

**HAND SANITIZER- ethyl alcohol gel**  
**Meijer Distribution, 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.*

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**Coastal Breeze Hand Sanitizer**  
**604.000/604AA**

**Active ingredient**

Ethyl alcohol 63%

**Purpose**

Antiseptic

**Uses**

- to decrease bacteria on the skin that could cause disease
- recommended for repeated use

**Warnings**

**For external use only: hands**

**Flammable. Keep away from heat and flame**

**When using this product**

- keep out of eyes. In case of contact with eyes, flush thoroughly with water
- avoid contact with broken skin
- do not inhale or ingest

**Stop use and ask a doctor if**

- irritation and redness develops
- condition persists for more than 72 hours

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- wet hands thoroughly with product and allow to dry without wiping
- for children under 6, use only under adult supervision

- not recommended for infants

**Other information**

- do not store above 105°F
- may discolor some fabrics
- harmful to wood finishes and plastics

**Inactive ingredients**

water, glycerin, tocopheryl acetate, retinyl palmitate, acrylates/C10-30 alkyl acrylate crosspolymer, benzophenone-4, mannitol, cellulose, hydroxypropyl methylcellulose, fragrance, ext. violet 2, blue 1, red 40, ultramarines

**adverse reaction**

\*Effective at eliminating 99.99% of many common harmful germs and bacteria in as little as 15 seconds.

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[www.meijer.com](http://www.meijer.com)

Questions 1-888-593-0593

**principal display panel**

Hand

Sanitizer

Coastal Breeze

Kills

99.99% of germs

2 FL OZ (59 mL)



## HAND SANITIZER

ethyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41250-606
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	63 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>SULISOBENZONE</b> (UNII: 1W6L629B4K)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>EXT. D&amp;C VIOLET NO. 2</b> (UNII: G5UX3K0728)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>ULTRAMARINE BLUE</b> (UNII: I39WR998BI)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-606-16	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/11/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/11/2016	

**Labeler** - Meijer Distribution, Inc. (006959555)

**Registrant** - Vi-Jon, LLC (790752542)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(41250-606)

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Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(41250-606)

Revised: 2/2023

Meijer Distribution, Inc.