

SAFETY DATA SHEETS

This SDS packet was issued with item:

077176043

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).

077083322 077083330 077083355 077176050

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**
- **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 AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN
- **Tel:** +423 235 35 35
Fax: +423 235 33 60
- **Further information obtainable from:**
Regulatory Affairs
msds@ivoclarvivadent.com
- **Emergency telephone number:** +423 / 235 33 13

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
-  Xi; Irritant
R36/38: Irritating to eyes and skin.
-  Xi; Sensitising
R43: May cause sensitisation by skin contact.
- R10: Flammable.
- **Information concerning particular hazards for human and environment:**
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **Label elements**
- **Labelling according to EU guidelines:**
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.
- **Code letter and hazard designation of product:**
-  Xi Irritant
- **Hazard-determining components of labelling:**
2-hydroxyethyl methacrylate
- **Risk phrases:**
10 Flammable.
36/38 Irritating to eyes and skin.
43 May cause sensitisation by skin contact.
- **Safety phrases:**
7 Keep container tightly closed.

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Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.02.2011

Version number 3

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Trade name: **ExcITE F DSC**







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- 16 Keep away from sources of ignition - No smoking.
- 23 Do not breathe fumes/aerosol.
- 24 Avoid contact with skin.
- 37 Wear suitable gloves.
- 60 This material and its container must be disposed of as hazardous waste.
- **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 substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 1565-94-2	Bis-GMA	 Xi R36/38	25-50%
CAS: 64-17-5 EINECS: 200-578-6	ethanol	 F R11	10-25%
CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate	 Xi R36/38;  Xi R43	10-25%
CAS: 223681-84-3	phosphonic acid acrylate	 Xi R36/38	10-25%
CAS: 7789-23-3 EINECS: 232-151-5	potassium fluoride	 T R23/24/25	≤ 2.5%

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

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:** 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, 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.

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Trade name: **Excite F DSC**

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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** Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:**
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:** 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 container tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

64-17-5 ethanol

WEL () Long-term value: 1920 mg/m³, 1000 ppm

- **Additional information:** The lists valid during the making 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.
- **Respiratory protection:** Not necessary if room is well-ventilated.

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· **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 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

· **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

· Form:	Fluid
· Colour:	Colourless
· Odour:	Characteristic
· Odour threshold:	Not determined.

· **pH-value (10 g/l) at 20°C:** 2.5

· **Change in condition**

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.

· **Flash point:** 24°C

· **Ignition temperature:** 425°C

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product is not explosive. However, formation of explosive air/ vapour mixtures are possible.

· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure at 20°C:** 59 hPa

· **Density at 20°C:** 1.066 g/cm³

· **Relative density** Not determined.

· **Vapour density** Not determined.

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Trade name: **Excite F DSC**

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· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Partly miscible.
· Segregation 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** 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 the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant
- **Sensitisation** May cause sensitisation by skin contact.

12 Ecological information

- **Toxicity**
- **Acquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour 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 (German Regulation) (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.

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Trade name: **ExciTE F DSC**

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13 Disposal considerations· **Waste treatment methods**· **Recommendation***Must not be disposed together with household garbage. Do not allow product to reach sewage system.*· **European waste catalogue**

18 01 06* chemicals consisting of or containing dangerous substances

· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.**14 Transport information**· **Land transport ADR/RID (cross-border)**· **ADR/RID class:** 3 (F1) Flammable liquids.· **Danger code (Kemler):** 30· **UN-Number:** 1170· **Packaging group:** III· **Hazard label:** 3· **UN proper shipping name:** 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)· **Tunnel restriction code** D/E· **Maritime transport IMDG:**· **IMDG Class:** 3· **UN Number:** 1170· **Label** 3· **Packaging group:** III· **EMS Number:** F-E,S-E· **Marine pollutant:** No· **Proper shipping name:** ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)· **Air transport ICAO-TI and IATA-DGR:**· **ICAO/IATA Class:** 3· **UN/ID Number:** 1170· **Label** 3· **Packaging group:** III· **Proper shipping name:** ETHANOL SOLUTION· **Special precautions for user Warning:** Flammable liquids.· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

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Trade name: *Excite F DSC*

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15 Regulatory information

- *Safety, health and environmental regulations/legislation specific for the substance or mixture*
- *National regulations:*
- *Other regulations, limitations and prohibitive regulations*
The product is a medical device according to the EC-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.

· **Relevant phrases**

R11 Highly flammable.

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R36/38 Irritating to eyes and skin.


R43 May cause sensitisation by skin contact.

