

CEFLA S.C.

Via Selice Provinciale 23/A,
40026 Imola BO
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www.cefla.com
www.ceflamedicalequipment.com

SAFETY DATA SHEET

Regulation (EC) n. 1907/2006 – Regulation (EC) 1272/2008 - Regulation (EU) n. 453/2010

Product: **Peroxy Ag+**
DISINFECTANT FOR DENTAL UNIT WATER CONDUITS

Rev. 7

Date: 11.03.2019

page 1 of 8

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1. PRODUCT IDENTIFIER Peroxy Ag+
Hydrogen Peroxide, Silver (ionic form), stabilizers, water
- 1.2. RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST For professional use only
Exclusive use in the dental unit: pure for disinfecting water pipes of the dental unit, diluted 1:50 for water supply to dental instruments and for oral rinses.
Do not use for other purposes, such as skin or surfaces disinfection.
- 1.3. DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET CEFLA S.C. Via Selice Provinciale 23/A
40026 Imola BO (Italy)
Tel. +39 0542 653111 – Fax +39 0542 653444
service.dental@cefla.it
- LOCAL SUPPLIER of the Safety Data Sheet:
.....
.....
Phone
Mail
- 1.4. EMERGENCY TELEPHONE NUMBER
- AUSTRIA - Umweltbundesamt GmbH +43 1 31304 5620 – chemikalien@umweltbundesamt.at
 - BELGIUM - Centre Antipoisons +32022649636 – info@poisoncentre.be
 - BULGARIA - National Toxicology Information Center +359 2 9154 409 - poison_centre@mail.orbitel.bg
 - CROATIA - Croatian Institute for Toxicology and Anti-doping +38514686917 – hzt@hzt.hr
 - CYPRUS - Ministry of Labour, Welfare and Social Insurance, Department of Labour Inspection +35722405611 - cy-chemregistry@dli.mlsi.gov.cy
 - CZEK REPUBLIC - Ministry of Health of the Czech Republic +420267082257 – biocidy@mzcr.cz
 - DENMARK - Danish Environmental Protection Agency 45 72 54 40 00 – mst@mst.dk
 - ESTONIA – +3726943884 – info@16662.ee
 - FINLAND - Finnish Safety and Chemicals Agency (Tukes) +358 5052 000 – kirjaamo@tukes.fi
 - FRANCE - French National Products and Composition Database (B.N.P.C.); French Poison and toxicovigilance Centre Network + 33 3 83 85 21 92 – bnpc@chru-nancy.fr
 - GERMANY BfR Bundesinstitut für Risikobewertung / German Federal Institute for Risk Assessment +49-30-18412-0 - bfr@bfr.bund.de
 - GREECE - Hellenic Republic Independent Authority for Public Revenue D.G. of the General Chemical State Laboratory Directorate of Energy, Industrial and Chemical Products +302106479250, +302106479450 – chemicals@gcsl.gr, environment@gcsl.gr
 - HUNGARY - Ministry of Human Capacities, Department for Chemical Safety (phone not available) – bejelentes@emmi.gov.hu
 - ICELAND - Poisons Informaiton Center - Icelandic University Hospital +354 543 22 22 – eur@landspitali.is
 - IRELAND - National Poisons Information Centre +35318092566 – npicdublin@beaumont.ie
 - ITALY - Istituto Superiore di Sanità (ISS) +390649906140 – inscweb@iss.it
 - LATVIA - Latvian Environment, Geology and Meteorology Centre +371 67032600 – lvgmc@lvgmc.lv
 - LIECHTENSTEIN – not available
 - LITHUANIA - Environmental Protection Agency +370 70662008 – aaa@aaa.am.lt
 - LUXEMBOURG - Ministère-Direction de la Santé +352 24785551 - direction-sante@ms.etat.lu
 - MALTA - Malta Competition and Consumer Affairs Authority (MCCAA) +356 2395 2000 - info@mccaa.org.mt
 - NETHERLANDS - National Poisons Information Center / University Medical Center Utrecht +31 88 75 585 61 – productnotificatie@umcutrecht.nl
 - NORWAY - Norwegian Environment Agency +4573580500 – produktregisteret@miljodir.no
 - POLAND - Bureau for Chemical Substances +48 42 2538 400 – biuro@chemikalia.gov.pl
 - PORTUGAL - Centro de informação antivenenos +351213303271 - ciav.tox@inem.pt
 - ROMANIA - National Institute for Public Health +40213183606 – infotox@insp.gov.ro
 - SLOVAKIA - National Toxicological Information Centre +421 2 5465 2307 – ntic@ntic.sk
 - SLOVENIA - Chemicals Office of the Republic of Slovenia (CORS), Ministry of Health +38614006051 - gp-ursk.mz@gov.si
 - SPAIN - Instituto Nacional de Toxicología y Ciencias Forenses (INTCF) +34 917689800 – intcf@justicia.es, intcf.doc@justicia.es
 - SWEDEN - Swedish Poisons Information Centre +46104566750 – giftinformation@gic.se
 - UNITED KINGDOM - National Poisons Information Service +44 121 507 4123 – allistervale@npis.org, sallybradberry@npis.org

