

**HAND SANITIZER- alcohol gel**  
**PurCel Labs 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 Ingredient(s)**

Alcohol 70% v/v

**Purpose**

Antiseptic

**Uses**

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 heat or flame.

**Do not use**

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

**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 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.

**Directions**

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using products.

## Other information

- Store below 110°F (43°C).
- Avoid freezing and excessive heat above 104°F (40°C).
- May discolor certain fabrics or surfaces.

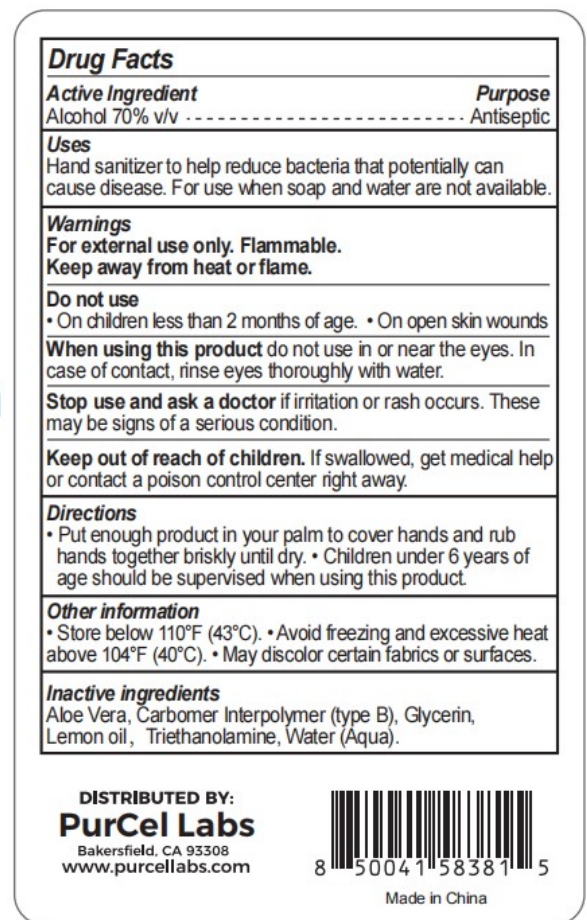
## Inactive ingredients

Aloe Vera, Carbomer Interpolymer (type B), Lemon oil, Glycerin, Triethanolamine, Water (Aqua).

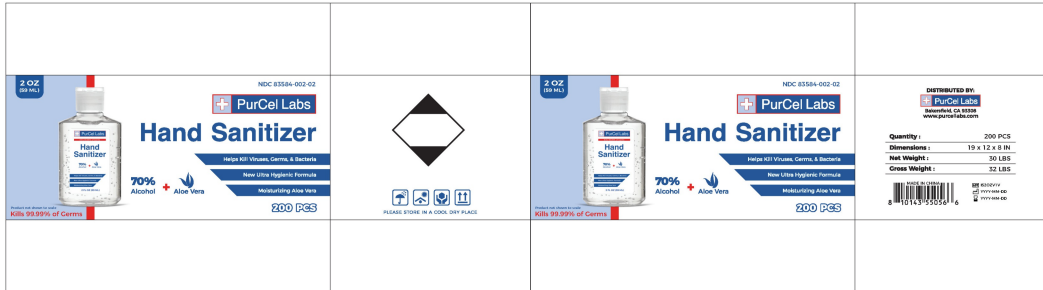
## Package label.principal display panel



45mm



2oz 470x300x210 mm



2708 c 7685 c 483 c



**Kills 99.99% of Germs**

# Hand Sanitizer

**70%**

Alcohol

+



Aloe Vera

Helps Kill Viruses, Germs, & Bacteria

New Ultra Hygienic Formula

Moisturizing Aloe Vera

**4 FL OZ (118 ML)**

**Drug Facts**

Active Ingredient	Purpose
Alcohol 70% v/v	Antiseptic

**Uses**  
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 heat or flame.**

**Do not use**

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

**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 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.

**Directions**


- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product.

**Other information**

- Store below 110°F (43°C).
- Avoid freezing and excessive heat above 104°F (40°C).
- May discolor certain fabrics or surfaces.

**Inactive ingredients**  
Aloe Vera, Carbomer Interpolymer (type B), Glycerin, Lemon oil, Triethanolamine, Water (Aqua).

