

HAND SANITIZING AND MOISTURIZING WIPES- isopropyl alcohol swab
Generic Specialties, 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.

This is a hand sanitizing & moisturizing wipes 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 sanitizing & moisturizing wipes are 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:

Alcohol (Isopropyl alcohol) (USP or Food Chemical Codex (FCC) grade) (67%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.

Glycerin

Sodium EDTA

PEG 40 Hydrogenated Castor Oil

Fragrance

Aqua.

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)

Isopropyl Alcohol 67% v/v. Purpose: Antimicrobial, Antibacterial

Purpose

Antimicrobial, Antibacterial Hand sanitizing and moisturizing wipes

Use

Hand Sanitizing wipes to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on injured or irritated skin
- If you are sensitive to any of its ingredients

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 at 1-800-222-1222

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Directions

- Wipe hands thoroughly with a towelette. Allow to dry. Discard after a single-use. For External use only.

Other information

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

Inactive ingredients

Aqua, Glycerin, Sodium EDTA, PEG 40 Hydrogenated Castor Oil, Fragrance

Kills 99.99% of most common, germs that may cause illness
Drug Facts
Active ingredient Purpose Isopropyl alcohol 67% v/v... Antimicrobial
Uses Hand Sanitizing Wipes to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
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Product Info:
Product: Hand Sanitizing & Moisturizing Wipes
Material: Non Woven Fabric
Size: 150 x 200 mm ± 5%

Other

Generic
HAND SANITIZING & MOISTURIZING
WIPES

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HAND SANITIZING & MOISTURIZING
WIPES

ABSOLUTE PROTECTION GENTLE ON HANDS
PARABEN FREE
KILLS 99.99% OF VIRUSES & BACTERIA
CLEAN REFRESHING SCENT
20 WIPES
OPEN HERE

RO Pure Water
Fine Non-woven Fabric
67% Alcohol
Daily Cleaning

Antibacterial
Paraben free
Super Soft
Hygiene

HANDS & BODY
PLANE
CAR
TRAIN
TOILET
GYM
FOOD

DIRECTION OF USE:

Open resealable label and pull one sheet from pack. Thoroughly clean hands and do not flush. Allow to dry without wiping. Be sure to reseal label completely to retain moisture.

CAUTION:
Avoid contact with eyes & face. Store at normal temperature. Do not flush.

FLAMMABLE DO NOT FLUSH

8 09332 41000 2

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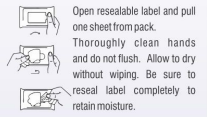


- › RO Pure Water
- › Fine Non-woven Fabric
- › 67% Alcohol
- › Daily Cleaning

- › Super Soft
- › Antibacterial
- › Paraben free
- › Hygiene

- HANDS & BODY
- PLANE
- CAR
- TRAIN
- TOILET
- GYM
- FOOD

DIRECTION OF USE:



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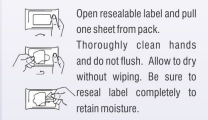


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DIRECTIONS FOR DISPENSING :

1. Remove lid by lifting upward.
2. Pull towel from center of the roll.
3. Close lid. Pull towel from canister at 90° angle.
4. Snap hinged cap back into place to ensure towels stay moist.

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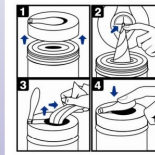
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isopropyl alcohol swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78985-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	67 mL in 100

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
EDETATE SODIUM (UNII: MP1J8420LU)	0.15 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	0.2 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78985-002-11	60 in 1 POUCH; Type 0: Not a Combination Product	09/21/2020	
2	NDC:78985-002-18	180 in 1 CANISTER; Type 0: Not a Combination Product	09/21/2020	
3	NDC:78985-002-19	20 in 1 POUCH; Type 0: Not a Combination Product	09/21/2020	
4	NDC:78985-002-09	30 in 1 POUCH; Type 0: Not a Combination Product	09/21/2020	

5	NDC:78985-002-20	160 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 - Generic Specialties, Inc. (012830710)

Registrant - Generic Specialties, Inc. (012830710)

Establishment			
Name	Address	ID/FEI	Business Operations
Generic Specialties, Inc.		012830710	manufacture(78985-002)

Revised: 9/2020

Generic Specialties, Inc.