SECTION 2. HAZARDS IDENTIFICATION

2.1. CLASSIFICATION OF THE SUBSTANCE OR MIXTURE the mixture does not meet the criteria for classification in accordance with Regulation (EC) No 1272/2008

2.2. LABEL ELEMENTS

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DISINFECTANT FOR DENTAL UNIT WATER CONDUITS

Rev. 7

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page 2 of 8

hazard pictograms	Not applicable
signal words	Not applicable
hazard statements	Not applicable
precautionary statements	P262 - Do not get in eyes, on skin, or on clothing P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

2.3. OTHER HAZARDS

The mixture does not meet the criteria for PBT or vPvB
No other hazards are identified which do not result in classification but which may contribute to the overall hazards of the mixture

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**3.1. SUBSTANCES**

The product is a mixture. Not applicable

3.2. MIXTURES

Hydrogen Peroxide solution, Silver (ionic form), Stabilizers, water

Substances presenting a health or environmental hazard within the meaning of Regulation (EC) 1272/2008	Concentration % by mass	Classification under European Regulation (EC) 1272/2008
HYDROGEN PEROXIDE SOLUTION Synonym Oxigenated Water Substance N. 008-003-00-9 EC N. 231-765-0 (EINECS) CAS 7722-84-1	3	At a concentration < 5%: no hazard classification Ox. Liq. 1; H271: C ≥ 70 % (****) Ox. Liq. 2; H272: 50 % ≤ C < 70 % (****) (*) Skin Corr. 1A; H314: C ≥ 70 % Skin Corr. 1B; H314: 50 % ≤ C < 70 % Skin Irrit. 2; H315: 35 % ≤ C < 50 % Eye Dam. 1; H318: 8 % ≤ C < 50 % Eye Irrit. 2; H319: 5 % ≤ C < 8 % STOT SE 3; H335; C ≥ 35 %
STABILIZERS	< 1,0	Does not concur to the mixture hazard classification
SILVER (as ionic form Ag+) CAS 7440-22-4	< 0,01 (as Ag)	Does not concur to the mixture hazard classification

The full text of each hazard statement mentioned in this paragraph is listed at Section 16.

SECTION 4: FIRST AID MEASURES**4.1. DESCRIPTION OF FIRST AID MEASURES****General indications**

In normal use, no specific conditions of inhalation, skin contact, eye contact or ingestion that require first aid intervention are expected

Inhalation:

move casualty to fresh air; in case of malaise seek medical advice.

Skin:

Wash affected skin with water, remove contaminated clothes.

Eye contact:

Wash with running water for a few minutes lifting lower and upper eyelids open.. If irritation persists seek medical advice.

Ingestion:

if symptoms occur, seek medical advice

Personal protective equipment for first aid responders:

Avoid exposure for yourself and others.

Wear protective gloves when handling contaminated objects or clothing.

4.2. MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED**Acute:**

EYES Possible temporary irritation in case of contact

INGESTION possible slight irritation of the mucous membranes of the digestive tract.

