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vivadeni:

Version number 4

Reviewed on 02/27/2013

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

- · Product identifier
- · Trade name: ExciTE F DSC

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

- · Application of the substance / the preparation Dual-curing dental adhesive with fluoride release
- · 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 Irritant Irritating to eyes and skin. May cause sensitisation by skin contact.
   Flammable.
   Information concerning particular hazards for human and environment: The product has to be labelled due to the calculation procedure of international guidelines.
   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. (Contd. on page 2)

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## Trade name: ExciTE F DSC

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Code letter and hazard designation of product:
 Irritant
 Hazard-determining components of labelling:

- *Hazard-determining components of labelling:* 2-hydroxyethyl methacrylate
- Risk phrases: Flammable. Irritating to eyes and skin. May cause sensitisation by skin contact.
- · Safety phrases:

Keep container tightly closed. 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)



• HMIS-ratings (scale 0 - 4)



- · 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:		
1565-94-2	Bis-GMA	25-50%
64-17-5	ethanol	10-25%
868-77-9	2-hydroxyethyl methacrylate	10-25%
223681-84-3	phosphonic acid acrylate	10-25%
7789-23-3	potassium fluoride	<i>≤</i> 2.5%

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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. 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** 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 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

- · 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.
- 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: No special requirements.
- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions:
- Protect from exposure to the light.
- Protect from heat and direct sunlight.
- 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:

64-17-5 ethanol

PEL 1900 mg/m<sup>3</sup>, 1000 ppm

- REL 1900 mg/m<sup>3</sup>, 1000 ppm
- TLV Short-term value: 1880 mg/m<sup>3</sup>, 1000 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

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

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.

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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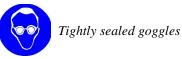
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· Eye protection:



Physical and chemical properti	
Information on basic physical and ch	nemical properties
General Information	
Appearance: Form:	Fluid
Color:	Colorless
Odor:	Characteristic
Odour threshold:	Not determined.
pH-value (10 g/l) at 20 °C (68 °F):	2.5
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
Flash point:	24 °C (75 °F)
Ignition temperature:	425 °C (797 °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:	Not determined.
Upper:	Not determined.
Vapor pressure at 20 °C (68 °F):	59 hPa (44 mm Hg)
Density at 20 °C (68 °F):	1.066 g/cm <sup>3</sup> (8.896 lbs/gal)
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Partly miscible.
Partition coefficient (n-octanol/water	r): 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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## Safety Data Sheet acc. to OSHA HCS

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- · Possibility of hazardous reactions No dangerous reactions known.
- *Conditions to avoid Protect from exposure to the light.*
- Keep away from heat and direct sunlight.
- · 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

· IARC (International Agency for Research on Cancer)

7631-86-9 silicon dioxide, chemically prepared

· 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 2 (Self-assessment): hazardous for water

Do not allow product 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.* 

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· Uncleaned packagings:

• Recommendation: Disposal must be made according to official regulations.

UN-Number DOT	UN1170
ADR, IMDG, IATA	1170
UN proper shipping name	
DOT, IATA ADR	ETHANOL SOLUTION
ADR IMDG	1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Transport hazard class(es)	
DOT	
FLAMMABLE LOUID	
Class	3 Flammable liquids.
Label	3
ADR	
3	
Class	3 (F1) Flammable liquids
Label	3
IMDG, IATA	
Class Label	3 Flammable liquids. 3
	5
Packing group DOT, ADR, IMDG, IATA	III
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Warning: Flammable liquids
Danger code (Kemler):	30
EMS Number:	F-E,S-E

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### **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):
- 1565-94-2 Bis-GMA
- 64-17-5 ethanol
- 868-77-9 2-hydroxyethyl methacrylate
- 7631-86-9 silicon dioxide, chemically prepared
- 7789-23-3 potassium fluoride
- · 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.
- · TLV (Threshold Limit Value established by ACGIH)
  - 64-17-5 ethanol
- 7789-23-3 potassium 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:



• *Hazard-determining components of labelling:* 2-hydroxyethyl methacrylate

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 Risk phrases: Flammable. Irritating to eyes and skin. May cause sensitisation by skin contact.

· Safety phrases:

Keep container tightly closed. 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.

USA