

HAND SANITIZER- alcohol gel
Punch Studio, 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.

Hand sanitizer

ACTIVE INGREDIENT

EHTANOL 62%. **PURPOSE:** ANTISEPTIC

PURPOSE

ANTISEPTIC

USES

- TO HELP REDUCE BACTERIA ON HANDS
- WHEN WATER & SOAP ARE NOT AVAILABLE

WARNINGS

- FOR EXTERNAL USE ONLY
- KEEP OUT OF EYES
- FLAMMABLE, KEEP AWAY FROM HEAT OR FLAME

DO NOT USE

- ON CHILDREN LESS THAN 2 YEARS OF AGE
- ON OPEN SKIN WOUNDS

KEEP OUT OF REACK OF CHILDREN.

IF SWALLOWED, GET MEDICAL HELP OR CALL A POISON CONTROL VENTER RIGHT AWAY.

DIRECTIONS

- APPLY AS NEEDED INTO PALM OF HANDS, RUB HANDS TOGETHER UNTIL DRY
- SUPERVISE CHILDREN UNDER 6 YEARS OLD

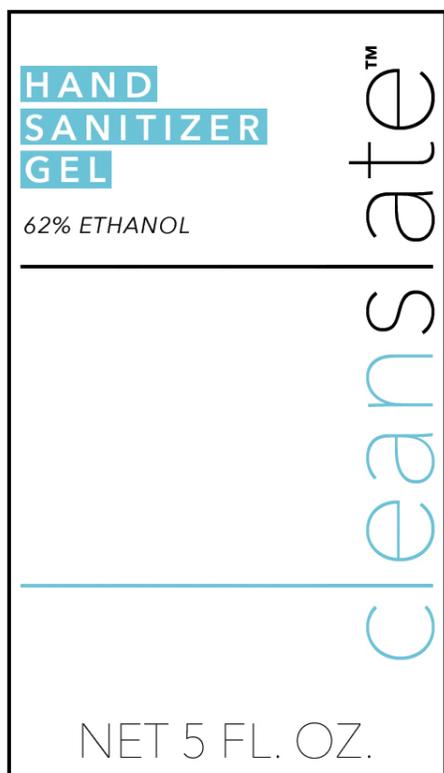
INACTIVE INGREDIENTS

WATER, TRIETHANOLAMINE, CARBOMER, GLYCERIN, PROPYLENE GLYCOL, ALOE BARBADENSIS EXTRACT, TOCOPHERYL ACETATE

Package Label - Principal Display Panel

150 mL NDC: 75601-0001-1

FRONT



7 cm

4 cm

BACK

DRUG FACTS	
ACTIVE INGREDIENT	PURPOSE
ETHANOL 62.0%.....	ANTISEPTIC
USES	
<ul style="list-style-type: none"> • TO HELP REDUCE BACTERIA ON HANDS • WHEN WATER & SOAP ARE NOT AVAILABLE 	
WARNINGS	
<ul style="list-style-type: none"> • FOR EXTERNAL USE ONLY • KEEP OUT OF EYES • FLAMMABLE, KEEP AWAY FROM HEAT OR FLAME 	
DO NOT USE	
<ul style="list-style-type: none"> • ON CHILDREN LESS THAN 2 YEARS OF AGE • ON OPEN SKIN WOUNDS 	
KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CALL A POISON CONTROL CENTER RIGHT AWAY.	
DIRECTIONS:	
<ul style="list-style-type: none"> • APPLY AS NEEDED INTO PALM OF HANDS, RUB HANDS TOGETHER UNTIL DRY • SUPERVISE CHILDREN UNDER 6 YEARS OLD 	
INACTIVE INGREDIENTS:	
WATER, TRIETHANOLAMINE, CARBOMER, GLYCERIN, PROPYLENE GLYCOL, ALOE BARBADENSIS EXTRACT, TOCOPHERYL ACETATE	

7 cm

DISTRIBUTED BY:
PUNCH STUDIO
6025 W. SLAUSON AVE
CULVER CITY, CA 90230

4 cm

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75601-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	93 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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GLYCERIN (UNII: PDC6A3C0OX)	0.3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	55.707 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.0015 mL in 100 mL
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.0015 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.15 mL in 100 mL
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.42 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.42 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75601-0001-1	150 mL in 1 BOTTLE, PUMP; 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 - Punch Studio, LLC (843912440)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Pretty Tourism Manufacture Co., Ltd.		553193489	manufacture(75601-0001)

Establishment

Name	Address	ID/FEI	Business Operations
Punch Studio, LLC		843912440	relabel(75601-0001)

Revised: 1/2022

Punch Studio, LLC