

HAND SANITIZER - FOUR THIEVES BLEND- alcohol gel

Mount Royal Soaps, 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.

Hand Sanitizer - Four Thieves Gel Blend

Product Description & Introduction

This is a gel-form hand sanitizer (topical antiseptic rub) with a minimum of 62% Ethanol concentration and additional cosmetic fragrances manufactured in accordance with 21CFR330 and 21CFR333a.

Active Ingredient(s)

Ethyl Alcohol 62% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Decreases bacteria on hands

Warnings

For external use only

Flammable

Keep away from flame or high heat

When using this product keep out of eyes. In case of contact with eyes, flush eyes with water. Avoid contact with broken skin.

Stop use and ask a doctor if irritation or redness develop.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Rub hands thoroughly with product and allow to dry.

Inactive ingredients

Water (aqua), Glycerine, Carbomer, Triethanolamine, Citrus Medica Limonum (Lemon) Peel Oil, Eugenia Caryophyllus (Clove) Flower Oil, Cinnamomum Zeylanicum (Cinnamon) Leaf Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Eucalyptus Globulus Leaf Oil

Package Label - Principal Display Panel

Size: 59.1471 mL (2 Oz)

NDC: 74322-002-01

Label:



Size: 118.294 mL (4 Oz)

NDC: 74322-002-02

Label:



Size: 3785.41 mL (1 gal)

NDC: 74322-002-03

Label:



HAND SANITIZER - FOUR THIEVES BLEND

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74322-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	63 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
LEMON OIL (UNII: I9GRO824LL)	0.19 mL in 100 mL
ROSEMARY OIL (UNII: 8LGU7VM393)	0.13 mL in 100 mL
TEA TREE OIL (UNII: VIF565UC2G)	0.13 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.4 mL in 100 mL
CLOVE OIL (UNII: 578389D6D0)	0.08 mL in 100 mL
EUCALYPTUS OIL (UNII: 2R04ONI662)	0.11 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.4 mL in 100 mL
WATER (UNII: 059QF0K00R)	34 mL in 100 mL
CINNAMON LEAF OIL (UNII: S92U8SQ71V)	0.06 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74322-002-01	59.1471 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2020	
2	NDC:74322-002-02	118.294 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2020	
3	NDC:74322-002-03	3785.41 mL in 1 JUG; Type 0: Not a Combination Product	04/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	04/03/2020	

Labeler - Mount Royal Soaps, LLC (081382906)**Registrant** - Mount Royal Soaps, LLC (081382906)**Establishment**

Name	Address	ID/FEI	Business Operations
Charm City Meadworks		051441049	manufacture(74322-002) , pack(74322-002) , label(74322-002)

Establishment			
Name	Address	ID/FEI	Business Operations
Mount Royal Soaps, LLC		081382906	manufacture(74322-002) , pack(74322-002) , label(74322-002)

Revised: 4/2020

Mount Royal Soaps, LLC