SAFETY DATA SHEET

[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

CHLORAXID 2 %

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

Relevant identified uses: liquid for rinsing root canals. Product for professional use.

Uses advised against: other than mentioned above.

1.3 Details of the supplier of the safety data sheet

Manufacturer: **PPH 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: jadwiga.maziarz@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 Irrit. 2** H319, **Aquatic Chronic 2** H411

Causes skin irritation. Causes serious eye irritation. Toxic to aquatic life with long lasting effects.

2.2 Label elements

Hazard pictograms and signal words



WARNING

Substances which influenced product classification

None.

Hazard statements

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

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.
P332+P313 If skin irritation occurs: Get medical advice/ attention.
P337+P313 If eye irritation persists: Get medical advice/ attention.
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. 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 (3) or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1 % by weight.

SAFETY DATA SHEET

Section 3: Composition/information on ingredients

3.1 Substances

Not applicable.

3.2 Mixtures

CAS number: 7681-52-9 EC number: 231-668-3 Index number: 017-011-00-1 Registration number: 01-2119488154-34-XXXX	sodium hypochlorite, solution min. 12.5 % Cl active Met. Corr. 1 H290, Skin Corr. 1B H314, Eye Dam. 1 H318, Aquatic Acute 1 H400 (M=10), Aquatic Chronic 1 H410 (M=1), EUH031[2)] Specific concentration limits: EUH031: C ≥ 5 %	2 ± 0,5 %*
CAS number: 7775-09-9 EC number: 231-887-4 Index number: 017-005-00-9 Registration number: —	sodium chlorate Ox. Sol. 1 H271, Acute Tox. 4 H302, Aquatic Chronic 2 H411	

1) Substance with a specific value at the European Union level of the permissible concentration in the work environment.

2) Additional hazard statement.

* % (w/w) Cl active.

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. Consult a doctor, if disturbing symptoms occur.

Eye contact: wash out an contaminated eye thoroughly with plenty of water for 10-15 min. Protect non-irritated eye, remove contact lenses. Consult an ophthalmologist, if disturbing symptoms occur.

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

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: in case of prolonged contact, possible burning, drying, cracking of the skin, irritation.

Eye contact: possible redness, tearing, burning, irritation.

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

Inhalation: high concentration of vapours can cause temporary irritation of the upper respiratory tract.

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.

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. 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. In case of large spills, isolate the exposed area. Avoid eyes and skin contamination. Ensure adequate ventilation. Wear personal protective equipment.

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

Large spillage isolate and pump away the collected liquid. Absorb small spillage with liquid-binding materials (e.g. sand, universal binding agent). Collect spilled material in labeled 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 vapors 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 containers only in original, tightly closed containers in a dry, cool and well-ventilated place. Avoid direct expose to sunlight and high temperatures. Keep away from food, beverages or feed for animals. Keep away from incompatible materials (see subsection 10.5). After opening, seal the container and store it in an upright position to avoid leakage. Keep unused containers tightly closed.

7.3 Specific end use(s)

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

Section 8: Exposure controls/personal protection

8.1 Control parameters

Specification	TWA 8 hour	STEL 15 min
chlorine [CAS 7782-50-5]*	-	1.5 mg/m^3

* Data for the degradation product of sodium hypochlorite

The table above shows the maximum workplace concentration values on the Community level. Please check also any national occupational exposure limit values in your country.

Legal Basis: Commission Directive 2000/39/EC, 2006/15/EC, 2009/161/EU, 2017/164/EU, 2019/1831/EU.

Substance	CAS number	Workplace exposure limit				Comments
		Long-term exposure limit (8-hr TWA reference period)		Short-term exposure limit (15-minute reference period)		
		ppm	mg/m^3	ppm	mg/m^3	
chlorine*	7782-50-5	-	-	0.5	1.5	—

* Data for the degradation product of sodium hypochlorite

EH40/2005 Workplace exposure limits. Fourth Edition 2020.

