

## **HELIOS HAND SANITIZER- isopropyl alcohol liquid**

**Pretty Woman 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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### **Hand Sanitizer**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

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

Isopropyl Alcohol 75% 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

### **Do not use**

- in children less than 2 months of age
- on open skin 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 signs of a serious condition.

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

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**

- 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, hydrogen peroxide, purified water USP

**Package Label - Principal Display Panel**

Drug Facts		Ingrédient Médicinal	
Active ingredient(s)	Purpose	Ingrédient (s) actif (s)	Objectif
Isopropyl alcohol 75% v/v.....	Antiseptic	Alcool isopropylique 75% v/v.....	Antiseptique
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.		<b>Usage (s)</b> Désinfectant pour les mains pour aider à réduire les bactéries qui peuvent potentiellement causer des maladies. À utiliser lorsque le savon et l'eau ne sont pas disponibles.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.		<b>Précautions</b> Pour usage externe seulement. Inflammable. Tenir loin de la chaleur ou des flammes.	
<b>Do not use</b> • On children less than 2 months of age • On open skin wounds		<b>Ne pas utiliser</b> • Sur les enfants de moins de 2 mois • Sur les plaies cutanées ouvertes	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eye, rinse eyes thoroughly with water.		<b>Lors de l'usage de ce produit</b> éviter le contact avec les yeux, les oreilles et la bouche. Au cas de contact avec les yeux rincer abondamment avec de l'eau.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.		<b>Arrêter l'usage et demander à un docteur</b> en cas d'irritation ou d'éruption cutanée. Ceux-ci peuvent être signes d'un état grave.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact at Poison Control Center right away.		<b>Garder hors de la portée des enfants.</b> Si le produit est avalé, obtenir de l'aide médicale ou contacter immédiatement un centre antipoison.	
<b>Directions</b> • 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.		<b>Mode d'emploi</b> • Placer suffisamment de produit sur les mains pour couvrir toutes les surfaces. Frotter les mains ensemble jusqu'à ce qu'elles soient sèches. • Surveiller les enfants de moins de 6 ans lors de l'usage de ce produit pour éviter d'avaler.	
<b>Other information</b> • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)		<b>Autre information</b> • Conserver entre 15-30°C (59-86°F) • Éviter congélation gel et chaleur au-dessus de 40°C (104°F)	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP		<b>Ingrédients inactifs</b> glycérine, peroxyde d'hydrogène, eau purifiée USP	

100 ml NDC: 74140-100-02

HELIOS HAND SANITIZER			
isopropyl alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74140-100

**Route of Administration** TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74140-100-02	100 mL in 1 BOTTLE, SPRAY; 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** - Pretty Woman LLC (008134996)

### Establishment

Name	Address	ID/FEI	Business Operations
Pretty Woman LLC		008134996	manufacture(74140-100) , pack(74140-100) , label(74140-100)

Revised: 4/2020

Pretty Woman LLC