

MATERIAL SAFETY DATA SHEET

According to Regulation (EC) No 1907/2006 of the EP as amended by Regulation EU 2020/878

Date of issue: 9 May 2009

Page: 1 / 9

Date of revision: 20 June 2022

Previous date: 6 May 2022

Version: 11.3

Product name:

chirosan® plus

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

1.1 Product identifier

Trade name: **chirosan® plus**

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

Intended or recommended use of the mixture: disinfection and cleaning of medical device surfaces.
Medical device class II.b. Only for professional use.
Uses advised against: not to be used in any other way than specified.

1.3 Details of the supplier of the safety data sheet

Name of supplier: **Schulke CZ, s.r.o.**
Address: Lidická 445, 735 81 Bohumín, Czech Republic
Phone number: +420 558320 260
e-mail: schulkecz@schuelke.com
e-mail of person responsible for the Safety Data Sheet: MSDS@bochemie.cz

1.4 Emergency telephone number

Toxikologické informační středisko, Na Bojišti 1, 128 08 Praha 2, Czech Republic: +420 224 91 92 93 or +420 224 91 54 02.

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

According to Regulation No 1272/2008/EC

Acute Tox. 4, H302; Eye Dam. 1, H318

For the full wording of hazard statements see section 16.

The most important adverse physicochemical, human health and environmental effects: The mixture is harmful if swallowed, causes serious eye damage.

2.2 Label elements

Hazard pictograms:



Signal word:

Danger

Hazard statements:

H302 Harmful if swallowed.
H318 Causes serious eye damage.

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection.
P260 Do not breathe dust.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P314 Get medical advice/attention if you feel unwell.

2.3 Other hazards

The mixture does not meet the PBT/vPvB criteria according to REACH, annex XIII. The mixture contains no compounds, which are listed in annex as Substance of Very High Concern (SVHC) under Article 59, REACH Regulation. The mixture does not contain substances with endocrine disrupting properties according to Regulation (EU) 2017/2100 or (EU) 2018/605.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

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Not relevant.

3.2 Mixtures

3.2.1 Substances in the mixture

The active ingredient is peroxyacetic acid, which is generated in-situ in the water environment reaction of the sodium percarbonate and tetraacetyldiamine - TAED. Further contains: surfactants, organic acids, corrosion inhibitors, auxiliary substances (phosphate, enzymes). Substances classified as dangerous:

| Hazardous components | w/w (%) | CAS EC Index REACH | Classification acc. to Regulation 1272/2008/EC, CLP | Note |
|--|---------|--|--|---|
| Disodium carbonate, compound with hydrogen peroxide | ≤ 50 | 15630-89-4 239-707-6 01-2119457268-30 | Ox. Sol. 2, H272; Acute Tox.4, H302; Eye Dam 1, H318 | -- |
| Citric acid | < 15 | 77-92-9 201-069-1 607-750-00-3 01-2119457026-42 | Eye Irrit. 2, H319; STOT SE 3, H335 | Substance with exposure limits EU CZ – NV 41/2020 Sb. |
| (1-hydroxyethylidene)bisphosphonic acid, sodium salt | < 5 | 29329-71-3 249-559-4 01-2119510382-52 | Acute Tox. 4, H302; Eye Irrit. 2, H319 | -- |
| Potassium carbonate | < 1 | 584-08-7 209-529-3 01-2119532646-36 | Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | Substance with exposure limits- NV 195/2021 |

For the full wording of hazard statements see section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation: Shut off source of exposure, if possible. Bring the person to the fresh air, keep at rest (avoid even walking if necessary, seek medical attention).

Skin contact: Remove affected clothing. Wash thoroughly with water and soap.

Eye contact: Flush immediately with large amounts of fresh water at least 15 minutes to get the water under the eyelids. Remove contact lenses if present and easy to do. Continue rinsing. Seek medical attention.

Ingestion: Rinse mouth with potable water and leave person to drink 0.5 L of water. Do not induce vomiting, seek medical aid.

4.2 Most important symptoms and effects, both acute and delayed

The mixture irritates mucous membranes, respiratory tract, is harmful if swallowed, causes perforation of the esophagus and stomach, vomiting and diarrhea. Risk of serious damage to eyes - redness, itching and burning eyes.

