

SAFETY DATA SHEET

Issuing date: 03-30-2015

Revision date: 09-21-2017

Revision number: 3.0

1. Identification of the substance/preparation and the company/undertaking

GHS Product identifier

Product name: CALMOSEPTINE OINTMENT

Other mean of identification

Product code(s): NDC 0799-0001-02, NDC 0799-0001-03,
NDC 0799-0001-04, NDC 0799-0001-05, NDC 0799-0001-06

UN-Number: None

Synonyms: None

Recommended use of the chemical and restrictions on use

Recommended use: A moisture barrier that prevents & helps heal skin irritations from: urine, diarrhea, perspiration, fistula drainage, feeding tube site leakage, wound drainage (peri-wound skin), minor burns, cuts, scrapes, and itching.

Uses advised against: **For External Use Only.** Not for deep or puncture wounds. If symptoms persist consult a doctor.

Supplier address/information

Manufacturer's Name:
Calmo Manufacturing, Inc.

Address:
16601 Burke Lane
Huntington Beach, CA 92647

Telephone Number for Information:
(714) 840-3405

Emergency telephone number:
IN CASE OF ACCIDENTAL INGESTION SEEK PROFESSIONAL ASSISTANCE OR
CONTACT A POISON CONTROL CENTER IMMEDIATELY AT 1-800-222-1222.

2. Hazards Identification

Classification Non-Hazardous

Hazard identifier

Category

None

None

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GHS label elements, including precautionary statements

For external use only. Not for deep or puncture wounds. Avoid contact with eyes. Keep out of reach of children. In case of accidental ingestion contact a physician or poison control center immediately. If condition worsens or does not improve within 7 days, consult a doctor.

Emergency overview

IN CASE OF ACCIDENTAL INGESTION SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY AT 1-800-222-1222.

Appearance: Light Pink

Physical state: Thick Smooth Cream

Odor: Mild Menthol

Precautionary statements

General advice: **For external use only. Keep out of reach of children**

Eyes: **Avoid contact with eyes**

Inhalation: None

Storage: Between 15-30°C (59-86°F)

Disposal: None

Hazard not otherwise classified (HNOC)

None

Other information

None

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3. Composition/Information on ingredients

Chemical name	CAS-No	Weight % (W/W)	Trade Secret
Zinc Oxide	1314-13-2	20.6	No
Menthol	2216-51-5	0.44	No
Calamine	8011-96-9		Yes
Lanolin	8006-54-0		Yes
Glycerin	56-81-5		Yes
Phenol	108-95-2	≤ 0.3	Yes
Sodium Bicarbonate	144-55-8		Yes
Thymol	89-83-8		Yes
Chlorothymol	89-68-9		Yes

4. First aid measures

Description of necessary first-aid measures

Eye contact: Avoid contact with eyes. Flush eyes with water if Calmoseptine Ointment contacts eyes.

Skin contact: None

Inhalation: None

Ingestion: IN CASE OF ACCIDENTAL INGESTION SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY AT 1-800-222-1222.

Most important symptoms/effects, acute and delayed

Most important symptoms/effects: None

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician: Calmoseptine Ointment is a topical OTC with no dosage. Patients may experience a burning sensation if sensitive to menthol.

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5. Fire-fighting measures

Suitable extinguishing media: USE MEDIA SUITABLE FOR OIL BASED PRODUCTS such as a type B fire extinguisher.

Unsuitable extinguishing media: None

Specific hazards arising from the chemical: None

Explosion data: None

Protective equipment and precautions for firefighters: USE SELF CONTAINED BREATHING APPARATUS.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures: None

Environmental precautions: None

Methods and materials for containment and cleaning up

- Methods for containment: FOLLOW NORMAL GOOD HYGIENE CONDITIONS.
- Methods for cleaning up: FOLLOW NORMAL GOOD HYGIENE CONDITIONS.

7. Handling and storage

Precautions for safe handling

Handling: None

Conditions for safe storage, including any incompatibilities

Storage: Between 15-30°C (59-86°F)

Incompatible products: None

8. Exposure controls/personal protection

Control parameters

Exposure guidelines

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
None			

Appropriate engineering controls

Engineering measures: None

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Individual protection measures, such as personal protective equipment

Eye/face protection: None

Skin and body protection: None

Respiratory protection: None

Thermal hazards: None

Hygiene measures: FOLLOW NORMAL GOOD HYGIENE CONDITIONS.

