# BUCK-U DISTILLERY QUARENTINE- alcohol solution Buck Monster Distillery

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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# **BUCK-U DISTILLERY Antiseptic Hand Rub**

# **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

# **Topical Solution**

# **Non-Sterile Solution**

# **Packaging**



Alcohol Antiseptic 80% Topical Solution Antiseptic Hand Rub Non-Sterile Solution

Volume size: 500mL 74729 080 07



Alcohol Antiseptic 80% Topical Solution Volume size: 1000mL 74729 080 06 Antiseptic Hand Rub Non-Sterile Solution

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alcohol solution

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:74729-080

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)		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)		
WATER (UNII: 059QF0KO0R)		

F	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:74729-080- 08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2020		
2	NDC:74729-080-07	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2020		
3	NDC:74729-080- 06	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2020		
4	NDC:74729-080-05	1882 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2020		
5	NDC:74729-080-04	$3785\ mL$ in $1\ BOTTLE;$ Type $0$ : Not a Combination Product	04/18/2020		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/18/2020	

# Labeler - Buck Monster Distillery (061340335)

Establishment				
Name	Address	ID/FEI	Business Operations	
Buck Monster Distillery		061340335	manufacture(74729-080)	

Revised: 4/2020 Buck Monster Distillery