KELLYS DELIGHT HAND SANITIZER (APPLE CIDER)- 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.

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, Fragrance (Parfum), Glycerin, Isopropyl Myristate, PEG-6 & AMP Acrylates I Vinyl Isodecanoate Crosspolymer, Tocopheryl Acetate.

Package Label - Principal Display Panel



Active Ingredient[s] Ethyl Alcohol 70% v/v.

Purpose

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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

Packaged by: Waco Bottling Co. 209 Otis Drive Woodway, TX 76712











topical solution



8 FL 0Z / 240 mL

KELLYS DELIGHT HAND SANITIZER (APPLE CIDER)

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:79175-010

MADE IN

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 70 mL in 100 mL

Inactive Ingredients Ingredient Name Strength GLYCERIN (UNII: PDC6A3C0OX) ISOPROPYL MYRISTATE (UNII: 0 RE8K4LNJS)

POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)

ACRYLATES/VINYL ISODECANO ATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%) (UNII: 2N8 MDB 79 NA)

ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)

2-TERT-BUTYLCYCLOHEXYL ACETATE (UNII: 364FV60913)

METHYL CINNAMATE (UNII: 533CV2ZCQL)

ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)

LIMO NENE, (+)- (UNII: GFD7C86Q1W)

CARYOPHYLLENE (UNII: BHW853AU9H)				
METHYL DIHYDRO JASMO NATE, (-)-TRANS- (UNII: XM1C2C5MMN)				
.ALPHAISOPROPYL-PHENETHYL ALCOHOL (UNII: N06AQ6J88Y)				
DIETHYL MALONATE (UNII: 53A58PA183)				

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:79175-010- 01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020				
2	NDC:79175-010- 02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020				
3	NDC:79175-010- 03	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020				
4	NDC:79175-010- 04	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020				
5	NDC:79175-010- 05	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020				
6	NDC:79175-010- 06	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020				
7	NDC:79175-010- 07	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020				
8	NDC:79175-010- 08	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020				
9	NDC:79175-010- 09	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020				
10	NDC:79 175-0 10 - 10	18927 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020				
11	NDC:79 175-0 10 - 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(79175-010)				

Revised: 8/2020 WACO BOTTLING LLC