KELLYS DELIGHT HAND SANITIZER- 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.

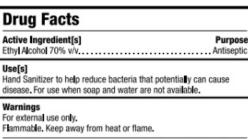
Other information

- Store at $20-25^{\circ}C(68-77^{\circ}F)$
- 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



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.

- · 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, Fragrance(parfum), Glycerin, Isopropyl Myristate, PEG-6 & AMP Acrylates / Vinyl Isodecanoate Crosspolymer, Tocopheryl Acetate.

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

Route of Administration



TOPICAL



8 FL oz / 240 ml

KELLYS DELIGHT HAND SANITIZER

alcohol gel

Product Information HUMAN OTC DRUG Product Type Item Code (Source) NDC:79175-003

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 RE8 K4LNJS)			
POLYETHYLENE GLYCOL 300 (UNII: 5655G9 Y8 AQ)			
ADENO SINE PHO SPHATE (UNII: 415SHH325A)			
ACRYLATES/VINYL ISODECANO ATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%) (UNII: 2N8 MDB79 NA)			
ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
DIPROPYLENE GLYCOL (UNII: E107L85C40)			
1-(2,3,8,8-TETRAMETHYL-1,2,3,4,5,6,7,8-O CTAHYDRO NAPHTHALEN-2-YL) ETHANO NE (UNII: 1GD7O DM28 Y)			
LINALYL ACETATE (UNII: 5K47SSQ51G)			

LINALOOL, (+/-)- (UNII: D81QY6188E)	
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)	
ETHYL LINALOOL (UNII: SF2JS9GF5T)	
2-ISOBUTYL-4-METHYLTETRAHYDROPYRAN-4-OL (UNII: VK5ZHH2T3F)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	
3-HEXENYL SALICYLATE, CIS- (UNII: C78 Y9 O R6 YH)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:79175-003- 01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020			
2	NDC:79175-003- 02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020			
3	NDC:79175-003- 03	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020			
4	NDC:79175-003- 04	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020			
5	NDC:79175-003- 05	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020			
6	NDC:79175-003- 06	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020			
7	NDC:79175-003- 07	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020			
8	NDC:79175-003- 08	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020			
9	NDC:79175-003- 09	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020			
10	NDC:79175-003- 10	18927 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020			
11	NDC:79175-003- 11	208198 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020			

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part333A	06/08/2020					

Labeler - WACO BOTTLING LLC (080331158)

Establishment							
Name	Address	ID/FEI	Business Operations				
WACO BOTTLING LLC		080331158	manufacture(79175-003)				

Revised: 6/2020 WACO BOTTLING LLC