

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Date of issue: 01-07-2014 Revision date: 15-02-2023 Supersedes: 19-08-2021 Version: 5.0

SECTION 1: Identification of the	e substance/mixture and of the company/undertaking			
1.1. Product identifier				
Product form	: Mixture			
Product name	e : Tubulicid Plus			
Product group	: Trade product			
1.2. Relevant identified uses of the	e substance or mixture and uses advised against			
1.2.1. Relevant identified uses				
Main use category	: Professional use			
Use of the substance/mixture	: Cleaning of root canals and dental tubule apertures			
Use of the substance/mixture	: Dentistry			
Title	Use descriptors			
Tubulicid Plus	SU20			
Full text of use descriptors: see section 16	3			
1.2.2. Uses advised against				
No additional information available				
1.3. Details of the supplier of the s	safety data sheet			
Dental Therapeutics AB	salety data sheet			
Paviljongvägen 3-5				
SE-13240 SALTSJO-BOO - Sweden				
T +46(0)8 12 29 69 21				
info@therapeutics.se - www.therapeutics.	<u>se</u>			
1.4. Emergency telephone numbe	r			
Emergency number	<ul> <li>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.)</li> </ul>			
SECTION 2: Hazards identificat	ion			
2.1. Classification of the substance				
Classification according to Regulation	(EC) No. 1272/2008 [CLP]			
Not classified				
NOLCIASSINEU				
Adverse physicochemical, human heal	th and environmental effects			
No additional information available				
2.2. Label elements				
Labelling according to Regulation (EC)	No. 1272/2008 [CLP]			
EUH-statements	: EUH210 - Safety data sheet available on request			
2.3. Other hazards				
No additional information available				
SECTION 3: Composition/inform	mation 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]
2-[2-[bis(carboxymethyl)amino]ethyl- (carboxymethyl)amino]acetic acid	(CAS-No.) 6381-92-6	1 - 5	Acute Tox. 4 (Oral), H302

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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.
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 effect	ts, both acute and delayed
No additional information available	
4.3. Indication of any immediate medica	l attention and special treatment needed
No additional information available	
SECTION 5: Firefighting measures	
5.1. Extinguishing media	
Suitable extinguishing media	: Use extinguishing agent suitable for surrounding fire.
5.2. Special hazards arising from the su	bstance or mixture
Fire hazard	: The product is not flammable.
Hazardous decomposition products in case of fire	: On heating/burning: release of toxic and corrosive gases/vapours nitrous vapours mercury vapours.
5.3. Advice for firefighters	
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.
<b>SECTION 6: Accidental release meas</b>	sures
6.1. Personal precautions, protective eq	uipment 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.
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.	
6.3. Methods and material for containme	ent 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.
6.4. Reference to other sections	
For further information refer to section 8: "Expos	ure 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	: Handling and storage of this material do not require special precaution.
Precautions for safe handling	: Avoid contact with skin and eyes. 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 it without risk.
7.2. Conditions for safe storage, includi	ng any incompatibilities
Storage conditions	: Store in a well-ventilated place. Keep cool.
Storage temperature	: < 30 °C
7.3. Specific end use(s)	
No additional information available	
SECTION 8: Exposure controls/pers	onal protection
8.1. Control parameters	
No additional information available	

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### 8.2. Exposure controls

### Appropriate engineering controls:

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

### Hand protection:

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

#### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment.

#### Environmental exposure controls:

SECTION 12.

<b>SECTION 9: Physical and chemical</b>	properties	
9.1. Information on basic physical and	chemical properties	
Physical state	: Liquid	
Colour	: Colourless.	
Odour	: odourless.	
Odour threshold	: No data available	
рН	: 7,3	
Relative evaporation rate (butylacetate=1)	: No data available	
Melting point	: No data available	
Freezing point	: No data available	
Boiling point	: 100 °C (@ 101325 pa)	
Flash point	: No data available	
Auto-ignition temperature	: No data available	
Decomposition temperature	: No data available	
Flammability (solid, gas)	: No data available	
Vapour pressure	: No data available	
Relative vapour density at 20 °C	: No data available	
Relative density	: No data available	
Solubility	: Water: Dispersible	
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	: No data available	
9.2. Other information		
No additional information available		
<b>SECTION 10: Stability and reactivity</b>	/	
10.1. Reactivity		
No dangerous reactions known under normal co	onditions of use.	
10.2. Chemical stability		
Stable under normal conditions.		
10.3. Possibility of hazardous reactions		
No dangerous reactions known under normal c	onditions of use.	
10.4. Conditions to avoid		
Stable in use and storage conditions as recomm	nended in item 7.	
10.5. Incompatible materials		
No additional information available		
10.6. Hazardous decomposition product	S	
Nitrogen dioxide.		

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SECTION 11: Toxicological informa	ation
11.1. Information on toxicological effect	
Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
	pH: 7,3
Serious eye damage/irritation	: Not classified
	рН: 7,3
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
Aspiration hazard	: Not classified
Potential adverse human health effects and	: Based on available data, the classification criteria are not met.
symptoms	
<b>SECTION 12: Ecological informatio</b>	n i
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	: Not classified
12.2. Persistence and degradability	
No additional information available	
12.3. Bioaccumulative potential	
No additional information available	
12.4. Mobility in soil	
No additional information available	
12.5. Results of PBT and vPvB assessm	nent
No additional information available	
12.6. Other adverse effects	Defense discharges internetienen einerte die einer die ternere die ternetie in einer der installigen die
Additional information	: Before discharge into sewage plants the product normally needs to be neutralised.
SECTION 13: Disposal consideration	bns
13.1. Waste treatment methods	
Regional legislation (waste)	: Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	
Additional information	: Presents no specific risk for the environment.
Ecology - waste materials	: Avoid release to the environment.
<b>SECTION 14: Transport information</b>	n
In accordance with ADR / RID / IMDG / IATA /	
ADR IMDG	IATA ADN RID
14.1 UN number	

ADK	IWDG	IATA	ADN	עוא
14.1. UN number				
Not applicable	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not applicable	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not applicable	Not regulated	Not regulated	Not regulated	Not regulated

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ADR	IMDG	IATA	ADN	RID
14.4. Packing group				
Not applicable	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not applicable	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

#### 14.6. Special precautions for user

- Overland transport

Not applicable

#### - Transport by sea

Not regulated

#### - Air transport

Not regulated

#### - Inland waterway transport

Not regulated

### - Rail transport

Not regulated

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

Contains no REACH substances with Annex XVII restrictions 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	
H302	Harmful if swallowed	
EUH210	Safety data sheet available on request	
SU20	Health services	

#### 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