4.3 Indication of any immediate medical attention and special treatment needed.

In case of eyes contact, ingestion and in other health problems or should the symptoms persist, always seek medical advice and provide information contained in this MSDS.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable: Water, water fog. Use extinguishing media according to the character other burning materials in the place of fire.

Unsuitable: do not use waterjet

5.2 Special hazards arising from the substance or mixture

High temperature can cause active substance decomposition (oxygen release). The product can cause burn. Avoid whirl of dust.

5.3 Advice for fire fighters

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In case fires wear full protective clothing, eyes and skin protection and suitable respiratory system protection. In case of release to the sewers act upon emergency plans.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Ensure removal of released product by trained personnel. Wear suitable personal protective equipment. See section 8. Ensure a good ventilation of the area.

6.1.2 For emergency responders

Wear suitable personal protective equipment, see section 8. Avoid contact with skin and eyes. Do not use the substance in the closed area and flammable materials. Avoid release to the environment, contact to water and dampness. Ensure a good ventilation of the area.

6.2 Environmental precautions

Avoid release to the water courses, soil or environment and contact with flammable materials (do not use sawdust and pulp as absorption). In case of accidental discharge of large amount of the concentrated product to the surface water, ground water or waste water, notify local authorities according to local regulations.

6.3 Methods and material for containment and cleaning up

In case spill the product, use suitable absorbents (special absorbents for aggressive materials or universal absorbents) and put into the labelled lockable container. Avoid accidental discharge into sewers or water courses. In case of accidental discharge into sewers or water courses, dilute the product with sufficient amount of water act according to local regulations and emergency plans and notify local authorities.

6.4 Reference to other sections

See section 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

It is necessary to observe safety regulations for work with preparations and to use the prescribed personal protective equipment. Avoid whirl of dust during handling. Furthermore, the preparation must be protected from potential manipulation by unauthorized persons. Sufficient ventilation of the workplace must be ensured. Avoid contact with acids and acidic substances. Do not eat, drink and smoke during the manipulation with the preparation. Keep containers tightly closed. Avoid contamination of environment. Avoid release to the environment.

7.2 Conditions for safe storage, including any incompatibilities

Keep in original, tightly closed containers. Store in dry areas protected against weather conditions preventing possible spillage and entry of unauthorized persons. Do not store to direct sunlight Store away from food, beverages and feed. Storage temperature: from -10 to +25°C.

7.3 Specific and use(s)

Important information is provided by material data safety sheet, by instructions on the label. For professional use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Exposure limits values

Czech Regulation of Government No. 195/2021:

| Substance | CAS | PEL (mg/m ³) | NPK-P (mg/m ³) | Conversion factor to ppm |
|---------------------|----------|--------------------------|----------------------------|--------------------------|
| Potassium carbonate | 584-08-7 | 5 | 10 | - |

Czech Regulation of Government No. 41/2020:

| Substance | type | Value (mg/m ³) | Conversion factor to ppm |
|-------------|------|----------------------------|--------------------------|
| Citric acid | PELc | 4 | - |

8.1.2 Biological limit values

Notice No. 107/2013 of Czech Act Collection does not set indication limits of biological exposure tests.

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8.1.3 Value of DNEL and PNEC

