QUALITY METALCRAFT ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION HAND SANITIZER NON-STERILE SOLUTION- alcohol gel Sunless, 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.

Quality Metalcraft Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-sterile Solution

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.

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



Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-sterile Solution

2 fl. oz. / 59mL

Manufactured for QMC-EMI by: Sunless, Inc. 8909 S. Freeway Drive, Macedonia, OH 44056 SUNLESSINC.COM | 888-974-9977 | Made in

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alcohol gel

 Product Information

 Product Type
 HUMAN OTC DRUG
 Item Code (Source)
 NDC:72553-009

 Route of Administration
 TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

ALCOHOL (Bo mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)				
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)				

WATER (UNII: 059QF0KO0R) Packaging # Item Code Package Description Marketing Start Date NDC:72553-009-01 59 mL in 1 BOTTLE; Type 0: Not a Combination Product 12/10/2020 Marketing Information

Marketing Start Date

12/10/2020

Marketing End Date

Labeler - Sunless, Inc. (002603202)

OTC monograph not final part333A

Marketing Category

Establishment				
Name	Address	ID/FEI	Business Operations	
Sunless, Inc.		002603202	manufacture(72553-009)	

Application Number or Monograph Citation

Revised: 12/2020 Sunless, Inc.