H225 Highly flammable liquid and vapour.

- Classification according to Directive 67/548/EEC or Directive 1999/45/EC Highly flammable
- Highly flammable.
- · 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.
- · Code letter and hazard designation of product:



Highly flammable

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Risk phrases: Highly flammable. Safety phrases: Version number 2

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Keep container tightly closed and in a well-ventilated place.

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Keep away from sources of ignition - No smoking. This material and its container must be disposed of as hazardous waste. • Hazard description:

· WHMIS-symbols:

B2 - Flammable liquid



· Classification system:

· NFPA ratings (scale 0 - 4)

 $\begin{array}{c} \textbf{Health} = 0\\ Fire = 3\\ Reactivity = 0 \end{array}$

· HMIS-ratings (scale 0 - 4)

HEALTH 0	Health = 0
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:	
64-17-5	ethanol	50-100%
12125-01-8	ammonium fluoride	1-<2.5%

4 First-aid measures

· General information: Immediately remove any clothing soiled by the product.

• After inhalation:

Supply fresh air; consult doctor in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact: Rinse with water.

· 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.

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- (Contd. of page 2) • 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.
- Additional information 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: 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

- *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 in a cool location. Store only in the original receptacle.*
- Information about storage in one common storage facility: Store away from oxidizing agents.
- Further information about storage conditions:
- Keep receptacle tightly sealed. 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.

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· Control parameters
\cdot Components with limit values that require monitoring at the workplace:
64-17-5 ethanol
EL Short-term value: 1000 ppm
EV 1.900 mg/m ³ , 1.000 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.
Wash hands before breaks and at the end of work.
· Breathing equipment:
Not required.
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.
• Recommended filter device for short term use: Filter AX
· Protection of hands:
Protoctive along
Protective gloves
After use of gloves apply skin-cleaning agents and skin cosmetics.
· Material of gloves
Butyl rubber, BR
Fluorocarbon rubber (Viton)
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.
· Eye protection: Safety glasses

Information on basic physical and General Information	chemical properties	
Appearance: Form:	Fluid	
Color:	Colorless	
Odor:	like peppermint	
Odour threshold:	Not determined.	
pH-value:	Not applicable.	
Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined.	
Flash point:	20 °C	
Flammability (solid, gaseous):	Not applicable.	

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• Auto igniting:	Product is not selfigniting.
Danger of explosion:	<i>Product is not explosive. However, formation of explosive air/ vapor mixtures are possible.</i>
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not determined.
Density:	Not determined.
Relative density	Not determined.
Vapour 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 Reacts with oxidizing agents.
- *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: No irritant effect.
- on the eye: No irritating effect.
- Sensitization: No sensitizing effects known.
- \cdot Additional toxicological information:

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

81-07-2 1,2-benzisothiazol-3(2H)-one 1,1-dioxide

· NTP (National Toxicology Program)

None of the ingredients is listed.

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12 Ecological information

- · Toxicity
- Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · 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.

UN-Number	
DOT, TDG, IMDG, IATA	UN1170
UN proper shipping name	
DOT, IATA	ETHANOL SOLUTION
TDG	1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION
IMDG	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Transport hazard class(es)	
DOT	
RAMMARE LOUD	
Class	3 Flammable liquids.
Label	3
TDG (Transport dangerous goods):	

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· 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-D
· Transport in bulk according to Annex	· II of
MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	UN1170, ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 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):

81-07-2 1,2-benzisothiazol-3(2H)-one 1,1-dioxide

· 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:

64-17-5 ethanol

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

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A3

A4

· TLV (Threshold Limit Value established by ACGIH)

64-17-5 ethanol

12125-01-8 ammonium fluoride

· 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:



Highly flammable

• **Risk phrases:** Highly flammable.

· Safety phrases:

Keep container tightly closed and in a well-ventilated place. Keep away from sources of ignition - No smoking. 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 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.

· Abbreviations and acronyms:

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)
WHMIS: Workplace Hazardous Materials Information System (Canada)

 \cdot * Data compared to the previous version altered.