HAND SANITIZER- isopropyl alcohol gel
Enter Labeler Name

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.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

a. Isopropyl Alcohol (70%) (ACTIB)
b. Water (IACT)
c. Polyethylene Glycol, Unspecified (IACT)
d. Aminomethylpropanol (IACT)
e. Acrylates/Vinyl Isodecanoate Crosspolymer (10000 MPA.S Neeutranlized at 0.5% (IACT)
f. Glycerin (IACT)

Active Ingredient(s)

Isopropyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

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 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 or rash 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

deionized water, polyethylene glycol, AMP-acrylates vinyl isodecanoate crosspolymer, glycerin

Package Label - Principal Display Panel

60 ml NDC: 79839-360-02

474 ml NDC: 79839-360-16

3780 ml NDC: 79839-360-01

HAND SANITIZER

isopropyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79839-360
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79839-360-01	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79839-360-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:79839-360-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Enter Labeler Name (117488989)

Establishment

Name	Address	ID/FEI	Business Operations
Shotwell Hydrogenics, LLC		108985732	manufacture(79839-360)

Revised: 9/2020 Enter Labeler Name