

HYGIENI-KLEAN HAND SANITIZER GEL- 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 supervision. Do not drink. Not edible. In case of accidental 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



Hygieni-Klean

Hand Sanitizer Gel

'WHEN YOU NEED THE BEST CLEAN'



Manufactured in the USA

1 Gallon (128 fl. oz.)



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78 174-0 19
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75.0128 L in 100 L

Inactive Ingredients

Ingredient 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)	24.4820 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78 174-0 19-01	3.78541 L in 1 JUG; Type 0: Not a Combination Product	01/03/2021	
2	NDC:78 174-0 19-02	0.946353 L in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2021	
3	NDC:78 174-0 19-03	0.473176 L in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2021	
4	NDC:78 174-0 19-04	0.354882 L in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2021	
5	NDC:78 174-0 19-05	0.236588 L in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2021	
6	NDC:78 174-0 19-06	0.118294 L in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2021	
7	NDC:78 174-0 19-07	0.0591471 L in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/03/2021	

Labeler - Custom Chemical Services, LLC (078305908)**Establishment**

Name	Address	ID/FEI	Business Operations
Custom Chemical Services, LLC		078305908	manufacture(78 174-0 19)

