

Chlorhexidine (4.79%) Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.09.2024 |
| 5.0 | 14.04.2025 | 10839981-00008 | Date of first issue: 25.08.2022 |

SECTION 1. IDENTIFICATION

Product name : Chlorhexidine (4.79%) Formulation

Other means of identification : Hibitane (A000585)

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Serious eye damage/eye irritation : Category 2A

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic hazard : Category 2

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H319 Causes serious eye irritation.
H411 Toxic to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.

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| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.09.2024 |
| 5.0 | 14.04.2025 | 10839981-00008 | Date of first issue: 25.08.2022 |

P280 Wear eye protection/ face protection.

Response:

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.

P391 Collect spillage.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|--------------------------|-----------|-----------------------|
| Chlorhexidine | 55-56-1 | $\geq 2,5$ -< 5 |
| Nonylphenol, ethoxylated | 9016-45-9 | ≥ 1 -< 2,5 |

SECTION 4. FIRST AID MEASURES

| | |
|---|---|
| General advice | : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled | : If inhaled, remove to fresh air. Get medical attention if symptoms occur. |
| In case of skin contact | : In case of contact, immediately flush skin with soap and plenty of water. Get medical attention if symptoms occur. |
| In case of eye contact | : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention. |
| If swallowed | : If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : Causes serious eye irritation. |
| Protection of first-aiders | : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| Notes to physician | : Treat symptomatically and supportively. |

SECTION 5. FIRE-FIGHTING MEASURES

Chlorhexidine (4.79%) Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.09.2024 |
| 5.0 | 14.04.2025 | 10839981-00008 | Date of first issue: 25.08.2022 |

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|--|---|---|
| Suitable extinguishing media | : | Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire fighting | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |
-

SECTION 6. ACCIDENTAL RELEASE MEASURES

- | | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained. |
| Methods and materials for containment and cleaning up | : | Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

Chlorhexidine (4.79%) Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 10839981-00008 Date of last issue: 06.09.2024
Date of first issue: 25.08.2022

SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe mist or vapors.
Do not swallow.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---------------------------------|---------|----------------------------------|--|----------|
| Chlorhexidine | 55-56-1 | TWA | 40 µg/m ³ (OEB 3) | Internal |
| Further information: RSEN, DSEN | | | | |
| | | Wipe limit | 100 µg/100 cm ² | Internal |

- Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.

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| | | | |
|---------|----------------|----------------|---------------------------------|
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| 5.0 | 14.04.2025 | 10839981-00008 | Date of first issue: 25.08.2022 |

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| Eye protection | : | Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Skin and body protection | : | Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing. |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- | | | |
|--|---|---------------------|
| Appearance | : | Aqueous solution |
| Color | : | blue |
| Odor | : | No data available |
| Odor Threshold | : | No data available |
| pH | : | 5,55 - 6,65 (20 °C) |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | No data available |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapor pressure | : | No data available |

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| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.09.2024 |
| 5.0 | 14.04.2025 | 10839981-00008 | Date of first issue: 25.08.2022 |

| | | |
|--|---|--|
| Relative vapor density | : | No data available |
| Relative density | : | 1,010 - 1,020 |
| Density | : | No data available |
| Solubility(ies) | : | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Autoignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | : | |
| Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight | : | No data available |
| Particle characteristics | : | |
| Particle size | : | Not applicable |

SECTION 10. STABILITY AND REACTIVITY

| | | |
|------------------------------------|---|--|
| Reactivity | : | Not classified as a reactivity hazard. |
| Chemical stability | : | Stable under normal conditions. |
| Possibility of hazardous reactions | : | Can react with strong oxidizing agents. |
| Conditions to avoid | : | None known. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

SECTION 11. TOXICOLOGICAL INFORMATION

| | | |
|--|---|--|
| Information on likely routes of exposure | : | Inhalation Skin contact Ingestion Eye contact |
|--|---|--|

Acute toxicity

Not classified based on available information.