Delayed: no available data

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Rev. 7

Date: 11.03.2019

page 4 of 8

**7.2. CONDITIONS FOR SAFE STORAGE,
INCLUDING ANY INCOMPATIBILITIES**

How to manage risks associated with:

explosive atmospheres: not applicable
corrosive conditions: not applicable
flammability hazards: not applicable
incompatible substances or mixtures: strong reducing substances
evaporative conditions: keep container well closed
potential ignition sources (including electrical equipment): not applicable

how to control the effects of:

weather conditions: not expected dangerous atmospheric conditions
ambient pressure: not expected dangerous ambient pressure conditions
temperature: keep between 10 to 40 °C
sunlight: Avoid direct and prolonged sunlight exposure
humidity: not expected dangerous effects for the product
vibration: not expected dangerous effects for the product

How to maintain the integrity of the substance or mixture by the use of:

stabilisers: not necessary
antioxidants: not necessary

other advice:

ventilation requirements: not necessary
specific designs for storage rooms or vessels: not necessary
quantity limits under storage conditions: not applicable
packaging compatibilities: not contemplated any different packaging other than original ones

7.3. SPECIFIC END USE(S)

Use in Dental Unit following the instructions for use of the dental unit

- waterlines disinfection: introduce the product into the disinfectant tank
- disinfectant addition to the water supply for instruments and the glass manual: introduce 20 mL of product per each liter of water into the independent supply tank (1:50 dilution in water)
- automatic: introduce the product into the disinfectant tank.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. CONTROL PARAMETERS

Hydrogen Peroxide	TLV-TWA	1,4 mg/m ³	1 ppm
Silver (ionic form)	TLV-TWA	0,01 mg/m ³	

8.2. EXPOSURE CONTROLS

8.2.1. Appropriate engineering controls The identified uses of this product do not prefigure any need of exposure controls

8.2.2. Individual protection measures, such as personal protective equipment

Eye / face protection:
wear protective glasses
Skin protection:
Hand protection: wear protective gloves (rubber, nitrile rubber, etc)
Other: wear ordinary work clothes
Respiratory protection
The identified uses of this product do not prefigure any need of respiratory protection
Thermal hazards: not applicable

Use normal hygiene precautions:
do not eat, drink or smoke while using the product

8.2.3. Environmental exposure controls The identified uses of this product do not prefigure any need of environmental exposure controls

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

**9.1. INFORMATION ON BASIC
PHYSICAL AND CHEMICAL
PROPERTIES**

a) Appearance	Transparent, not coloured liquid
b) Odour	Slight hydrogen peroxide
c) Odour threshold	Not defined
d) pH	4,5 ± 0,5 pH units
e) Melting point/freezing point	Approx 0°C
f) Initial boiling point and boiling range	Approx 100 °C

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DISINFECTANT FOR DENTAL UNIT WATER CONDUITS

Rev. 7

Date: 11.03.2019

page 5 of 8

g) Flash point	Not applicable non-combustible aqueous solution
h) Evaporation rate	Not available
i) Flammability (solid, gas)	Not applicable
j) Upper/lower flammability or explosive limits	Not applicable
k) Vapour pressure	23 hPa at 25°C
l) Vapour density	Not available
m) Relative density	1,008 ± 0,002 g/cm ³ at 25°C
n) solubility (ies)	Completely miscible
o) Partition coefficient: n-octanol/water	Not available
p) Auto-ignition temperature	Not applicable
q) Decomposition temperature	Not available
r) Viscosity	Not available
s) Explosive properties	Not applicable
t) Oxidising properties	Oxidising solution
9.2. OTHER INFORMATION	miscibility fat solubility conductivity gas group redox potential radical formation potential photocatalytic properties
	Information about these further parameters is retained not necessary
VOC (Volatile Organic Compounds)	Absent (0.0 %)

SECTION 10: STABILITY AND REACTIVITY

10.1. REACTIVITY	Mixture is packaged in an adequate container resistant to contact Dangerous reactions due to mixture reactivity are not expected
10.2. CHEMICAL STABILITY	Stable in normal conditions
10.3. POSSIBILITY OF HAZARDOUS REACTIONS	Dangerous reactions are not expected in normal use
10.4. CONDITIONS TO AVOID	Temperatures exceeding 40 °C
10.5. INCOMPATIBLE MATERIALS	Reducing agents
10.6. HAZARDOUS DECOMPOSITION PRODUCTS	Can generate Oxygen gas

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicological data have not been determined specifically for this product.
Information given is based on the knowledge of the components and the toxicology of similar products.

