# BALTIMORE SPIRITS CO HAND SANITIZER- alcohol liquid Baltimore Whiskey Company 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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## Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-sterile Solution

Ethanol 80%

### Antiseptic

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

For external use only. Flammable. Keep away from heat or flame

- in children less than 2 months of age
- on open skin wounds

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 denatonium benzoate, glycerin, hydrogen peroxide, purified water USP

Alcohol Antiseptic 80%

**Topical Solution** 

Hand Sanitizer
Non-sterile Solution



3785 mL

Lot #:

<b>BALTIMORE</b>	SPIRITS	CO HAND	SANITIZER

alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73865-000	
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)	
HYDROGEN PERO XIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	
DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)	

l	Packaging				
	#	Item Code Package Description		Marketing Start Marketing End Date Date	
	1	NDC:73865-000- 00	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/23/2020	

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

## **Labeler** - Baltimore Whiskey Company LLC (086903343)

Establishment				
Name	Address	ID/FEI	Business Operations	
Baltimore Whiskey Company LLC		086903343	manufacture(73865-000)	

Revised: 4/2020 Baltimore Whiskey Company LLC