SECTION 1. IDENTIFICATION

Product name : Chlorhexidine Formulation

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 OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
Specific target organ toxicity - repeated exposure : Category 2 (Liver)

GHS label elements
Hazard pictograms : 

Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H373 May cause damage to organs (Liver) through prolonged or repeated exposure.

Precautionary Statements : Prevention:
P260 Do not breathe mist or vapors.

Response:
P314 Get medical attention if you feel unwell.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.
Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol#</td>
<td>Concentration (% w/w)</td>
</tr>
<tr>
<td></td>
<td>Ethanol: 64-17-5</td>
</tr>
<tr>
<td>Chlorhexidine</td>
<td>55-56-1</td>
</tr>
</tbody>
</table>

# Voluntarily-disclosed substance

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: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

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: Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical 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 spillages cannot be contained.

Methods and materials for containment and cleaning up:
Soak up with inert absorbent material.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
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:
Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation Advice on safe handling:
Use only with adequate ventilation.
Do not breathe mist or vapors.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety
practice, based on the results of the workplace exposure assessment.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
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>Ethanol</td>
<td>64-17-5</td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>1,000 ppm, 1,900 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<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>Wipe limit</td>
<td>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:
  - General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.
  - Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide...
### Hand protection

**Material:** Chemical-resistant gloves  
**Remarks:** Consider double gloving.

### Eye protection

**Remarks:** 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

**Remarks:** 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

**Remarks:** 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>liquid</td>
</tr>
<tr>
<td>Color</td>
<td>light pink</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>5.0 - 6.5</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>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Chlorhexidine Formulation

<table>
<thead>
<tr>
<th>Version</th>
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<td>1.10</td>
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<td>5322116-00011</td>
<td>02/14/2023</td>
<td>11/25/2019</td>
</tr>
</tbody>
</table>

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapor pressure: No data available

Relative vapor density: No data available

Relative density: No data available

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: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

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: > 5,000 mg/kg
Method: Calculation method

**Components:**

**Ethanol:**
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): 124.7 mg/l
Exposure time: 4 h
Test atmosphere: vapor

**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

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**Ethanol:**
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**Ethanol:**
Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

**Chlorhexidine:**
Species : Rabbit
Result : Mild eye irritation
Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Ethanol:
Test Type : Local lymph node assay (LLNA)
Routes of exposure : Skin contact
Species : Mouse
Result : negative

Germ cell mutagenicity
Not classified based on available information.

Components:

Ethanol:
Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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

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

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified based on available information.

Components:

Ethanol:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

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:

Ethanol:
Species: Rat
NOAEL: 1,280 mg/kg
LOAEL: 3,156 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

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 damage

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Ethanol:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
**SAFETY DATA SHEET**

**Chlorhexidine Formulation**

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<tr>
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</tr>
</tbody>
</table>

Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates**
- EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l
- Exposure time: 48 h

**Toxicity to algae/aquatic plants**
- ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
- EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l
- Exposure time: 72 h

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
- NOEC (Daphnia magna (Water flea)): 9.6 mg/l
- Exposure time: 9 d

**Toxicity to microorganisms**
- EC50 (Pseudomonas putida): 6,500 mg/l
- Exposure time: 16 h

**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)

**Persistence and degradability**

**Components:**

**Ethanol:**
- Biodegradability: Result: Readily biodegradable.
- Biodegradation: 84 %
- Exposure time: 20 d

**Chlorhexidine:**
- Biodegradability: Remarks: Not inherently biodegradable.

**Bioaccumulative potential**

**Components:**

**Ethanol:**
- Partition coefficient: n-
- log Pow: -0.35
SAFETY DATA SHEET

Chlorhexidine Formulation

Version 1.10  Revision Date: 04/04/2023  SDS Number: 5322116-00011  Date of last issue: 02/14/2023  Date of first issue: 11/25/2019

octanol/water

**Chlorhexidine:**
Partition coefficient: n-octanol/water: log Pow: 4.85

**Mobility in soil**
No data available

**Other adverse effects**
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

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

Class: 9
Packing group: III
Labels: 9

**IATA-DGR**
UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Chlorhexidine)

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)

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

49 CFR
UN/ID/NA number: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s.
(Chlorhexidine)
Class: 9
Packing group: III
Labels: CLASS 9
ERG Code: 171
Marine pollutant: yes (Chlorhexidine)
Remarks: Above applies only to containers over 119 gallons or 450 liters.
Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards: Combustible dust
Specific target organ toxicity (single or repeated exposure)

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
Water: 7732-18-5
Ethanol: 64-17-5
Chlorhexidine: 55-56-1
Polyethylene glycol sorbitan monooleate: 9005-65-6

California List of Hazardous Substances
Ethanol: 64-17-5
California Permissible Exposure Limits for Chemical Contaminants

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
</tr>
</tbody>
</table>

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

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

SECTION 16. OTHER INFORMATION

Further information

**NFPA 704:**

- Flammability: 1
- Health: 0
- Instability: 0

**HMIS® IV:**

- HEALTH: *
- FLAMMABILITY: 3
- PHYSICAL HAZARD: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL: USA. NIOSH Recommended Exposure Limits
- OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- ACGIH / STEL: Short-term exposure limit
- NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- OSHA Z-1 / TWA: 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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 Sys-

Revision Date: 04/04/2023

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.

US / Z8