KELLYS DELIGHT HAND SANITIZER (CLEANLINESS)- 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, lsopropyl Myristate, PEG-6 & AMP Acrylates I Vinyl lsodecanoate Crosspolymer, Tocopheryl Acetate.

Package Label - Principal Display Panel

KELLYS DELIGHT HAND SANITIZER (CLEANLINESS)

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79175-008
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: 0RE8K4LNJS)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
LEMON TERPENES (UNII: 5DHA4TVW63)	
LIME TERPENES (UNII: E1D70XB3OY)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

LINALOOL, (+/-)- (UNII: D81QY6I88E)	
TERPINEOL (UNII: R53Q4ZWC99)	
CITRONELLYL NITRILE, (+/-)- (UNII: GP9AT16H16)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79175-008-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
2	NDC:79175-008-02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
3	NDC:79175-008-03	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
4	NDC:79175-008-04	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
5	NDC:79175-008-05	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
6	NDC:79175-008-06	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
7	NDC:79175-008-07	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
8	NDC:79175-008-08	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
9	NDC:79175-008-09	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
10	NDC:79175-008-10	18927 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/03/2020	
11	NDC:79175-008-11	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(79175-008)

Revised: 8/2020 WACO BOTTLING LLC