| <i>Disodium carbonate, compound with hydrogen peroxide</i> | | | | | | | | |
|---|-------------------------|-------------------------|--------------------------|-----------------------------|------------------------|-------------------------|--------------------------|-----------------------------|
| DNEL | worker | | | | consumer | | | |
| Route of exposure | Acute exposure local | Acute exposure systemic | Long term exposure local | Long term exposure systemic | Acute exposure local | Acute exposure systemic | Long term exposure local | Long term exposure systemic |
| Inhalation | -- | -- | 5 mg/m ³ | -- | -- | -- | -- | -- |
| Dermal | 12.8 mg/cm ² | -- | 12.8 mg/cm ² | -- | 6.4 mg/cm ² | -- | 6.4 mg/cm ² | -- |
| Oral | Not required | | | | | -- | -- | -- |
| PNEC | | | | | | | | |
| fresh water | | 0.035 mg/l | | | | | | |
| marine water | | 0.035 mg/l | | | | | | |
| intermittent release | | 0.035 mg/l | | | | | | |
| sewerage plant | | 16.24 mg/l | | | | | | |
| <i>(1-hydroxyethylidene)bisphosphonic acid, sodium salt</i> | | | | | | | | |
| DNEL | worker | | | | consumer | | | |
| Route of exposure | Acute exposure local | Acute exposure systemic | Long term exposure local | Long term exposure systemic | Acute exposure local | Acute exposure systemic | Long term exposure local | Long term exposure systemic |
| Inhalation | -- | -- | -- | -- | -- | -- | -- | -- |
| Dermal | -- | -- | -- | -- | -- | -- | -- | -- |
| Oral | Not required | | | | | -- | -- | 6.5 mg/kg bw/d |
| PNEC | | | | | | | | |
| fresh water | | 0.136 mg/l | | | | | | |
| marine water | | 0.0136 mg/l | | | | | | |
| fresh water, sediment | | 59 mg/kg wet | | | | | | |
| marine water, sediment | | 5.9 mg/kg wet | | | | | | |
| soil | | 96 mg/kg wet | | | | | | |
| sewerage plant | | 20 mg/l | | | | | | |
| <i>Citric acid</i> | | | | | | | | |
| PNEC | | | | | | | | |
| fresh water | | 0.44 mg/l | | | | | | |
| marine water | | 0.044 mg/l | | | | | | |
| fresh water, sediment | | 34.6 mg/kg | | | | | | |
| marine water, sediment | | 3.46 mg/kg | | | | | | |
| soil | | 33.1 mg/kg | | | | | | |
| sewerage plant | | 1000 mg/l | | | | | | |

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Keep usual hygienic rules for handling the product. Do not drink, eat or smoke during the work. Wash hands by drinking water and soap at the end of working shift and use protective cream on the skin. Wear suitable personal protective equipment. Ensure good ventilation/exhaustion at workplace. Only the personnel familiar with the properties of the product, with handling instructions and principles of personal and environmental protection and wearing personal protective equipment is allowed to handle the product. Contaminated clothes can be reused only after thorough clean-up.

8.2.2 Individual protection measures, such as personal protective equipment

Eye/face protection (EN 166): Safety goggles

Skin protection (EN 14605): Protective clothing, shoes.

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Hand protection (EN 374): no need special protective equipment, recommended preventive hand protection

Respiratory protection (EN 143, 14387): Ensure suitable ventilation. Wear suitable respiratory protection (suitable filter, type A) to eliminate risk. In case of accident, fire, high concentration use isolation breathing apparatus..

8.2.3 Environmental exposure controls

Observe instructions for handling and storage, particularly ensure provisions preventing spill of concentrated mixture into watercourses, soil and sewerage (for further information see Handling Conditions according to Act No 254/2001 of Czech Act Coll.).

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

| | |
|---|--|
| Physical state (°C): | solid (powder) |
| Colour: | white to cream |
| Odour: | odourless |
| Melting point/Freezing point: | at 70°C generated active substance is decomposed |
| Boiling point or initial boiling point and boiling range: | not estimated |
| Flammability: | non-flammable in rate 4:6 – 9:1 |
| Lower and upper explosion limit: | not estimated |
| Flash point (°C): | not estimated |
| Auto-ignition temperature; | not flammable |
| Decomposition temperature: | not estimated |
| pH (at 20°C): | alkaline reaction (pH of 2% solution is 7.5-8.5) |
| Kinematic viscosity: | not determined |
| Solubility: | miscible |
| Partition coefficient n-octanol/water: | not determined |
| Vapour pressure (°C): | not determined |
| Density and/or relative density (20°C): | Bulk density 890-960 kg/m ³ |
| Relative vapour density: | not determined |
| Particle characteristics | not determined |

9.2 Other information

No other information.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The mixture may react with concentrated and strong acids, reducing agents (hydrides), Chlorine-based products.

10.2 Chemical stability

Stable in normal conditions of usage and storage (keep temperature range for storage, security against radiant heat and intensive sun radiation).

10.3 Possibility of hazardous reactions

Under normal conditions there are no known hazardous reactions of the mixture, but contact with concentrated and dilute acids and substances of an acidic nature, reducing agents (e.g. hydrides) may cause undesirable reactions. In combination with chlorine-based products, chlorine releases.

10.4 Conditions to avoid

Avoid raised temperature, long-lasting direct exposure to sun, influence of weather conditions, humidity, rainfall and influence of acids and acidic substances and solution.

10.5 Incompatible materials

Concentrated and strong acids, acidic substance, reducing agents (hydrides), powder metals, organic compounds and slightly combustible material.

