HYGIENI-KLEAN HAND SANITIZER GEL LAVENDER- ipa gel Custom Chemical Services, 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.

Active Ingredients

Isopropanol 75% v/v

Purpose

Antibacterial

Uses Hand sanitizer to help reduce bacteria on the skin. Recommended for repeated use.

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

When using this product avoid contact with eyes, ears, and mouth. In case of contact with eyes, flush eyes with water immediately. Avoid contact with broken skin. Discontinue use if irritation or redness develops. If condition persists, consult a doctor.

Keep out of reach of children. Children should only use this product under adult supervison. Do not drink. Not edible. In case of accidential ingestion, seek professional assistance or contact a Poison Control Center immediately.

Other Information Store under 105°F.

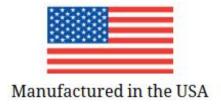
Directions Place hand sanitizer in your palm, thoroughly cover hands, including between fingers, under fingernails, and around wrists. Rub briskly until dry. No rinsing required.

Inactive Ingredients Purified water, Glycerin USP, PEG-600, Carbomer, Fragrance



LAVENDER SCENT

'WHEN YOU NEED THE BEST CLEAN'



HYGIENI-KLEAN HAND SANITIZER GEL LAVENDER

ipa gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78174-021	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII: ND2M416302)	ISOPROPYL ALCOHOL	75.015 L in 100 L	

Inactive Ingredients		
In	gredient Name	Strength

GLYCERIN (UNII: PDC6A3C0OX)	0.067 L in 100 L
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	0.0409 L in 100 L
AMMONIUM POLYACRYLOYLDIMETHYL TAURATE (55000 MPA.S) (UNII: F01RIY4371)	0.3974 in 100 L
water (UNII: 059QF0KO0R)	24.398 L in 100 L
FRAGRANCE LAVENDER ORC1800979 (UNII: 1B40MIN2W5)	0.0818 in 100 L

# Item Code	Packaging				
1 021-01 Product 01/06/2021 2 NDC:78174- 021-02 0.946353 L in 1 BOTTLE; Type 0: Not a Combination Product 01/06/2021 3 NDC:78174- 021-03 0.473176 L in 1 BOTTLE; Type 0: Not a Combination Product 01/06/2021 4 NDC:78174- 021-04 0.354882 L in 1 BOTTLE; Type 0: Not a Combination Product 01/06/2021 5 NDC:78174- 021-05 0.236588 L in 1 BOTTLE; Type 0: Not a Combination Product 01/06/2021 6 NDC:78174- 021-06 0.118294 L in 1 BOTTLE; Type 0: Not a Combination Product 01/06/2021 7 NDC:78174- 0.0591471 L in 1 BOTTLE; Type 0: Not a 01/06/2021	#	Item Code	Package Description		_
2 021-02 Product 01/06/2021 3 NDC:78174- 0.473176 L in 1 BOTTLE; Type 0: Not a Combination 01/06/2021 4 NDC:78174- 0.354882 L in 1 BOTTLE; Type 0: Not a Combination 01/06/2021 5 NDC:78174- 0.236588 L in 1 BOTTLE; Type 0: Not a Combination 01/06/2021 6 NDC:78174- 0.118294 L in 1 BOTTLE; Type 0: Not a Combination 01/06/2021 7 NDC:78174- 0.0591471 L in 1 BOTTLE; Type 0: Not a Combination 01/06/2021	1			01/06/2021	
4 NDC:78174- 021-04 0.354882 L in 1 BOTTLE; Type 0: Not a Combination Product 01/06/2021 5 NDC:78174- 021-05 0.236588 L in 1 BOTTLE; Type 0: Not a Combination Product 01/06/2021 6 NDC:78174- 021-06 0.118294 L in 1 BOTTLE; Type 0: Not a Combination Product 01/06/2021 7 NDC:78174- 0.0591471 L in 1 BOTTLE; Type 0: Not a 01/06/2021	2			01/06/2021	
6 NDC:78174- 021-06 0.236588 L in 1 BOTTLE; Type 0: Not a Combination Product 01/06/2021 6 NDC:78174- 021-06 0.118294 L in 1 BOTTLE; Type 0: Not a Combination Product 01/06/2021 7 NDC:78174- 0.0591471 L in 1 BOTTLE; Type 0: Not a 01/06/2021	3	NDC:78174- 021-03		01/06/2021	
6 NDC:78174- 021-06 0.118294 L in 1 BOTTLE; Type 0: Not a Combination Product 01/06/2021 7 NDC:78174- 0.0591471 L in 1 BOTTLE; Type 0: Not a 01/06/2021	4			01/06/2021	
021-06 Product 01/06/2021 7 NDC:78174- 0.0591471 L in 1 BOTTLE; Type 0: Not a 01/06/2021	5			01/06/2021	
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	6			01/06/2021	
021-07 Combination Product	7	NDC:78174- 021-07	0.0591471 L in 1 BOTTLE; Type 0: Not a Combination Product	01/06/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/06/2021	

Labeler - Custom Chemical Services, LLC (078305908)

Establishment				
Name	Address	ID/FEI	Business Operations	
Custom Chemical Services, LLC		078305908	manufacture(78174-021)	

Revised: 2/2021 Custom Chemical Services, LLC