KYLIESKIN BY KYLIE JENNER HAND SANITIZER NON-STERILE SOLUTION ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION- alcohol liquid Coty US 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.

KYLIESKIN by Kylie Jenner Hand Sanitizer Non-Sterile Solution Alcohol Antiseptic 80% Topical Solution

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 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

480 mL NDC 66184-167-01



BY KYLIE JENNER **HAND SANITIZER**

Non-Sterile Solution

Alcohol Antiseptic 80%

Topical Solution

DEDICATED, IN PARTNERSHIP WITH COTY, TO 1ST RESPONDERS SUPPORTING OUR COMMUNITIES

480 mL (16 FL OZ)

Sample - not for resale

Made in Sanford, NC 27332 by Coty Inc.

KYLIESKIN BY KYLIE JENNER HAND SANITIZER NON-STERILE SOLUTION ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION

alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66184-167

Route of Administration TOPICAL

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (LINII: 3K9958)/90M) (ALCOHOL - LINII: 3K9958)/90M)	ALCOHOL	80 ml in 100 ml

Inactive Ingredients

Ingredient Name Strength
GLYCERIN (UNII: PDC6A3C0OX)

HYDROGEN PEROXIDE (UNII: BBX060AN9V)

WATER (UNII: 059QF0KO0R)

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:66184-167-	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2020	

Marketing Information

Marketing Application Number or Monograph Marketing Start Marketing End
Category Citation Date Date

final	part333A	03/27/2020	

Labeler - Coty US LLC (039056361)

Establishment					
Name	Address	ID/FEI	Business Operations		
Coty US LLC		039056361	manufacture(66184-167)		

Revised: 10/2021 Coty US LLC