

**ALCOHOL ANTISEPTIC 80% HAND SANITIZER NON-STERILE SOLUTION-
alcohol liquid**

Merle Norman Cosmetics

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.

Alcohol Antiseptic 80% Hand Sanitizer Non-sterile Solution

Active Ingredients Purpose

Alcohol 80%v/v Antiseptic

Uses

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

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 serious signs of a serious condition.

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.

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.

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Alcohol Antiseptic 80%

Topical Solution

Hand Sanitizer

Non-Sterile Solution

Merle Norman

177mL 6 FL. OZ.

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Topical Solution
Hand Sanitizer
Non-sterile Solution**

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Drug Facts	
Active ingredient[s] Alcohol 80% v/v	Purpose Antiseptic
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 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.	
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	

Formula is consistent with World Health Organization recommendations

MANUFACTURED BY: MERLE NORMAN COSMETICS
LOS ANGELES, CA 90045
MADE IN USA



ARTWORK is at 100%
KEYLINE FOR DIE-CUT DOES NOT PRINT

ITEM: Alcohol Antiseptic 80% Topical Solution
Hand Sanitizer Non-Sterile Solution
DESCRIPTION: Label
STOCK NO: 68702
DECORATION:
NEW ART: 03/23/20 by SK
REVISIONS: 03/23/20 by SK - Laid out by Julina 3/20
Updated fonts and measurements
Lot/Exp -Ink Jet

APPROVALS

Packaging Design	SK	
Q.C.U.1		
Q.C.U.2		
Marketing		
New Item	Initials	Dept.
<input checked="" type="checkbox"/>	N/A	N/A
ECN Required	Initials	Dept.
ECN Not Required		50

MERLE NORMAN
15180 Bledsoe St., Sylmar, CA 91342

ALCOHOL ANTISEPTIC 80% HAND SANITIZER NON-STERILE SOLUTION

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57627-190
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
GLYCERIN (UNII: PDC6A3C0OX)	

WATER (UNII: 059QF0KO0R)

HYDROGEN PEROXIDE (UNII: BBX060AN9V)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57627-190-01	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2020	
2	NDC:57627-190-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2020	
3	NDC:57627-190-03	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/23/2020	

Labeler - Merle Norman Cosmetics (008479388)

Registrant - Merle Norman Cosmetics (008479388)

Establishment

Name	Address	ID/FEI	Business Operations
Merle Norman Cosmetics		008479388	manufacture(57627-190)

Revised: 5/2020

Merle Norman Cosmetics