Recommended control procedures

Adapt procedures concerning the control over the dangerous components concentrations in the air and over the air quality in the workplace – if they are available and justified for the position –in accordance with the European Standards taking into account the conditions within the exposure place and a proper test methodology adapted to the working conditions.

DNEL values - sodium hypochlorite, solution min. 12.5 % Cl active [CAS 7681-52-9]

Exposure route	Exposure scheme	DNEL (workers)
inhalation	Long-term exposure, systemic effects	1.55 mg/m^3
inhalation	Short-term exposure, systemic effects	3.1 mg/m^3
inhalation	Long-term exposure, local effects	1.55 mg/m^3
inhalation	Short-term exposure, local effects	3.1 mg/m^3
skin	Long-term exposure, local effects	0.5 %
Exposure route	**Exposure scheme**	**DNEL (consumers)**
inhalation	Long-term exposure, systemic effects	1.55 mg/m^3
inhalation	Short-term exposure, systemic effects	3.1 mg/m^3
inhalation	Long-term exposure, local effects	1.55 mg/m^3
inhalation	Short-term exposure, local effects	3.1 mg/m^3
skin	Long-term exposure, local effects	0.5 %
oral	Long-term exposure, systemic effects	0.26 mg/kg b.w./day

PNEC values - sodium hypochlorite, solution min. 12.5 % Cl active [CAS 7681-52-9]

	PNEC
Fresh water	0.21 µg/l
Marine water	0.042 µg/l
Sewage treatment plant	4.69 mg/l
Second poisoning	11.1 mg/kg

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. Provide effective general and/or local ventilation in the workplace. Avoid contact with skin and eyes. Do not inhale vapors.

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 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 protective glasses in accordance with EN 166 if there is a risk of eye contamination.

Respiratory protection

Not required with adequate ventilation. In case of emergency situations use properly selected respiratory protection.

Thermal hazards

Do not occur.

Environmental exposure controls

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

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state:	liquid
Colour:	colourless or slightly straw
Odour	not determined
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:	12.4
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:	1.033 g/cm^3
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, heat sources.

10.5 Incompatible materials

Not known.

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.

Toxicity of the components

sodium hypochlorite, solution min. 12.5 % Cl active [CAS 7681-52-9]

LD_{50} (oral, rat)	1100 mg/kg
LD_{50} (skin, rabbit)	20000 mg/kg
LC_{50} (inhalation, rat)	> 10,5 mg/l

sodium chlorate [CAS 7775-09-9]

LD_{50} (oral, rat)	1200 mg/kg

Toxicity of the mixture

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} (oral) > 2 000 mg/kg

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

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/irritation

Causes serious eye irritation.

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

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

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

No data.

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

No data.

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 (3) or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1 % by weight.

Other information

Not applicable.

Section 12: Ecological information

12.1 Toxicity

Toxicity of the components

sodium hypochlorite, solution min. 12.5 % Cl active [CAS 7681-52-9]

Toxicity to fish:	LC_{50}	0.032 mg/l/96 h/*Coho salmon* (marine water)
	LC_{50}	0.05 mg/l/120 h/*Ictalurus punctatus* (fresh water)
	LC_{50}	0.05 mg/l/120 h/*Salmo gairdneri* (fresh water)
	NOEC	0.04 mg/l/28 days/*Menidia peninsulae* (marine water)
Toxicity to crustaceans:	EC_{50}	0.026 mg/l/48 h/*Crassostrea virginica* (marine water)
	EC_{50}	0.035 mg/l/48 h/*Ceriodaphnia dubia* (fresh water)
	NOEC	0.007 mg/l/15 days/*Crassostrea virginica* (marine water)
Toxicity to algae:	EC_{50}	0.0365 mg/l/72 h/*Pseudokirchneriella subcapitata* (fresh water)
	NOEC	0.02 mg/l/96 h/*Myriophyllum* (fresh water)
	NOEC	0.0021 mg/l/7 days (fresh water)
Toxicity to microorganisms:	EC_{10}	46.9 mg/l/3 h (fresh water)
	EC_{50}	77.1 mg/l/3 h (fresh water)

sodium chlorate [CAS 7775-09-9]

