

HAND SANITIZER WIPES- alcohol cloth
BrantMed 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 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)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer 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 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.

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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, fragrance, isopropyl alcohol, denatonium benzoate, purified water USP

Package Label - Principal Display Panel

BRANT + MED

HAND SANITIZER WIPES
70% Alc. v/v

KILLS HARMFUL BACTERIA AND GERMS

PLANT BASED ALCOHOL | NO HARSH CHEMICALS | RINSE FREE FORMULA

100
WET WIPES
15 cm x 18 cm

BRANTMED INC.
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Made in Canada
Fabriqué au Canada

CONTAINER DIRECTIONS FOR USE: Pull up tab and remove large cover. Thread first sheet in center of roll through slit in cover. Replace cover. Pull sheet up and slightly to the side. Always snap lid securely shut between uses to prevent moisture loss.

INDICATIONS: KILLS HARMFUL GERMS/BACTERIA. DOSAGE FORM: WIPE. MEDICATIONAL INGREDIENTS: Ethyl Alcohol (Etanol) 70% v/v

NON-MEDICINAL INGREDIENTS: Water, Glycerol, Isopropyl Alcohol, Denatonium Benzoate, Fragrance. This product does not contain mercury.

DIRECTIONS FOR USE: Rub thoroughly into hands for at least 30 seconds. Allow to dry. Supervise children when they use this product. For occasional and personal domestic use.

FLAMMABILITY WARNING: Keep away from open flame and sources of heat. For external use only. Keep out of reach of children. If swallowed, call a poison centre or get medical help right away. Stop use and consult a doctor if irritation develops. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Do not use on children less than 2 years of age (unless directed by a doctor).

BRANT + MED

LINGETTE DÉSINFECTANTE POUR LES MAINS
Alcool 70% v/v

TUE LES BACTÉRIES NOCIVES

ALCOOL À BASE DE PLANTES | PAS DE PRODUITS CHIMIQUES AGRESSIFS | FORMULE SANS RINÇAGE

100
LINGETTES HUMIDES
15 cm x 18 cm

MODE D'EMPLOI DU CONTENEUR: soulever la languette et enlever le grand couvercle. Tirer une première lingette au centre du rouleau et la faire passer par l'ouverture du couvercle. Remettre le couvercle. Tirer la lingette dans la fente vers le haut et légèrement en angle. Fermer toujours le couvercle amovible après chaque utilisation pour empêcher les lingettes de sécher.

INDICATIONS: TUE LES BACTÉRIES NOCIVES. FORME POSOLOGIQUE: LINGETTE. MÉDICAMENTAL: Topique.

INGRÉDIENT MÉDICAMENTEUX: Alcool d'éthyle 70% v/v

INGRÉDIENTS NON MÉDICAMENTEUX: Eau, Glycérine, Alcool isopropyle, Denatonium Benzoate, Parfum. Ce produit ne contient pas de mercure.

MODE D'EMPLOI: Destiné à un usage personnel domestique occasionnel. Appliquer suffisamment de produit pour couvrir les mains. Se frotter les mains pendant environ 30 secondes. Laisser sécher. Superviser les enfants lorsqu'ils utilisent ce produit.

AVERTISSEMENTS: Inflammable. Garder éloigné des flammes nues et autres sources de chaleur. Pour usage externe seulement. Éviter tout contact avec les yeux. S'il y a contact avec les yeux, rincer les yeux à grande eau. S'il y a de l'irritation, cesser l'utilisation du produit et consulter un médecin. Garder hors de portée des enfants. En cas d'ingestion, consulter un médecin ou appeler un centre antipoison immédiatement.

100 wipes NDC: 79362-266-06

HAND SANITIZER WIPES			
alcohol cloth			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79362-266
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 in 100	
Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)	1.2		

DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
WATER (UNII: 059QF0K00R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79362-266-06	100 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - BrantMed Inc. (204984169)

Establishment

Name	Address	ID/FEI	Business Operations
BrantMed Inc.		204984169	manufacture(79362-266)

Revised: 8/2020

BrantMed Inc.