

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

1.1. Product identifier

Product form : Mixture
 Product name : Tubulitec Cavity Liner
 Product group : Trade product

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

1.2.1. Relevant identified uses

Use of the substance/mixture : For isolation of cavities

Title	Use descriptors
Tubulitec Cavity Liner	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
 Serious eye damage/eye irritation, Category 1 H318
 Specific target organ toxicity — Single exposure, Category 3, Narcosis H336
 Hazardous to the aquatic environment — Chronic Hazard, Category 2 H411

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) :



Signal word (CLP) : Danger

Hazardous ingredients : Ethyl acetate; calcium dihydroxide

Hazard statements (CLP) : H225 - Highly flammable liquid and vapour
 H318 - Causes serious eye damage
 H336 - May cause drowsiness or dizziness
 H411 - Toxic to aquatic life with long lasting effects

Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
 P261 - Avoid breathing vapours

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P280 - Wear eye protection, face protection
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call Call a POISON CENTER or doctor/physician
P501 - Dispose of contents/container to an approved waste disposal plant

EUH-statements : EUH066 - Repeated exposure may cause skin dryness or cracking

2.3. Other hazards

No additional information available

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]
Ethyl acetate	(CAS-No.) 141-78-6 (EC-No.) 205-500-4 (EC Index-No.) 607-022-00-5 (REACH-no) 01-2119475103-46	>= 75	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
5,5'-diisopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihydroiodide	(CAS-No.) 552-22-7 (EC-No.) 209-007-5	5 - 10	Acute Tox. 4 (Oral), H302
zinc oxide	(CAS-No.) 1314-13-2 (EC-No.) 215-222-5 (EC Index-No.) 030-013-00-7 (REACH-no) 01-2119463881-32	1 - 5	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
calcium dihydroxide	(CAS-No.) 1305-62-0 (EC-No.) 215-137-3 (REACH-no) 01-2119475151-45	1 - 5	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335
Calcium oxide substance with a Community workplace exposure limit substance with national workplace exposure limit(s) (GB)	(CAS-No.) 1305-78-8 (EC-No.) 215-138-9	0,1 - 1	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person.

First-aid measures after inhalation : Nose and mouth rinse with clean water. Assure fresh air breathing. If you feel unwell, seek medical advice.

First-aid measures after skin contact : Remove/Take off immediately all contaminated clothing. Wash with plenty of soap and water.

First-aid measures after eye contact : Rinse immediately with plenty of water for 15 minutes. In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after ingestion : Drink plenty of water. Do NOT induce vomiting. Vomiting: prevent asphyxia/aspiration pneumonia. Give white mineral oil and saline purgative if victim completely conscious/alert. white paraffin oil (3ml/kg). sodium sulfate (1 tsp / 1/4 l water). If you feel unwell, seek medical advice.

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

No additional information available

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 (CO₂).

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Flammable liquid and vapour.

Reactivity in case of fire : The vapours mix well with air, explosive mixtures are easily formed.

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5.3. Advice for firefighters

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.
Other information : Vapours are heavier than air and spread above ground.

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. No flames, no sparks. Eliminate all sources of ignition. Potential explosion hazard.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material, e.g.: sand, earth, vermiculite. Collect all waste in suitable and labelled containers and dispose according to local legislation.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Vapours are heavier than air and spread above ground.
Precautions for safe handling : Avoid contact with skin and eyes. Carefully comply with the instructions for use. Try to stop release if without risk. See Heading 6. Do not eat, drink or smoke when using this product. Keep out of the reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharge.
Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Do not eat, drink or smoke when using this product. Wash contaminated clothing before reuse. Always wash hands after handling the product.

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. Protect from moisture. Store in dry, cool, well-ventilated area.
Storage temperature : < 30 °C

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ethyl acetate (141-78-6)		
EU	Local name	Ethyl acetate
EU	IOELV TWA (mg/m ³)	734 mg/m ³
EU	IOELV TWA (ppm)	200 ppm
EU	IOELV STEL (mg/m ³)	1486 mg/m ³
EU	IOELV STEL (ppm)	400 ppm
United Kingdom	Local name	Ethyl acetate
United Kingdom	WEL TWA (ppm)	200 ppm
United Kingdom	WEL STEL (ppm)	400 ppm
zinc oxide (1314-13-2)		
EU	Local name	Zinc oxide
EU	Notes	SCOEL Recommendations (Ongoing)
calcium dihydroxide (1305-62-0)		
EU	Local name	Calcium dihydroxide
EU	IOELV TWA (mg/m ³)	1 mg/m ³ Respirable fraction
EU	IOELV STEL (mg/m ³)	4 mg/m ³ Respirable fraction
EU	Regulatory reference	COMMISSION DIRECTIVE (EU) 2017/164
United Kingdom	Local name	Calcium hydroxide

