

PRANAROM GOOD SAMARITAN ALCOHOL ANTISEPTIC- alcohol liquid
Veriditas Botanicals 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.

Hand Sanitizer 2

Active Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Helps reduce bacteria on skin. Recommended for repeated use.

Warnings

For external use only.

Other information

- Flammable. Keep away from fire, sparks, and sources of ignition.
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

When using this product Keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin.

Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.

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

Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry. For children under 6, use adult supervision. Not recommended for infants.

Inactive ingredients

Water, Glycerin,* Ricinus communis (Castor) Oil,* Cinnamomum verum (Cinnamon) Leaf Oil,* Citrus limon (Lemon) Peel Oil,* Rosmarinus officinalis (Rosemary) Leaf Oil,* Eucalyptus radiata Leaf Oil,* Eugenia caryophyllus (Clove) Bud Oil,* Cinnamomum zeylanicum (Cinnamon) Bark Oil.*

Package Label - Principal Display Panel

PRANAROM

HAND SANITIZER

Moisturizing Formula

Non-Sterile Solution

GOOD SAMARITAN

Alcohol antiseptic 70% topical solution

Net wt xx fl. oz | xx ml

*CERTIFIED ORGANIC

pranarom.us

Minneapolis, MN 55427

Certified Organic

by ECOCERT ICO.

<p>Drug Facts</p> <p>Active ingredient Purpose Ethyl Alcohol 70% Antiseptic</p> <p>Uses Helps reduce bacteria on skin. Recommended for repeated use.</p> <p>Warnings • For external use only</p> <ul style="list-style-type: none"> • Flammable, keep away from fire, sparks & sources of ignition. • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F) <p>When using this product. Keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin.</p> <p>Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.</p> <p>Directions • Place enough product on hands to cover all surfaces • Rub hands together until dry • For children under 6, use adult supervision • Not recommended for infants</p> <p>Inactive ingredients Water, Glycerin,* Ricinus communis (Castor) Oil,* Cinnamomum verum (Cinnamon) Leaf Oil,* Citrus limon (Lemon) Peel Oil,* Rosmarinus officinalis (Rosemary) Leaf Oil,* Eucalyptus radiata Leaf Oil,* Eugenia caryophyllus (Clove) Bud Oil,* Cinnamomum zeylanicum (Cinnamon) Bark Oil.*</p>	 <p>PRANAROM </p> <p>HAND SANITIZER</p> <p>Moisturizing Formula Non-sterile solution</p> <p>GOOD SAMARITAN</p> <p>Alcohol antiseptic 70% topical solution Net wt 1.0 fl oz 30 ml</p>	<p>*CERTIFIED ORGANIC</p>  <p>8 59493 02172 2</p> <p></p> <p>pranarom.us Minneapolis, MN 55427</p> <p>Certified Organic by ECOCERT CO.</p>
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PRANAROM GOOD SAMARITAN ALCOHOL ANTISEPTIC

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78596-002
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
CLOVE OIL (UNII: 578389D6D0)	
EUCALYPTUS RADIATA LEAF OIL (UNII: SB9A7612BD)	

CINNAMON BARK OIL (UNII: XE54U569EC)
CINNAMON LEAF OIL (UNII: S92U8SQ71V)
LEMON OIL (UNII: I9GRO824LL)
ROSEMARY OIL (UNII: 8LGU7VM393)
WATER (UNII: 059QF0KO0R)
GLYCERIN (UNII: PDC6A3C0OX)
CASTOR OIL (UNII: D5340Y2I9G)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78596-002-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/08/2020	

Labeler - Veriditas Botanicals LLC (174766845)

Registrant - Veriditas Botanicals LLC (174766845)

Establishment

Name	Address	ID/FEI	Business Operations
Veriditas Botanicals LLC		174766845	manufacture(78596-002) , analysis(78596-002) , label(78596-002) , pack(78596-002) , relabel(78596-002) , repack(78596-002)

Revised: 9/2020

Veriditas Botanicals LLC