

Express Effervescent Denture Cleanser 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: 10/3/2018 Version: 1.0

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

1.1. Product identifier

Product form : Mixture
Trade name : Express Effervescent Denture Cleanser 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

Intended for general public
Use of the substance/mixture : 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]

Acute toxicity (oral), Category 4	H302
Skin corrosion/irritation, Category 1B	H314
Respiratory sensitisation, Category 1	H334
Skin sensitisation, Category 1	H317
Hazardous to the aquatic environment — Chronic Hazard, Category 3	H412

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

GHS07

GHS08

Signal word (CLP) : Danger
Hazardous ingredients : Sodium lauryl sulfate; Pentapotassium bis(peroxymonosulphate) bis(sulphate);
Hazard statements (CLP) : H302 - Harmful if swallowed.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H412 - Harmful to aquatic life with long lasting effects.

Express Effervescent Denture Cleanser Tablets Medical Device Class I

Safety Data Sheet

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

Precautionary statements (CLP)	: P101 - If medical advice is needed, have product container or label at hand. P102 - Keep out of reach of children. P261 - Avoid breathing dust. P264 - Wash hands thoroughly after handling. P303+P361+P353+P310 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor. 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. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
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

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]
Pentapotassium bis(peroxymonosulphate) bis(sulphate)	(CAS-No.) 70693-62-8 (EC-No.) 274-778-7	20-24	Acute Tox. 4 (Oral), H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Chronic 3, H412
CITRIC ACID ANHYDROUS	(CAS-No.) 77-92-9 (EC-No.) 201-069-1 (REACH-no) Not available	18 - 22	Eye Irrit. 2, H319
sodium carbonate	(CAS-No.) 497-19-8 (EC-No.) 207-838-8 (EC Index-No.) 011-005-00-2	2 - 4	Eye Irrit. 2, H319
Sodium lauryl sulfate	(CAS-No.) 151-21-3 (EC-No.) 205-788-1	1 - 2	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Chronic 3, H412
Potassium persulfate	(CAS-No.) 7727-21-1 (EC-No.) 231-781-8 (EC Index-No.) 016-061-00-1	0 - 1.2	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

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	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER/doctor.
First-aid measures after skin contact	: Wash off immediately with soap and plenty of water. Take off immediately all contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
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. Immediately call a POISON CENTER/doctor.

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

Symptoms/effects	: Causes severe skin burns and eye damage.
Symptoms/effects after inhalation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Symptoms/effects after skin contact	: May cause an allergic skin reaction.
Symptoms/effects after ingestion	: Swallowing a small quantity of this material will result in serious health hazard.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

Express Effervescent Denture Cleanser Tablets Medical Device Class I

Safety Data Sheet

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

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.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent firefighting 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.

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. Avoid release to the environment.

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. Avoid breathing dust.
Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations.
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.

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:

It is a good industrial hygiene practice to minimize skin contact. In case of repeated or prolonged contact (industrial environment), wear gloves; Chemical resistant gloves (according to European standard EN 374 or equivalent).

Eye protection:

Safety glasses equipped with side shields are recommended as minimum protection in industrial settings

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.

Express Effervescent Denture Cleanser Tablets Medical Device Class I

Safety Data Sheet

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

Colour	: white.
Odour	: peppermint odour.
Odour threshold	: No data available
pH	: one tabs dissolved in 150ml H ₂ O at 25°C (±3°C) pH: 5,65 bis 6,35
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	: soluble in water.
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

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

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. Thermal decomposition generates : Corrosive vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Oral: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

ATE CLP (oral)	500 mg/kg bodyweight
----------------	----------------------

CITRIC ACID ANHYDROUS (77-92-9)

LD50 oral rat	3000 mg/kg
---------------	------------

sodium carbonate (497-19-8)

LD50 dermal rat	2210 mg/kg
-----------------	------------

Pentapotassium bis(peroxymonosulphate) bis(sulphate) (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)

Express Effervescent Denture Cleanser Tablets Medical Device Class I

Safety Data Sheet

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

Potassium persulfate (7727-21-1)	
LD50 oral rat	802 mg/kg
LD50 dermal rabbit	> 10000 mg/kg
LC50 inhalation rat (mg/l)	> 42.9 mg/l (Exposure time: 1 h)
Skin corrosion/irritation	: Causes severe skin burns and eye damage. pH: one tabs dissolved in 150ml H ₂ O at 25°C (±3°C) pH: 5,65 bis 6,35
Serious eye damage/irritation	: Serious eye damage, category 1, implicit pH: one tabs dissolved in 150ml H ₂ O at 25°C (±3°C) pH: 5,65 bis 6,35
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
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	: Harmful if swallowed.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - water	: Harmful to aquatic life with long lasting effects.
Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Harmful to aquatic life with long lasting effects.

