# COTY 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.

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# Coty Hand Sanitizer 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.

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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

- 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

COTY

HAND SANITIZER

**Non-Sterile Solution** 

**Alcohol Antiseptic 80%** 

**Topical Solution** 

DEDICATED TO 1ST RESPONDERS

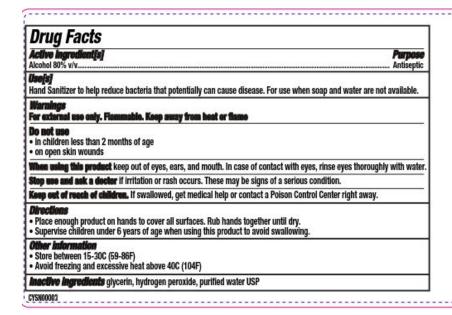
SUPPORTING OUR COMMUNITIES

480 mL (16 FL OZ)

Sample - not for resale

Made in Sanford, NC 27332 by Coty Inc.

480 mL NDC 66184-166



# COTY

#### HAND SANITIZER

Non-Sterile Solution

Alcohol Antiseptic 80% Topical Solution

DEDICATED TO 1ST RESPONDERS SUPPORTING OUR COMMUNITIES

480 mL (16 FL 0Z)

Sample - not for resale Made in Sanford, NC 27332 by Coty Inc.



#### COTY

#### HAND SANITIZER

Non-Sterile Solution

**Alcohol Antiseptic 80%** 

#### **Topical Solution**

DEDICATED TO 1ST RESPONDERS

SUPPORTING OUR COMMUNITIES

#### 480 mL (8 FL OZ)

Sample - not for resale

Made in Sanford, NC 27332 by Coty Inc.

#### Drug Facts Active ingredient[s] Purpose Use[s] 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 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. 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 CYSN00002

# COTY

### HAND SANITIZER

Non-Sterile Solution

Alcohol Antiseptic 80% Topical Solution

DEDICATED TO 1ST RESPONDERS SUPPORTING OUR COMMUNITIES

#### 240 mL (8 FL 0Z)

Sample - not for resale Made in Sanford, NC 27332 by Coty Inc.



# **COTY HAND SANITIZER NON-STERILE SOLUTION ALCOHOL**

## **ANTISEPTIC 80% TOPICAL SOLUTION**

alcohol liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66184-166

Route of Administration TOPICAL

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

Inactive Ingredients					
Ingredient Name	Strength				
GLYCERIN (UNII: PDC6A3C0OX)					
HYDROGEN PEROXIDE (UNII: BBX060AN9V)					
WATER (UNII: 059QF0KO0R)					

P	Packaging						
#	# Item Code Package Description		Marketing Start Date	Marketing End Date			
1	NDC:66184-166- 01	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2020				
2	NDC:66184-166- 02	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2020				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	03/27/2020			

# Labeler - Coty US LLC (039056361)

Establishment						
Name	Address	ID/FEI	Business Operations			
Coty US LLC		039056361	manufacture(66184-166)			

Revised: 10/2021 Coty US LLC