HAND SANITIZER- isopropyl alcohol liquid
SUN WAVE WELLNESS, 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.

VERSION 2: CORRECTION INTENDED TO REPLACE SETID SUBMISSION ENDING "..AB88E"
CORRECTION: (1) BACK LABEL REPLACEMENT
CONSUMER HAND SANITIZER; NON-EMERGENCY; ISOPROPYL ALCOHOL = DEFERRED GRASE ACTIVE INGREDIENT DETERMINATION EFFECTIVE APRIL 13, 2020; PART333E FOR OTC HAND RUB SANITIZERS (CONSUMER)

Active Ingredient(s)

Alcohol 70% v/v

Purpose

Antiseptic

Use(s)

To help reduce bacteria on the skin. 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
- around eyes
- in ears and mouth

When using this product

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

- avoid contact with broken skin
- do not inhale or ingest

Stop use and ask a doctor if

irritation or rash occurs.

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 or excessive heat above 40C (104F).

Inactive ingredients

Aloe Barbadensis (leaf) Extract, Fragrance, Glycerin, Purified Water

Manufactured by:

Sun Wave Wellness, LLC

1419 Chaffee Drive #101

Titusville, FL 32780-7933

HAND SANITIZER

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75023-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	1.325 L in 1.893 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	0.492 L in 1.893 L
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.019 L in 1.893 L
GLYCERIN (UNII: PDC6A3C0OX)	0.038 L in 1.893 L
LIMONENE, (+)- (UNII: GFD7C86Q1W)	0.019 L in 1.893 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75023-003-04	1.893 L in 1 BOTTLE; Type 0: Not a Combination Product	07/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/05/2020	

Labeler - SUN WAVE WELLNESS, LLC (117465590)

Registrant - SUN WAVE WELLNESS, LLC (117465590)

Establishment

Name	Address	ID/FEI	Business Operations
SUN WAVE WELLNESS, LLC		117465590	manufacture(75023-003)

Revised: 8/2020

SUN WAVE WELLNESS, LLC