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

Trade name: **Chlorhexidine digluconate 2 %**

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

Relevant identified uses: reagent. Product for professional use.

Uses advised against: no uses advised against have been identified.

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: anna.szwedo@cerkamed.pl

1.4 Emergency telephone number

112

Section 2: Hazards identification

2.1 Classification of the substance or mixture

Eye Irrit. 2 H319, **Aquatic Chronic 3** H412

Causes serious eye irritation. Harmful 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

H319 Causes serious eye irritation.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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.

Additional information

None.

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

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Section 3: Composition/information on ingredients

3.1 Substances

Not applicable.

3.2 Mixtures

CAS number: 18472-51-0 EC number: 242-354-0 Index number: — REACH number: 01-2119946568-22-XXXX	D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) Eye Dam. 1 H318, Aquatic Acute 1 H400 (M=10), Aquatic Chronic 1 H410 (M=1)	≤ 2 %

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 few minutes. Consult a doctor, if disturbing symptoms occur.

Eye contact: protect non-irritated eye, remove contact lenses. Wash out an contaminated eyes thoroughly with plenty of water for few minutes. Avoid strong stream of water - the risk of corneal damage. 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.

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: possible redness, burning sensation.

Eye contact: possible redness, tearing, blurred vision, irritation.

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

Inhalation: no adverse effects by exposure in this route.

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: adapt the extinguishing media to 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 consisting of carbon oxides and other unidentified 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 extinguishing media.

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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. Do not touch or pass over spilled material. Avoid eyes and skin contamination. Do not inhale vapours of the product. Ensure adequate ventilation.

6.2 Environmental precautions

Do not enter into the sewage system, surface water and groundwater. 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 nonflammable liquid-binding materials (e.g. sand, universal binding agent) and place 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 and from 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.

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

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

DNEL for D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) [CAS 18472-51-0]

Exposure route	Exposure scenario	DNEL (worker)
inhalation	Long-term, systemic	0,42 mg/m^3
skin	Long-term, systemic	5 mg/kg

Exposure route	Exposure scenario	DNEL (consumer)
inhalation	Long-term, systemic	0,1 mg/m^3
oral	Long-term, systemic	0,03 mg/kg
oral	Short-term, systemic	2 mg/kg
skin	Long-term, systemic	3 mg/kg
skin	Short-term, systemic	5 mg/kg

PNEC for D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) [CAS 18472-51-0]

PNEC	Value
fresh water	0,002mg/l
marine water	0 mg/l
fresh water sediment	0,433 mg/kg
marine water sediment	0,043 mg/kg
STP	0,25 mg/l
intermittent release	0,002 mg/l
soil	5,26 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 vapours.

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 skin protection

Protective gloves resistant to the product in accordance with EN 374 are recommended. The material for gloves should be selected individually at the workplace. Wear protective clothing.

The material that the gloves are made of must be impenetrable and resistant to the product's effects. The selection of material must be performed with consideration of breakthrough time, penetration speed and degradation. Moreover, the selection of proper gloves depends not only on the material, but also on other quality features and changes depending on the manufacturer. The producer should provide detailed information regarding the exact breakthrough time. This information should be followed.

Eye protection

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

Respiratory protection

In case of sufficient ventilation, it is not required. In case of emergency use properly selected respiratory system protection.

Thermal hazards

Do not occur.

Environmental exposure controls

Do not allow large amounts of the product to enter sewage system. Uncontrolled release of the product into the environment should be reported to appropriate authorities in accordance with national and local regulations.

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Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state:	liquid
Colour:	colourless
Odour	odourless
Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	not determined
Flammability:	product is not classified as hazardous
Lower and upper explosion limit:	not determined
Flash point:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not determined
pH:	6,8
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:	1,003 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 and ignition sources.

10.5 Incompatible materials

Strong oxidising agents, strong bases.

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 components

D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) [CAS 18472-51-0]

LD_{50} (oral, rat): 2270 mg/kg

Toxicity of mixture

Acute toxicity

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

Skin corrosion/irritation

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

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

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

Toxicity of components

D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) [CAS 18472-51-0]

Toxicity for fish	LC_{50}	2,08 mg/l/96 h/ *Brachydanio rerio*
Toxicity for daphnia	EC_{50}	0,087 mg/l/48 h/ *Daphnia magna*
Toxicity for algae	EC_{50}	0,0871 mg/l/72 h/ *Scenedesmus subspicatus*

Toxicity of mixture

Harmful to aquatic life with long lasting effects.

12.2 Persistence and degradability

Data for components:

D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) [CAS 18472-51-0]

It undergoes biodegradation in 5 % within 28 days (concentration 15 mg/l)

2.3 Bioaccumulative potential

Data for components:

D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) [CAS 18472-51-0]

BCF=42

logPow=1,58

Moderate potential for 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 meets 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 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. Waste code should be given in the place of waste 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

Not applicable. Product is not classified as dangerous during transportation.

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.

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

H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Clarification of aberrations and acronyms

PBT	Persistent, Bioaccumulative and Toxic substance
vPvB	very Persistent, very Bioaccumulative substance
Aquatic Acute 1	Hazardous to the aquatic environment - Acute - category 1
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic - category 1
Eye Dam. 1	Serious eye damage category 1

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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:	17.11.2023
Version:	2.0/EN
Changes:	section: 1.2 (uses advised against), 16 (additional information)
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.