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[In accordance with the criteria of Regulation No 1907/2006 (REACH) as amended]

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

1.1 Product identifier

Endo Prep-Cream

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

Relevant identified uses: root canal preparation cream. Product for professional use.

Uses advised against: other than those listed above .

1.3 Details of the supplier of the safety data sheet

Manufacturer: **Przedsiębiorstwo Produkcyjno-Handlowe CERKAMED Wojciech Pawłowski**

Address: ul. Kwiatkowskiego 1, 37-450 Stalowa Wola, Poland

Telephone number: +48 15 842 35 85

E-mail address for a competent person responsible for SDS: agnieszka.walilko@cerkamed.pl

1.4 Emergency telephone number

112

Section 2: Hazards identification

2.1 Classification of the substance or mixture

Skin Irrit. 2 H315, **Eye Dam. 1** H318, **STOT RE 2** H373

Causes skin irritation. Causes serious eye damage. May cause damage to organs (respiratory tract) through prolonged or repeated exposure (inhalation).

2.2 Label elements

Hazard pictograms and signal words



DANGER

Substances which influenced product classification

Contains: ethylenediaminetetraacetic acid disodium salt dehydrate; hydrogen peroxide-urea.

Hazard statements

H315	Causes skin irritation.
H318	Causes serious eye damage
H373	May cause damage to organs (respiratory tract) through prolonged or repeated exposure (inhalation).

Precautionary statements

P260	Do not breathe vapours.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302 + P352	IF ON SKIN: Wash with plenty of water and soap.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P501	Dispose of contents/container to properly labeled waste containers in accordance with national legislation.

2.3 Other hazards

The substances contained in the product do not meets criteria for PBT or vPvB in accordance with Annex XIII of REACH Regulation.

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The product does not contain substances included in the list established in accordance with Article 59(1) for having endocrine disrupting properties, or substances identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1 % by weight.

Section 3: Composition/information on ingredients

3.1 Substances

Not applicable.

3.2 Mixtures

CAS number: 57-55-6 EC number: 200-338-0 Index number: - Registration number: 01-2119456809-23-XXXX	propane-1,2-diol substance is not classified as hazardous	< 21 %
CAS number: 6381-92-6 EC number: 205-358-3 Index number: - Registration number: -	ethylenediaminetetraacetic acid disodium salt dehydrate Acute Tox. 4 H332, STOT RE 2 H373	< 18 %
CAS number: 124-43-6 EC number: 204-701-4 Index number: - Registration number: -	hydrogen peroxide-urea Ox. Sol. 3 H272, Skin Irrit. 2 H315, Eye Dam. 1 H318, STOT SE 3 H335	≤ 11 %
CAS number: 56-81-5 EC number: 200-289-5 Index number: - Registration number: substance exempt from registration	glycerol substance is not classified as hazardous	< 1 %

Full text of each relevant H phrase is given in section 16 of SDS.

Section 4: First aid measures

4.1 Description of first aid measures

Skin contact: take off the contaminated clothing. Wash a contaminated skin with plenty of soap and water for 10 minutes. Consult a doctor, if disturbing symptoms occur.

Eye contact: protect non-irritated eye, remove contact lenses. Wash out an contaminated eye thoroughly with plenty of water for 15 min. Avoid strong stream of water – risk of damage of the cornea. Put on a sterile dressing. Immediately consult an ophthalmologist.

Ingestion: do not induce vomiting. Rinse mouth with water. Never give anything to drink to an unconscious person. Consult a doctor.

Inhalation: remove the victim to fresh air. Keep warm and calm. Consult a doctor, if disturbing symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed

Skin contact: redness, burning, irritation.

Eye contact: redness, tearing, pain, irritation, serious eye damage.

Ingestion: possible stomach pain, nausea, vomiting, diarrhea.

Inhalation: irritation of the respiratory tract, cough. May cause damage to organs (respiratory tract) through prolonged or repeated exposure (inhalation).

4.3 Indication of any immediate medical attention and special treatment needed

Physician makes a decision regarding further medical treatment after thoroughly examination of the injured. Symptomatic treatment.

