Safety Data Sheet

according to OSHA HCS (29CFR 1910.1200)

Revision: September 22, 2022

1 Identification

· **Product identifier**

· **Trade name: Irrisept Irrigation Devices containing 0.05% Chlorhexidine Gluconate**

· **Recommended use and restriction on use**
· **Recommended use:** Mechanical cleansing and removal of debris, dirt and foreign materials, including microorganisms from wounds

· **Restrictions on use:** No relevant information available.

· **Details of the supplier of the Safety Data Sheet**
· **Manufacturer/Supplier:**

Irrimax
1665 Lakes Parkway, Ste 102
Lawrenceville, GA 30043
Corporate Office: 770-807-3355
cs@irrisept.com

· **Emergency telephone number:** 770-807-8445

2 Hazard(s) identification

· **Classification of the substance or mixture**
The substance is not classified as hazardous according to the Globally Harmonized System (GHS).

· **Label elements**
The product is not classified as hazardous according to OSHA GHS regulations within the United States.
· **GHS label elements** Not regulated.
· **Hazard pictograms:** None.
· **Signal word:** None
· **Hazard statements:** None.
· **Precautionary statements:** None.

· **Other hazards** There are no other hazards not otherwise classified that have been identified.

3 Composition/information on ingredients

· **Chemical characterization: Substances**

· **Components:**		
18472-51-0	D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) Eye Irrit. 2A, H319	0.05%

· **Additional information:** For the wording of the listed Hazard Statements, refer to section 16.

4 First-aid measures

· **Description of first aid measures**

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· **After inhalation:** Supply fresh air; consult doctor in case of complaints.
· **After skin contact:**
Product is manufactured for topical use.
If skin irritation is experienced, consult a doctor.
· **After eye contact:**
Remove contact lenses if worn.
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:**
Rinse out mouth and then drink plenty of water.
Do not induce vomiting; immediately call for medical help.
· **Most important symptoms and effects, both acute and delayed:** No relevant information available.
· **Indication of any immediate medical attention and special treatment needed:**
No relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
The product is not flammable.
Use fire fighting measures that suit the environment.
· **For safety reasons unsuitable extinguishing agents:** No relevant information available.
· **Special hazards arising from the substance or mixture** No relevant information available.
· **Advice for firefighters**
· **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation.
· **Environmental precautions** No special measures required.
· **Methods and material for containment and cleaning up**
Wipe up small spills with paper towel and discard.
For larger spills, add sawdust, chalk or other inert binding material, then sweep up and discard.
Dispose of the collected material according to regulations.
· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Handling**
· **Precautions for safe handling:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**

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· **Requirements to be met by storerooms and receptacles:** Store in a cool location.
· **Information about storage in one common storage facility:** No relevant information available.
· **Further information about storage conditions:**
Keep containers tightly sealed.
Storage Temperatures: 50-86 ºF / 10-30 ºC.
· **Specific end use(s)** No relevant information available.

8 Exposure controls/personal protection

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· **Exposure controls**
· **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
Keep away from foodstuffs, beverages and feed.
· **Engineering controls:** No relevant information available.
· **Breathing equipment:** Not required under normal conditions of use.
· **Protection of hands:** Gloves not required under normal conditions of use.
· **Eye protection:** Follow relevant national guidelines concerning the use of protective eyewear.
· **Body protection:** Not required under normal conditions of use.
· **Limitation and supervision of exposure into the environment** No special requirements.
· **Risk management measures** No special requirements.

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **Appearance:**	
Form:	Liquid
Color:	Clear
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value:**	5.0-7.0
· **Melting point/Melting range:**	~0 °C (~32 °F)
· **Boiling point/Boiling range:**	~100 °C (~212 °F)
· **Flash point:**	The product is not flammable.
· **Flammability (solid, gaseous):**	Not applicable.
· **Auto-ignition temperature:**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits**	
Lower:	Not determined.

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Upper:	Not determined.
· **Oxidizing properties:**	Non-oxidizing.
· **Vapor pressure:**	Not determined.
· **Density:**	
Relative density:	~1
Vapor density:	Not determined.
Evaporation rate:	~1
· **Solubility in / Miscibility with**	
Water:	Fully miscible.
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity**	
Dynamic:	Not determined.
Kinematic:	Not determined.
· **Other information**	No relevant information available.

10 Stability and reactivity

· **Reactivity:** No relevant information available.
· **Chemical stability:** Stable under normal temperatures and pressures.
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** No relevant information available.
· **Incompatible materials** No relevant information available.
· **Hazardous decomposition products** Possible in traces.

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:** Based on available data, the classification criteria are not met.
· **LD/LC50 values that are relevant for classification:** None.
· **Primary irritant effect:**
· **On the skin:** Based on available data, the classification criteria are not met.
· **On the eye:** Based on available data, the classification criteria are not met.
· **Sensitization:** Based on available data, the classification criteria are not met.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer):**
None of the ingredients are listed.

