NIVANA HAND SANITIZER- alcohol gel
Dinasty 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.

Nivana Hand Sanitizer

Drug Facts

Active ingredient

Ethanol (Ethyl Alcohol)75%v/v

Purpose

Antiseptic

Use

to help reduce bacteria on the skin that could potentially cause disease

Warnings

Flammable, keep away from fire or flame.

For external use only:hands

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

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age, use only under adult supervision
- not recommended for infants

Other information

- Store below 104°F (40°C)
- May discolor certain fabrics or surfaces

Inactive ingredients

Purified water USP, Glycerin, Propylene Glycol, Carbomer, Triethanolamine, Fragrance, Aloe Barbadensis (Aloe Vera) Gel, Tocopheryl Acetate (Vitamin E)

Package Labeling:

NIVANA HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78554-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78554-004-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/11/2020	

Labeler - Dinasty Inc. (097919383)

Revised: 10/2020 Dinasty Inc.