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Section 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: a non-flammable product, adapt the extinguishing agent to the surrounding materials.

Unsuitable extinguishing media: water jet – risk of the propagation of the flame.

5.2 Special hazards arising from the substance or mixture

During the fire, may produce harmful fumes of carbon oxides and other hazardous thermal decomposition products. Do not inhale combustion products, may cause health risk.

5.3 Advice for firefighters

Personal protection typical in case of fire. Do not stay in the fire zone without protective clothing resistant to chemicals and self-contained breathing apparatus. In case of fire cool endangered containers with water fog from safe distance. Do not let the product to enter sewage system, surface water and ground water. Collect used the extinguishing media.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Limit the access for the outsiders into the breakdown area, until the suitable cleaning operations are completed. Ensure that the effects of breakdown are removed only by trained personnel. Wear personal protective equipment. In case of large spills, isolate the exposed area. Avoid eyes and skin contamination. Do not inhale product vapours. Ensure adequate ventilation.

6.2 Environmental precautions

In case of a release of large amounts of the product, it is necessary to take appropriate steps to prevent it from spreading into the environment. Notify relevant emergency services.

6.3 Methods and material for containment and cleaning up

Collect mechanically and place in labelled containers. Treat the collected material as a waste. Clean and ventilate the contaminated place.

6.4 Reference to other sections

Personal protective equipment – see section 8. Appropriate conduct with waste product – see section 13.

Section 7: Handling and storage

7.1 Precautions for safe handling

Handle in accordance with good occupational hygiene and safety practices. Wear personal protective equipment. Avoid eyes and skin contamination. Do not inhale vapours of the product. Do not eat, drink or smoke while working. Before break and after work wash hands carefully. Ensure adequate general and / or local ventilation.

7.2 Conditions for safe storage, including any incompatibilities

Keep only in original, tightly closed containers in a dry, cool and well-ventilated place. Avoid direct sunlight and high temperatures. Keep away from food, beverages or feed for animals and incompatible materials (see subsection 10.5). After opening, seal the container and store it in an upright position to avoid leakage.

7.3 Specific end use(s)

No information about other uses than those mentioned in subsection 1.2.

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Section 8: Exposure controls/personal protection

8.1 Control parameters

Product does not contain components with occupational exposure limit values established on the European Union level.

Legal Basis: 91/322/EEC as amended, 98/24/EC as amended, 2000/39/EC as amended, 2004/37/EC as amended.

Please check also any national occupational exposure limit values in your country.

PNEC values

propane-1,2-diol [CAS 57-55-6]

fresh water	260 mg/dm^3
marine water	26 mg/dm^3
fresh water sediment	572 mg/kg
marine water sediment	57,2 mg/kg
soil	50 mg/kg
sewage treatment plant	20000 mg/dm^3

8.2 Exposure controls

Appropriate engineering controls

Use the product in accordance with good occupational hygiene and safety practices. Do not eat, drink or smoke when using the product. Before break and after work wash hands carefully. Take off contaminated clothing and wash it before reuse. Do not inhale vapours of the product. Provide effective general and/or local ventilation in the workplace. Avoid contact with skin and eyes. Do not inhale vapours. Near the workplace separate showers for eye washing should be installed.

Individual protection measures, such as personal protective equipment

The necessity to use and selection of appropriate personal protective equipment should take into account the type of risk posed by the product, working conditions and the way of handling the product. The personal protective equipment used must meet the requirements of Regulation (EU) 2016/425 and the relevant standards. The employer is obliged to provide protection measures appropriate to the activities performed and meeting all quality requirements, including their maintenance and cleaning. Any contaminated or damaged PPE must be replaced immediately.

Hand and body protection

Use protective gloves resistant to the product in accordance with EN 374. The material for gloves should be selected individually at the workplace In case of a short contact, use protective gloves with effectiveness level 2 or higher (breakthrough time > 30 min.). In case of a prolonged contact, use protective gloves with effectiveness level 6 (breakthrough time > 480 min.). Wear protective clothing.

