

Safety Data Sheet

acc. to OSHA HCS (29 CFR 1910.1200) and WHMIS 2015 regulations

Printing date: 07/21/2016

Revision: 07/21/2016

1 Identification

- **Product identifier**
- **Trade name:** Lantiseptic CaldaZinc® Ointment
- **Product code:** CZO (CZO4)
- **Recommended use and restriction on use**
- **Recommended use:** Over The Counter Pharmaceutical
- **Restrictions on use:** Contact manufacturer
- **Details of the supplier of the Safety Data Sheet**
- **Manufacturer/Supplier:**
Santus, LLC
3575 Koger Blvd., Suite 240
Duluth, GA 30096
844.772.6887 (844.7SANTUS)
- **Emergency telephone number:** 844.772.6887

2 Hazard(s) identification

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


- **Label elements**
- **GHS label elements** None.
- **Hazard pictograms:** Not regulated.
- **Signal word:** Not regulated.
- **Hazard statements:** None.
- **Precautionary statements:** Not regulated.

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

3 Composition/information on ingredients

- **Chemical characterization:** Mixtures

- **Components:**

1314-13-2	zinc oxide		10-20%
9011-96-9	Calamine		1-5%
56-81-5	glycerol		1-5%
1303-96-4	disodium tetraborate, decahydrate	 Repr. 1B, H360	1-5%

- **Additional information:**

For the listed ingredient(s), the identity and/or exact percentage(s) are being withheld as a trade secret.
For the wording of the listed Hazard Statements refer to section 16.

4 First-aid measures

- **Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.

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- **After skin contact:**
Product is a topical medication. If irritation occurs, discontinue use and wash affected area with soap and water.
- **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:**
Gastric or intestinal disorders when ingested.
- **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:** None.
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
- **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.
For large spills, wear protective clothing.
- **Environmental precautions:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Methods and material for containment and cleaning up:**
Pick up mechanically.
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.

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7 Handling and storage

- **Handling**
- **Precautions for safe handling:** Keep out of reach of children.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:**
Avoid storage near extreme heat, ignition sources or open flame.
- **Information about storage in one common storage facility:** Store away from oxidizing agents.
- **Further information about storage conditions:** Keep containers tightly sealed.
- **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:**

56-81-5 glycerol

PEL (USA)	Long-term value: 15* 5** mg/m ³ mist; *total dust **respirable fraction
TLV (USA)	TLV withdrawn-insufficient data human occup. exp.
EL (Canada)	Long-term value: 10* 3** mg/m ³ *mist; **mist, respirable
EV (Canada)	Long-term value: 10 mg/m ³
LMPE (Mexico)	Long-term value: 10 mg/m ³

1303-96-4 disodium tetraborate, decahydrate

REL (USA)	Long-term value: 5 mg/m ³
TLV (USA)	Short-term value: 6* mg/m ³ Long-term value: 2* mg/m ³ *as inhalable fraction
EL (Canada)	Short-term value: 6 mg/m ³ Long-term value: 2 mg/m ³
EV (Canada)	Short-term value: 6 mg/m ³ Long-term value: 2 mg/m ³ inorganic, inhalable
LMPE (Mexico)	Short-term value: 6* mg/m ³ Long-term value: 2* mg/m ³ A4, *fracción inhalable

- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
Keep away from foodstuffs, beverages and feed.

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- **Engineering controls:** No relevant information available.
- **Breathing equipment:** Not required under normal conditions of use.
- **Protection of hands:**
Not required under normal conditions of use.
Protection may be required for spills.
- **Eye protection:** Follow relevant national guidelines concerning the use of protective eyewear.
- **Body protection:**
Not required under normal conditions of use.
Protection may be required for spills.
- **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: Highly viscous

Color: Pink

· **Odor:** Characteristic

· **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Melting point/Melting range:** Not determined.

· **Boiling point/Boiling range:** Not determined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

· **Auto-ignition temperature:** Not determined.

· **Decomposition temperature:** Not determined.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits**

Lower: Not determined.

Upper: Not determined.

· **Oxidizing properties:** Not determined.

· **Vapor pressure at 20 °C (68 °F):** 23 hPa (17 mm Hg)

· **Density:**

Relative density: Not determined.

Vapor density: Not determined.

Evaporation rate: Not determined.