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

a) Acute toxicity	Acute Toxicity ORAL DL50 (rat): Hydrogen Peroxide 35% 1232 mg/kg Acute Toxicity DERMAL DL 50 (rabbit) Hydrogen Peroxide 35% 2 mg/kg Acute Toxicity INHALATION CL 50 (4 h rat) Hydrogen Peroxide : 2 mg/m ³
b) Skin corrosion / irritation	Not classified as hazardous for skin corrosion / irritation according to European Regulation (EC) 1272/2008
c) Serious eye damage/irritation	Not classified as hazardous for serious damage / eye irritation according to Regulation (EC) 1272/2008
d) Respiratory or skin sensitisation	Contained substances are not classified as hazardous for respiratory or skin sensitisation according to Regulation (EC) 1272/2008
e) Germ cell mutagenicity	Contained substances are not classified as hazardous for germ cell mutagenicity according to Regulation (EC) 1272/2008

- f) Carcinogenicity Contained substances are not classified as hazardous for carcinogenicity according to European Regulation (EC) 1272/2008
- g) Reproductive toxicity Contained substances are not classified as hazardous for reproductive toxicity according to European Regulation (EC) 1272/2008
- h) STOT-single exposure The substances in the concentrations present do not meet the specific toxicity criteria for target organs in single exposure according to Regulation (EC) 1272/2008
- i) STOT-repeated exposure The substances in the concentrations present do not meet the specific toxicity criteria for target organs on repeated exposure according to Regulation (EC) 1272/2008
- j) Aspiration hazard The substances in the concentrations present do not meet the hazard criteria in the event of aspiration according to Regulation (EC) 1272/2008
- Information on likely routes of exposure
- INHALATION** Pure product: NOT APPLICABLE
the use for the filling of the use tanks does not involve the formation of aerosols
Diluted product 1:50: the presence of product in the water supplied by dental instruments can expose to water aerosol inhalation containing diluted product
- INGESTION** Pure product: NOT APPLICABLE
the use for the filling of the use tanks does not involve the formation of aerosols
Diluted product 1:50: the presence of product in the water supplied by the dental instruments in the oral cavity and by the oral rinsing glass can expose small quantities of water containing diluted product to accidental ingestion
- SKIN/EYE EXPOSURE**
- EYES**
Pure product: the use for filling the use tanks can expose to contact of product splashes with eyes
Diluted product 1:50: the presence of product in the water supplied by dental instruments can expose to contact of water aerosol containing diluted product with eyes
- SKIN**
Pure product: the use for filling the use tanks can expose to contact of product splashes with skin
Diluted product 1:50: the presence of product in the water supplied by dental instruments can expose to contact of water aerosol containing diluted product with skin
- Symptoms related to the physical, chemical and toxicological characteristics See point 11.1, letters from a) to j)
 - Delayed and immediate effects as well as chronic effects from short and long-term exposure See point 11.1, letters from a) to j)
 - Interactive effects Not available data
 - Absence of specific data Product specific toxicological data: not available and not used.
The information is based on the knowledge of the components and toxicological data of the substances contained
 - Mixtures The mixture has not been tested for its health effects as a whole. The information provided is relevant to the substances listed in Section 3
 - Mixture versus substance information Not expected interactions between substances with each other in the body resulting in different rates of absorption, metabolism and excretion or resulting in an overall toxicity of the mixture different from that of the substances in it.
 - Other information Not applicable

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DISINFECTANT FOR DENTAL UNIT WATER CONDUITS

Rev. 7

Date: 11.03.2019

page 7 of 8

SECTION 12: ECOLOGICAL INFORMATION

Eco-toxicological data have not been determined specifically for this product. Information given is based on the knowledge of the substances contained in the mixture and the eco-toxicology data of similar products.

12.1. TOXICITY	Acute Aquatic Toxicity on fish - LC 50 Hydrogen Peroxide LC50 (<i>Pimephales promelas</i> 96h) 16,4 mg/L
	Acute Aquatic Toxicity on crustaceans - CE 50 Hydrogen Peroxide L50: (<i>Daphnia</i> 24h) 7,7 mg/L
	Acute Aquatic toxicity on algae and other aquatic plants - CE0 Hydrogen Peroxide EC(I)50: (<i>Chlorella vulgaris</i> 7 2h) 4,3 mg/L
	Acute Toxicity on soil micro and macroorganisms - CE0 Hydrogen Peroxide not available
	Inhibitory effects on microorganisms in sewage treatment plants - CE 50 Hydrogen Peroxide bacterial inhibition >30 mg/L
12.2. PERSISTENCE AND DEGRADABILITY	Hydrogen Peroxide spontaneously decomposes to O ₂ and H ₂ O
12.3. BIOACCUMULATIVE POTENTIAL	Hydrogen Peroxide spontaneously decomposes to O ₂ and H ₂ O
12.4. MOBILITY IN SOIL	Hydrogen Peroxide spontaneously decomposes to O ₂ and H ₂ O
12.5. RESULTS OF PBT AND VPVB ASSESSMENT	Not applicable
12.6. OTHER ADVERSE EFFECTS	
• • photochemical ozone creation potential	Not expected
• • ozone depletion potential	Not expected
• • endocrine disrupting potential	Not available
• • global warming potential	Not available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. WASTE TREATMENT METHODS	Mixture: dispose according to European and national waste regulations Packaging: Polyethylene bottle. Prefer re-use destination, instead of incineration or disposal into dump Avoid any sewage disposal
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SECTION 14: TRANSPORT INFORMATION

