

SAFETY DATA SHEET

according to the Globally Harmonized System



Chlorhexidine (4.79%) Formulation

Version 4.0 Revision Date: 21.11.2023 SDS Number: 10839979-00006 Date of last issue: 30.09.2023
Date of first issue: 25.08.2022

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Chlorhexidine (4.79%) Formulation

Other means of identification : Hibitane (A000585)

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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.

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H411 Toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:
P264+P265 Wash hands thoroughly after handling. Do not touch eyes.
P273 Avoid release to the environment.
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 + P317 If eye irritation persists: Get medical help.
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.

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	$\geq 1 - < 2.5$

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 : Causes serious eye irritation.

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- II** delayed
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.

5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
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 firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

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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 vapours.
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 labelled containers.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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				
		Wipe limit	400 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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- 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : Aqueous solution
- Colour : blue
- Odour : No data available
- Odour 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
- Vapour pressure : No data available

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Relative vapour 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

Auto-ignition 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 size : Not applicable

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.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

|| Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

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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
Method : OECD Test Guideline 405
Result : Irreversible effects on the eye

Respiratory or skin sensitisation

Skin sensitisation

|| Not classified based on available information.

Respiratory sensitisation

|| Not classified based on available information.

Components:

Nonylphenol, ethoxylated:

Test Type : Maximisation Test
Exposure routes : Skin contact

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Species : Guinea pig
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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Components:

Chlorhexidine:

Effects on fertility : Species: Rat
Fertility: NOAEL: 100 mg/kg body weight

Effects on foetal 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 yr

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

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Symptoms: Gastrointestinal disturbance, Gastrointestinal tract damage

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

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M-Factor (Acute aquatic toxicity)	:	1
Toxicity to fish (Chronic toxicity)	:	NOEC: > 0.1 - 1 mg/l Exposure time: 100 d Species: <i>Oryzias latipes</i> (Japanese medaka) Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: > 0.001 - 0.01 mg/l Exposure time: 28 d Species: <i>Mysidopsis bahia</i> (opossum shrimp) 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

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 han-

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ding site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, 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 IMO instruments

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.

15. REGULATORY INFORMATION

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

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

16. OTHER INFORMATION

Revision Date : 21.11.2023

Further information

Sources of key data used to compile the 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.

Date format : dd.mm.yyyy

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 Substances 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

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IN / EN