

# **NOVAPUR CREAMY MOISTURIZING HAND SANITIZER- benzalkonium chloride gel**

**Les Entreprises Stefmar 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.*

-----

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)**

Benzalkonium Chloride 0.15% w/w

## **Purpose**

Antimicrobial

## **Use**

For hand-washing to decrease bacteria on the skin, only when water is not available. For occasional personal domestic use.

## **Warnings**

For external use only.

## **Do not use**

- in children less than 2 years old
- on open wounds

When using this product

- do not get into eyes.
- if contact occurs, rinse thoroughly with water.

.

Stop use and ask a doctor if  
irritation and redness develops.

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

## **Directions**

Directions

- Supervise children when they use this product
- Rub thoroughly into hands for at least 30 seconds and allow to dry

## **Other information**

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

## **Inactive ingredients**

Aqua, Caprylic/Capric Triglyceride, Propylene glycol, Phenoxyethanol, Sodium polyacrylate, Ethylhexylglycerin, Aloe barbadensis leaf juice, Tocopherol

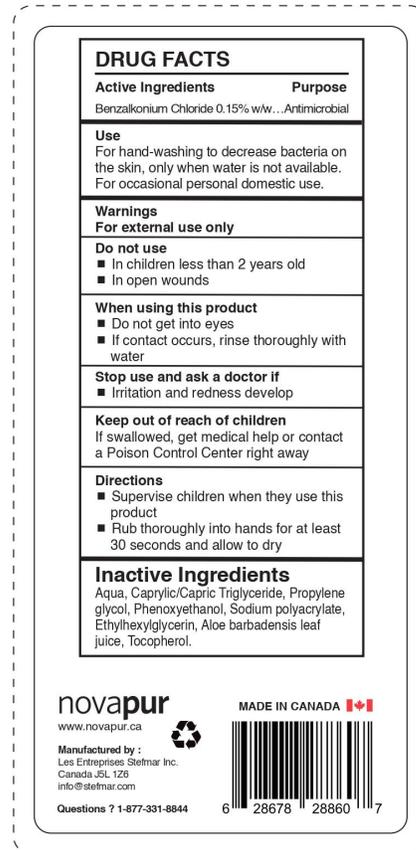
## **Package Label - Principal Display Panel**

# STEFMAR



500ml Bullet  
FRONT LABEL

4.875"H x 2.25"W  
0.1" RADIUS  
.125" print area  
.125" bleed



500ml Bullet  
BACK LABEL

4.875"H x 2.25"W  
0.1" RADIUS  
.125" print area  
.125" bleed

UPC: 80% HORIZONTAL or VERTICAL

500 mL NDC: 71316-100-50

150 mL NDC: 71316-100-15

NO SAC : \_\_\_\_\_  
 DOCKET No. : TEMPLATE STEFMAR

NO PRODUCTION : \_\_\_\_\_  
 PRODUCTION No. : TUBE ? MM

6.25" x 5.875"  DIRECTION

Lot XXXXXXXX      EXP YYYY/MM

**DRUG FACTS**

Active Ingredients	Purpose
Benzalkonium Chloride 0.15% w/w...	Antimicrobial

**Use**  
 For hand-washing to decrease bacteria on the skin, only when water is not available. For occasional personal domestic use.

**Warnings**  
 For external use only

**Do not use**

- In children less than 2 years old
- In open wounds

**When using this product**

- Do not get into eyes
- If contact occurs, rinse thoroughly with water

**Stop use and ask a doctor if**

- Irritation and redness develop

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

**Directions**

- Supervise children when they use this product
- Rub thoroughly into hands for at least 30 seconds and allow to dry

**Inactive Ingredients**  
 Aqua, Caprylic/Capric Triglyceride, Propylene glycol, Phenoxyethanol, Sodium polyacrylate, Ethylhexylglycerin, Aloe barbadensis leaf juice, Tocopherol.

**novapur**  
**CREAMY  
 MOISTURIZING  
 HAND SANITIZER**

**Alcohol-free**

Nourishing  
**2 IN 1**  
 Protecting

5.1 fl oz (150 mL)  
 NDC 71316-100-15

OVERLAP AREA / NO VARNISH

novapur

www.novapur.ca

MADE IN CANADA 



Manufactured by :  
 Les Entreprises Stefmar Inc.  
 Canada J0L 1Z6  
 info@stefmar.com



Questions ? 1-877-331-8844

6 28678 28852 2



Q-MARK



MATRICE  
 DIE



ESPACE RÉQUISITAIRE POUR TEXTE  
 PRINTABLE SPACE FOR TEXT



ESPACE SANS VERNIS  
 NONE VARNISH SPACE

benzalkonium chloride gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71316-100
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.15 g in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SODIUM POLYACRYLATE (8000 MW)</b> (UNII: 285CYO341L)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:71316-100-15	150 mL in 1 TUBE; Type 0: Not a Combination Product	08/23/2021	
2	NDC:71316-100-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/23/2021	
3	NDC:71316-100-04	40 mL in 1 TUBE; Type 0: Not a Combination Product	08/23/2021	
4	NDC:71316-100-08	80 mL in 1 TUBE; Type 0: Not a Combination Product	08/23/2021	
5	NDC:71316-100-90	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/23/2021	
6	NDC:71316-100-95	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/23/2021	

## Marketing Information

<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	part333A	08/23/2021	

**Labeler** - Les Entreprises Stefmar Inc (240496385)

## Establishment

Name	Address	ID/FEI	Business Operations
Les Entreprises Stefmar Inc		240496385	manufacture(71316-100)

Revised: 8/2021

Les Entreprises Stefmar Inc