· **Solubility in / Miscibility with**

Water: Emulsifiable.

· **Partition coefficient (n-octanol/water):** Not determined.

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- **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:**
Toxic fumes may be released if heated above the decomposition point.
Reacts with strong acids and oxidizing agents.
- **Conditions to avoid:** Excessive heat.
- **Incompatible materials:** No relevant information available.
- **Hazardous decomposition products:**

Under fire conditions only:
Carbon monoxide and carbon dioxide
Toxic metal oxide smoke

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:**
- 1314-13-2 zinc oxide**
- Oral | LD50 | > 5000 mg/kg (rat)
- **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.

- **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.

- **Probable route(s) of exposure:**

Ingestion.
Inhalation.
Eye contact.

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Skin contact.

- **Acute effects (acute toxicity, irritation and corrosivity):** From product as supplied: None.
- **Repeated dose toxicity:** From product as supplied: None.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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** Toxic to aquatic life with long lasting effects.
- **Persistence and degradability** No relevant information available.
- **Bioaccumulative potential:** No relevant information available.
- **Mobility in soil:** No relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Toxic for fish
- **Additional ecological information**
- **General notes:** Avoid release to the environment.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects:** No relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
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** Not regulated.
- **ADR, IMDG, IATA** UN3082

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<ul style="list-style-type: none"> · UN proper shipping name · DOT · ADR, IATA · IMDG 	<p>Not regulated. ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc oxide, Calamine) ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc oxide, Calamine), MARINE POLLUTANT</p>
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<ul style="list-style-type: none"> · Transport hazard class(es) · DOT · Class 	<p>Not regulated.</p>
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<ul style="list-style-type: none"> · ADR 	
<ul style="list-style-type: none"> · Class · Label 	<p>9 (M6) Miscellaneous dangerous substances and articles 9</p>

<ul style="list-style-type: none"> · IMDG, IATA 	
<ul style="list-style-type: none"> · Class · Label 	<p>9 Miscellaneous dangerous substances and articles 9</p>

<ul style="list-style-type: none"> · Packing group · DOT · ADR, IMDG, IATA 	<p>Not regulated. III</p>
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<ul style="list-style-type: none"> · Environmental hazards · Marine pollutant: 	<p>Product contains environmentally hazardous substances: zinc oxide, Calamine Symbol (fish and tree)</p>
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<ul style="list-style-type: none"> · Special precautions for user · Danger code (Kemler): · EMS Number: 	<p>Warning: Miscellaneous dangerous substances and articles 90 F-A,S-F</p>
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<ul style="list-style-type: none"> · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code 	<p>Not applicable.</p>
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- **Transport/Additional information:** Not regulated when carried in single or combination packaging containing a net quantity of 5L or less for liquids or 5 kg or less for solids per the following:
 DOT: 171.4(c)(2)
 ADR: SP 375
 IMDG: 2.10.2.7
 IATA: special provision A197

- **DOT**
- **Remarks:** Transport labeling is not required for non-bulk single package shipments by motor vehicle, rail car or aircraft. Bulk packaging consists of a maximum capacity of greater than 450L (119 gallons) for a liquid and a maximum net mass greater than 400kg (882 pounds) for a solid.

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 355 (extremely hazardous substances):**

None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

Substance / component not listed individually, but listed under family group as Zinc salts.

1314-13-2	zinc oxide
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· **TSCA (Toxic Substances Control Act)**

All ingredients are listed.

· **Proposition 65 (California)**

· **Chemicals known to cause cancer:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed.

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· Carcinogenic categories
· EPA (Environmental Protection Agency):

1314-13-2 | zinc oxide

D, I, II

· IARC (International Agency for Research on Cancer):

None of the ingredients are listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health):

None of the ingredients are listed.

· Canadian Domestic Substances List (DSL):

All ingredients are listed or exempt.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.

· Date of preparation / last revision 07/21/2016 / -

· 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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

LDLo: Lowest Lethal Dose Observed

Repr. 1B: Reproductive toxicity – Category 1B

· 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: ISBN: 978-0-470-07488-6

Casarett and Doull's Toxicology: The Basic Science of Poisons, 8th Ed., Klaassen, Curtis D., ed., ISBN: 978-0-07-176923-5.

Safety Data Sheets, Individual Manufacturers

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