

**VANITIZER I-200- isopropyl alcohol gel**  
**Vantage Specialties, 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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**Vaneitizer I-200**

**Active Ingredient(s)**

Isopropyl Alcohol 70% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

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.

When using this product keep out of eyes, ears and mouth. 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.

**Do not use**

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

**Directions**

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

**Other information**


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

## Inactive ingredients

glycerin, purified water USP, hydroxypropyl cellulose

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

## Package Label - Principal Display Panel

		
Isopropyl Alcohol Antiseptic, 70% Solution Hand Sanitizer Gel Non-Sterile Solution 1 gallon ( 3.8 liters)		
<b>Drug Facts</b> <span style="color: red;">DRAFT 07/22/2020 not for use</span>		
<b>Active ingredient</b> Isopropyl alcohol 70% v/v.....	<b>Purpose</b> Antiseptic	<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.
<b>Uses</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.		<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame		<b>Directions</b> <ul style="list-style-type: none"> <li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>
<b>Do Not Use</b> <ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wound</li> </ul>		<b>Other Information</b> <ul style="list-style-type: none"> <li>• Store between 15-30 °C (59-86 °F)</li> <li>• Avoid freezing and excessive heat above 40 °C (104 °F)</li> </ul>
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.		<b>Inactive Ingredients:</b> glycerin, water, hydroxypropyl cellulose
Vantage Specialties, Inc.		Lot Number:
3938 Porett Drive, Gurnee, IL 60031		Expiry date:
phone: (847) 244-3410, fax 847-249-6792		NDC number: XXXX-XXXX-XX (to be entered)
www.vantagegrp.com		

## VANITIZER I-200

isopropyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79491-008
<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	70 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDROXYPROPYL CELLULOSE (1200000 WAMW)</b> (UNII: U3JF91U133)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79491-008-01	3800 mL in 1 JUG; Type 0: Not a Combination Product	07/24/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/20/2020	

**Labeler** - Vantage Specialties, Inc. (191349898)**Establishment**

Name	Address	ID/FEI	Business Operations
Vantage Specialties, Inc.		191349898	api manufacture(79491-008)

Revised: 1/2022

Vantage Specialties, Inc.