SUN WAVE CONSUMER ANTISEPTIC HAND SANITIZER- isopropyl alcohol spray
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.

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)

Isopropyl 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 and excessive heat above 40C (104F).

Inactive ingredients

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

ANTISEPTIC

HAND

SANITIZER

SPRAY GEL

ALCOHOL ANTISEPTIC 70%

enriched with aloe

CLEAN SCENT

TOPICAL SOLUTION

KILLS

GERMS &

BACTERIA

3.4OZ 100ML

NO-STERILE SOLUTION

SUN WAVE CONSUMER ANTISEPTIC HAND SANITIZER

isopropyl alcohol spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75023-001
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**
LIMONENE, (+)- (UNII: GFD7C86Q1W)	1 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	26 mL in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:75023-001-01	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/30/2020	

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(75023-001)

Revised: 4/2020 SUN WAVE WELLNESS, LLC