

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 substance/mixture and of the company/undertaking			
1.1. Product identifier			
Product form	: Mixture		
Product name	: Tubulicid Red		
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	: Cleaning and fluoride-impregnation of cavities and dentinal surfaces.		
Use of the substance/mixture	: Dentistry		
Title	Use descriptors		
Tubulicid Red	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 safe	ety data sheet		
Dental Therapeutics AB			
Paviljongvägen 3			
SE-13240 SALTSJO-BOO - Sweden T +46(0)8 12 29 69 21			
info@therapeutics.se - www.therapeutics.se			
1.4. Emergency telephone number	: National Poisons Information Centre +31 (0)30 - 274 8888		
Emergency number	(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	n		
2.1. Classification of the substance of	or mixture		
Classification according to Regulation (EC	C) No. 1272/2008 [CLP]		
Not classified			
Adverse physics chemical human health			
Adverse physicochemical, human health a No additional information available	and environmental effects		
2.2. Label elements			
Labelling according to Regulation (EC) No			
EUH-statements	: EUH031 - Contact with acids liberates toxic gas EUH210 - Safety data sheet available on request		
2.3. Other hazards			
No additional information available			
SECTION 3: Composition/informa	tion on ingredients		
3.1. Substances			
Not applicable			
3.2. Mixtures			

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Name	Product identifier	Conc. (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
sodium fluoride	(CAS-No.) 7681-49-4 (EC-No.) 231-667-8 (EC Index-No.) 009-004-00-7 (REACH-no) 01-2119539420-47	0,1 - 1	Acute Tox. 3 (Oral), H301 Eye Irrit. 2, H319 Skin Irrit. 2, H315

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 e	ffects, both acute and delayed
No additional information available	
4.3. Indication of any immediate med	lical attention and special treatment needed
No additional information available	
SECTION 5: Firefighting measure	s
5.1. Extinguishing media	
Suitable extinguishing media	: Use extinguishing agent suitable for surrounding fire.
5.2. Special hazards arising from the	substance or mixture
Fire hazard	: The product is not flammable.
5.3. Advice for firefighters	
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.
SECTION 6: Accidental release m	easures
	e 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.
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 contain	oment 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: "Ex	posure 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	: Carefully comply with the instructions for use. Do not eat, drink or smoke when using this product. Keep out of the reach of children.
7.2. Conditions for safe storage, incl	
Storage conditions	: Store in a well-ventilated place. Keep cool.
Information on mixed storage	: acids.
7.3. Specific end use(s)	
No additional information available	

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SECTION 8: Exposure controls/personal protection		
8.1.	Control parameters	

sodium fluoride (7681-49-4)		
DNEL/DMEL (Workers)		
Acute - systemic effects, inhalation	2,5 mg/m³	
Long-term - systemic effects, dermal	0,36 mg/kg bodyweight/day	
PNEC (Water)		
PNEC aqua (freshwater)	0,9 mg/l	
PNEC (Soil)		
PNEC soil	11 mg/kg dwt	
PNEC (STP)		
PNEC sewage treatment plant	51 mg/l	
8.2 Exposure controls		

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:

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SECTION 9: Physical and chemical 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			
SECTION 10: Stability and reactivit	у		

Violent exothermic reaction with (some) acids/bases: (increased) risk of fire.

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10.2.	Chemical stability			
	Stable under normal conditions.			
10.3.	Possibility of hazardous reactions			
No dang	gerous reactions known under normal conditions of use.			
10.4.	Conditions to avoid			
Stable in	n use and storage conditions as recommended in item 7.			
10.5.	Incompatible materials			
acids.				
10.6.	Hazardous decomposition products			

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

SECTION 11: Toxicological informa	tion
11.1. Information on toxicological effects	S
Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
sodium fluoride (7681-49-4)	
LD50 oral rat	148,5 mg/kg
LD50 dermal rat	> 2000 mg/kg
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 symptoms	: 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 deposited where it can affect ground or surface waters.	be
Acute aquatic toxicity :	Not classified	
Chronic aquatic toxicity :	Not classified	
sodium fluoride (7681-49-4)		
LC50 fishes	164,5 ppm	
NOEC (acute)	4 mg/l 21d	
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 assessment		
No additional information available		
12.6. Other adverse effects		
Additional information :	Before discharge into sewage plants the product normally needs to be neutralised.	
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: Disposal must be done according to official regulations.
: Dispose in a safe manner in accordance with local/national regulations.
: Presents no specific risk for the environment.
: Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN					
ADR	IMDG	IATA	ADN	RID	
14.1. UN number	14.1. UN number				
Not applicable	Not regulated	Not regulated	Not regulated	Not regulated	
14.2. UN proper shippi	ng 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	
14.4. Packing group	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

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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. 3 (Oral)	Acute toxicity (oral), Category 3	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
H301	Toxic if swallowed	
H315	Causes skin irritation	
H319	Causes serious eye irritation	
EUH031	Contact with acids liberates toxic gas	
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