

HAND SANITIZER- alcohol liquid

Rebels Refinery Inc

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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat and flame

Do not use

- on children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with

eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Do not store above 105° F
- May discolor some fabric
- Harmful to wood finishes and plastics

Inactive ingredients

glycerol, hydrogen peroxide, Japanese peppermint oil, water

Package Label - Principal Display Panel

2 fl oz / 60 ml

80% alc. / vol

The image shows a vertical rectangular panel with a white background. The word "SOLIS" is written vertically in a large, bold, black, sans-serif font. The letters are stacked from top to bottom: 'S', 'O', 'L', 'I', 'S'. The panel is framed by thin red vertical lines on both the left and right sides.

refillable

hand



sanitizer

WORLD HEALTH ORGANIZATION
HANDRUB FORMULATION

PREMIUM SKINCARE FOR HUMANS

2 FL OZ | 60 ML | 80% alc./vol

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82013-669
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K0OR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82013-669-02	60 mL in 1 BOX; Type 0: Not a Combination Product	07/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/01/2021	

Labeler - Rebels Refinery Inc (203764969)

Establishment

Name	Address	ID/FEI	Business Operations
Square M LLC		117467455	label(82013-669) , manufacture(82013-669)

Revised: 7/2021

Rebels Refinery Inc