NATURAL SENSE- antibacterial aerosol, spray INTERNATIONAL GENERAL TRADING CORP

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.

NATURAL SENSE SPRAY

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

ETHYL ALCOHOL 75%

Purpose

Antiseptic, Hand Sanitizer

Use

Decreases bacteria on skin

Recommended for repeat use

Warnings

- -Extremely flammable aerosol, keep away from fire and flame
- -Keep away from heat, hot surfaces, open flames and other ignition sources
- -Pressurized container. Do not pierce or burn even after use
- -Protect from sunlight
- -For external use only

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.

-IRRITATION PERSIST

OR IF PRODUCT IS SWALLOWED

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

Directions

-SHAKE WELL BEFORE USE

HOLD CAN UPRIGHT AT 6-7 INCHES AWAY FROM SURFACE AND SPRAY EVENLY ALLOW TO AIR DRY FOR 5-10 MINUTS REPEAT IF NECCESARRY SUPERVISE CHILDREN UNDER 6 YEARS

Other information

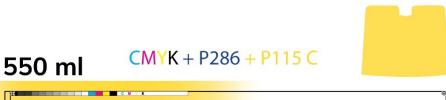
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

BUTANE, PROPANE, ISO BUTANE, FRAGANCE

Package Label - Principal Display Panel







550 ML 78440-001-01

NATURAL SENSE

antibacterial aerosol, spray

ı	Product Information			
ı	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78440-002

Route of Administration TOPICAL

Active	Ingred	lient/ <i>E</i>	Active	Moiety
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Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
PROPANE (UNII: T75W9911L6)	6.22 mL in 100 mL

ISOBUTANE (UNII: BXR49TP611)	4.345 mL in 100 mL
BUTANE (UNII: 6LV4FOR43R)	14 mL in 100 mL

Product Characteristics				
Color	Score			
Shape	Size			
Flavor	Imprint Code			
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:78440-002-01	550 mL in 1 CAN; Type 0: Not a Combination Product	09/21/2020			
2	NDC:78440-002-02	550 mL in 1 CAN; Type 0: Not a Combination Product	09/21/2020			
3	NDC:78440-002-03	550 mL in 1 CAN; Type 0: Not a Combination Product	09/21/2020			

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Marketing Information

Marketing Category	Marketing Category Application Number or Monograph Citation		Marketing End Date
OTC monograph not final	part333A	09/21/2020	

Labeler - International General trading Corp (825499598)

Registrant - INTERNATIONAL GENERAL TRADING CORP (825499598)

Establishment			
Name	Address	ID/FEI	Business Operations
COSMOLIVE KOZMETIK SANAYI VE TICARET ANONIM SIRKETI		595671824	manufacture(78440-002)

Establishment				
Name	Address	ID/FEI	Business Operations	
INTERNATIONAL GENERAL TRADING CORP		825499598	manufacture(78440-002)	

Revised: 9/2020 INTERNATIONAL GENERAL TRADING CORP