

PROSANA SKIN AND BODY- ethanol spray
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.

- Spray 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.

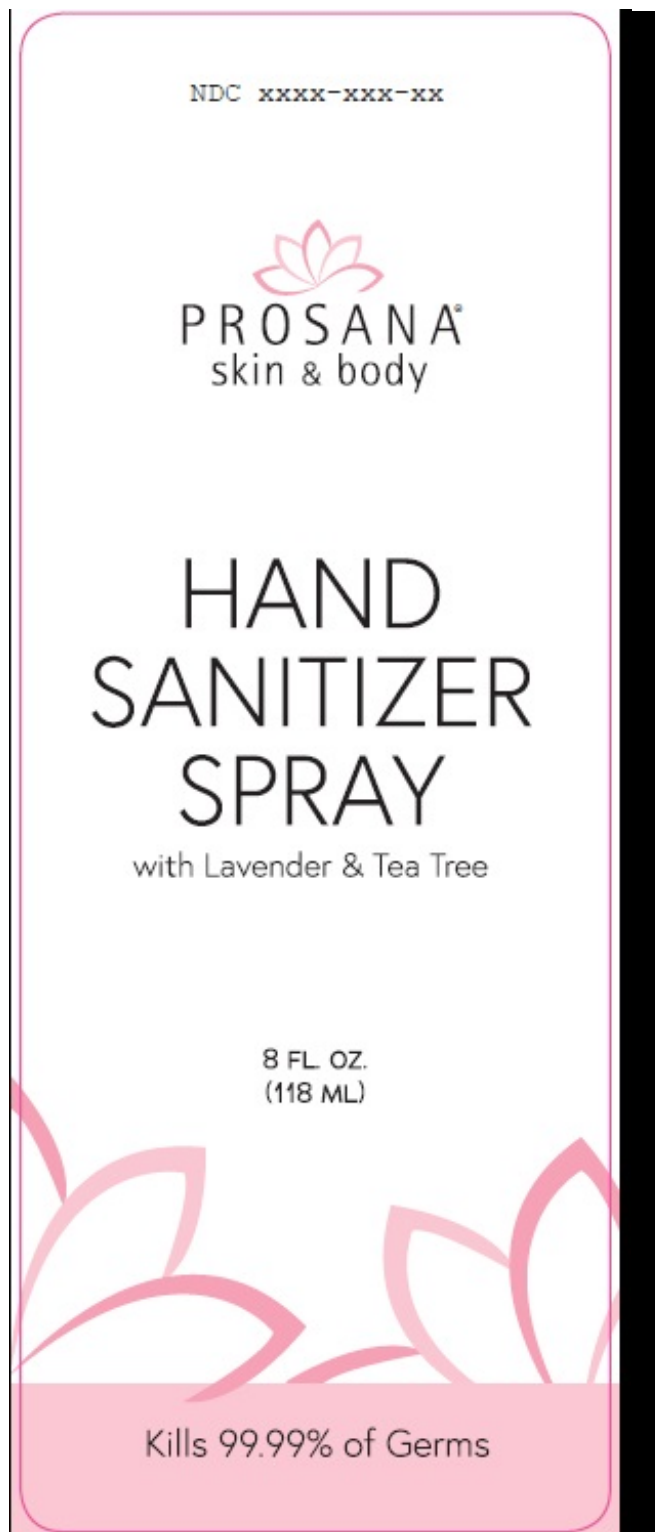
- Store between 15-30C (59-86F).

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

Inactive Ingredients


Aqua, Aloe Barbadensis (Aloe Vera) Leaf Juice, Glycerin, Tocopherol (Vitamin E), Lavandula Angustifolia (Lavender) Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil

Product Image




Drug Facts	
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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • Spray 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. 	
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Made in Canada
Dist. By Universal Companies
Abingdon, VA
800-558-5571
UniversalCompanies.com



Batch# 201231 EXP: 2023-12



PROSANA SKIN AND BODY

ethanol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81441-002
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)	
TOCOPHEROL (UNII: R0ZB2556P8)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
TEA TREE OIL (UNII: VIF565UC2G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81441-002-01	118 mL in 1 PACKAGE; Type 0: Not a Combination Product	01/04/2021	
2	NDC:81441-002-02	3785 mL in 1 PACKAGE; Type 0: Not a Combination Product	02/09/2021	
3	NDC:81441-002-03	236 mL in 1 PACKAGE; Type 0: Not a Combination Product	02/09/2021	
4	NDC:81441-002-04	118 mL in 1 PACKAGE; Type 0: Not a Combination Product	02/09/2021	

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(81441-002)