Pentapotassium bis(peroxymonosulphate) bis(sulphate) (70693-62-8)

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

12.2. Persistence and degradability

Express Effervescent Denture Cleanser Tablets Medical Device Class I

Persistence and degradability	May cause long-term adverse effects in the environment.
-------------------------------	---

12.3. Bioaccumulative potential

Express Effervescent Denture Cleanser Tablets Medical Device Class I

Bioaccumulative potential	Not established.
---------------------------	------------------

Pentapotassium bis(peroxymonosulphate) bis(sulphate) (70693-62-8)

BCF fish 1	(no bioaccumulation expected)
------------	-------------------------------

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. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
--	---

Express Effervescent Denture Cleanser Tablets Medical Device Class I

Safety Data Sheet






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

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				
1759	1759	1759	1759	1759
14.2. UN proper shipping name				
CORROSIVE SOLID, N.O.S.	CORROSIVE SOLID, N.O.S.	Corrosive solid, n.o.s.	CORROSIVE SOLID, N.O.S.	CORROSIVE SOLID, N.O.S.
Transport document description				
UN 1759 CORROSIVE SOLID, N.O.S., 8, II, (E)	UN 1759 CORROSIVE SOLID, N.O.S., 8, II	UN 1759 Corrosive solid, n.o.s., 8, II	UN 1759 CORROSIVE SOLID, N.O.S., 8, II	UN 1759 CORROSIVE SOLID, N.O.S., 8, II
14.3. Transport hazard class(es)				
8	8	8	8	8
				
14.4. Packing group				
II	II	II	II	II
14.5. Environmental hazards				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available				

14.6. Special precautions for user

Overland transport

Classification code (ADR) : C10
 Special provisions (ADR) : 274
 Limited quantities (ADR) : 1kg
 Excepted quantities (ADR) : E2
 Packing instructions (ADR) : P002, IBC08
 Special packing provisions (ADR) : B4
 Mixed packing provisions (ADR) : MP10
 Portable tank and bulk container instructions (ADR) : T3
 Portable tank and bulk container special provisions (ADR) : TP33
 Tank code (ADR) : SGAN, L4BN
 Vehicle for tank carriage : AT
 Transport category (ADR) : 2
 Special provisions for carriage - Packages (ADR) : V11
 Hazard identification number (Kemler No.) : 80
 Orange plates :



Tunnel restriction code (ADR) : E
 EAC code : 2X

Transport by sea

Special provisions (IMDG) : 274
 Packing instructions (IMDG) : P002

Express Effervescent Denture Cleanser Tablets Medical Device Class I

Safety Data Sheet

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

IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B21, B4
Tank instructions (IMDG)	: T3
Tank special provisions (IMDG)	: TP33
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-B
Stowage category (IMDG)	: A
Properties and observations (IMDG)	: Causes burns to skin, eyes and mucous membranes.

Air transport

PCA Excepted quantities (IATA)	: E2
PCA Limited quantities (IATA)	: Y844
PCA limited quantity max net quantity (IATA)	: 5kg
PCA packing instructions (IATA)	: 859
PCA max net quantity (IATA)	: 15kg
CAO packing instructions (IATA)	: 863
CAO max net quantity (IATA)	: 50kg
Special provisions (IATA)	: A3, A803
ERG code (IATA)	: 8L

Inland waterway transport

Classification code (ADN)	: C10
Special provisions (ADN)	: 274
Limited quantities (ADN)	: 1 kg
Excepted quantities (ADN)	: E2
Equipment required (ADN)	: PP, EP
Number of blue cones/lights (ADN)	: 0

Rail transport

Classification code (RID)	: C10
Special provisions (RID)	: 274
Limited quantities (RID)	: 1kg
Excepted quantities (RID)	: E2
Packing instructions (RID)	: P002, IBC08
Special packing provisions (RID)	: B4
Mixed packing provisions (RID)	: MP10
Portable tank and bulk container instructions (RID)	: T3
Portable tank and bulk container special provisions (RID)	: TP33
Tank codes for RID tanks (RID)	: SGAN, L4BN
Transport category (RID)	: 2
Special provisions for carriage – Packages (RID)	: W11
Colis express (express parcels) (RID)	: CE10
Hazard identification number (RID)	: 80

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

A chemical safety assessment has been carried out

Express Effervescent Denture Cleanser Tablets Medical Device Class I

Safety Data Sheet

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

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
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 and 2-Isopropyl-5-methylcyclohexanone. May produce an allergic reaction.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Acute Tox. 4 (Oral)	H302	Expert judgment
Skin Corr. 1B	H314	Expert judgment
Resp. Sens. 1	H334	Expert judgment
Skin Sens. 1	H317	Expert judgment
Aquatic Chronic 3	H412	Expert judgment

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