NATURAL SENSE WIPES- alcohol cloth 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 WIPES

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% v/v. Purpose: Antiseptic

Purpose

DECREASES BACTERIA ON SKIN

Use

DECREASES BACTERIA ON SKIN

Warnings

FOR EXTERNAL USE ONLY

DO NOT USE IF YOU ARE ALLERGIC TO ANY OF THE INGRIDIENTS

KEEP PACK TIGHTLY CLOSED WHEN NOT IN USE

STORE IN COOL AND DRY PLACE

WHEN USING THIS PRODUCT DO NOT GET INTO EYES. IF CONTACT OCCURS RINSE WITH WATER

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 and continious for more than 72 hrs.

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.

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

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



1 PACKAGE WITH 80 WIPES

NDC:

NATURAL SENSE WIPES

alcohol cloth

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78440-003	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)	0.2 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	24.8 mL in 100 mL		

Product Characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

l	Pa	ckaging			
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 N	NDC:78440-003-01	3 mL in 1 CANISTER; Type 0: Not a Combination Product	09/21/2020	



Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	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	
INTERNATIONAL GENERAL TRADING CORP		825499598	manufacture(78440-003)	

Revised: 9/2020 INTERNATIONAL GENERAL TRADING CORP