9. Physical and chemical properties**Information on basic physical and chemical properties****Physical state:** Thick Ointment**Odor:** Mild Menthol**Appearance:** Light Pink**Odor threshold:** None

Property	Values	Remarks/Method
pH	9.5	
Melting point/range	> 97°F	
Boiling point/boiling range	None	
Flash point	None	
Evaporation rate	None	
Flammability (solid, gas)	None	
Flammability limits in air	None	
-upper flammability limit	None	
-lower flammability limit	None	
Vapor pressure	None	
Vapor density	None	
Specific gravity	1.2	
Water solubility	INSOLUBLE	
Solubility in other solvents	Mineral Oil	
Partition coefficient: n-octanol/water	None	
Autoignition temperature	None	
Decomposition temperature	None	
Viscosity	About 30000 cP	
Flammable properties	None	
Explosive properties	None	
Oxidizing properties	None	

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Other information

VOC content (%): None

10. Stability and reactivity

Reactivity: None

Chemical stability: Calmoseptine Ointment is stable for over 3 years.

Possibility of hazardous reactions: None

Conditions to avoid: None

Incompatible materials: None

Hazardous decomposition products: None

11. Toxicological information

Information on likely routes of exposure

Product information:

- Inhalation: None
- Eye contact: **Avoid contact with eyes**
- Skin contact: None
- Ingestion: IN CASE OF ACCIDENTAL INGESTION SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY AT 1-800-222-1222.

Chemical name

LD50 oral

LD50 dermal

LC50 inhalation

None

Symptoms related to the physical, chemical and toxicological characteristics: None

Delayed and immediate effects and also chronic effects from short and long term exposure

- Sensitization: None
- Mutagenic effects: None
- Carcinogenicity: None
- Reproductive toxicity: None
- STOT – single exposure: None
- STOT – repeated exposure: None
- Aspiration hazard: None

Numerical measures of toxicity – product: None

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12. Ecological information

Ecotoxicity

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
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None

Persistence and Degradability: Calmoseptine Ointment is stable for 3 years.

Bioaccumulation: None

Chemical name	Low Pow
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None

Other adverse effects: None

13. Disposal considerations

Waste disposal methods: CONSULT CURRENT FEDERAL, STATE AND LOCAL REGULATIONS PERTAINING TO PROPER WASTE DISPOSAL.

Contaminated packaging: None

Chemical name	RCRA	RCRA – Basis for listing	RCRA – D series wastes	RCRA – U series wastes
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None

14. Transport information

Notes:

Calmoseptine Ointment is not hazardous.

DOT

- | | |
|----------------------------|----------------|
| • UN-Number | Not Applicable |
| • Proper shipping name | Not Applicable |
| • Hazard class | Not Applicable |
| • Reportable quantity (RQ) | Not Applicable |
| • Description | Not Applicable |
| • Emergency response guide | Not Applicable |
| • Number | Not Applicable |

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15. Regulatory information

Interventional inventories

- TSCA Calmoseptine Ointment does not contain any ingredients listed on the TSCA Inventory list
- IECSC Not Applicable

Legend

TSCA: United States Toxic Substances Control Act 8(b) inventory

U.S. Federal regulations

Calmoseptine Ointment is FDA regulated and approved.

SARA 311/312 Hazard categories

- Acute health hazard
- Chronic health hazard
- Fire hazard
- Sudden release of pressure hazard
- Reactive hazard

Calmoseptine Ointment is not hazardous according to all the SARA 311/312 Categories.

Clean Water Act

Phenol is the only ingredient in Calmoseptine Ointment that is regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42), but the concentration of phenol in Calmoseptine Ointment is extremely low (below the level of pollutants).

CERCLA

Chemical name	Hazardous substances RQs	Extremely hazardous substances RQs	RQ
Phenol	1000	500	1000

U.S. state regulations

California Proposition 65: This product does not contain any Proposition 65 chemicals.

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U.S. state Right-to-Know regulations

"X" designates that the ingredients are listed on the state Right-to-Know list

Chemical name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Zinc Oxide	X	X	X		
Lanolin			X		
Iron Oxide		X	X		
Borax	X	X			
Glycerin	X	X	X		
Phenol	X	X	X		X

U.S. EPA label information

EPA Pesticide registration number: Not Applicable

16. Other information

	Health hazard	Flammability	Instability/Physical Hazard	Physical/Chemical Hazards/Personal protection
NFPA	NONE	NONE	NONE	NONE
HMIS	NONE	NONE	NONE	NONE

Prepared by: Musa Aldajani
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Revision note: Added Product name CALMOSEPTINE OINTMENT (showing on every page).

General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.