Toxicity to fish:	LC_{50}	1100 mg/l/96 h/*Oncorhynchus masou* (fresh water)
Toxicity to crustaceans:	EC_{50}	3 100 mg/l/48 h/*Asellus communis* (fresh water)
Toxicity to algae:	EC_{50}	298 mg/l/72 h/*Phaeodactylum tricornutum* (fresh water)
	NOEC	50 mg/l/72 h/ *Phaeodactylum tricornutum*
Toxicity to daphnia:	EC_{50}	919.3 ppm/48 h/*Daphnia magna* (fresh water)
	NOEC	526 ppm/21 days/*Daphnia magna*

Toxicity of the mixture

Toxic to aquatic life with long lasting effects.

12.2 Persistence and degradability

No data for mixture.

2.3 Bioaccumulative potential

Bioaccumulation is not expected.

Data for components:

sodium hypochlorite, solution min. 12.5 % Cl active [CAS 7681-52-9]

log Po/w = -3,42

sodium chlorate [CAS 7775-09-9]

log Po/w = <-2,9

12.4 Mobility in soil

The product is mobile in the soil. It dissolves in water and spreads in the aquatic environment. 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 meets criteria for PBT or vPvB in accordance with Annex XIII of REACH Regulation.

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 (3) 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. Waste code should be given in the place of waste formation.

Disposal methods for used packing: reuse / recycle / liquidate empty containers in accordance with the local legislation. Only completely emptied packaging can be recycled.

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

Section 14: Transport information

14.1 UN number or ID number

UN 3082

14.2 UN proper shipping name

ENVIROMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (sodium hypochlorite, sodium chlorate)

14.3 Transport hazard class(es)

9

14.4 Packing group

III

14.5 Environmental hazards

Product is hazardous for environment in accordance with transport regulations.

14.6 Special precautions for user

If any substances have leaked and been spilled in a vehicle or container, it may not be reused until after it has been thoroughly cleaned and, if necessary, disinfected or decontaminated. Any other goods and articles carried in the same vehicle or container shall be examined for possible contamination.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

Section 15: Regulatory information

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

ADR Agreement concerning the International Carriage of Dangerous Goods by Road
IMDG Code International Maritime Dangerous Goods Code.
IATA Dangerous Goods Regulations.
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 as amended.

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), establishing a 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/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC 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).
European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste as amended.
Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives as amended.
Regulation (EU) No 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.
Commission Directive 2000/39/EC 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.
Commission Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC.
Commission Directive 2009/161/EU of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC.
Commission Directive 2017/164/EU of 31 January 2017 establishing a fourth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC, and amending Commission Directives 91/322/EEC, 2000/39/EC and 2009/161/EU.
Commission Directive 2019/1831/EU of 24 October 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC.

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

H271	May cause fire or explosion; strong oxidiser.
H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
EUH031	Contact with acids liberates toxic gas.

Clarification of aberrations and acronyms

TWA	Time Weighted Average
STEL	Short Term Exposure Limit
PBT	Persistent, Bioaccumulative and Toxic substance
vPvB	very Persistent, very Bioaccumulative substance
DNEL	Derived No Effect Level
PNEC	Predicted No Effect Concentration
Acute Tox. 4	Acute toxicity, category 4
Aquatic Chronic 1, 2	Toxicity for aquatic organisms – chronic toxicity category 1, 2
Aquatic Acute 1	Toxicity for aquatic organisms – acute toxicity category 1
Eye Dam. 1	Serious eye damage category 1
Met. Corr. 1	Substance or mixture corrosive to metals category 1
Ox. Sol. 1	Oxidising solid category 1
Skin Corr. 1B	Skin corrosion category 1B

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.

SAFETY DATA SHEET

Persons related to the transportation of the dangerous goods in compliance with the ADR Agreement should be properly trained within the scope of performed tasks (general training, on-the-job training and training related to the safety issues).

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:	17.03.2023
Version:	2.0/EN
Changes:	sections: 3, 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.