ALCOHOL ANTISEPTIC 80% - alcohol antiseptic 80% solution Aurohealth 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.

Alcohol Antiseptic 80% Topical Solution

Antiseptic Hand Rub

ACTIVE INGREDIENT(S)

Alcohol 80% v/v

PURPOSE

Antiseptic

USE(S)

Health care personnel hand rub to help reduce bacteria that potentially causes disease.

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.

STOP USE AND ASK DOCTOR IF

Stop using and ask doctor if irritation or rash occurs. These may be signs of a serious condition.

KEEP OUT OF REACH OF CHILDREN

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 15-30°C (59-86°F)

• Avoid freezing and excessive heat above 40°C (104°F)

INACTIVE INGREDIENT SECTION

glycerin, hydrogen peroxide, purified water USP

QUESTIONS OR COMMENTS

Call 1-855-274-4122

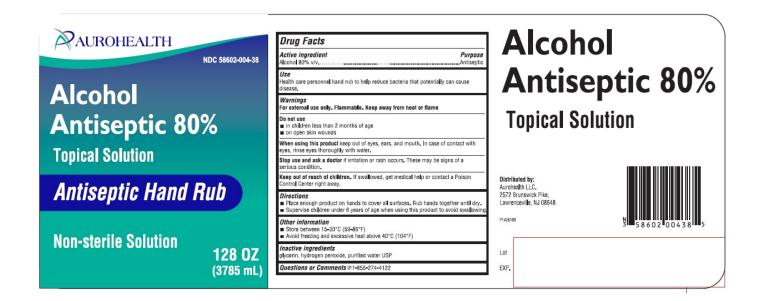
PRINCIPAL DISPLAY PANEL

ALCOHOL ANTISEPTIC 80%

Ingredient Name

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

AUROHEALTH NDC 58602-004-38 Alcohol Aniseptic 80% Topical Solution Antiseptic Hand Rub Non-sterile Solution 128 OZ (3785 mL)



Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:58602-004 Route of Administration TOPICAL Active Ingredient/Active Moiety

Basis of Strength

ALCOHOL

Strength

80 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	Marketing End Date		
1	NDC:58602-004-38	3785 mL	in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2020			
Marketing Information							
	Marketing Categ	ory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
О	TC MONOGRAPH NO	T FINAL	part333A	06/25/2020			

Labeler - Aurohealth LLC (078728447)

Establishment						
Name	Address		Business Operations			
Auro life Pharma LLC		080970299	ANALYSIS(58602-004), RELABEL(58602-004), REPACK(58602-004), LABEL(58602-004), MANUFACTURE(58602-004), PACK(58602-004)			

Revised: 6/2020 Aurohealth LLC