

Printing date 07/12/2021 Version number 1 Reviewed on 10/28/2020

1 Identification

- · Product identifier
- · Trade name: Cervitec F
- · Application of the substance / the mixture Protective dental varnish
- · 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

The product is not classified, according to the Globally Harmonized System (GHS).

- · Label elements
- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Precautionary statements

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

Avoid breathing dust/fume/gas/mist/vapors/spray

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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



Health = 1 Fire = 3Reactivity = 0

· HMIS-ratings (scale 0 - 4)



REACTIVITY 0 Reactivity = 0

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

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · Description:

INGREDIENTS (INCI):

Alcohol, Aqua, VA/Crotonates Copolymer, Cetylpyridinium chloride, Chlorhexidine diacetate, Ammonium fluoride, Aroma, Saccharin

· Dangerous components:

CAS: 64-17-5 ethanol

50-100%

4 First-aid measures

- Description of first aid measures
- · General information: No special measures required.
- · After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

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

· After skin contact:

Rinse with water.

Generally the product does not irritate the skin.

- · 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.
- · 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 Cool endangered receptacles with water spray.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: Do not allow to enter sewers/surface or ground water.

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· Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

· 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.

Protective Action Criteria for Chemicals

· PAC-1:		
CAS: 64-17-5 ethanol	1,800 ppm	
· PAC-2:		
CAS: 64-17-5 ethanol	3300* ppm	
· PAC-3:		
CAS: 64-17-5 ethanol	15000* ppm	

7 Handling and storage

- · Handling:
- · 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: Not required.
- · Further information about storage conditions: Keep receptacle tightly sealed.
- · 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:

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

CAS.	CAS: 64-17-5 ethanol		
PEL	Long-term value: 1900 mg/m³, 1000 ppm		
REL	Long-term value: 1900 mg/m³, 1000 ppm		
TLV	Short-term value: 1880 mg/m³, 1000 ppm		

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

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- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Usual hygienic measures for dental practice and dental laboratories.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Do not inhale gases / fumes / aerosols.

- · Breathing equipment: Not required. · Protection of hands: Not required.
- · Material of gloves -
- · Penetration time of glove material -
- · Eye protection: Safety glasses

Information on basic physical and c	rhemical properties	
General Information		
Appearance:		
Form:	Fluid	
Color:	Clear	
Odor:	like peppermint Not determined.	
Odor threshold:		_
pH-value:	Not determined.	
Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined.	
Flash point:	21 °C (69.8 °F) (ASTM D7094)	
Flammability (solid, gaseous):	Not applicable.	
Ignition temperature:	425 °C (797 °F)	
Decomposition temperature:	Not determined.	
Auto igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	3.5 Vol %	
Upper:	15 Vol %	
Vapor pressure at 20 °C (68 °F):	59 hPa (44.3 mm Hg)	
Density at 20 °C (68 °F):	0.87 g/cm³ (7.26 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	e r): Not determined.	
Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	

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VOC content: Other information	71.01 % No further relevant information available.	
· Solvent content:	71.01.07	

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
- Additional toxicological information:

The substance ethanol is listed by IARC as carcinogen in alcoholic beverages (Group 1). This product contains ethanol but is not a consumable alcoholic beverage. Therfore it is not classified and labelled as carcinogenic.

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

CAS: 64-17-5 ethanol

1

· 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 2 (Self-assessment): hazardous for water
- · 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. 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/RID/ADN, IMDG, IATA	UN1170
UN proper shipping name	
DOT	Ethanol solution
ADR/RID/ADN	1170 ETHANOL (ETHYL ALCOHOL) solution
IMDG	ETHANOL (ETHYL ALCOHOL) solution
IATA	ETHANOL solution
Transport hazard class(es)	
DOT	
TI AMMADIT ECOLO	
3	
Class	3 Flammable liquids
Label	3
ADR/RID/ADN	
Class	3 (F1) Flammable liquids
Label	3
IMDG, IATA	
3	
Class	3 Flammable liquids
Label	3
Packing group	
DOT, ADR/RID/ADN, IMDG, IATA	II
Environmental hazards:	Not applicable.
Special precautions for user	Warning: Flammable liquids
Hazard identification number (Kemler co.	

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· Stowage Category	A
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)	IL
Excepted quantities (\widetilde{EQ})	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
· UN ''Model Regulation'':	UN 1170 ETHANOL (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):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

CAS: 64-17-5 ethanol

ACTIVE

· Hazardous Air Pollutants

None of the ingredients is 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:

CAS: 64-17-5 ethanol

- · Carcinogenic categories
- · EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value)

CAS: 64-17-5 ethanol

A3

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

None of the ingredients is listed.

· GHS label elements Void

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- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Precautionary statements

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

Avoid breathing dust/fume/gas/mist/vapors/spray

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

- · 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.

· 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.

- · Contact:
- · Date of preparation / last revision 07/12/2021 / -
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international 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

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)

VOC: Volatile Organic Compounds (USA, EU)

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

IIS.