

VIOLA ROUGE ANTISEPTIC HAND RUB 75 PERCENT- alcohol solution
DELICATE COSMETICS 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.

VIOLA ROUGE ANTISEPTIC HAND RUB

ACTIVE INGREDIENT

ISOPROPYL ALCOHOL 75% V/V

PURPOSE

ANTISEPTIC

USES

HEALTH CARE PERSONNEL HAND RUB TO HELP REDUCE BACTERIA THAT POTENTIALLY CAN CAUSE DISEASE. HAND SANITIZER TO HELP REDUCE BACTERIA ON THE SKIN IF SOAP AND WATER ARE NOT AVAILABLE.

WARNINGS

FOR EXTERNAL USE ONLY. FLAMMABLE. KEEP AWAY FROM HEAT OR FLAME.

DO NOT USE

- ON CHILDREN LESS THAN 2 MONTHS OF AGE
- ON OPEN SKIN 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 A DOCTOR IF IRRITATION OR RASH 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 15-30°C (59-86°F)
- AVOID FREEZING AND EXCESSIVE HEAT ABOVE 40°C (104°F)

INACTIVE INGREDIENTS

PURIFIED WATER USP, GLYCERIN, HYDROGEN PEROXIDE

VIOLA
ROUGE.

Isopropyl Alcohol
Antiseptic 75%
Topical Solution
With vegetable-based glycerin

Antiseptic Hand Rub
Non-sterile Solution
Hand Sanitizer

1.1 FL OZ / 35 ML

Drug Facts

Active ingredient
Isopropyl Alcohol 75% w/v.....

Purpose
Antiseptic

Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease. Hand Sanitizer to help reduce bacteria on the skin if 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 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 or rash 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 and excessive heat above 40C (104F)

Inactive ingredients Purified Water USP, Glycerin, Hydrogen Peroxide
Dist. by Delicate Cosmetics, Inc. Sun Valley, CA 91352.
Produced in USA From Globally Sourced Components.
www.violarougecosmetics.com. NOT FOR RESALE.

VIOLA ROUGE ANTISEPTIC HAND RUB 75 PERCENT

alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54594-201
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)		ISOPROPYL ALCOHOL	75 mL in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			
Packaging			
#	Item Code	Package Description	Marketing Start Date Marketing End Date

1	NDC:54594-201-11	35 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part333E		04/30/2020	

Labeler - DELICATE COSMETICS INC (137997602)

Establishment			
Name	Address	ID/FEI	Business Operations
DELICATE COSMETICS INC		137997602	manufacture(54594-201)

Revised: 4/2020

DELICATE COSMETICS INC