ZURI 70.5% TOPICAL SOLUTION HAND SANITIZER- alcohol gel Kaizen Global Partners 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.

ZuRI™ Hand Sanitizer

Drug Facts

Active Ingredient(s)

Alcohol 70.5% v/v

Purpose

Antiseptic

Uses(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

- On children less than 2 months of age
- On open skin wounds

When using this product keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients: glycerin, hydrogen peroxide, purified water USP

70.5% Topical Solution

Alcohol Antiseptic

Kaizen Global Partners, LLC

36718 Detroit Rd.

Avon, OH 44011

Packaging



Facts

Drug

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DRUG FACTS LABEL

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alcohol gel

Product Information	oduct Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80347-070			
Route of Administration	TOPICAL					

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70.5 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)		
WATER (UNII: 059QF0KO0R)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80347-070- 02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/25/2020	
2	NDC:80347-070- 04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/25/2020	
3	NDC:80347-070- 08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/25/2020	
4	NDC:80347-070-12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/25/2020	
5	NDC:80347-070-16	473.17 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/25/2020	
6	NDC:80347-070-10	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/25/2020	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	09/25/2020			

Labeler - Kaizen Global Partners Llc (052778124)

Revised: 9/2020 Kaizen Global Partners Llc