

HAND SANITIZER- alcohol gel
Onpoint, Inc

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.

Advanced Hand Sanitizer
370

Active Ingredient

Ethyl alcohol 70%

Purpose

Antiseptic

Uses

- to decrease bacteria on the skin that could cause disease
- recommended for repeated use

Warnings

For external use only-hands

Flammable. Keep away from heat and flame.

When using this product

- keep out of eyes. In case of contact with eyes, flush thoroughly with water.
- avoid contact with broken skin
- do not inhale or ingest

Stop use and ask a doctor if

- irritation or redness develops
- condition persists 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 thoroughly with product and allow to dry without wiping
- for children under 6, use only under adult supervision
- not recommended for infants

Other information

- do not store above 105° F
- may discolor some fabrics
- harmful to wood finishes and plastics

Inactive ingredients

water, glyceryl caprylate/caprates, glycerin, isopropyl myristate, tocopheryl acetate, acrylates/C10-30 alkyl acrylate crosspolymer, fragrance, benzophenone-4

Effective at eliminating more than 99.99% of many common harmful germs and bacteria in as little as 15 seconds*

DISTRIBUTED BY ONPOINT, INC

2 PARAGON DRIVE

MONTVALE, NJ 07645

370.000/370AB

Principal display panel

Live Better

Hand Sanitizer

ADVANCED

More Effective Formula

- KILLS MORE THAN 99.99% OF GERMS*

8 FL OZ (236 mL)



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51143-370
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
water (UNII: 059QF0KO0R)	
GLYCERYL CAPRYLATE/CAPRATE (UNII: G7515SW10N)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
SULISOBENZONE (UNII: 1W6L629B4K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51143-370-34	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/28/2014	
2	NDC:51143-370-16	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/28/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/28/2014	

Labeler - Onpoint, Inc (001367366)**Registrant** - Vi-Jon (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon		088520668	manufacture(51143-370)