

**CALAMINE - ferric oxide red lotion**  
**Wakefern Food Corp**

*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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**Shop Rite 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

**Adverse Reaction Section**

DISTRIBUTED BY

WAKEFERN FOOD CORP.

5000 RIVERSIDE DRIVE

KEASBEY, NJ 08832

**principal display panel**

ShopRite

SKIN PROTECTANT

CALAMINE

LOTION

CALAMINE TOPICAL SUSPENSION U.S.P.

POISON IVY, OAK, SUMAC DRYING LOTION

6 FL OZ (177 mL)



## CALAMINE

ferric oxide red lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-063
Route of Administration	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)	
<b>CALCIUM HYDROXIDE</b> (UNII: PF5DZW74VN)	

<b>GLYCERIN</b> (UNII: PDC6A3C0OX)				
<b>WATER</b> (UNII: 059QF0KO0R)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41190-063-30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1989	
<b>Marketing Information</b>				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part347	07/15/1989	

**Labeler** - Wakefern Food Corp (069722418)

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

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		790752542	manufacture(41190-063)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		088520668	manufacture(41190-063)