When using protective gloves during work with chemical products, it should be noted that the efficacy levels and corresponding breakthrough times do not indicate actual times of protection at a particular workplace, because the protection can be affected by many factors, e.g. temperature, other substances etc. If there are any signs of degradation, damage or change in appearance (colour, flexibility, shape), it is recommended to replace the gloves with a new pair. Please follow the manufacturer's instructions, not only in terms of gloves' usage, but also in terms of their cleaning, maintenance and storage. It is also important to know how to take off the gloves in order to avoid hands contamination.

Eye/face protection

Wear thightly sealed protective glasses in accordance with EN 166.

Respiratory protection

In case of sufficient ventilation, it is not required. In case of emergency, formation of vapours use equipment or suitable protection class filter (class 1/protection against gases or vapours with a concentration in the air volume not exceeding 0.1 %, class 2 / protection against gases or vapours with a concentration in the air not exceeding 0.5 %, class 3 / protect against gases or vapours at concentrations in the air volume to 1 %).

Thermal hazards

Do not occur.

Environmental exposure controls

Do not allow large amounts of the product to enter groundwater, sewage system, sewage or soil.

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Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state:	solid/cream
Colour:	white
Odour	characteristic
Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	not determined
Flammability:	non-flammable product
Lower and upper explosion limit:	not determined
Flash point:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not determined
pH:	5±0,8
Kinematic viscosity:	not determined
Solubility:	not determined
Partition coefficient n-octanol/water (log value):	not determined
Vapour pressure:	not determined
Density and/or relative density:	not determined
Relative vapour density:	not determined
Particle characteristics:	not applicable

9.2 Other information

No additional test results.

Section 10: Stability and reactivity

10.1 Reactivity

The product is feebly reactive. It does not undergo dangerous polymerization. See also subsections 10.3-10.5.

10.2 Chemical stability

The product is stable under normal conditions of handling and storage.

10.3 Possibility of hazardous reactions

Hazardous reactions are not known.

10.4 Conditions to avoid

Avoid direct sunlight.

10.5 Incompatible materials

Strong oxidants,strong bases, strong acids.

10.6 Hazardous decomposition products

Not known.

Section 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on acute and / or delayed effects of exposure has been determined based on information about the product classification and / or toxicological tests as well as the manufacturer's knowledge and experience.

Acute toxicity

The acute toxicity estimate (ATE_{mix}) for the classification of a substance in a mixture was determined using the appropriate conversion value from Table 3.1.2 that relates to a classification category (Annex I to CLP as amended).

ATE_{mix} (inhalation, vapours) > 20 mg/l

Based on available data, the classification criteria are not met.

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/irritation

Causes serious eye damage.

Respiratory or skin sensitisation

Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

May cause damage to organs (respiratory tract) through prolonged or repeated exposure (inhalation).

Aspiration hazard

Based on available data, the classification criteria are not met.

Information on likely routes of exposure

Routes of exposure: skin contact, eye contact, inhalation, ingestion. See subsection 4.2 for more information on the effects from each possible route of exposure.

Symptoms related to the physical, chemical and toxicological characteristics

See subsection 4.2

Delayed and immediate effects as well as chronic effects from short and long-term exposure

See subsection 4.2

11.2 Information on other hazards

Endocrine disrupting properties

The product does not contain substances included in the list established in accordance with Article 59(1) for having endocrine disrupting properties, or substances identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1 % by weight.

Other information

Not known.

Section 12: Ecological information

12.1 Toxicity

The product is not classified as hazardous to the aquatic environment.

12.2 Persistence and degradability

Data of components:

ethylenediaminetetraacetic acid disodium salt dehydrate [CAS 6381-92-6]

Substance is readily biodegradable.

propane-1,2-diol [CAS 57-55-6]

Substance is readily biodegradable.

2.3 Bioaccumulative potential

Data of components:

ethylenediaminetetraacetic acid disodium salt dehydrate [CAS 6381-92-6]

Bioaccumulation is not expected.

propane-1,2-diol [CAS 57-55-6]

Low potential of bioaccumulation.

