# INCREDIBLY CLEAN HAND SANITIZER- alcohol gel JFL Distribution

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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## **Incredibly Clean Hand Sanitizer**

#### **DRUG FACTS**

## **Active Ingredient:**

Alcohol 75% (v/v)

## **Purpose:**

Antiseptic

#### USE(S)

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

#### **WARNINGS**

For external use only. Flammable, keep away from flame.

#### **DO NOT USE**

- On children less than 2 months of age
- On open wounds

## 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 sign of a serious condition.

#### Keep out of reach of children.

if swallowed, get medical help or contact a Poison Control Center right away.

## **DIRECTIONS**

- Place enough product on hands to cover all surfaces.
- Rub hands together until dry.
- For children under 6, use adult supvervision.

#### OTHER INFORMATION

- Store between 15-30 °C( (59-86 °F)
- Avoid freezing and excessive heat above 40 °C (104 °F)

#### **INACTIVE INGREDIENTS:**

WATER, PROPYLENE GLYCOL, CARBOMER, TRIETHANOLAMINE, ALLANTOIN, ALOE BARBADENSIS LEAF JUICE POWDER, BUTYLENE GLYCOL, ARTEMISIA VULGARIS EXTRACT.

## **Package Labeling:**





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#### INCREDIBLY CLEAN HAND SANITIZER

alcohol gel

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76759-003

**Route of Administration TOPICAL** 

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)	

CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
TROLAMINE (UNII: 903K93S3TK)	
ALLANTO IN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

l	Packaging				
l	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1 NI	OC:76759-003-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	05/20/2020		

## Labeler - JFL Distribution (080377004)

Revised: 5/2020 JFL Distribution