Product:

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| Acute oral toxicity | : | Acute toxicity estimate: > 5.000 mg/kg Method: Calculation method |
|---------------------|---|--|

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| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.09.2024 |
| 5.0 | 14.04.2025 | 10839981-00008 | Date of first issue: 25.08.2022 |

Components:**Chlorhexidine:**

| | | |
|---|---|---------------------------------|
| Acute oral toxicity | : | LD50 Oral (Mouse): 1.260 mg/kg |
| | | LD50 Oral (Rabbit): 1.100 mg/kg |
| | | LD50 Oral (Rat): 2.000 mg/kg |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): 21 mg/kg |
| | | Application Route: Intravenous |

Nonylphenol, ethoxylated:

| | | |
|---------------------|---|-------------------------------|
| Acute oral toxicity | : | LD50 (Rat): 500 - 2.000 mg/kg |
|---------------------|---|-------------------------------|

Skin corrosion/irritation

Not classified based on available information.

Components:**Nonylphenol, ethoxylated:**

| | | |
|---------|---|-------------------------|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 404 |
| Result | : | No skin irritation |

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:**Chlorhexidine:**

| | | |
|---------|---|---------------------|
| Species | : | Rabbit |
| Result | : | Mild eye irritation |

Nonylphenol, ethoxylated:

| | | |
|---------|---|---------------------------------|
| Species | : | Rabbit |
| Result | : | Irreversible effects on the eye |
| Method | : | OECD Test Guideline 405 |

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Nonylphenol, ethoxylated:**

| | | |
|--------------------|---|-------------------|
| Test Type | : | Maximization Test |
| Routes of exposure | : | Skin contact |
| Species | : | Guinea pig |

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| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.09.2024 |
| 5.0 | 14.04.2025 | 10839981-00008 | Date of first issue: 25.08.2022 |

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|---------|--|
| Result | : negative |
| Remarks | : Based on data from similar materials |

Germ cell mutagenicity

Not classified based on available information.

Components:**Chlorhexidine:**

| | |
|-----------------------|---|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative |
| Genotoxicity in vivo | : Test Type: dominant lethal test Species: Mouse Result: negative Test Type: Cytogenetic assay Species: Hamster Result: negative |

Nonylphenol, ethoxylated:

| | |
|-----------------------|---|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials |
|-----------------------|---|

Carcinogenicity

Not classified based on available information.

Components:**Chlorhexidine:**

| | |
|------------------------|-------------------------|
| Species | : Rat |
| Application Route | : oral (drinking water) |
| Exposure time | : 2 Years |
| Frequency of Treatment | : daily |
| NOAEL | : 38 mg/kg body weight |
| Result | : negative |

| | |
|------------------------|-------------------------|
| Species | : Rat |
| Application Route | : oral (drinking water) |
| Exposure time | : 2 Years |
| Frequency of Treatment | : daily |
| NOAEL | : 158 mg/kg body weight |
| Result | : negative |

Reproductive toxicity

Not classified based on available information.

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| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.09.2024 |
| 5.0 | 14.04.2025 | 10839981-00008 | Date of first issue: 25.08.2022 |

Components:**Chlorhexidine:**

| | | |
|------------------------------|---|--|
| Effects on fertility | : | Species: Rat Fertility: NOAEL: 100 mg/kg body weight |
| Effects on fetal development | : | Species: Rat Developmental Toxicity: NOAEL: 300 mg/kg body weight |
| | : | Species: Rabbit Developmental Toxicity: NOAEL: 40 mg/kg body weight |

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Components:**Chlorhexidine:**

| | | |
|---------------|---|--|
| Target Organs | : | Liver |
| Assessment | : | May cause damage to organs through prolonged or repeated exposure. |

Repeated dose toxicity**Components:****Chlorhexidine:**

| | | |
|-------------------|---|-----------|
| Species | : | Rat |
| NOAEL | : | 158 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 2 y |

| | | |
|-------------------|---|-------------|
| Species | : | Rabbit |
| LOAEL | : | 250 mg/kg |
| Application Route | : | Dermal |
| Exposure time | : | 13 Weeks |
| Target Organs | : | Skin, Liver |

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Chlorhexidine:**

| | | |
|---------------------|---|--|
| General Information | : | Symptoms: Headache |
| Inhalation | : | Target Organs: Lungs Symptoms: Asthmatic appearance, bronchospasm, discomfort in the chest, upper respiratory tract infection |
| Ingestion | : | Target Organs: Gastrointestinal tract Symptoms: Gastrointestinal disturbance, Gastrointestinal tract |