12.4 Mobility in soil

Mobility of components of the mixture depends on the hydrophilic and hydrophobic properties and biotic and abiotic conditions of soil, including its structure, climatic conditions, seasons and soil organisms.

12.5 Results of PBT and vPvB assessment

The substances contained in the product do not meet criteria for PBT or vPvB.

12.6 Endocrine disrupting properties

The product does not contain substances included in the list established in accordance with Article 59(1) for having endocrine disrupting properties, or substances identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1 % by weight.

12.7 Other adverse effects

The mixture is not classified as hazardous to the ozone layer. Consider other harmful effects of individual components of the mixture on the environment (eg, global warming potential).

Section 13: Disposal considerations

13.1 Waste treatment methods

Disposal methods for the product: disposal in accordance with the local legislation. Store residues in original containers. Do not empty into drains. Do not dispose of with municipal waste. Waste code should be given in the place of its formation.

Disposal methods for used packing: reuse / recycle / liquidate empty containers in accordance with the local legislation. Only completely emptied packaging can be recycled. Waste code should be given in the place of its formation.

Legal basis: Directive 2008/98/EC as amended, 94/62/EC as amended.

Section 14: Transport information

14.1 UN number or ID number

Product is not dangerous during transport.

14.2 UN proper shipping name

Not applicable.

14.3 Transport hazard class(es)

Not applicable.

14.4 Packing group

Not applicable.

14.5 Environmental hazards

Not applicable.

14.6 Special precautions for user

Not applicable.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

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Section 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishinga European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EECand Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC as amended.

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 (Text with EEA relevance)as amended.

Commission Regulation (EU) No 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives as amended.

European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste as amended.

Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (Text with EEA relevance).

Directive 2004/37/EC Of The European Parliament and Of The Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) as amended.

2000/39/EC COMMISSION DIRECTIVE of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work as amended.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) as amended.

91/322/ECC Commission Directive of 29 May 1991 on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work as amended.

ADR Agreement concerning the International Carriage of Dangerous Goods by Road.

IMDG Code International Maritime Dangerous Goods Code

IATA Dangerous Goods Regulations

15.2 Chemical safety assessment

It is not necessary to carry out a chemical safety assessment for the mixture.

Section 16: Other information

Full text of indicated H phrases mentioned in section 3

H272	May intensify fire; oxidiser.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H373	May cause damage to organs through prolonged or repeated exposure.

Clarification of aberrations and acronyms

Ox. Sol. 3	Oxidising solid, category 3
Acute Tox. 4	Acute toxicity category 4
Skin Irrit. 2	Skin irritation category 2
Eye Dam. 1	Serious eye damage/eye irritation, category 1
STOT SE 3	Specific target organ toxicity — single exposure, category 3
STOT RE 2	Specific target organ toxicity — repeated exposure, category 2
PBT	Persistent, Bioaccumulative and Toxic substance
vPvB	very Persistent, very Bioaccumulative substance
DNEL	Derived No Effect Level

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Trainings

Before commencing working with the product, the user should learn the Health & Safety regulations, regarding handling chemicals, and in particular, undergo a proper workplace training.

Key literature references and data sources

This SDS was prepared on the basis of sheets of the individual components, literature data, online databases, as well as our knowledge and experience, taking into account current legislation.

Procedures used to classify of the mixture

Classification was made on the basis of the manufacturer's data, physicochemical data of the mixture and content of the hazardous substances by calculation method under the guidance of Regulation 1272/2008/EC (CLP) as amended.

Additional information

Date of update:	28.02.2025
Version:	2.0/EN
Changes:	sections: 1-16
Safety Data Sheet made by:	**THETA Consulting Sp. z o.o.** (based on manufacturer's data)

The information above is based on a current available data concerning the product, but also on the experience and knowledge in this field of the producer. They are neither a quality description of the product nor a guarantee of particular features. They are to be treated as aid to safety in transport, storage and usage of the product. That does not free the user from the responsibility of improper usage of the information above and also of improper compliance with the law norms in the field.