

INSTANT HAND SANITIZER- alcohol gel
Hydrox Laboratories

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

Drug Facts

Active ingredient

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Uses

- hand sanitizer to help reduce bacteria on the skin that could cause disease

Warnings

Flammable. Keep away from fire or flame

For external use only - hands.

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a physician if skin irritation or rash develops.

Keep out of reach of children. If accidentally ingested, seek medical help or contact a Poison Control Center immediately.

Directions

- place enough product in your palm to thoroughly cover your hands
- rub hands together briskly until dry
- children under 6 years of age should be supervised when using this product

Other Information

- store at normal room temperature
- may discolor certain fabrics
- may be harmful to wood finishes and plastics

Inactive ingredients

carbomer, fragrance, glycerin, isopropyl alcohol, isopropyl myristate, propylene glycol, purified water, tocopheryl acetate, aloe vera gel, AMP-95

MFG BY: HYDROX LABORATORIES
825 Tollgate Road ELGIN, IL 60123

PRINCIPAL DISPLAY PANEL

NDC 10565-076-04

**Hydrox
Laboratories**

**INSTANT
HAND
SANITIZER**
*with moisturizers
aloe & vitamin E*

**KILLS 99.9%
OF GERMS***

4 FL OZ 118 mL

Made in USA

NDC 10565-076-04

Hydrox
Laboratories

**INSTANT
HAND
SANITIZER**
honey scented
*with moisturizers
aloe & vitamin E*

**KILLS 99.9%
OF GERMS***

**4 FL OZ (118 mL)
Made in USA**

0 21599 32114 7 1-07-14650C

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v.....	Antiseptic

Uses ■ hand sanitizer to help reduce bacteria on the skin that could cause disease

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Other Information
■ store at normal room temperature ■ may discolor certain fabrics ■ may be harmful to wood finishes and plastics

Inactive ingredients Purified Water, Isopropyl Alcohol, Propylene Glycol, Fragrance, Aloe Barbadensis Leaf Juice (Decolorized), Carbomer, Glycerin, Aminomethyl Propanol, Isopropyl Myristate, Tocopheryl Acetate

***Effective at eliminating 99.9% of many common harmful germs and bacteria.**
MFG BY: HYDROX LABORATORIES
ELGIN, IL 60123 • www.hydroxlabs.com

INSTANT HAND SANITIZER

alcohol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:10565-076

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
Carbomer Homopolymer Type C (UNII: 4Q93RCW27E)	
Glycerin (UNII: PDC6A3C0OX)	
Isopropyl Alcohol (UNII: ND2M416302)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	
Alpha-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Aminomethylpropanol (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10565-076-02	59 mL in 1 CYLINDER; Type 0: Not a Combination Product	01/09/2012	
2	NDC:10565-076-04	118 mL in 1 CYLINDER; Type 0: Not a Combination Product	01/09/2012	
3	NDC:10565-076-08	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/09/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333A	01/09/2012	

Labeler - Hydrox Laboratories (025164302)**Registrant** - Hydrox Laboratories (025164302)**Establishment**

Name	Address	ID/FEI	Business Operations
Hydrox Laboratories		025164302	MANUFACTURE(10565-076) , label(10565-076) , pack(10565-076)