GB

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**
- **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 AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN
- **Tel:** +423 235 35 35
Fax: +423 235 33 60
- **Further information obtainable from:**
Regulatory Affairs
msds@ivoclarvivadent.com
- **Emergency telephone number:** +423 / 235 33 13

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
 -  Xi; Irritant
R36/38: Irritating to eyes and skin.
 -  Xi; Sensitising
R43: May cause sensitisation by skin contact.
 - R10: Flammable.
- **Information concerning particular hazards for human and environment:**
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **Label elements**
- **Labelling according to EU guidelines:**
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.
- **Code letter and hazard designation of product:**
 -  Xi Irritant
- **Hazard-determining components of labelling:**
2-hydroxyethyl methacrylate
- **Risk phrases:**
10 Flammable.
36/38 Irritating to eyes and skin.
43 May cause sensitisation by skin contact.
- **Safety phrases:**
7 Keep container tightly closed.

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Trade name: **ExcITE F DSC**







(Contd. of page 1)

- 16 Keep away from sources of ignition - No smoking.
- 23 Do not breathe fumes/aerosol.
- 24 Avoid contact with skin.
- 37 Wear suitable gloves.
- 60 This material and its container must be disposed of as hazardous waste.
- **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 substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 1565-94-2	Bis-GMA	 Xi R36/38	25-50%
CAS: 64-17-5 EINECS: 200-578-6	ethanol	 F R11	10-25%
CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate	 Xi R36/38;  Xi R43	10-25%
CAS: 223681-84-3	phosphonic acid acrylate	 Xi R36/38	10-25%
CAS: 7789-23-3 EINECS: 232-151-5	potassium fluoride	 T R23/24/25	≤ 2.5%

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

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:** 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, 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.

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Trade name: **Excite F DSC**

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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** Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:**
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:** 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 container tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

64-17-5 ethanol

WEL () Long-term value: 1920 mg/m³, 1000 ppm

- **Additional information:** The lists valid during the making 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.
- **Respiratory protection:** Not necessary if room is well-ventilated.

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Revision: 22.02.2011

Trade name: **ExcITE F DSC**

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· **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 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

· **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

· Form:	Fluid
· Colour:	Colourless
· Odour:	Characteristic
· Odour threshold:	Not determined.

· **pH-value (10 g/l) at 20°C:** 2.5

· **Change in condition**

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.

· **Flash point:** 24°C

· **Ignition temperature:** 425°C

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product is not explosive. However, formation of explosive air/ vapour mixtures are possible.

· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure at 20°C:** 59 hPa

· **Density at 20°C:** 1.066 g/cm³

· **Relative density** Not determined.

· **Vapour density** Not determined.

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Trade name: **Excite F DSC**

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· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Partly miscible.
· Segregation 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** 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 the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant
- **Sensitisation** May cause sensitisation by skin contact.

12 Ecological information

- **Toxicity**
- **Acquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour 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 (German Regulation) (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.

GB

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.02.2011

Version number 3

Revision: 22.02.2011

Trade name: **ExciTE F DSC**

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13 Disposal considerations· **Waste treatment methods**· **Recommendation***Must not be disposed together with household garbage. Do not allow product to reach sewage system.*· **European waste catalogue**

18 01 06* chemicals consisting of or containing dangerous substances

· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.**14 Transport information**· **Land transport ADR/RID (cross-border)**· **ADR/RID class:** 3 (F1) Flammable liquids.· **Danger code (Kemler):** 30· **UN-Number:** 1170· **Packaging group:** III· **Hazard label:** 3· **UN proper shipping name:** 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)· **Tunnel restriction code** D/E· **Maritime transport IMDG:**· **IMDG Class:** 3· **UN Number:** 1170· **Label** 3· **Packaging group:** III· **EMS Number:** F-E,S-E· **Marine pollutant:** No· **Proper shipping name:** ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)· **Air transport ICAO-TI and IATA-DGR:**· **ICAO/IATA Class:** 3· **UN/ID Number:** 1170· **Label** 3· **Packaging group:** III· **Proper shipping name:** ETHANOL SOLUTION· **Special precautions for user** Warning: Flammable liquids.· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

GB

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Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.02.2011

Version number 3

Revision: 22.02.2011

Trade name: *Excite F DSC*

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15 Regulatory information

- *Safety, health and environmental regulations/legislation specific for the substance or mixture*
- *National regulations:*
- *Other regulations, limitations and prohibitive regulations*
The product is a medical device according to the EC-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.

· **Relevant phrases**

R11 Highly flammable.

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R36/38 Irritating to eyes and skin.

R43 May cause sensitisation by skin contact.

GB