

NitrAdine anti-Candida and anti-biofilm cleaning tablets (Medical Device Class I)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 9/7/2018 Version: 1.0

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

1.1. Product identifier

Product form : Mixture
Trade name : NitrAdine anti-Candida and anti-biofilm cleaning tablets (Medical Device Class I)

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For general public
Use of the substance/mixture : Anti-Candida and anti-biofilm cleaning tablets for removable dental appliances.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

Bonyf AG
Heiligkreuz 16 FL-9490
FL-9490 Vaduz - Liechtenstein
Phone.: 00423 232 78 15
Emergency Number: +41445869967
Fax: 00423 232 51 88
chemist@bonyf.com
www.bonyf.com

1.4. Emergency telephone number

Emergency number : +41445869967

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] Mixtures/Substances: SDS EU 2015: According to Regulation (EU) 2015/830 (REACH Annex II)

Skin corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category 1 H318
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) :



GHS05

Signal word (CLP) : Danger
Hazardous ingredients : Sodium lauryl sulfate; Pentapotassium bis(peroxymonosulphate) bis(sulphate).
Hazard statements (CLP) : H315 - Causes skin irritation.
H318 - Causes serious eye damage.
Precautionary statements (CLP) : P102 - Keep out of reach of children.
P264 - Wash hands thoroughly after handling.
P280 - Wear protective gloves, eye protection.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P305+P351+P338+P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor.
P332+P313 - If skin irritation occurs: Get medical advice/attention.
EUH-statements : EUH208 – Contains potassium persulfate and 2-Isopropyl-5-methylcyclohexanone. May produce an allergic reaction.

2.3. Other hazards not contributing to the classification

No additional information available

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Citric Acid Anhydrous	(CAS-No.) 77-92-9 (EC-No.) 201-069-1 (REACH-no) Not available	25 - 30	Eye Irrit. 2, H319
Sodium lauryl sulfate	(CAS-No.) 151-21-3 (EC-No.) 205-788-1	15 - 20	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Chronic 3, H412
Pentapotassium bis(peroxymonosulphate) bis(sulphate)	(CAS-No.) 70693-62-8 (EC-No.) 274-778-7	1-5	Acute Tox. 4 (Oral), H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Chronic 3, H412
Sodium Carbonate	(CAS-No.) 497-19-8 (EC-No.) 207-838-8 (EC Index-No.) 011-005-00-2	1 - 2	Eye Irrit. 2, H319
Potassium persulfate	(CAS-No.) 7727-21-1 (EC-No.) 231-781-8 (EC Index-No.) 016-061-00-1	0-0.3	Ox. Sol. 3, H272, Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319, Resp. Sens. 1, H334 Skin Sens. 1, H317 STOT SE 3, H335
2-Isopropyl-5-methylcyclohexanone	(CAS-No.) 89-80-5 (EC-No.) 233-944-9	0-0.5	H315 Skin Irrit. 2, H317 Skin Sens. 1B

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	: Allow victim to breathe fresh air. Allow the victim to rest.
First-aid measures after skin contact	: Wash with plenty of water/.... Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/attention. Specific treatment (see supplemental first aid instruction on this label).
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/effects after skin contact	: Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye damage.

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	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Non-flammable.
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5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protective equipment for firefighters	: 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

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.
Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.
Hygiene measures : Wash hands thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Heat sources. Keep container closed when not in use.
Incompatible products : Strong bases. Strong acids.
Incompatible materials : Sources of ignition. Direct sunlight.
Storage area : Store in dry, cool, well-ventilated area.

7.3. Specific end use(s)

Refer to section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

In case of repeated or prolonged contact (industrial environment), wear gloves; Chemical resistant gloves (according to European standard EN 374 or equivalent). Thickness of the glove material. > 0,11 mm. Breakthrough time : For prolonged contact, use nitrile or neoprene gloves or other material resistant to petroleum oils, Thickness of the glove material, > 0,11 mm, Breakthrough time : > 480 min

Eye protection:

Chemical goggles or safety glasses. Safety glasses equipped with side shields are recommended as minimum protection in industrial settings. Wear approved safety goggles. Chemical goggles should be consistent with EN166 or equivalent

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Wear appropriate mask

Personal protective equipment symbol(s):



Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Appearance : Tablets.
Colour : white.
Odour : peppermint odour.

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Odour threshold	: No data available
pH	: No data available
pH solution	: 3.6 - 4.3 one tabs dissolved in 150ml H ₂ O at 25°C (±3°C)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
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	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable in use and storage conditions as recommended in section 7.

10.3. Possibility of hazardous reactions

None under recommended storage and handling conditions (see section 7).

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide.

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

CITRIC ACID ANHYDROUS (77-92-9)

LD50 oral rat	3000 mg/kg
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sodium carbonate (497-19-8)

LD50 dermal rat	2210 mg/kg
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Potassium peroxydisulfate sulfate (K₂H₃(SO₃(O₂))₂(SO₄)₂) (70693-62-8)

LD50 oral rat	1204 mg/kg
LD50 dermal rabbit	> 11000 mg/kg
LC50 inhalation rat (mg/l)	> 14 mg/l (Exposure time: 1 h)

Potassium persulfate (7727-21-1)

LD50 oral rat	802 mg/kg
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LD50 dermal rabbit	> 10000 mg/kg
LC50 inhalation rat (mg/l)	> 42.9 mg/l (Exposure time: 1 h)
Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye damage.
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
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	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Potential Adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Not classified

Potassium peroxymonosulfate sulfate (K5H3(SO3(O2))2(SO4)2) (70693-62-8)

LC50 fish 1	> 32 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [semi-static])
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12.2. Persistence and degradability

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Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

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Bioaccumulative potential	Not established.
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Potassium peroxymonosulfate sulfate (K5H3(SO3(O2))2(SO4)2) (70693-62-8)

BCF fish 1	(no bioaccumulation expected)
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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 : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.
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 regulated	Not regulated	Not regulated	Not regulated	Not regulated

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14.2. UN proper shipping name

Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
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14.3. Transport hazard class(es)

Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
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14.4. Packing group

Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
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14.5. Environmental hazards

Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
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No supplementary information available

14.6. Special precautions for user

Overland transport

Not regulated

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

Directive 2012/18/EU (SEVESO III)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

A chemical safety assessment has been carried out

SECTION 16: Other information

Sources of Key data : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Ox. Sol. 3	Oxidising Solids, Category 3
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1

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STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation	
H272	May intensify fire; oxidiser.	
H302	Harmful if swallowed.	
H314	Causes severe skin burns and eye damage.	
H315	Causes skin irritation.	
H317	May cause an allergic skin reaction.	
H318	Causes serious eye damage.	
H319	Causes serious eye irritation.	
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
H335	May cause respiratory irritation.	
H412	Harmful to aquatic life with long lasting effects.	
EUH208	Contains Potassium persulfate(7727-21-1). May produce an allergic reaction.	
Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Irrit. 2	H315	Calculation method
Eye Dam. 1	H318	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