

**CALAMINE- ferric oxide red lotion**  
**Topco Associates LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Top Care 063.001/063AA**

**Active ingredients**

Calamine 8%  
Zinc oxide 8%

**Purpose**

Skin Protectant

**Use**

dries the oozing and weeping of poison: • ivy • oak • sumac

**Warnings**

**For external use only**

**When using this product**

Do not get into eyes

**Stop use and ask a doctor if**

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

**Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away

**Directions**

- shake well before using
- apply as needed

**Other information**

store at 59° - 86° F

**Inactive ingredients**

bentonite magma, calcium hydroxide, glycerin, purified water

**Questions or comments?**

1888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

TOPCO VIJA0622 QUESTIONS? 1-888-423-0139

1-888-423-0139

topcare@topco.com www.topcarebrand.com

Visit here for more information:

<http://topbrnds.com/4901jk>

QUALITY GUARANTEED

**principal display panel**

NDC 36800-063-30

TopCare health

Calamine Lotion USP

CALAMINE TOPICAL SUSPENSION USP

SKIN PROTECTANT

Drying Lotion for:

- Poison Ivy, Oak & Sumac

6 FL OZ (177 mL)

NDC 36800-063-30



# Calamine Lotion USP

CALAMINE TOPICAL SUSPENSION USP  
SKIN PROTECTANT

Drying Lotion for:

- Poison Ivy,  
Oak & Sumac

6 FL OZ (177 mL)

## CALAMINE

ferric oxide red lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-063
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	80 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	80 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BENTONITE</b> (UNII: A3N5ZCN45C)	

**CALCIUM HYDROXIDE** (UNII: PF5DZW74VN)

**GLYCERIN** (UNII: PDC6A3C0OX)

**WATER** (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-063-30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/1991	
2	NDC:36800-063-26	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/1991	05/28/2021
3	NDC:36800-063-34	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/1991	05/28/2021

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/15/1991	

**Labeler** - Topco Associates LLC (006935977)

**Registrant** - Vi Jon, LLC (790752542)

### Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		790752542	manufacture(36800-063)

### Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		088520668	manufacture(36800-063)

Revised: 8/2022

Topco Associates LLC