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| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.09.2024 |
| 5.0 | 14.04.2025 | 10839981-00008 | Date of first issue: 25.08.2022 |

II damage

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:**Chlorhexidine:**

| | | |
|---|---|--|
| Toxicity to fish | : | (Fish): 2,088 mg/l Exposure time: 96 h Method: ECOSAR (Ecological Structure Activity Relationships) |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 0,222 mg/l Exposure time: 48 h Method: ECOSAR (Ecological Structure Activity Relationships) |
| Toxicity to algae/aquatic plants | : | ErC50 (Pseudokirchneriella subcapitata (green algae)): 1,124 mg/l End point: Growth rate Exposure time: 96 hrs Method: ECOSAR (Ecological Structure Activity Relationships) |
| M-Factor (Acute aquatic toxicity) | : | 1 |
| M-Factor (Chronic aquatic toxicity) | : | 1 |

Nonylphenol, ethoxylated:

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): > 0,1 - 1 mg/l Exposure time: 96 h Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia dubia (water flea)): > 0,1 - 1 mg/l Exposure time: 48 h Remarks: Based on data from similar materials |
| Toxicity to algae/aquatic plants | : | ErC50 (Selenastrum capricornutum (green algae)): > 1 - 10 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials |
| | | EC10 (Selenastrum capricornutum (green algae)): > 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials |
| M-Factor (Acute aquatic toxicity) | : | 1 |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Oryzias latipes (Japanese medaka)): > 0,1 - 1 mg/l Exposure time: 100 d |

Chlorhexidine (4.79%) Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.09.2024 |
| 5.0 | 14.04.2025 | 10839981-00008 | Date of first issue: 25.08.2022 |

Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Mysidopsis bahia (opossum shrimp)): > 0,001 - 0,01 mg/l
Exposure time: 28 d
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 10

Persistence and degradability**Components:****Chlorhexidine:**

Biodegradability : Remarks: Not inherently biodegradable.

Nonylphenol, ethoxylated:

Biodegradability : Result: Not readily biodegradable.
Remarks: Based on data from similar materials

Bioaccumulative potential**Components:****Chlorhexidine:**

Partition coefficient: n-octanol/water : log Pow: 4,85

Nonylphenol, ethoxylated:

Partition coefficient: n-octanol/water : log Pow: 4,48

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

Chlorhexidine (4.79%) Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.09.2024 |
| 5.0 | 14.04.2025 | 10839981-00008 | Date of first issue: 25.08.2022 |

N.O.S.
(Chlorhexidine, Nonylphenol, ethoxylated)

| | | |
|---------------------------|---|-----|
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| Environmentally hazardous | : | yes |

IATA-DGR

| | | |
|--|---|--|
| UN/ID No. | : | UN 3082 |
| Proper shipping name | : | Environmentally hazardous substance, liquid, n.o.s. (Chlorhexidine, Nonylphenol, ethoxylated) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | Miscellaneous |
| Packing instruction (cargo aircraft) | : | 964 |
| Packing instruction (passenger aircraft) | : | 964 |
| Environmentally hazardous | : | yes |

IMDG-Code

| | | |
|----------------------|---|---|
| UN number | : | UN 3082 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Chlorhexidine, Nonylphenol, ethoxylated) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| EmS Code | : | F-A, S-F |
| Marine pollutant | : | yes |

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

| | | |
|---|---|----------------|
| Argentina. Carcinogenic Substances and Agents Registry. | : | Not applicable |
|---|---|----------------|

| | | |
|---|---|----------------|
| Control of precursors and essential chemicals for the preparation of drugs. | : | Not applicable |
|---|---|----------------|

The ingredients of this product are reported in the following inventories:

| | | |
|------|---|----------------|
| AICS | : | not determined |
| DSL | : | not determined |

Chlorhexidine (4.79%) Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.09.2024 |
| 5.0 | 14.04.2025 | 10839981-00008 | Date of first issue: 25.08.2022 |

IECSC : not determined

SECTION 16. OTHER INFORMATION

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|---------------|--------------|
| Revision Date | : 14.04.2025 |
| Date format | : dd.mm.yyyy |

Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided

Chlorhexidine (4.79%) Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 06.09.2024 |
| 5.0 | 14.04.2025 | 10839981-00008 | Date of first issue: 25.08.2022 |

relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

AR / Z8