

INSTANT HAND SANITIZER- instant hand sanitizer gel
Jean Pierre 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.

INSTANT HAND SANITIZER

Active Ingredient(s)

Ethyl Alcohol 60%

Purpose

Antiseptic

Use

Helps reduce bacteria on skin. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from fire or flame.

Do not use

do not use in or near tile eyes

When using this product do not use in or near tile eyes. In case of contact, rinse eyes thoroughly with water. Do not use on open skin wounds. Stop use and ask a doctor if irritation or rash appears and lasts. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children.

Directions

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

Other information

Do not store in temperature over 118°F.

Water, Carbomer, Triethanolamine, Fragrance, Glycerine, Tocopherol (Vitamin E), Aloe Barbadensis Leaf Juice

Package Label - Principal Display Panel

**HARMON
01601 HAND SANITIZER
SAM 5.18.20**

COLORS USED:



**MULTI-LAYER BACK LABEL
SHOULD PEEL HERE**



INSTANT HAND SANITIZER

instant hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70483-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	60 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PODOPHYLLUM RESIN (UNII: 16902YVY2B)	

TOCOPHEROL (UNII: R0ZB2556P8)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70483-008-01	52 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:70483-008-02	59 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 - Jean Pierre Inc. (138328393)

Establishment

Name	Address	ID/FEI	Business Operations
Jean Pierre Inc.		138328393	manufacture(70483-008)

Revised: 6/2020

Jean Pierre Inc.