# FORMALBEE DAILY INSTANT 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% v/v

#### INACTIVE INGREDIENT

Inactive ingredients:

Water, Butylene Glycol, Carbomer, Triethanolamine, PEG-60 Hydrogenated Castor Oil, Limonene, Fragrance, Aloe Barbadensis Leaf Extract, Citrus Limon (Lemon) Fruit Extract, Citral

#### **PURPOSE**

Purpose: Hand Sanitizer

#### **WARNINGS**

Warnings:

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 eyes 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. Do not eat.

#### Uses

Uses:

Hand sanitizer to help reduce bacteria on the skin

#### **Directions**

Directions:

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.

#### Other information

Other information Store between 15-30 °C (59-86 °F) Avoid freezing and excessive heat above 40 °C (104 °F)

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





#### Prevention of bacterial infection!

The beginning of a healthy life for our family

#### **Drug Facts**

Active ingredient Ethyl alcohol 70% v/v.

Purpose Hand Sanitizer

Hand sanitizer to help reduce bacteria on the skin.

#### Warnings

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 eyes thoroughly with water.

Stop use and ask a doctor If irritation or rash occurs. These may be signs of

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

- 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.

#### Other information

- Store between 15-30 °C (59-86 °F) Avoid freezing and excessive heat above 40 °C (104 °F)

#### Inactive ingredients

Water, Butylene Glycol, Carbomer, Triethanolamine, PEG-60 Hydrogenated Castor Oil, Limonene, Fragrance, Aloe Barbadensis Leaf Extract, Citrus Limon (Lemon) Fruit Extract, Citral

Manufacturer: Natuzen Co., Ltd.

289 Namdongdong-ro, Namdong-gu, Incheon, 21639, korea

#### Net Wt: 300ml

Sales company: Aidkorea Company Inc. #505, 5FI, 368, Gyeongchun-ro, Namyangju-si, Gyeonggi-do, Republic of Korea



Made in Korea

#### FORMALBEE DAILY INSTANT HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70930-140	
Route of Administration	TOPICAL			

	Active Ingredient/Active Moiety		
Ingredient Name		Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	210 mL in 300 mL

Inactive Ingredients			
Ingredient Name	Strength		
Water (UNII: 059QF0KO0R)			
Butylene Glycol (UNII: 3XUS85K0RA)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)			
TROLAMINE (UNII: 9O3K93S3TK)			
PEG-60 Hydrogenated Castor Oil (UNII: 02NG325BQG)			
LIMO NENE, (+)- (UNII: GFD7C86Q1W)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
LEMON (UNII: 24RS0A988O)			
CITRAL (UNII: T7EU0O9VPP)			

ı	Packaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1	NDC:70930-140- 01	300 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	05/01/2020		

# Labeler - Natuzen Co.,Ltd. (688201272)

## Registrant - Natuzen Co.,Ltd. (688201272)

Establishment				
Name	Address	ID/FEI	Business Operations	
Natuzen Co.,Ltd.		688201272	manufacture(70930-140)	

Revised: 5/2020 Natuzen Co.,Ltd.