10.6 Hazardous decomposition products

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Oxygen, carbon oxides.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

| | |
|--|---|
| a) acute toxicity | calculated <i>Disodium carbonate, compound with hydrogen peroxide</i> LD50, oral: rat = 1034 mg/kg LD50, dermal: rabbit > 2000 mg/kg <i>(1-hydroxyethylidene)bisphosphonic acid, sodium salt</i> LD50, oral: rat = 1100 mg/kg <i>Citric acid</i> LD50, oral: rat > 2000 g/kg LD50, dermal: rat > 2000 mg/kg <i>Potassium carbonate</i> LD50, oral: rat > 2000 mg/kg |
| b) skin corrosion/irritation: | Criteria for classification are not met based on available data. |
| c) serious eye damage/irritation: | The mixture causes serious eye damage. |
| d) respiratory or skin sensitisation: | Criteria for classification are not met based on available data. |
| e) germ cell mutagenicity: | Criteria for classification are not met based on available data. |
| f) carcinogenicity: | Criteria for classification are not met based on available data. |
| g) reproductive toxicity: | Criteria for classification are not met based on available data. |
| h) STOT-single exposure: | Criteria for classification are not met based on available data. |
| i) STOT-repeated exposure: | Criteria for classification are not met based on available data. |
| j) aspiration hazard: | Criteria for classification are not met based on available data. |

SECTION 12: ECOLOGICAL INFORMATION**12.1 Toxicity**

Not established for this mixture.

Disodium carbonate, compound with hydrogen peroxide

| | | | |
|--|------|-----------|-------|
| Toxicity to fish, <i>Pimephales promelas</i> | LC50 | 70.7 mg/l | 96 h |
| Toxicity to fish, <i>Pimephales promelas</i> | NOEC | 7.4 mg/l | 96 h |
| Toxicity to daphnia, <i>Daphnia pulex</i> | EC50 | 4.9 mg/l | 48 h |
| Toxicity to daphnia, <i>Daphnia pulex</i> | NOEC | 2 mg/l | 48 h |
| Toxicity to algae, <i>Anabaena sp.</i> | EC50 | 8 mg/l | 140 h |

(1-hydroxyethylidene)bisphosphonic acid, sodium salt

| | | | |
|---|------|-----------|------|
| Toxicity to fish, <i>Salmo gairdneri</i> | LC50 | >100 mg/l | 96 h |
| Toxicity to daphnia, <i>Daphnia magna</i> | EC50 | >170 mg/l | 96 h |

Citric acid

| | | | |
|---|------|----------|------|
| Toxicity to fish, <i>Leuciscus idus melanotus</i> | LC50 | 625 mg/l | 48 h |
| Toxicity to daphnia, <i>Daphnia magna, static</i> | LC50 | 100 mg/l | |
| Toxicity to algae, <i>Scenedesmus quadricauda</i> | NOEC | 425 mg/l | |

Potassium carbonate

| | | | |
|--------------------------------------|------|----------|------|
| Toxicity to fish, <i>Stickleback</i> | LC50 | 70 mg/kg | 48 h |
| Toxicity to invertebrates | EC50 | 160 mg/l | 6 h |

12.2 Persistence and degradability

Persistence and degradability not established for this mixture.

Disodium carbonate, compound with hydrogen peroxide

Inorganic substance.

Citric acid

The product is biodegradable according to OECD criteria.

12.3 Bioaccumulative potential

Not established.

Disodium carbonate, compound with hydrogen peroxide

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Inorganic substance.

Citric acid

Intermediate product of metabolic processes in the human body (TCA cycle): the substance is safe for human consumption.

12.4 Mobility in soil

Not established.

Disodium carbonate, compound with hydrogen peroxide

It is soluble in the water. Adsorption is low in the soil.

(1-hydroxyethylidene)bisphosphonic acid, sodium salt

Do not allow product to reach ground water, water course or sewage system. Danger to drinking water even if small quantities leak into the ground.

Citric acid

Soluble in water. It can penetrate into the groundwater or to disperse on great distance.

12.5 Results of PBT and vPvB assessment

The mixture does not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6 Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties according to Regulation (EU) 2017/2100 or (EU) 2018/605.

