SAFETY DATA SHEET

Chlorhexidine (20%) Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Chlorhexidine (20%) Formulation

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

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 2B
Specific target organ toxicity - repeated exposure : Category 2 (Liver)
Short-term (acute) aquatic hazard : Category 2
Long-term (chronic) aquatic hazard : Category 2

GHS label elements
Hazard pictograms : 

Signal word : Warning
Hazard statements : H320 Causes eye irritation.
                     H373 May cause damage to organs (Liver) through prolonged or repeated exposure.
                     H411 Toxic to aquatic life with long lasting effects.
Precautionary statements:

**Prevention:**
- P260 Do not breathe mist or vapours.
- P264 Wash skin thoroughly after handling.
- P273 Avoid release to the environment.

**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.
- P319 Get medical help if you feel unwell.
- 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

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chlorhexidine</td>
<td>55-56-1</td>
<td>&gt;= 20 - &lt; 25</td>
</tr>
</tbody>
</table>

### 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 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.
5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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.

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

<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>Further information: RSEN</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., 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: Chemical-resistant gloves

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
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: liquid
- Colour: clear
- Odour: odourless
- Odour Threshold: No data available
- pH: No data available
- 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
- Relative vapour density: No data available
- Relative density: No data available
SAFETY DATA SHEET

Chlorhexidine (20%) Formulation

Density : 1.06 - 1.07 g/cm³

Solubility(ies)
  Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity
  Viscosity, kinematic : 147 mm²/s

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

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

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

**Serious eye damage/eye irritation**
Causes eye irritation.

**Components:**

**Chlorhexidine:**
Species: Rabbit
Result: Mild eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**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

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Chlorhexidine:**
Species: Rat
SAFETY DATA SHEET

Chlorhexidine (20%) Formulation

Version: 1.2
Revision Date: 27.08.2021
SDS Number: 5491685-00003
Date of last issue: 10.10.2020
Date of first issue: 17.03.2020

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.

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
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:
Species: Rat
NOAEL: 158 mg/kg
Application Route: Oral
Exposure time: 2 yr

Species: Rabbit
LOAEL: 250 mg/kg
Application Route: Dermal
**SAFETY DATA SHEET**

**Chlorhexidine (20%) 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>1.2</td>
<td>27.08.2021</td>
<td>5491685-00003</td>
<td>10.10.2020</td>
<td>17.03.2020</td>
</tr>
</tbody>
</table>

Exposure time : 13 Weeks
Target Organs : Skin, Liver

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**Chlorhexidine:**

<table>
<thead>
<tr>
<th>General Information</th>
<th>Inhalation</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms: Headache</td>
<td>Target Organs: Lungs Symptoms: Asthmatic appearance, bronchospasm, discomfort in the chest, upper respiratory tract infection</td>
<td>Target Organs: Gastrointestinal tract Symptoms: Gastrointestinal disturbance, Gastrointestinal tract damage</td>
</tr>
</tbody>
</table>

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Chlorhexidine:**

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): 0.222 mg/l Exposure time: 48 h Method: ECOSAR (Ecological Structure Activity Relationships)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>ErC50 (Pseudokirchneriella subcapitata (green algae)): 1.124 mg/l End point: Growth rate Exposure time: 96 hrs Method: ECOSAR (Ecological Structure Activity Relationships)</td>
</tr>
</tbody>
</table>

M-Factor (Acute aquatic toxicity) : 1
M-Factor (Chronic aquatic toxicity) : 1

**Persistence and degradability**

**Components:**

**Chlorhexidine:**

Biodegradability : Remarks: Not inherently biodegradable.
Bioaccumulative potential

Components:

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

Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : 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.

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
SAFETY DATA SHEET

Chlorhexidine (20%) Formulation

Version 1.2
Revision Date: 27.08.2021
SDS Number: 5491685-00003
Date of last issue: 10.10.2020
Date of first issue: 17.03.2020

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 var-
iations in regional or country regulations.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mix-
ture

The components of this product are reported in the following inventories:
DSL: not determined
AICS: not determined
IECSC: not determined

16. OTHER INFORMATION

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 Agen-

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;
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