· **NTP (National Toxicology Program):**
None of the ingredients are listed.

· **OSHA-Ca (Occupational Safety & Health Administration):**
None of the ingredients are listed.

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· **Probable route(s) of exposure:**
Ingestion.
Inhalation.
Eye contact.
Skin contact.
· **Germ cell mutagenicity:** Based on available data, the classification criteria are not met.
· **Carcinogenicity:** Based on available data, the classification criteria are not met.
· **Reproductive toxicity:** Based on available data, the classification criteria are not met.
· **STOT-single exposure:** Based on available data, the classification criteria are not met.
· **STOT-repeated exposure:** Based on available data, the classification criteria are not met.
· **Aspiration hazard:** Based on available data, the classification criteria are not met.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity** No relevant information available.
· **Persistence and degradability** No relevant information available.
· **Bioaccumulative potential:** No relevant information available.
· **Mobility in soil:** No relevant information available.
· **Other adverse effects** No relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation:**
Smaller quantities can be disposed of with household waste.
Small amounts may be diluted with plenty of water and washed away. Dispose of bigger amounts in accordance with Local Authority requirements.
The user of this material has the responsibility to dispose of unused material, residues and containers in compliance with all relevant local, state and federal laws and regulations regarding treatment, storage and disposal for hazardous and nonhazardous wastes.

· **Uncleaned packagings**
· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **UN-Number**	
· **DOT, ADR/RID/ADN, IMDG, IATA**	Not regulated.
· **UN proper shipping name**	
· **DOT, ADR/RID/ADN, IMDG, IATA**	Not regulated.
· **Transport hazard class(es)**	
· **DOT, ADR/RID/ADN, IMDG, IATA**	
· **Class**	Not regulated.

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· **Packing group** · **DOT, ADR/RID/ADN, IMDG, IATA**	Not regulated.
· **Environmental hazards** · **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **United States (USA)**
· **SARA**

· **Section 302 (extremely hazardous substances):**
None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**
None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act)**
All ingredients are listed or exempt.

· **Proposition 65 (California)**

· **Chemicals known to cause cancer:**
None of the ingredients are listed.

· **Chemicals known to cause developmental toxicity for females:**
None of the ingredients are listed.

· **Chemicals known to cause developmental toxicity for males:**
None of the ingredients are listed.

· **Chemicals known to cause developmental toxicity:**
None of the ingredients are listed.

· **EPA (Environmental Protection Agency):**
None of the ingredients are listed.

· **IARC (International Agency for Research on Cancer):**
None of the ingredients are listed.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

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H319 Causes serious eye irritation.

· **Date of preparation / last revision** February 20, 2020 / -

· **Abbreviations and acronyms:**
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
OSHA: Occupational Safety & Health Administration
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

· **Sources**
Website, European Chemicals Agency (echa.europa.eu)
Website, US EPA Substance Registry Services (ofmpub.epa.gov/sor internet/registry/substreg/home/overview/home.do)
Website, Chemical Abstracts Registry, American Chemical Society (www.cas.org)
Patty's Industrial Hygiene, 6th ed., Rose, Vernon, ed. ISBN: 978-0-470-07488-6
Casarett and Doull's Toxicology: The Basic Science of Poisons, 8th Ed., Klaasen, Curtis D., ed., ISBN: 978-0-07-176923-5.
Safety Data Sheets, Individual Manufacturers

SDS Prepared by:
ChemTel Inc.
1305 North Florida Avenue
Tampa, Florida USA 33602-2902
Toll Free North America 1-888-255-3924 Intl. +01 813-248-0573
Website: www.chemtelinc.com

REVISION HISTORY

Version 01 Effective on 14-Sep-2021
Original version

Version 02 Effective on 22-Sep-2022
* Removed product code section. We will use the trade name to identify what products this SDS is for. This allows for us to use this for the new products without updating the SDS each time. * Updated the Recommended Use section to the new intended use. * Updated the date in the header

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

Mikki Shaub
Director, Quality & Training Coordinator
m.shaub@irrisept.com

I am the author of this document.
Signed 3:33:09 PM UTC 22-Sep-2022

Charles Brown
SR. Product Engineer
c.brown@irrisept.com

I am the author of this document.
Signed 4:30:28 PM UTC 22-Sep-2022

Required Workflow Steps for this Category

Venkat Katragadda
SR. DIR. Manufacturing & Engineering
v.katragadda@irrisept.com

Process Owner Signature
I have reviewed and approve this document.
Signed 8:50:10 PM UTC 22-Sep-2022

Rick Holecek
VP Quality & Management Representative
r.holecek@irrisept.com

Quality Signature
I have reviewed and approve this document.
Signed 5:10:32 PM UTC 22-Sep-2022