

**NITELA CLEAN HAND SANITIZER- alcohol gel**  
**Skin n Skin Co., Ltd.**

*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.*

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**Skin n Skin Co., Ltd. (daru) - nitela clean hand sanitizer**

Alcohol

water, glycerin, carbomers, trolamine, aloe extract (09), parsley extract, orange oil, limonene

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

keep out of reach of the children

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.

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 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.

for external use only

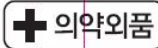
# CLEAN HAND SANITIZER

99.9% ANTIBACTERIAL



nitēla

500ml 16.91 fl.oz.



## DRUG FACTS

Active Ingredient : Ethanol (Synthetic Alcohol) 70% Purpose: Disinfecting Agent

Uses :  
 • Instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease.  
 • Instant hand antiseptic to decrease bacteria on the skin.

Warning :  
 For external use only when using this product  
 • If the following abnormal symptoms persist, discontinue use irritation around the eyes, ears, mucous membranes, including the mouth, irritation or rashes on the skin.  
 • Stop use immediately and consult a doctor if you experience the following :  
 1) Hypersensitivity symptoms such as erythema, itching and dermatitis.  
 2) Skin irritation  
 3) Follow instructions when using medication.  
 (1) For external use only (Do not use internally)  
 (2) Avoid getting into the eyes (If contact occurs, rinse thoroughly with clean water)  
 • Be careful not to inhale or use for extended periods of time (inhalation of ethanol repeatedly can cause irritation to mucous membranes and headaches or other symptoms may appear. When used repeatedly on the same area, skin irritation may occur.)  
 • Do not use the product on the same areas for extended periods of time as swelling, inflammation or sickness may occur due to absorption through the skin. It is not recommended to use on areas with open wounds that have been medically treated with a cast or bandage.  
 • Do not use in combination with soap or antibacterial cleansing agents.

Directions : Pour a small amount into hands, spread evenly and rub into the skin.

Other Information :  
 • Read the directions and warnings before use  
 • Avoid freezing and excessive heat above 40 degrees C (104 degrees F)

Inactive Ingredients :  
 Purified Water, Glycerin, Carbomers, Triethylamine, Rosemary Extract, Matricaria Extract, Rose Water, Orange Oil, Limonene.

Manufactured in Korea, Skin n Skin exclusively for DARU INC., 14-1, Donyu2-ro, Munsan-eup, Paju-si, Gyeonggi-do, Korea



**PROTECT BY HAND  
SANITIZER GEL**

## NITELA CLEAN HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74674-0005
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	350 mL in 500 mL

### Inactive Ingredients

Ingredient Name	Strength
PARSLEY (UNII: 58FMD0Q0EV)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	

**ALOE** (UNII: V5VD430YW9)

**ORANGE OIL** (UNII: AKN3KSD11B)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74674-0005-1	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/10/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/10/2020	

**Labeler** - Skin n Skin Co., Ltd. (631090037)

**Registrant** - Skin n Skin Co., Ltd. (631090037)

### Establishment

Name	Address	ID/FEI	Business Operations
Skin n Skin Co., Ltd.		631090037	manufacture(74674-0005) , label(74674-0005) , pack(74674-0005)

Revised: 5/2020

Skin n Skin Co., Ltd.