SPRINJENE- alcohol gel
Health and Natural Beauty USA Corp

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.

SprinJene®

DRUG FACTS

ACTIVE INGREDIENT

ETHYL ALCOHOL (70%)

PURPOSE

ANTIMICROBIAL

USES

- HAND SANITIZER TO HELP REDUCE BACTERIA ON THE SKIN THAT COULD CAUSE DISEASE
- RECOMMENDED FOR REPEATED USE

WARNINGS

FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME

FOR EXTERNAL USE ONLY

WHEN USING THIS PRODUCT DO NOT USE IN OR NEAR THE EYES. IN CASE OF CONTACT, RINSE EYES THOROUGHLY WITH WATER.

STOP USE AND ASK A DOCTOR IF IRRITATION OR RASH APPEARS AND LASTS

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- PLACE ENOUGH PRODUCT IN YOUR PALM TO THOROUGHLY COVER YOUR HANDS
- RUB HANDS TOGETHER BRISKLY UNTIL DRY
- NO RINSING REQUIRED
- NO TOWELS NEEDED

OTHER INFORMATION

- DO NOT STORE ABOVE 110°F (43°C)
- MAY DISCOLOR CERTAIN FABRICS OR SURFACES

INACTIVE INGREDIENTS

AQUA (WATER), GLYCERIN, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, TRIETHYLENEAMINE (TEA), TOCOPHERYLACETATE (VITAMIN E), NIGELLA SATIVA (BLACK SEED OIL)

QUESTIONS OR COMMENTS?

CALL 1-844-346-2872 MONDAY THROUGH FRIDAY 8:00 AM TO 5:00 PM

PRINCIPAL DISPLAY PANEL - 80 mL Bottle Label

SprinJene®

HAND
SANITIZER

KILLS 99.99% OF GERMS
70% ALCOHOL

Advanced Antimicrobial Formula with
BLACK SEED OIL (Nigella Sativa)

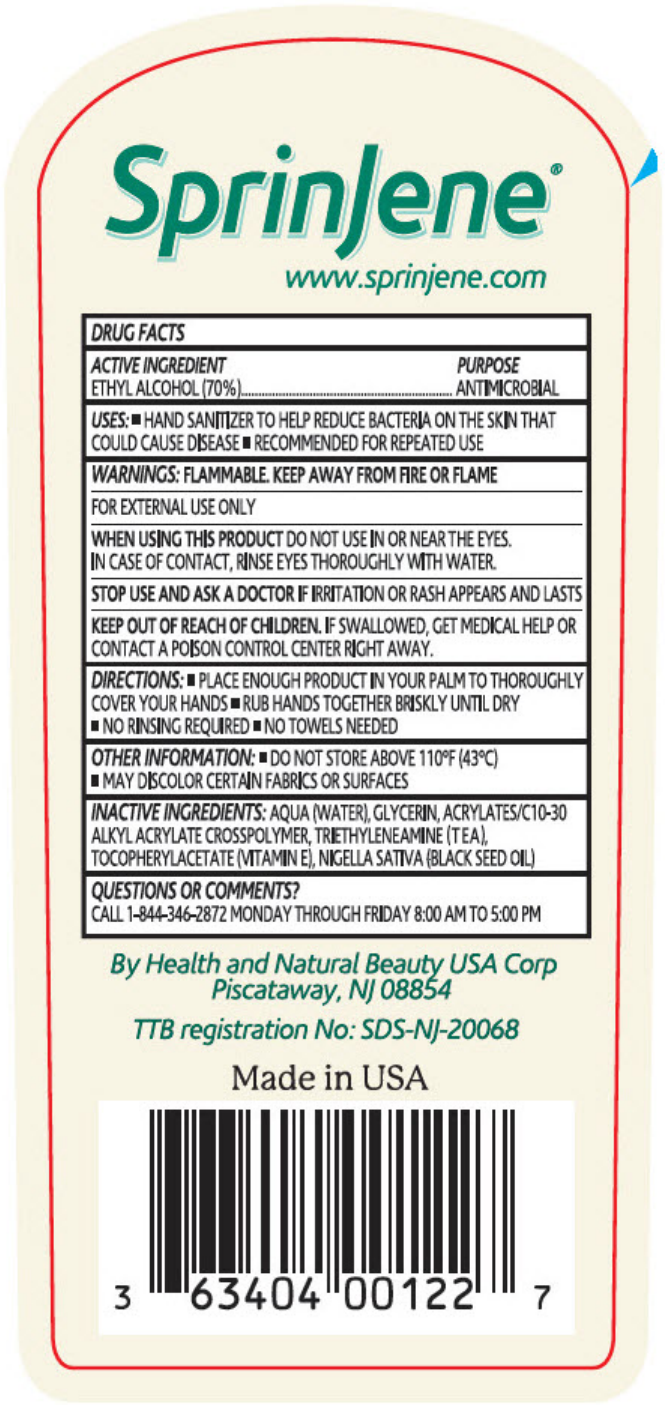
MOISTURIZING GEL

NOURISHES DRY SKIN

LEAVES HANDS FEELING SOFT

Vitamin E

NET WT 2.7 oz. (80 mL)



SPRINJENE

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63404-0720
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)	
Glycerin (UNII: PDC6A3C0OX)	
Carbomer Interpolymer Type A (Allyl Sucrose Crosslinked) (UNII: 59TL3WG5CO)	
TRIETHYLENE AMINE (UNII: VG267KM5GH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63404-0720-1	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2020	
2	NDC:63404-0720-2	300 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2020	
3	NDC:63404-0720-3	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2020	
4	NDC:63404-0720-4	80 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333E	08/01/2020	

Labeler - Health and Natural Beauty USA Corp (079129688)

Establishment

Name	Address	ID/FEI	Business Operations
Health and Natural Beauty USA Corp		079129688	MANUFACTURE(63404-0720)

Revised: 7/2020 Health and Natural Beauty USA Corp