according to the Globally Harmonized System



Chlorhexidine (4.79%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 21.11.2023

 4.1
 06.09.2024
 10839979-00007
 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 irri-

tation

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.

according to the Globally Harmonized System



Chlorhexidine (4.79%) Formulation

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 Revision Date:
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 4.1
 06.09.2024
 10839979-00007
 Date of first issue: 25.08.2022

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	>= 2.5 - < 5
Nonylphenol, ethoxylated	9016-45-9	>= 1 - < 2.5

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms : Cause

and effects, both acute and

delayed

Causes serious eye irritation.

according to the Globally Harmonized System



Chlorhexidine (4.79%) Formulation

Version Revision Date: SDS Number: Date of last issue: 21.11.2023 4.1 06.09.2024 10839979-00007 Date of first issue: 25.08.2022

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 prod: :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 absor-

hent

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

according to the Globally Harmonized System



Chlorhexidine (4.79%) Formulation

Version Revision Date: SDS Number: Date of last issue: 21.11.2023 4.1 06.09.2024 10839979-00007 Date of first issue: 25.08.2022

employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

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 as-

sessment

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/m3 (OEB 3)	Internal
	Further information: RSEN, DSEN			
		Wipe limit	100 μg/100 cm2	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 contain-

ment devices).

Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

according to the Globally Harmonized System



Chlorhexidine (4.79%) Formulation

Version Revision Date: SDS Number: Date of last issue: 21.11.2023 4.1 06.09.2024 10839979-00007 Date of first issue: 25.08.2022

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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 : No data available

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Chlorhexidine (4.79%) Formulation

Version Revision Date: SDS Number: Date of last issue: 21.11.2023 4.1 06.09.2024 10839979-00007 Date of first issue: 25.08.2022

flammability limit

Lower explosion limit / Lower :

flammability limit

No data available

Vapour pressure : No data available

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 characteristics

Particle size : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- :

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition : No haz

products

No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion Eye contact

according to the Globally Harmonized System



Chlorhexidine (4.79%) Formulation

Revision Date: Version SDS Number: Date of last issue: 21.11.2023 4.1 06.09.2024 10839979-00007 Date of first issue: 25.08.2022

Acute toxicity

Not classified based on available information.

Product:

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

Method: Calculation method

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 : LD50 (Rat): 21 mg/kg

administration)

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.

according to the Globally Harmonized System



Chlorhexidine (4.79%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 21.11.2023

 4.1
 06.09.2024
 10839979-00007
 Date of first issue: 25.08.2022

Respiratory sensitisation

Not classified based on available information.

Components:

Nonylphenol, ethoxylated:

Test Type : Maximisation Test
Exposure routes : Skin contact
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)

according to the Globally Harmonized System



Chlorhexidine (4.79%) Formulation

Version Revision Date: SDS Number: Date of last issue: 21.11.2023 4.1 06.09.2024 10839979-00007 Date of first issue: 25.08.2022

Exposure time : 2 Years Frequency of Treatment : daily

NOAEL : 158 mg/kg body weight

Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Chlorhexidine:

Effects on fertility : Species: Rat

Fertility: NOAEL: 100 mg/kg body weight

Effects on foetal develop-

ment

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.

according to the Globally Harmonized System



Chlorhexidine (4.79%) Formulation

Version Revision Date: SDS Number: Date of last issue: 21.11.2023 4.1 06.09.2024 10839979-00007 Date of first issue: 25.08.2022

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

damage

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Chlorhexidine:

Toxicity to fish : (Fish): 2.088 mg/l

Exposure time: 96 h

Method: ECOSAR (Ecological Structure Activity Relation-

ships)

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 Relation-

ships)

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 Relation-

ships)

M-Factor (Acute aquatic tox-

icity)

: 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

according to the Globally Harmonized System



Chlorhexidine (4.79%) Formulation

Version Revision Date: SDS Number: Date of last issue: 21.11.2023 4.1 06.09.2024 10839979-00007 Date of first issue: 25.08.2022

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 tox-

icity)

1

Toxicity to fish (Chronic tox-

icity)

NOEC: > 0.1 - 1 mg/l Exposure time: 100 d

Species: Oryzias latipes (Japanese medaka) Remarks: Based on data from similar materials

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: > 0.001 - 0.01 mg/l Exposure time: 28 d

Species: Mysidopsis bahia (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

according to the Globally Harmonized System



Chlorhexidine (4.79%) Formulation

Version Revision Date: SDS Number: Date of last issue: 21.11.2023 4.1 06.09.2024 10839979-00007 Date of first issue: 25.08.2022

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-

dling 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 : 964

aircraft)

Packing instruction (passen: 964

ger aircraft)

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.

according to the Globally Harmonized System



Chlorhexidine (4.79%) Formulation

Version Revision Date: SDS Number: Date of last issue: 21.11.2023 4.1 06.09.2024 10839979-00007 Date of first issue: 25.08.2022

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

cy, http://echa.europa.eu/

Internal technical data, data from raw material SDSs, OECD

eChem Portal search results and European Chemicals Agen-

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 : 06.09.2024

Further information

Sources of key data used to

compile the Safety Data Sheet

1.1

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, Bioaccumu-

according to the Globally Harmonized System



Chlorhexidine (4.79%) Formulation

Version Revision Date: SDS Number: Date of last issue: 21.11.2023 4.1 06.09.2024 10839979-00007 Date of first issue: 25.08.2022

lative 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; TECI - 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 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.

IN / EN