# KELLYS DELIGHT HAND SANITIZER (CHRISTMAS EVERGREEN)- 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**



## KELLYS DELIGHT HAND SANITIZER (CHRISTMAS EVERGREEN)

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79175-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)		
ACRYLATECATING ICORECANOATE CROCCROLVMER (10000 MRA C MELITRALIZER AT 0 E0/3 //INIII.		

2N8MDB79NA)
GLYCERIN (UNII: PDC6A3C0OX)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
BENZYL BENZOATE (UNII: N863NB338G)
PINE NEEDLE OIL (PINUS MUGO) (UNII: 6KF1RLN1CI)
BUTYL HEXANOATE (UNII: EBK588Q27T)
COUMARIN (UNII: A4VZ 22K1WT)
2-TERT-BUTYLCYCLOHEXYL ACETATE (UNII: 364FV60913)
CINNAMALDEHYDE (UNII: SR60A3XG0F)
CEDAR LEAF OIL (UNII: BJ169U4NLG)
HELIOTROPINE BUTANE-2,3-DIOL ACETAL (UNII: 7Y4ZV19ZDP)
CINNAMON OIL (UNII: E5GY4I6YCZ)

Pa	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:79175- 014-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020		
2	NDC:79175- 014-02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020		
3	NDC:79175- 014-03	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020		
4	NDC:79175- 014-04	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020		
5	NDC:79175- 014-05	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020		
6	NDC:79175- 014-06	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020		
7	NDC:79175- 014-07	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020		
8	NDC:79175- 014-08	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020		
9	NDC:79175- 014-09	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020		
10	NDC:79175- 014-10	18927 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020		
11	NDC:79175- 014-11	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(79175-014)

Revised: 11/2022 WACO BOTTLING LLC