12.7 Other adverse effects

Toxicity for other environment was not determined.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

a) Recommended Methods of Substance and Contaminated Packaging Disposal

It is dangerous waste. Personal protective equipment should be used and provisions to be applied when handling and collecting wastes regarding protection of waste spill into environment. Waste hand over to specialized competent company, if need be hand over within the framework of dangerous waste collection in your community. Used absorbents dispose of as dangerous waste. Packaging can be recycled after thorough cleaning.

b) Physical/chemical properties that may affect waste treatment options

Avoid contact to with acids and strong oxidizing and reducing agents.

c) Sewage disposal shall be discouraged

Waste should not be disposed of by release to sewers.

d) Special precautions for any recommended waste treatment

Suggestion of waste classification

| | | |
|----------|-----------|---|
| Subgroup | 20 01 | Separately collected fractions. |
| | 20 01 29* | Detergents containing hazardous substances. |

Suggestion of waste container classification

Containers with residues of the mixture:

15 01 10* packaging containing residues of or contaminated by dangerous substances.

Waste Legal Regulations

Directive 2018/851/EC on waste and repealing certain Directives. If this mixture and its packaging become waste, the last user has to assign relevant waste code – European Waste Code (EWC code) according to Commission Decision (2014/955/EU).

SECTION 14: TRANSPORT INFORMATION

The product is not classified as dangerous from the point of view of transport.

SECTION 15: REGULATORY INFORMATION

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

Legislation regulating individual issues of the environmental protection and occupational hygiene conditions. Regulation 1907/2006 (REACH).

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Regulation 1272/2008/EC (CLP).

Regulation 648/2004 on detergents.

Regulation No. 745/2017/EU on medical devices.

Directive 93/42/EEC concerning medical devices.

15.2 Chemical safety assessment

A chemical safety assessment was not carried out for the mixture.

SECTION 16: OTHER INFORMATION

a) Changes during Revision of the MSDS

Revision No. 11.0 – a new format of MSDS

Version 11.1 - a new information – citric acid

Version 11.2 – exposure limits in section 8.

The changed sections are indicated with bold line: |

b) A key or legend to abbreviations and acronyms used

| | |
|-------------|--|
| Ox. Sol. | Oxidising solid |
| Acute Tox. | Acute toxicity |
| Skin Irrit. | Skin irritation |
| Eye Dam. | Serious eye damage |
| Eye Irrit. | Eye irritation |
| STOT SE | Specific target organ toxicity – single exposure |
| IC 50 | The half maximal inhibitory concentration |
| LC50 | Lethal concentration, 50 percent |
| EC50 | Effective Concentration, 50 percent |
| LD50 | Lethal dose, 50 percent |
| PBT | Persistent, Bioaccumulative and Toxic |
| vPvB | Very Persistent and Very Bioaccumulative |
| NOEC | No observed effect concentration |
| DNEL | Derived no-effect level |
| PNEC | Predicted no-effect concentration |
| NPK-P | Maximum Permissible Concentration |
| PEL | Permissible Exposure Limit |

c) Key literature references and sources for data

Information contained herein is based on our best knowledge and current legislation, according to regulation 1272/2008/EC. Further, this Material Safety Data Sheet was elaborated on grounds of information provided by suppliers of particular components of the mixture. The MSDS contains information needed for security of safety and occupational health protection and the environmental protection. The mentioned information refers to present state of knowledge and experience and is in accordance with legislation in force. It cannot be considered warrantee of suitability or usability of the product for particular application. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

d) The methods of evaluating information

The mixture was classified according to method described in Regulation 1272/2008/EC.

e) List of relevant hazard statements

| | |
|-------|-----------------------------------|
| H 272 | May intensify fire; oxidiser. |
| H 302 | Harmful if swallowed. |
| H 315 | Causes skin irritation. |
| H 318 | Causes serious eye damage. |
| H 319 | Causes serious eye irritation |
| H 335 | May cause respiratory irritation. |

f) Instructions for Training

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Personnel handling the preparation must be instructed about manipulation risks and on requirements for health and environmental protection (relevant provisions of the Labor Code as amended) and further, they must be demonstrably familiarized with dangerous properties, occupational health and environmental protection principles and first aid measures (Act No. 258/2000 Coll. on public health protection as amended).

g) Recommended Use Limitations

The mixture can't be used for any other purpose than determined (see section 1.2). As specific conditions of use of the substance are beyond control of the supplier, the user is the only responsible to adapt the information and warnings contained herein to local legislation and regulations. The safety information describes the product from perspective of its safety and it cannot be deemed technical specifications of the product.