SECTION 1. IDENTIFICATION

Product name: Chlorhexidine (4.79%) Formulation
Other means of identification: Hibitane (A000585)

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.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 in accordance with the Hazardous Products Regulations
Eye irritation: Category 2A
Specific target organ toxicity - repeated exposure: Category 2 (Liver)

GHS label elements
Hazard pictograms:

Signal Word: Warning

Hazard Statements:
H319 Causes serious eye irritation.
H373 May cause damage to organs (Liver) through prolonged or repeated exposure.

Precautionary Statements:
Prevention:
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P280 Wear eye protection and 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.
P314 Get medical attention if you feel unwell.
P337 + P313 If eye irritation persists: Get medical attention.

Disposal:
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Chlorhexidine (4.79%) Formulation

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>Common Name/Synonym</td>
</tr>
<tr>
<td>Chlorhexidine</td>
<td>No data available</td>
</tr>
<tr>
<td>Nonylphenol, ethoxylated</td>
<td>Poly(oxy-1,2-ethanediyl), .alpha.- (nonylphenyl)-.omega.-hydroxy-</td>
</tr>
</tbody>
</table>

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. May cause damage to organs through prolonged or repeated exposure.
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

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 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 spills 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.

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.
Chlorhexidine (4.79%) Formulation

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine</td>
<td>55-56-1</td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: RSEN</td>
<td>Wipe limit 400 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures:
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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.

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Aqueous solution</td>
</tr>
<tr>
<td>Color</td>
<td>blue</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>5.55 - 6.65 (20 °C)</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>1.010 - 1.020</td>
</tr>
</tbody>
</table>
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 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:
  Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
  Method: Calculation method

Components:
Chlorhexidine:
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Chlorhexidine (4.79%) Formulation

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
Result: negative
Remarks: Based on data from similar materials
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Chlorhexidine (4.79%) Formulation

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.
## Chlorhexidine (4.79%) Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>11/21/2023</td>
<td>10839984-00006</td>
<td>09/30/2023</td>
<td>08/25/2022</td>
</tr>
</tbody>
</table>

### 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

May cause damage to organs (Liver) through prolonged or repeated exposure.

### Components:

#### Chlorhexidine:

**Target Organs**
- Liver

**Assessment**
- May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### Chlorhexidine:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>158 mg/kg</td>
<td>Oral</td>
<td>2 y</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>250 mg/kg</td>
<td>Dermal</td>
<td>13 Weeks</td>
<td>Skin, Liver</td>
</tr>
</tbody>
</table>

### 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
## 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) |

**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 |

| Toxicity to fish (Chronic toxicity) | NOEC (Oryzias latipes (Japanese medaka)): > 0.1 - 1 mg/l  
| Exposure time: 100 d  
| Remarks: Based on data from similar materials |

| Toxicity to daphnia and other | NOEC (Mysidopsis bahia (opossum shrimp)): > 0.001 - 0.01 |
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Chlorhexidine (4.79%) Formulation

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,
  N.O.S.
  (Chlorhexidine, Nonylphenol, ethoxylated)
- Class: 9
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Chlorhexidine (4.79%) Formulation

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.

Domestic regulation

TDG
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
   (Chlorhexidine, Nonylphenol, ethoxylated)
Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes (Chlorhexidine, Nonylphenol, ethoxylated)

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

The ingredients of this product are reported in the following inventories:
AICS : not determined
Chlorhexidine (4.79%) Formulation

SECTION 16. OTHER INFORMATION

Full text of other abbreviations


Revision Date: 11/21/2023
Date format: mm/dd/yyyy

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

CA / Z8