

**HYGIENI-KLEAN HAND SANITIZER FLUID FRESH- ipa liquid**  
**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.*

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**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, Fragrance

01 - 1 Gallon:



# Hygieni-Klean Hand Sanitizer Fluid

**FRESH SCENT**

**'WHEN YOU NEED THE BEST CLEAN'**



Manufactured in the USA

1 Gallon (128 fl. oz.)

02 - 32 oz:



# Hygieni-Klean Hand Sanitizer Fluid

**FRESH SCENT**

**'WHEN YOU NEED THE BEST CLEAN'**



Manufactured in the USA

32 Oz.

03 - 16 oz:

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Isopropanol 75% v/v	Antibacterial
<b>Uses</b> Hand sanitizer to help reduce bacteria on the skin. Recommended for repeated use.	
<b>Warning</b> Flammable. Keep away from fire or flame. For external use only.	
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<b>Other Information</b> Store under 105°F	
<b>Directions</b> Place hand sanitizer in your palm, thoroughly cover hands, including between fingers, under fingernails, and around wrists. Rub briskly until dry. No rinsing required.	
<b>Inactive Ingredients</b> Purified Water, Glycerin USP PEG-600, Fragrance	
<b>PACKAGED &amp; DISTRIBUTED BY</b> Custom Chemical Services, LLC 8230 FM 2004 Hitchcock, TX 77563 (409) 925-7818	

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Isopropanol 75% v/v	Antibacterial
<b>Uses</b> Hand sanitizer to help reduce bacteria on the skin. Recommended for repeated use.	
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# Hygieni-Klean Hand Sanitizer Fluid

**FRESH SCENT**

**'WHEN YOU NEED THE BEST CLEAN'**



Manufactured in the USA

16 Oz.

04 - 12 oz:



# Hygieni-Klean Hand Sanitizer Fluid

**FRESH SCENT**

**'WHEN YOU NEED THE BEST CLEAN'**



Manufactured in the USA

12 Oz.

05 - 8 oz:

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Isopropanol 75% v/v	Antibacterial
<b>Uses</b> Hand sanitizer to help reduce bacteria on the skin. Recommended for repeated use.	
<b>Warning</b> Flammable. Keep away from fire or flame. For external use only.	
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<b>PACKAGED &amp; DISTRIBUTED BY</b> Custom Chemical Services, LLC 8230 FM 2004 Hitchcock, TX 77563 (409) 925-7818	

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
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# Hygieni-Klean Hand Sanitizer Fluid

**FRESH SCENT**

**'WHEN YOU NEED THE BEST CLEAN'**



Manufactured in the USA

8 Oz.

06 - 4 oz:



# Hygieni-Klean Hand Sanitizer Fluid

**FRESH SCENT**

**'WHEN YOU NEED THE BEST CLEAN'**



Manufactured in the USA

4 Oz.

07 - 2 oz:

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Isopropanol 75% v/v	Antibacterial
<b>Uses</b> Hand sanitizer to help reduce bacteria on the skin. Recommended for repeated use.	
<b>Warning</b> Flammable. Keep away from fire or flame. For external use only.	
<b>When using this product</b> 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.	
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<b>Directions</b> Place hand sanitizer in your palm, thoroughly cover hands, including between fingers, under fingernails, and around wrists. Rub briskly until dry. No rinsing required.	
<b>Inactive Ingredients</b> Purified Water, Glycerin USP PEG-600, Fragrance	
<b>PACKAGED &amp; DISTRIBUTED BY</b> Custom Chemical Services, LLC 8230 FM 2004 Hitchcock, TX 77563 (409) 925-7818	

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Isopropanol 75% v/v	Antibacterial
<b>Uses</b> Hand sanitizer to help reduce bacteria on the skin. Recommended for repeated use.	
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<b>Other Information</b> Store under 105°F	
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<b>Inactive Ingredients</b> Purified Water, Glycerin USP PEG-600, Fragrance	
<b>PACKAGED &amp; DISTRIBUTED BY</b> Custom Chemical Services, LLC 8230 FM 2004 Hitchcock, TX 77563 (409) 925-7818	



# Hygieni-Klean

## Hand Sanitizer Fluid

**FRESH SCENT**

**'WHEN YOU NEED THE BEST CLEAN'**



Manufactured in the USA

2 Oz.

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Isopropanol 75% v/v	Antibacterial
<b>Uses</b> Hand sanitizer to help reduce bacteria on the skin. Recommended for repeated use.	
<b>Warning</b> Flammable. Keep away from fire or flame. For external use only.	
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<b>PACKAGED &amp; DISTRIBUTED BY</b> Custom Chemical Services, LLC 8230 FM 2004 Hitchcock, TX 77563 (409) 925-7818	

### HYGIENI-KLEAN HAND SANITIZER FLUID FRESH

ipa liquid

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78174-023
<b>Route of Administration</b>	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75.0271 L in 100 L

#### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	0.067 L in 100 L
<b>POLYETHYLENE GLYCOL 600</b> (UNII: NL4J9F21N9)	0.0409 L in 100 L
<b>water</b> (UNII: 059QF0K00R)	24.7832 L in 100 L
<b>FRAGRANCE CUCUMBER ALOE ORC1802955</b> (UNII: FSS3TH6V9M)	0.0818 in 100 L

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:78174-023-01	3.78541 L in 1 JUG; Type 0: Not a Combination Product	04/27/2021	
2	NDC:78174-023-02	0.946353 L in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2021	
3	NDC:78174-023-03	0.473176 L in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2021	
4	NDC:78174-023-04	0.354882 L in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2021	
5	NDC:78174-023-05	0.236588 L in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2021	
6	NDC:78174-023-06	0.118294 L in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2021	
7	NDC:78174-023-07	0.0591471 L in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/27/2021	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Chemical Services, LLC		078305908	manufacture(78174-023)

Revised: 4/2021

Custom Chemical Services, LLC