# HAND SANITIZER- alcohol spray FIFTEEN DEGREES co.,ltd

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 Fifteen Degrees 80% alcohol

#### Active Ingredient(s)

Alcohol 80% v/v. Purpose: Topical Antimicrobial

#### **Purpose**

Topical Antimicrobial

#### Use

Hand Sanitizer to help reduce bacteria on the skin.

#### Warnings

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

When using this product, do not use in or near 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 Poison Control Center right away.

#### Directions

- Spray a small amount of product into palm of hand.
- Rub thoroughly over all surfaces of both hands.
- Supervise children under 6 years of age when using this product.

#### Other information

- Store between 10-30C (59-86F)
- May discolor certain fabrics or surfaces

#### **Inactive ingredients**

water, glycerin, citrus limon (lemon) peel oil, limonene, citral

#### Package Label - Principal Display Panel

120 mL NDC: 74753-784-12 250 mL NDC: 74753-784-25





## HAND SANITIZER

alcohol spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74753-784	
Route of Administration	TOPICAL			

active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
LEMON OIL (UNII: 19 GRO 824LL)	$0.0323\;mL$ in $100\;mL$		
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	18.45 mL in 100 mL		
CITRAL (UNII: T7EU0O9VPP)	0.0017 mL in 100 mL		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:74753-784-	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/01/2020		
2 NDC:74753-784- 25	250 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/01/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/08/2020		

## Labeler - FIFTEEN DEGREES co.,ltd (694982014)

## **Registrant -** FARMER'S GRAIN KOREA LTD (694439983)

Revised: 1/2021 FIFTEEN DEGREES co.,ltd