### PROSANA SKIN AND BODY- ethanol gel Bodywell Natural Skin Care 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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### **Prosana Skin and Body**

### **Active Ingredients**

Fthanol 70%

### **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•** in children less than 2 months of age.

• on open skin or wounds.

**When using this product** keep out of eyes, earsand mouth. In case of contact with eyes, rinseeyes thoroughly with water.

## Stop use and ask a doctor

- if irritation 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)

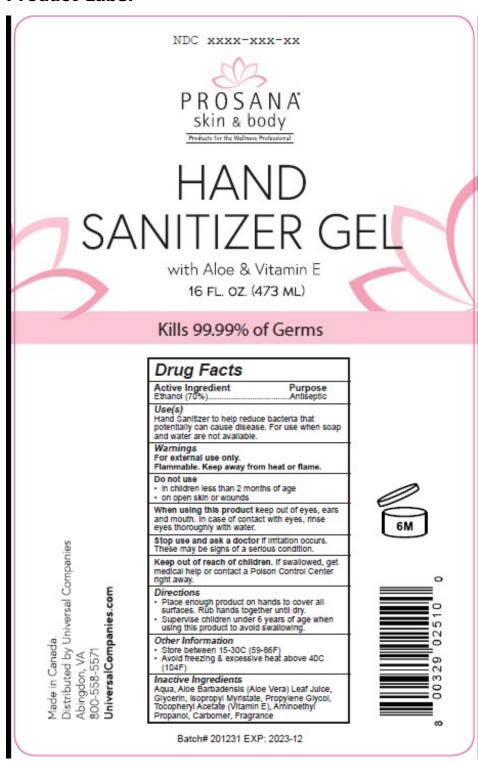
Avoid freezing & excessive heat above 40C(104F)

### Inactive Ingredients.

Aqua, Aloe Barbadensis (Aloe Vera) Leaf Juice, Glycerin, Isopropyl Myristate, Propylene Glycol,

Tocopheryl Acetate (Vitamin E), Aminoethyl Propanol, Carbomer, Fragrance.

### **Product Label**





Drug	<b>Facts</b>
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Made in Canada. Distributed by Universal Companies Abingdon, VA. 800-558-5571 UniversalCompanies.com

### PROSANA SKIN AND BODY

ethanol gel

### **Product Information**

**Product Type** HUMAN OTC DRUG Item Code (Source) NDC:81441-001

**TOPICAL Route of Administration** 

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

**Basis of Strength** Strength **Ingredient Name** ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M) ALCOHOL 70 mL in 100 mL

### **Inactive Ingredients Ingredient Name** Strength WATER (UNII: 059QF0KO0R) ALOE VERA LEAF (UNII: ZY81Z83H0X) **GLYCERIN** (UNII: PDC6A3C0OX)

ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS) PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

**CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)** 

FRAGRANCE FLORAL ORC0902236 (UNII: R66Z4YW3X0)

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:81441- 001-01	473 mL in 1 PACKAGE; Type 0: Not a Combination Product	01/04/2021		
2	NDC:81441- 001-02	3785 mL in 1 PACKAGE; Type 0: Not a Combination Product	02/09/2021		
3	NDC:81441- 001-03	946 mL in 1 PACKAGE; Type 0: Not a Combination Product	02/09/2021		
4	NDC:81441- 001-04	473 mL in 1 PACKAGE; Type 0: Not a Combination Product	02/09/2021		
5	NDC:81441- 001-05	177 mL in 1 PACKAGE; Type 0: Not a Combination Product	02/09/2021		
6	NDC:81441- 001-06	88 mL in 1 PACKAGE; Type 0: Not a Combination Product	02/09/2021		
7	NDC:81441- 001-07	3 mL in 1 PACKET; Type 0: Not a Combination Product	04/21/2023		

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part333A	01/04/2021					

# Labeler - Bodywell Natural Skin Care Inc (201162026)

Establishment							
Na me	Address	ID/FEI	<b>Business Operations</b>				
Bodywell Natural Skin Care Inc		201162026	manufacture(81441-001)				

Revised: 4/2023 Bodywell Natural Skin Care Inc