according to the Hazardous Products Regulations



# **Chlorhexidine Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 1.11 09/30/2023 5322105-00012 Date of first issue: 11/25/2019

#### **SECTION 1. IDENTIFICATION**

Product name : Chlorhexidine Formulation

Other means of identification : No data available

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

Specific target organ toxicity : Category 2 (Liver)

- repeated exposure

**GHS label elements** Hazard pictograms

label elements



Signal Word : Warning

Hazard Statements : 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.

May form explosive dust-air mixture during processing, handling or other means.

according to the Hazardous Products Regulations



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### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture Mixture

#### Components

	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Ethanol#	Ethyl alcohol	64-17-5	5.56
Chlorhexidine	No data availa- ble	55-56-1	5

<sup>#</sup> 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.

: If in eyes, rinse well with water. In case of eye contact

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.

May cause damage to organs through prolonged or repeated

Most important symptoms

and effects, both acute and

Protection of first-aiders

exposure.

delayed

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

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).

Treat symptomatically and supportively. Notes to physician

#### **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

Exposure to combustion products may be a hazard to health.

fiahtina

Hazardous combustion prod-

Carbon oxides

Specific extinguishing meth-Use extinguishing measures that are appropriate to local cir-

according to the Hazardous Products Regulations



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ods 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:

ment : In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec-:

tive equipment and emergency procedures

for fire-fighters

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

according to the Hazardous Products Regulations



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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

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis	
Ethanol	64-17-5	TWA	1,000 ppm 1,880 mg/m <sup>3</sup>	CA AB OEL	
		STEL	1,000 ppm	CA BC OEL	
		STEV	1,000 ppm	CA QC OEL	
		STEL	1,000 ppm	ACGIH	
Chlorhexidine	55-56-1	TWA	40 μg/m3 (OEB 3)	Internal	
	Further information: RSEN				
		Wipe limit	400 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

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

Combined particulates and organic vapor type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

according to the Hazardous Products Regulations



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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.

### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : light pink

Odor : No data available

Odor Threshold : No data available

pH : 5.0 - 6.5

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) : May form explosive dust-air mixture during processing,

handling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

according to the Hazardous Products Regulations



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No data available Vapor pressure

Relative vapor density No data available

No data available Relative density

No data available Density

Solubility(ies)

No data available Water solubility

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 reac-

tions

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

according to the Hazardous Products Regulations



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#### **Acute toxicity**

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 2,000 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

according to the Hazardous Products Regulations



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#### 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

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)

Species: Mouse

Application Route: Ingestion

Result: equivocal

**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.

according to the Hazardous Products Regulations



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#### **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.

### 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.

according to the Hazardous Products Regulations



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#### 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

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 : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l

according to the Hazardous Products Regulations



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plants Exposure time: 72 h

EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l

Exposure time: 72 h

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

Toxicity to microorganisms

NOEC (Daphnia magna (Water flea)): 9.6 mg/l

Exposure time: 9 d

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 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)

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-

octanol/water

log Pow: -0.35

**Chlorhexidine:** 

Partition coefficient: n-

octanol/water

log Pow: 4.85

according to the Hazardous Products Regulations



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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)

Class 9 Ш Packing group Labels 9 yes

Environmentally hazardous

**IATA-DGR** 

UN/ID No. UN 3082

Proper shipping name Environmentally hazardous substance, liquid, n.o.s.

(Chlorhexidine)

Class 9 Ш Packing group

Miscellaneous Labels

Packing instruction (cargo 964

aircraft)

Packing instruction (passen-964

ger aircraft)

Environmentally hazardous yes

**IMDG-Code** 

**UN** number UN 3082

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, Proper shipping name

N.O.S.

(Chlorhexidine)

Class 9 Packing group Ш Labels 9

**EmS Code** F-A, S-F Marine pollutant yes

according to the Hazardous Products Regulations



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#### 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)

Class : 9
Packing group : III
Labels : 9
ERG Code : 171

Marine pollutant : yes(Chlorhexidine)

### 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

DSL : not determined

IECSC : not determined

### **SECTION 16. OTHER INFORMATION**

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

ACGIH / STEL : Short-term exposure limit

CA AB OEL / TWA : 8-hour Occupational exposure limit

CA BC OEL / STEL : short-term exposure limit CA QC OEL / STEV : Short-term exposure value

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;

according to the Hazardous Products Regulations



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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 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

Sources of key data used to compile the Material Safety

Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

Revision Date : 09/30/2023 Date format : mm/dd/yyyy

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