

## **HAND SANITIZER GEL- alcohol solution**

**AgroChem Inc**

*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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### **Hand Sanitizer Gel**

#### **Active Ingredient(s)**

Ethyl alcohol 70% v/v

#### **Purpose**

Antiseptic, Hand Sanitizer Antimicrobial

#### **Use**

Hand sanitizer to help reduce bacteria on the skin that could cause disease Recommended for repeated use.

#### **Warnings**

For external use only. Flammable. Keep away from heat or flame

#### **Do not use**

- in children less than 2 months of age
- on open skin wounds

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

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

Place enough product in your palm to thoroughly cover your hands Rub hands together briskly until dry

No rinsing required

No towels needed.

#### **Other information**

Do not store above 110°F (43°C). May discolor certain fabrics or surfaces.

## Inactive ingredients

Water (Aqua), Aloe Vera, Propylene Glycol, Carboxethyl Acrylate Crosspolymer, Fragrance, FD&C Blue #1, FD&C Yellow #5

## Hand Sanitizer Gel

### Moisturizing with Aloe

Effective at eliminating more than 99.9% of many common harmful germs & bacteria in as little as 15 seconds.

### Package Label - Principal Display Panel

# Hand Sanitizer Gel

Moisturizing with Aloe.

NDC 17307-1115



Effective at eliminating more than 99.9% of many common harmful germs & bacteria in as little as 15 seconds.

NET CONTENTS: 1 GALLON

LOT#:

DOM:



<b>Drug Facts</b>	
<b>Active ingredient</b> Ethyl alcohol 70% v/v	<b>Purpose</b> Antimicrobial
<b>Uses</b> Hand sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use.	
<b>Warnings</b> Flammable. Keep away from fire or flame. For external use only 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 doctor if irritation or rash appears and lasts. Keep out of reach of children. If swallowed, get medical help or contact a <b>Poison Control Center</b> right away.	
<b>Directions</b> Place enough product in your palm to thoroughly cover your hands. Rub hands together briskly until dry. No rinsing required. No towels needed.	
<b>Other information</b> Do not store above 110°F (43°C). May discolor certain fabrics or surfaces.	
<b>Inactive ingredients</b> Water (Aqua), Aloe Vera, Propylene Glycol, Carboxethyl Acrylate Crosspolymer, Fragrance, FD&C Blue #1, FD&C Yellow #5	
<b>Question or comments?</b> Call 518-226-4850 Monday through Friday 8AM-5:00PM	



# AgroChem

Manufactured By:

AgroChem, Inc. 26 Freedom Way • Saratoga Springs, NY 12866 • (518)226-4850

3780 mL NDC: 17307-1115-3

## HAND SANITIZER GEL

alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17307-1115
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HEPTANAL (UNII: 92N104S3HF)	
WATER (UNII: 059QF0K00R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE (UNII: KBC00G95HI)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17307-1115-1	470 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/27/2020	
2	NDC:17307-1115-2	940 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2020	
3	NDC:17307-1115-3	3780 mL in 1 JUG; Type 0: Not a Combination Product	04/27/2020	
4	NDC:17307-1115-4	18927 mL in 1 DRUM; Type 0: Not a Combination Product	04/27/2020	
5	NDC:17307-1115-5	56781 mL in 1 DRUM; Type 0: Not a Combination Product	04/27/2020	
6	NDC:17307-1115-6	208198 mL in 1 DRUM; Type 0: Not a Combination Product	04/27/2020	
7	NDC:17307-1115-7	1003025 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/27/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/27/2020	

**Labeler** - AgroChem Inc (805427700)

**Registrant** - AgroChem Inc (805427700)

## Establishment

Name	Address	ID/FEI	Business Operations
AgroChem Inc		805427700	manufacture(17307-1115)