

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 safety data sheet

Dental Therapeutics AB
Paviljongvägen 3
SE-13240 SALT SJÖ-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]**

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

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/information on ingredients**3.1. Substances**

Not applicable

3.2. Mixtures

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

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 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 : 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 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.

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 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.

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 : 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, including any incompatibilities

- 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/m ³
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

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.

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
pH	: 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 reactivity

10.1. Reactivity

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 dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Stable in 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 information

11.1. Information on toxicological effects

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
pH: 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 be deposited where it can affect ground or surface waters.

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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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.
Additional information	: Presents no specific risk for the environment.
Ecology - waste materials	: 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				
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
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.
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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