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calcium dihydroxide (1305-62-0)		
United Kingdom	WEL TWA (mg/m ³)	5 mg/m ³
United Kingdom	Regulatory reference	EH40. HSE
Calcium oxide (1305-78-8)		
EU	Local name	Calcium oxide
EU	IOELV TWA (mg/m ³)	1 mg/m ³ Respirable fraction
EU	IOELV STEL (mg/m ³)	4 mg/m ³ Respirable fraction
EU	Regulatory reference	COMMISSION DIRECTIVE (EU) 2017/164
United Kingdom	Local name	Calcium oxide
United Kingdom	WEL TWA (mg/m ³)	2 mg/m ³
United Kingdom	Regulatory reference	EH40. HSE

zinc oxide (1314-13-2)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	83 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	5 mg/m ³
Long-term - local effects, inhalation	500 µg/m ³
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	0,83 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	2,5 mg/m ³
Long-term - systemic effects, dermal	83 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	20,6 µg/l
PNEC aqua (marine water)	6,1 µg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	117,8 mg/kg dwt
PNEC sediment (marine water)	56,5 mg/kg dwt
PNEC (Soil)	
PNEC soil	35,6 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	100 µg/L

calcium dihydroxide (1305-62-0)	
DNEL/DMEL (Workers)	
Long-term - local effects, inhalation	1 mg/m ³
DNEL/DMEL (General population)	
Long-term - local effects, inhalation	1 mg/m ³
PNEC (Water)	
PNEC aqua (freshwater)	0,49 mg/l
PNEC aqua (marine water)	0,32 mg/l
PNEC aqua (intermittent, freshwater)	0,49 mg/l
PNEC (Soil)	
PNEC soil	1080 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	3 mg/l

Calcium oxide (1305-78-8)	
DNEL/DMEL (Workers)	
Acute - systemic effects, dermal	200 mg/kg bodyweight/day
Acute - systemic effects, inhalation	4 mg/m ³
Acute - local effects, dermal	4 mg/cm ²
Acute - local effects, inhalation	4 mg/m ³
Long-term - systemic effects, dermal	5 mg/kg bodyweight/day
Long-term - local effects, dermal	4 mg/cm ²
Long-term - systemic effects, inhalation	1 mg/m ³
Long-term - local effects, inhalation	1 mg/m ³
DNEL/DMEL (General population)	
Acute - systemic effects, dermal	100 mg/kg bodyweight
Acute - systemic effects, inhalation	16 mg/m ³
Acute - systemic effects, oral	100 mg/kg bodyweight
Acute - local effects, dermal	2 mg/cm ²

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Calcium oxide (1305-78-8)	
Acute - local effects, inhalation	4 mg/m ³
Long-term - systemic effects, oral	100 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	1,75 mg/m ³
Long-term - systemic effects, dermal	2,5 mg/kg bodyweight/day
Long-term - local effects, dermal	2 mg/cm ²
Long-term - local effects, inhalation	1 mg/m ³
PNEC (Sediment)	
PNEC sediment (freshwater)	37,5 mg/kg dwt
PNEC sediment (marine water)	660 mg/kg dwt
PNEC (Soil)	
PNEC soil	400 - 817,4 mg/kg dwt

8.2. Exposure controls

Appropriate engineering controls:

Avoid all unnecessary exposure. Ensure good ventilation of the work station.

Personal protective equipment:

Gloves. Safety glasses.

Hand protection:

Wear suitable gloves resistant to chemical penetration. Suitable material: Viton, Latex. Layer thickness : No data available. Time of penetration is to be checked with the glove producer

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

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	: No data available
Odour threshold	: No data available
pH	: 7,3
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: -83 °C
Freezing point	: No data available
Boiling point	: 77 °C (101325 Pa)
Flash point	: -5 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: 9,7 kPa
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 3
Solubility	: No data available

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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	: 2,1 - 11,5 vol %

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Moisture.

10.5. Incompatible materials

hydriker. Strong oxidizers. Alkali metals.

