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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

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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

OR MIXTURE AND USES

For professional use only USES OF THE SUBSTANCE 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. ADVISED AGAINST

1.3. DETAILS OF THE SUPPLIER OF THE SAFETY 40026 Imola BO (Italy)

CEFLA S.C. Via Selice Provinciale 23/A

DATA SHEET

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service.dental@cefla.it

LOCAL	SUPP	LIER	of the	Safety	Data	Sheet:
Phone						
N / - : I						

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 Helalth 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
- ICÉLAND Poisons Informaiton Center Icelandic University Hospital +354 543 22 22 eitur@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 gpursk.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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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: $C \ge 70 \%(^{****})$ Ox. Liq. 2; H272: $50 \% \le C < 70 \%(^{****})$ Skin Corr. 1A; H314: $C \ge 70 \%$ Skin Corr. 1B; H314: $50 \% \le C < 70 \%$ Skin Irrit. 2; H315: $35 \% \le C < 50 \%$ Eye Dam. 1; H318: $8 \% \le C < 50 \%$ Eye Irrit. 2; H319: $5 \% \le C < 8 \%$ STOT SE 3; H335; $C \ge 35 \%$
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.

Eve 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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4.3. INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

Not expected to give rise to acute symptoms, under normal conditions of use, which could require immediate medical attention and special treatment.

SECTION 5: FIREFIGHTING MEASURES

5.1. EXTINGUISHING MEDIA Suitable extinguishing media: al

Unsuitable extinguishing media: not known

5.2. SPECIAL HAZARDS ARISING FROM

THE SUBSTANCE OR MIXTURE

No specific hazards arising from the mixture

5.3. ADVICE FOR FIREFIGHTERS Not specific measures required for this product

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES For non-emergency personnel:

Evacuate from the hazard area any non-emergency person

For emergency responders:

in case of dust/vapours/aerosols, wear protective devices for respiratory system

Wear personal Protective equipment:

protective glasses and waterproof gloves (eg in nitrile rubber)

6.2. . ENVIRONMENTAL PRECAUTIONS

Avoid that undiluted or large amounts of product arrive into drains, surface and ground

water.

6.3. METHODS AND MATERIAL FOR CONTAINMENT

FOR CONTAINMENT AND CLEANING UP How to contain a spill:

Collect liquid in an appropriate container or absorb with absorbent material (e. g., wipes, paper, dry sand). Do not flush to sewer cleaning techniques wash with water

Vacuuming techniques: not necessary

6.4. REFERENCE TO OTHER SECTIONS See

See Sections 8 e 13

SECTION 7: HANDLING AND STORAGE

7.1. PRECAUTIONS FOR SAFE HANDLING

Recommendations to allow safe handling:

Use as instructed. Avoid vapours / aerosols formation.

Protect eyes and skin from any contact.

Do not eat, drink or smoke when using the product

Rinse hands with water after use

Recommendations to prevent fire: not necessary

Recommendations to prevent handling of incompatible substances or mixtures

Avoid contact with strong reducing substances

Recommendations to reduce the release of the substance or mixture to the

environment:

use away from drains and use as indicated in label instructions

Other information: see Section 8

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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/m³ 1 ppm

Silver (ionic form) TLV-TWA 0,01 mg/m³

8.2. EXPOSURE CONTROLS

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

 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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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 Not applicable

23 hPa at 25°C k) Vapour pressure Vapour density Not available

 $1,008 \pm 0,002 \text{ g/cm}^3 \text{ at } 25^{\circ}\text{C}$ m)Relative density

n) solubility (ies) Completely miscible

o) Partition coefficient: n-octanol/water Not available p) Auto-ignition temperature Not applicable g) Decomposition temperature Not available r) Viscosity Not available s) Explosive properties Not applicable Oxidising solution

t) Oxidising properties

9.2. OTHER INFORMATION

miscibility fat solubility conductivity gas group redox potential

radical formation potential photocatalytic properties

VOC (Volatile Organic Compounds)

Information about these further parameters is retained

not necessary

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 Dangerous reactions are not expected in normal use

REACTIONS

10.4. CONDITIONS TO AVOID Temperatures exceeding 40 °C

10.5. INCOMPATIBLE MATERIALS Reducing agents

10.6. HAZARDOUS DECOMPOSITION Can generate Oxygen gas

PRODUCTS

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

b) Skin corrosion / irritation Not classified as hazardous for skin corrosion / irritation according to European Regulation

(EC) 1272/2008

Not classified as hazardous for serious damage / eye irritation according to Regulation (EC) c) Serious eye damage/irritation

1272/2008

d) Respiratory or skin Contained substances are not classified as hazardous for respiratory or skin sensitisation

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

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Contained substances are not classified as hazardous for carcinogenicity according to f) Carcinogenicity

European Regulation (EC) 1272/2008

Contained substances are not classified as hazardous for reproductive toxicity according to g) Reproductive toxicity

European Regulation (EC) 1272/2008

The substances in the concentrations present do not meet the specific toxicity criteria for target h) STOT-single exposure

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

The substances in the concentrations present do not meet the hazard criteria in the event of j) Aspiration hazard

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

Pure product: NOT APPLICABLE **INGESTION**

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

Pure product: the use for filling the use tanks can expose to contact of product splashes

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 See point 11.1, letters from a) to j) as well as chronic effects from short and long-term exposure

Not available data Interactive effects

Product specific toxicological data: not available and not used. Absence of specific data

The information is based on the knowledge of the components and toxicological data of the

substances contained

The mixture has not been tested for its health effects as a whole. The information provided is Mixtures

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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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 (Pimephales promelas 96h) 16,4 mg/L

Acute Aquatic Toxicity on crustaceans - CE 50

Hydrogen Peroxide L50: (Daphnia 24h) 7,7 mg/L

Acute Aquatic toxicity on algae and other aquatic plants - CE0

Hydrogen Peroxide EC(I)50: (Chlorella vulgaris 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 O2 and H2O

12.3. BIOACCUMULATIVE POTENTIAL Hydrogen Peroxide spontaneously decomposes to O2 and H2O

12.4. MOBILITY IN SOIL Hydrogen Peroxide spontaneously decomposes to O2 and H2O

12.5. RESULTS OF PBT AND VPVB

ASSESSMENT

Not applicable

12.6. OTHER ADVERSE EFFECTS

photochemical ozone creation potential

Not expected

• ozone depletion potential
 • endocrine disrupting potential
 Not expected
 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

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

Not applicable

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

97052000_EN

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SECTION 15. REGULATORY INFORMATION

15.1. SAFETY, HEALTH AND **ENVIRONMENTAL**

REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE

OR MIXTURE

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)

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

ADR: European Agreement Concerning the International Carriage of Dangerous Goods

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

International Carriage of Dangerous Goods by Rail RID:

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

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

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.