14.1 UN NUMBER	not assigned to Hydrogen Peroxide 3% solution
14.2 UN PROPER SHIPPING NAME	not assigned to Hydrogen Peroxide 3% solution
14.3. TRANSPORT HAZARD CLASSE(S)	Not assigned to Hydrogen Peroxide 3% solution
14.4. PACKING GROUP	not assigned to Hydrogen Peroxide 3% solution
14.5. ENVIRONMENTAL HAZARDS	IMDG – non disponibile ADR – not classified as dangerous for the environment (ADR 2015) RID – not classified as dangerous for the environment (ADR 2015) ADN – not classified as dangerous for the environment (ADR 2015) ICAO/ IATA – not available
14.6. SPECIAL PRECAUTIONS FOR USER	Transport into the original packaging Do not expose to temperature exceeding 40 °C Recommended not to expose to temperature exceeding 40°C when stored
14.7. TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL AND THE IBC CODE	Not applicable

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DISINFECTANT FOR DENTAL UNIT WATER CONDUITS

Rev. 7

Date: 11.03.2019

page 8 of 8

SECTION 15. REGULATORY INFORMATION

15.1. SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE	<p>European Directive 93/42/CEE (Medical Devices) European Regulation 2017/745 Medical Devices European Regulation (EC) 1272/2008 (on classification, labelling and packaging of substances and mixtures) European Regulation (EC) 1907/2006 , 453/2010 (Safety Data Sheet) Not applicable regulations: Regulation (EC) 1005/2009 (Ozone layer depleting substances) Regulation (EC) 850/2004 (Persistent organic pollutants) Regulation (EC) 689/2008 (export / import of dangerous chemicals)</p>
15.2. CHEMICAL SAFETY ASSESSMENT	Not applicable

SECTION 16. OTHER INFORMATION

a) Information on revision of the safety data sheet	Revision 7: Sections n 1, 2, 3, 4, 6, 7, 8, 9, 11, 15, 16.
b) Key or legend to abbreviations and acronyms	<p>ADR: European Agreement Concerning the International Carriage of Dangerous Goods by Road AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways IATA: International Air Transport Association ICAO: International Civil Aviation Organization IMDG: International Maritime Dangerous Goods Code IMO: International Maritime Organization RID: International Carriage of Dangerous Goods by Rail</p>
c) Key literature references and sources for data	Safety Data Sheets of Substances contained into the mixture European Directive and Regulations (see 15.1)
d) Method of evaluating information referred to in Article 9 of Regulation (EC) No 1272/2008 used for the purpose of classification	Regulation (EC) 1272/2008 – Art 9, p1: Classification or differentiation criteria according to Annex I, parts 2 to 5
e) List of relevant hazard statements and/or precautionary statements	<p>H271 May cause fire or explosion; strong oxidiser H272 May intensify fire; oxidiser H314 Causes severe skin burns and eye damage H315 Causes skin irritation. H318 Causes serious eye damage H319 Causes serious eye irritation H335 May cause respiratory irritation</p>
f) Training appropriate for workers	Apply the instruction for use indicated on the label and this Safety Data Sheet

NOTE

The information contained in this Safety Data Sheet is to the best of our knowledge the most up-to-date available, and is passed on to the user in good faith. It is intended to describe the product for the purposes of health, safety and environmental requirements only. In no way, however, does it exempt the user from strictly adhering to the directions as given for storing, handling and utilizing the product, and for doing so in accordance with normal hygienic standards and practice and local regulations. The producer therefore declines all responsibility for any eventual improper or incorrect use.