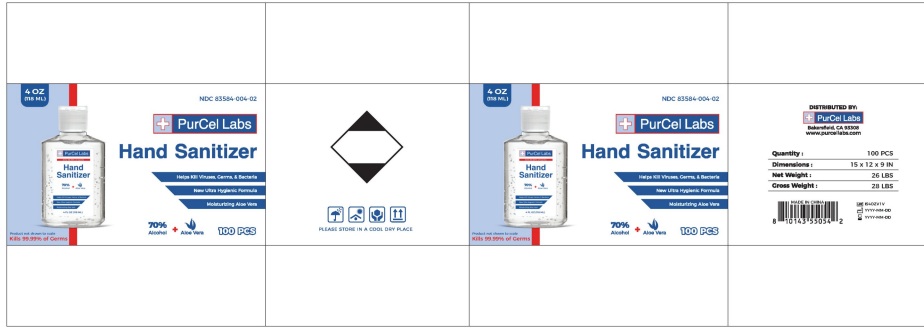
**DISTRIBUTED BY:**  
**PurCel Labs**  
Bakersfield, CA 93308  
www.purcellabs.com



8 5004 158382 2

Made in China

4oz 375x295x235 mm



2708 c 7685 c 483 c

**PurCel Labs**  
Kills 99.99% of Germs

# Hand Sanitizer

Helps Kill Viruses, Germs, & Bacteria  
New Ultra Hygienic Formula  
Moisturizing Aloe Vera

**70% Alcohol** + **Aloe Vera**  
16 FL OZ (473 ML)

**Drug Facts**

**Active Ingredient**  
Alcohol 70% v/v

**Purpose**  
Antiseptic

**Uses**  
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 heat or flame.

**Do not use**  
• On children less than 2 months of age.  
• On open skin wounds.

**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 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.

**Drug Facts (continued)**

**Directions**  
• Put enough product in your palm to cover hands and rub hands together Gently until dry.  
• Children under 6 years of age should be supervised when using this product.

**Other information**  
• Store below 104°F (40°C).  
• Avoid freezing and excessive heat above 104°F (40°C).  
• May discolor certain fabrics or surfaces.

**Inactive ingredients**  
Aloe Vera, Carbomer Interepolymer (type B), Glycerin, Lemon oil, Triethanolamine, Water (Aqua).

**DISTRIBUTED BY:**  
**PurCel Labs**  
Sausalito, CA 94965  
www.purcelabs.com

8 1014355000 9  
Made in China

16oz 535x450x170 mm



2708 c 7685 c 483 c

## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83584-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 mL in 100 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>				<b>Strength</b>
<b>LEMON OIL</b> (UNII: I9GRO824LL)				
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)				
<b>CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 132584PQMO)				
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)				
<b>TRIETHANOLAMINE DODECYLBENZENESULFONATE</b> (UNII: 8HM7ZD48HN)				
<b>WATER</b> (UNII: 059QF0KO0R)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:83584-002-02	200 in 1 CARTON	08/06/2023	
1	NDC:83584-002-01	59 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333E		08/06/2023	

<b>HAND SANITIZER</b>			
alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83584-116
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 mL in 100 mL
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>
<b>LEMON OIL</b> (UNII: I9GRO824LL)			
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)			
<b>CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 132584PQMO)			

132584PQMO)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>TRIETHANOLAMINE DODECYLBENZENESULFONATE</b> (UNII: 8HM7ZD48HN)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83584-116-02	30 in 1 CARTON	08/06/2023	
1	NDC:83584-116-01	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/06/2023	

## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83584-004
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>LEMON OIL</b> (UNII: I9GRO824LL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 132584PQMO)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TRIETHANOLAMINE DODECYLBENZENESULFONATE</b> (UNII: 8HM7ZD48HN)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83584-004-02	100 in 1 BOTTLE, PUMP	08/06/2023	
1	NDC:83584-004-01	118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/06/2023	

**Labeler** - PurCel Labs LLC (127672531)

**Registrant** - Jiangsu Intco Medical Products Co., Ltd (529128686)

### Establishment

Name	Address	ID/FEI	Business Operations
Jiangsu Intco Medical Products Co., Ltd		529128686	manufacture(83584-116, 83584-002, 83584-004)

Revised: 8/2023

PurCel Labs LLC