SKY ORGANICS HAND SANITIZER- alcohol gel Natural Essentials, 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.

Drug Facts

Active ingredient

Ethyl Alcohol 70%

Purpose

Antibacterial

Uses

Hand sanitizer to help decrease bacteria on the skin.

Warnings

Flammable, keep away from fire, sparks, and sources of ignition.

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. Avoid contact with broken skin.

Stop use and ask doctor if irritation or redness develops and persists.

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

Directions

 Put enough product in your palm to cover hands and rub hands together promptly until dry. Adult supervision required during application to children.

Not recommended for infants.

Other information

■ Do not store above 105°F (41 °C).

Inactive ingredients

Acrylates/Vinyl Isodecanoate Crosspolymer, Aloe barbadensis (Aloe vera) leaf, PEG-6, PEG-12 Dimethicone, Water (Aqua). *Not an organic product

Sky Organics, 429 Lenox Ave, Suite 435 Miami Beach, FL 33139 ■ Contact: help@skyorganics.com, 1-(888) 899-9305 FDA# 20590. Made in USA.

Principal Display Panel – 16 FL OZ Bottle Label sky organics*

UNSCENTED

Hand Sanitizer Gel

with moisturizing aloe vera

kills 99.9% of germs

90% natural ingredients

crueltyfree

Made in USA

16 FL OZ e 473 ML



SKY ORGANICS HAND SANITIZER

alcohol gel

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:66902-843 Route of Administration TOPICAL Active Ingredient/Active Moiety

16 FL OZ @ 473 ML

Ingi	edient Name	Basis of Streng	th Strength
Alcohol (UNII: 3K9958V90M) (Alc	ohol - UNII:3K9958V90M)	Alcohol	0.70 mL in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
ACRYLATES/VINYL ISODECANO ATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%) (UNII: 2N8 MDB 79 NA)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
POLYETHYLENE GLYCOL 300 (UNII: 5655G9 Y8 AQ)			
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)			
WATER (UNII: 059QF0KO0R)			

ı	Pá	ackaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:66902-843- 16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	09/15/2020		

Labeler - Natural Essentials, Inc. (947484713)

Establishment				
Name	Address	ID/FEI	Business Operations	
NATURAL ESSENTIALS, INC.		947484713	MANUFACTURE(66902-843)	

Revised: 9/2020 Natural Essentials, Inc.