

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.

Prosana Skin and Body

Active Ingredients

Ethanol 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, ears and mouth. In case of contact with eyes, rinse eyes 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

NDC xxxx-xxx-xx



**HAND
SANITIZER GEL**

with Aloe & Vitamin E
16 FL. OZ. (473 ML)

Kills 99.99% of Germs

Drug Facts	
Active Ingredient Ethanol (70%).....	Purpose Antiseptic
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Made in Canada.
Distributed by Universal Companies
Abingdon, VA
800-558-5571
UniversalCompanies.com

Batch# 201231 EXP: 2023-12



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PROSANA SKIN AND BODY

ethanol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81441-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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: 0RE8K4LNJS)	
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

Name	Address	ID/FEI	Business Operations
Bodywell Natural Skin Care Inc		201162026	manufacture(81441-001)

Revised: 4/2023

Bodywell Natural Skin Care Inc