10.6. Hazardous decomposition products

Ethanol. Acetic acid.

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
Additional information	: Repeated exposure may cause skin dryness or cracking

Ethyl acetate (141-78-6)	
LD50 oral	5620 mg/kg bodyweight
LD50 dermal	> 18000 mg/kg bodyweight
LC50 inhalation rat (Dust/Mist - mg/l/4h)	57700 mg/l

zinc oxide (1314-13-2)	
LD50 oral rat	2000 - 5000 mg/kg
LD50 dermal rat	2000 mg/kg
LC50 inhalation rat (mg/l)	1.79 - 5.7
LC50 inhalation rat (Vapours - mg/l/4h)	> 1,79 mg/l/4h

calcium dihydroxide (1305-62-0)	
LD50 oral rat	> 2000 mg/kg
LD50 dermal rabbit	> 2500 mg/kg

Calcium oxide (1305-78-8)	
LD50 oral rat	790 - 8500 mg/kg bodyweight
LD50 oral	1940 - 7300 mg/kg bodyweight mouse
LD50 dermal rabbit	2500 - 5000 mg/kg bodyweight
LC50 inhalation rat (mg/l)	1026 mg/l (60 min)

Skin corrosion/irritation	: Not classified pH: 7,3
Serious eye damage/irritation	: Causes serious eye damage. pH: 7,3
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified

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Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met

STOT-single exposure	: May cause drowsiness or dizziness.
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met

Calcium oxide (1305-78-8)	
LOAEL (oral, rat, 90 days)	300 mg/kg bodyweight/day
NOAEL (oral, rat, 90 days)	100 - 2000 mg/kg bodyweight/day

Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Large amounts of the product should not be allowed to enter drains or water courses or be deposited where it can affect ground or surface waters.
Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Toxic to aquatic life with long lasting effects.

Ethyl acetate (141-78-6)	
LC50 fishes	230 mg/l
EC50 other aquatic organisms 1	717 mg/l waterflea
EC50 other aquatic organisms 2	3300 mg/l

zinc oxide (1314-13-2)	
LC50 fishes	112 - 8062 µg/l
EC50 other aquatic organisms 1	155 - 100000 µg/L
NOEC chronic crustacea	300 µg/l 3 months.
NOEC chronic algae	1071 mg/l 16 days.

calcium dihydroxide (1305-62-0)	
LC50 fishes	457 mg/l (96h)

Calcium oxide (1305-78-8)	
LC50 fishes	33,884 - 4839 mg/l
EC50 Daphnia	49,1 - 187,8 mg/l
NOEC (chronic)	307 mg/l
NOEC chronic fish	100 mg/l

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Ethyl acetate (141-78-6)	
Log Pow	0,7

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

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	: Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials	: Avoid release to the environment.

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SECTION 14: Transport information

In accordance with ADR

ADR	
14.1. UN number	1173
14.2. UN proper shipping name	ETHYL ACETATE
Transport document description (ADR)	UN 1173 ETHYL ACETATE, 3, II, (D/E), ENVIRONMENTALLY HAZARDOUS
14.3. Transport hazard class(es)	3
14.4. Packing group	II
14.5. Environmental hazards	Dangerous for the environment : Yes
	No supplementary information available

14.6. Special precautions for user

- Overland transport

Classification code (ADR)	: F1
Limited quantities (ADR)	: 11
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:

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	Ethyl acetate
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 Cavity Liner - Ethyl acetate

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3(b) 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 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10	Tubulitec Cavity Liner - Ethyl acetate
3(c) 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 class 4.1	Tubulitec Cavity Liner
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.	Ethyl acetate

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:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4	
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1	
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Flam. Liq. 2	Flammable liquids, Category 2	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Narcosis	
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation	
H225	Highly flammable liquid and vapour	
H302	Harmful if swallowed	
H315	Causes skin irritation	
H318	Causes serious eye damage	
H319	Causes serious eye irritation	
H335	May cause respiratory irritation	
H336	May cause drowsiness or dizziness	
H400	Very toxic to aquatic life	
H410	Very toxic to aquatic life with long lasting effects	
H411	Toxic to aquatic life with long lasting effects	
EUH066	Repeated exposure may cause skin dryness or cracking	
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
Eye Dam. 1	H318	Calculation method
STOT SE 3	H336	Calculation method
Aquatic Chronic 2	H411	Calculation method

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