

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Product name : Tubulitec Primer
Product group : Trade product

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : For isolation of cavities
Use of the substance/mixture : Dentistry

Title	Use descriptors
Tubulitec Primer	SU20

Full text of use descriptors: see section 16

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Dental Therapeutics AB
Paviljongvägen 3-5
SE-13240 SALTSJO-BOO - Sweden
T +46(0)8 12 29 69 21
info@therapeutics.se - www.therapeutics.se

1.4. Emergency telephone number

Emergency number : National Poisons Information Centre +31 (0)30 - 274 8888
(Only for the purpose of informing medical personnel in cases of accidental intoxications. The emergency phone number is 24 hours/day available.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flammable liquids, Category 2 H225

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS02

Signal word (CLP) : Danger
Hazard statements (CLP) : H225 - Highly flammable liquid and vapour
Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
P233 - Keep container tightly closed
P501 - Dispose of contents/container to an approved waste disposal plant

2.3. Other hazards

No additional information available

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	Conc. (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethanol substance with national workplace exposure limit(s) (GB)	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5 (REACH-no) 01-2119457610-43	75-100	Flam. Liq. 2, H225

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: If you feel unwell, seek medical advice.
First-aid measures after skin contact	: Wash with plenty of soap and water. Hand protection : skin cream may be used.
First-aid measures after eye contact	: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
First-aid measures after ingestion	: Give milk to drink. On ingestion in large quantities: Get medical advice/attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation	: High concentration of vapours may induce: headache, dizziness, drowsiness, nausea and vomiting.
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4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Powder. Carbon dioxide (CO ₂). Water spray.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Flammable.
Reactivity in case of fire	: The vapours mix well with air, explosive mixtures are easily formed.
Hazardous decomposition products in case of fire	: Combustion produces toxic gases. Carbon monoxide. Carbon dioxide.

5.3. Advice for firefighters

Firefighting instructions	: Fight fire with normal precautions from a reasonable distance. Cool down the containers exposed to heat with a water spray.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Concerning personal protective equipment to use, see section 8. Ensure adequate air ventilation. Avoid all eye and skin contact and do not breathe vapour and mist. Access forbidden to unauthorised personnel. No flames, no sparks. Eliminate all sources of ignition.
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6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Avoid release to the environment. Prevent soil and water pollution.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Collect all waste in suitable and labelled containers and dispose according to local legislation. Contaminated surfaces: clean (treat) with an excess of water.
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6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". Concerning disposal elimination after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: Highly flammable.
Precautions for safe handling	: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Carefully comply with the instructions for use. Do not eat, drink or smoke when using this product. Keep out of the reach of children. Try to stop release if without risk. See Heading 6. Take precautionary measures against static discharge. Keep container tightly closed. Ensure good ventilation of the work station.
Hygiene measures	: Remove contaminated clothes.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Emergency safety showers should be available in the immediate vicinity of any potential exposure.
Storage temperature	: Store at ambient temperature
Information on mixed storage	: Oxidizer.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ethanol (64-17-5)		
United Kingdom	Local name	Ethanol
United Kingdom	WEL TWA (mg/m ³)	1920 mg/m ³
United Kingdom	WEL TWA (ppm)	1000 ppm
United Kingdom	WEL STEL (mg/m ³)	5760 mg/m ³ (calculated)
United Kingdom	WEL STEL (ppm)	3000 ppm (calculated)
United Kingdom	Regulatory reference	EH40. HSE

Ethanol (64-17-5)	
DNEL/DMEL (Workers)	
Acute - local effects, inhalation	1900 mg/m ³
Long-term - systemic effects, dermal	343 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	950 mg/m ³
DNEL/DMEL (General population)	
Acute - local effects, inhalation	950 mg/m ³
Long-term - systemic effects, oral	87 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	114 mg/m ³
Long-term - systemic effects, dermal	206 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	<= 0,96 mg/l
PNEC aqua (marine water)	0,79 mg/l
PNEC aqua (intermittent, freshwater)	2,75 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	3,6 mg/kg dwt
PNEC sediment (marine water)	2,9 mg/kg dwt
PNEC (Soil)	
PNEC soil	0,63 mg/kg dwt
PNEC (Oral)	
PNEC oral (secondary poisoning)	0,72 g/kg
PNEC (STP)	
PNEC sewage treatment plant	580 mg/l

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protective equipment:

In case of splash hazard: safety glasses.

