RX CLEANSE HAND SANITIZER- alcohol gel
360 Labs, 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.

Rx Cleanse Hand Sanitizer - Sample Not for Resale

Active Ingredient(s)

Alcohol 70% 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 or flame

Do not use

- in 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.

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.

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

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water (aqua), Glycerin, Carbomer, Triethanolamine, Aloe Barbadensis Leaf Juice, Peppermint Oil, Tea

Tree Oil.

Package Label - Principal Display Panel

3.79L NDC: 74321-100-01

RX Cleanse Hand Sanitizer 70% Alcohol

Kills 99% of Germs and Bacteria

Made in a FDA Registered Facility

Warning: Flammable. Keep away from flame, keep out of eyes, for external use only. Keep out of reach from children. Do not store above 110 F

RX CLEANSE HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74321-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.002 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.004 mL in 100 mL
PEPPERMINT OIL (UNII: AV092KU4JH)	0.994 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.001 mL in 100 mL
TEA TREE OIL (UNII: VIF565UC2G)	0.0004 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.04 mL in 100 mL
WATER (UNII: 059QF0KO0R)	21 mL in 100 mL

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:74321-100-08	236.588 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74321-100-02	59.1471 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74321-100-16	473.176 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74321-100-01	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74321-100-00	118.294 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:74321-100-06	177.441 mL in 1 POUCH; Type 0: Not a Combination Product	03/30/2020	
7	NDC:74321-100-05	18927.1 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:74321-100-55	208197.648 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - 360 Labs, Inc. (137111923)

Registrant - 360 Labs, Inc. (137111923)

Establishment

Name	Address	ID/FEI	Business Operations

360 Labs, Inc.		137111923	manufacture(74321-100)