

**RED OIL- menthol and camphor oil**  
**The Red Oil Company**

*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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**Actives**

Camphor 1 %

Menthol 1%

**Purpose**

External Analgesic

**Indication**

Temporary relief from pain and itching associated with minor skin irritations , insect bites, minor burns or sun burns, poison oak and minor reactions due to use of soaps, detergents or cosmetics.

**Directions**

Apply directly to affected area

Do not use more than four times per day

[www.RedOilHealingSolution.com](http://www.RedOilHealingSolution.com)

RED  
OIL™



Healing Solution

*"Got a little hurt.  
Get a little Red Oil"*

NET 8 FL. OZ.

**Drug Facts**

<b>Active Ingredients:</b>	<b>Purpose:</b>
Menthol 1.00% .....	External Analgesic
Camphor 1.00% .....	External Analgesic

**Uses:** temporary relief of pain and itching associated with minor skin irritations, insect bites, minor burns or sunburns, poison oak and minor reactions due to use of soaps, detergents or cosmetics.

**Warnings: For external use only.**

- Avoid contact with eyes.
- Do not apply to open wounds or damaged skin.
- If symptoms persist for more than seven days, discontinue use and consult physician.
- Keep out of reach of children. If swallowed, consult a physician.

**Directions:**

- Apply directly to effected area.
- Do not use more than four times per day.

**Inactive Ingredients:** Mineral Oil, Acetone, Pine Oil, Isopropyl Alcohol, Benzocaine, Chlorothymol, Phenol, D & C Red # 17.

Distributed by:  
The Red Oil Company  
Thomasville, NC 27360  
336-475-1528  
NDC 70537-001-08

(expiration date)



(expiration date)





## RED OIL

menthol and camphor oil

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70537-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 1 mL
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	10 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
ACETONE (UNII: 1364PS73AF)	
WHITE PINE OIL (UNII: HA5CX6676U)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
BENZOCAINE (UNII: U3RSY48JW5)	
CHLOROTHYMOL (UNII: LJ25TI0CVT)	
PHENOL (UNII: 339NCG44TV)	

### Product Characteristics

Color	red (D&C Red #17)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70537-001-08	237 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	04/04/2016	
2	NDC:70537-001-16	473 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	04/04/2016	
3	NDC:70537-001-02	59 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	04/04/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/04/2016	

**Labeler** - The Red Oil Company (011947497)

**Registrant** - The Red Oil Company (011947497)

### Establishment

Name	Address	ID/FEI	Business Operations
Filltech USA, LLC		926433855	manufacture(70537-001)