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Hand protection:

No special clothing/skin protection equipment is recommended under normal conditions of use

Eye protection:

If there is a risk of liquid being splashed : Safety glasses

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment.



Environmental exposure controls:

SECTION 12.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Yellow.
Odour	: Alcohol odour.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: 78 °C
Flash point	: 13 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Highly flammable liquid and vapour
Vapour pressure	: 5,87 kPa
Relative vapour density at 20 °C	: No data available
Relative density	: 1,6
Density	: 7,91 Relative density
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: 3,5 - 11,5 vol %

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Keep away from oxidizing agents.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

May form explosive compounds. Reacts vigorously with strong oxidizers and acids. Reacts with : Hydrogen peroxide, Nitric acid.

10.4. Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

10.5. Incompatible materials

Attacks some forms of plastic, rubber and coatings.

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10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Ethanol (64-17-5)	
LD50 oral rat	10470 mg/kg (Symptoms may include dizziness, headache, nausea and loss of coordination)
LD50 dermal rabbit	> 2000 mg/kg (Symptoms: Redness, pain)
LC50 inhalation rat (mg/l)	124,7 mg/l/4h (Symptoms include headache, dizziness, fatigue, muscular weakness, drowsiness and in extreme cases, loss of consciousness)

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified
Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified

Ethanol (64-17-5)	
NOAEL (oral, rat, 90 days)	4 ml/kg (male)

Aspiration hazard : Not classified

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Ecological problems are not known or expected under normal use.
Acute aquatic toxicity : Not classified
Chronic aquatic toxicity : Not classified

Ethanol (64-17-5)	
LC50 fishes	14,2 g/l
LC50 fish 2	13000 mg/l (Oncorhynchus mykiss (Rainbow trout))
EC50 Daphnia	12340 mg/l
EC50 72h algae (1)	275 mg/l Chlorella vulgaris
NOEC (chronic)	> 1 mg/l 24d

12.2. Persistence and degradability

Ethanol (64-17-5)	
Persistence and degradability	Readily biodegradable.

12.3. Bioaccumulative potential

Ethanol (64-17-5)	
Log Pow	-0,32
Bioaccumulative potential	No bioaccumulation.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	: Disposal must be done according to official regulations.
Additional information	: Hazardous waste due to potential risk of fire.
Ecology - waste materials	: Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR

ADR

14.1. UN number

1170

14.2. UN proper shipping name

ETHANOL (ETHYL ALCOHOL) / ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

Transport document description (ADR)

UN 1170 ETHANOL (ETHYL ALCOHOL) / ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II, (D/E)

14.3. Transport hazard class(es)

3



14.4. Packing group

II

14.5. Environmental hazards

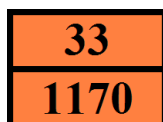
Dangerous for the environment : No

No supplementary information available

14.6. Special precautions for user

- Overland transport

Classification code (ADR)	: F1
Special provisions (ADR)	: 144, 601
Limited quantities (ADR)	: 1I
Excepted quantities (ADR)	: E2
Packing instructions (ADR)	: P001, IBC02, R001
Mixed packing provisions (ADR)	: MP19
Portable tank and bulk container instructions (ADR)	: T4
Portable tank and bulk container special provisions (ADR)	: TP1
Tank code (ADR)	: LGBF
Vehicle for tank carriage	: FL
Transport category (ADR)	: 2
Special provisions for carriage - Operation (ADR)	: S2, S20
Hazard identification number (Kemler No.)	: 33
Orange plates	:



Tunnel restriction code (ADR) : D/E

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

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3. Liquid substances or mixtures which are regarded as dangerous in accordance with Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008	Ethanol
3(a) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F	Tubulitec Primer - Ethanol
40. Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or not.	Ethanol

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

SECTION 16: Other information

Other information : **DISCLAIMER OF LIABILITY** The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable.

Full text of H- and EUH-statements:

Flam. Liq. 2	Flammable liquids, Category 2
H225	Highly flammable liquid and vapour
SU20	Health services

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Flam. Liq. 2	H225	On basis of test data
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SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product