

**KELLYS DELIGHT HAND SANITIZER (CANDY CANE)- alcohol gel  
WACO BOTTLING 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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**Active Ingredient**

Ethyl Alcohol 70% v/v.

**Purpose**

Antiseptic

**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 the eyes.** In case of contact, rinse eyes thoroughly with water.

**Stop use and ask a doctor if** irritation and redness develop and persist 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.
- Briskly rub hands together until dry.
- Supervise children in the use of this product.

**Other Information**

- Store at 20-25C(68-77F)
- Avoid freezing and excessive heat above 40C (104F)

## Inactive Ingredients

Water, Glycerin, Isopropyl Myristate, PEG-6 & AMP Acrylates/Vinyl Isodecanoate Crosspolymer, Tocopheryl Acetate, Fragrance.

## Package Label - Principal Display Panel

### Drug Facts

Active Ingredient(s)	Purpose
Ethyl Alcohol 70% v/v	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 the eyes. In case of contact, rinse eyes thoroughly with water.

**Stop use and ask a doctor** if irritation and redness develop and persist 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  
• Briskly rub hands together until dry  
• Supervise children in the use of this product

**Other Information**  
• Store at 20° to 25°C (68° to 77°F)  
• May discolor certain fabrics

**Inactive Ingredients**  
Water, Glycerin, Isopropyl Myristate, PEG-6 & AMP Acrylates/Vinyl Isodecanoate Crosspolymer, Tocopheryl Acetate, Fragrance.

**HAND SANITIZER GEL**

VIRUSES HATE IT. BACTERIA DREAD IT.  
**KILLS 99.99% OF GERMS**  
alcohol antiseptic 70%  
topical solution

**CANDY CANE SCENT**

**8 FL OZ / 240 mL**

## KELLYS DELIGHT HAND SANITIZER (CANDY CANE)

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79175-013
<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	70 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYETHYLENE GLYCOL 300</b> (UNII: 5655G9Y8AQ)	
<b>ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPA'S NEUTRALIZED AT 0.5%)</b> (UNII: ...)	

<b>ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPAS NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)</b>	
<b>GLYCERIN (UNII: PDC6A3C0OX)</b>	
<b>ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)</b>	
<b>ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)</b>	
<b>DIPROPYLENE GLYCOL (UNII: E107L85C40)</b>	
<b>PEPPERMINT OIL (UNII: AV092KU4JH)</b>	
<b>MENTHA ARVENSIS FLOWER OIL (UNII: Q129Z1W6Y2)</b>	
<b>ETHYL VANILLIN (UNII: YC9ST449YJ)</b>	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79175-013-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
2	NDC:79175-013-02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
3	NDC:79175-013-03	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
4	NDC:79175-013-04	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
5	NDC:79175-013-05	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
6	NDC:79175-013-06	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
7	NDC:79175-013-07	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
8	NDC:79175-013-08	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
9	NDC:79175-013-09	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
10	NDC:79175-013-10	18927 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
11	NDC:79175-013-11	208198 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/03/2020	

**Labeler** - WACO BOTTLING LLC (080331158)

## Establishment

Name	Address	ID/FEI	Business Operations
WACO BOTTLING LLC		080331158	manufacture(79175-013)