

LAFLARE SANTIX HAND SANITIZER- alcohol gel
Natuzen 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.

ACTIVE INGREDIENT

Active ingredients: Ethyl alcohol 70%

INACTIVE INGREDIENT

Inactive ingredients:

Water, Propylene Glycol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, PEG-60 Hydrogenated Castor Oil, Triethanolamine, Panthenol, Tocopheryl Acetate, Camellia Sinensis Leaf Extract, Aloe Barbadosis Leaf Extract, Fragrance, Limonene, Citral

PURPOSE

Purpose: Antimicrobial

WARNINGS

Warnings:

- For external use only.
- Flammable.
- Keep away from fire or flame.

• When using this product avoid contact with eyes.
In case of contact, rinse thoroughly with water.

• Stop use and ask a doctor if irritation or rash develops

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- Keep out of reach of children
 - Do not eat.
 - If swallowed, get medical help or contact a Poison Control Center immediately
 - not recommended for infants

KEEP OUT OF REACH OF CHILDREN

- Keep out of reach of children
- Do not eat.
- If swallowed, get medical help or contact a Poison Control Center immediately
- not recommended for infants

Uses

Uses:

- hand sanitizer to help reduce bacteria on the skin

- recommended for repeated use

Directions

Directions:

- Put enough amount onto palm and thoroughly rub until it dries
- Children under 6 years of age should be supervised when using product

Other information

Other information

- Store below 110°F (43°C)
- May discolor certain fabrics or surfaces

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

LAFLARE SANTIX HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70930-120
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	42 mL in 60 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Propylene Glycol (UNII: 6DC9Q167V3)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
PEG-60 Hydrogenated Castor Oil (UNII: 02NG325BQG)	
TROLAMINE (UNII: 9O3K93S3TK)	
Panthenol (UNII: WV9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRAL (UNII: T7EU0O9VPP)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70930-120-01	60 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/01/2020	

Labeler - Natuzen Co.,Ltd. (688201272)**Registrant** - Natuzen Co.,Ltd. (688201272)**Establishment**

Name	Address	ID/FEI	Business Operations
Natuzen Co.,Ltd.		688201272	manufacture(70930-120)

Revised: 4/2020

Natuzen Co.,Ltd.