

COLOURPOP HAND SANITIZER- isopropyl alcohol liquid

Colourpop Cosmetics 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.

Colourpop Hand Sanitizer

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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% 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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

CP:
HAND SANITIZER PRIMARY LABEL

DIE : 5.1 x 3.3756 in

☐

CLEAR

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BLACK

GLOSSY

COLOURPOP

HAND
SANITIZER

spray

Isopropyl Alcohol Antiseptic 75%
Topical Solution
Antiseptic Hand Rub
Non-sterile Solution

4.19 fl. oz. (122.75 mL)

INDIC ACTS	Product
Active Ingredients	Antiseptic
Active 75% V/V	
Uses	
Use this antiseptic hand rub to help reduce bacteria that potentially can cause illness.	
Warnings	
For external use only. Flammable. Keep away from heat or flame.	
Do not use on open skin wounds.	
Do not use on children less than 2 months of age.	
Do not use near eyes, nose, mouth, or throat.	
Do not use near open flames.	
Do not use near heat sources.	
Do not use near children.	
Do not use near pets.	
Do not use near children.	
Do not use near pets.	
Directions	
Place enough product on hands to cover all surfaces. Rub hands together until dry.	
Use on hands and wrists.	
Use on hands and wrists.	
Use on hands and wrists.	
Other Information	
Store between 15-30C (59-86F).	
Do not use near heat sources.	
Do not use near open flames.	
Do not use near children.	
Do not use near pets.	
Inactive Ingredients	glycerin, hydrogen peroxide, water

COLOURPOP

ANTISEPTIC HAND RUB
SANTA MONICA, CA 90401 MADE IN THE USA COLOURPOP.COM

122.75 ml NDC: 77692-000-00

COLOURPOP HAND SANITIZER
isopropyl alcohol liquid

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:77692-122
Route of Administration		TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77692-122-01	6000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/25/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/25/2020	

Labeler - Colourpop Cosmetics LLC (080174532)

Establishment

Name	Address	ID/FEI	Business Operations
Colourpop Cosmetics LLC		080174532	manufacture(77692-122)

Revised: 5/2020

Colourpop Cosmetics LLC