according to the OSHA Hazard Communication Standard



Chlorhexidine (20%) Formulation

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SECTION 1. IDENTIFICATION

Product name Chlorhexidine (20%) 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)

Eye irritation Category 2B

Specific target organ toxicity : Category 2 (Liver)

- repeated exposure

Other hazards

None known.

GHS label elements

Hazard pictograms



Signal Word Warning

Hazard Statements H320 Causes eve 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.

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.

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Disposal:

P501 Dispose of contents and container to an approved waste

disposal plant.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Chlorhexidine	55-56-1*	>= 10 - <= 30	TSC

^{*} Indicates that the identifier is a CAS No.

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, 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 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.

TSC- the actual concentration or concentration range is withheld as a trade secret

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Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

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

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, protec- : tive equipment and emer-

gency 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 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 Advice on safe handling

Use only with adequate ventilation. Do not breathe mist or vapors.

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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 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	Control parame-	Basis		
		(Form of	ters / Permissible			
		exposure)	concentration			
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-loss guide connections)

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

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

adequate protection.

Hand protection

according to the OSHA Hazard Communication Standard



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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

Appearance : liquid

Color : clear

Odor : odorless

Odor 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

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Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure No data available

No data available Relative vapor density

Relative density No data available

1.06 - 1.07 g/cm³ Density

Solubility(ies)

Water solubility soluble

Partition coefficient: n-

octanol/water

Not applicable

Autoignition 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 characteristics

Particle size Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

Conditions to avoid None known. Oxidizing agents Incompatible materials

Hazardous decomposition No hazardous decomposition products are known.

products

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

according to the OSHA Hazard Communication Standard



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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

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 sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

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

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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.

OSHANo 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:

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.

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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 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:

Chlorhexidine:

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

Exposure time: 96 h

Method: ECOSAR (Ecological Structure Activity Relation-

ships)

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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:

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

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

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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)

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)

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.

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.

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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 : Specific target organ toxicity (single or repeated exposure)

Serious eye damage or eye irritation

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 Chlorhexidine 55-56-1

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

DSL : not determined

AICS : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

according to the OSHA Hazard Communication Standard

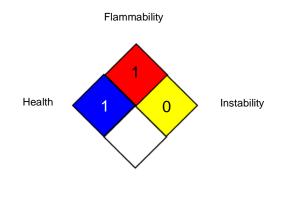


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NFPA 704:



Special hazard

HMIS® IV:



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

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 System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory: TECI - Thailand Existing Chemicals Inventory: TSCA - Toxic Substances Control Act

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(United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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/

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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.

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