

BEAPCO HAND SANITIZER- isopropyl alcohol gel SIM 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.

Beapco Hand Sanitizer

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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% 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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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

430 ml NDC: 79376-001-04



The image shows the principal display panel of a BEAP Hand Sanitizer package. The label features the BEAP logo (Bug Elimination & Prevention Co.) and the product name 'Hand Sanitizer' in large, bold letters. Below the name, it says 'Gel Hydroalcoolique'. The label also includes a red maple leaf logo and the text 'Made in Canada / Fabriqué au Canada'. On the left, it states '14.5 fl.oz. / 430 ml' and '75% Alcohol'. On the right, there is a graphic of two hands being washed. At the bottom right, there is a barcode and the NPN number 80100161. The label contains detailed directions and warnings in both English and French.

BEAP
BUG ELIMINATION & PREVENTION
Hand Sanitizer
Gel Hydroalcoolique

14.5 fl.oz. / 430 ml
75% Alcohol

Made in Canada
Fabriqué au Canada

BEAP
BUG ELIMINATION & PREVENTION
Bug Elimination & Prevention
Corporation
173 Roger St, Unit 3
Waterloo, ON Canada
N2L 1R1
www.beapco-products.com

DIRECTIONS: Put a thumbnail size amount in your palm and rub hands briskly until dry.
ACTIVE INGREDIENTS: Alcohol 75%
NOTE: Children under 6 years of age should be supervised during use.
Do not store above 110°F. May discolor certain fabrics.
CAUTION: Flammable. Keep away from fire and flame. For external use only.
Keep out of eyes. In case of eye contact, immediately flush with water.
Call a physician.
If swallowed, call a physician. Discontinue use if irritation or redness develop.
If condition persists for more than 72 hours, consult a physician.
KEEP OUT OF REACH OF CHILDREN.

MODE D'EMPLOI: Mettez une petite quantité dans votre paume et frottez-vous vivement les mains jusqu'à ce qu'elles soient sèches.
INGRÉDIENT ACTIF: Alcool 75%
REMARQUE: Les enfants de moins de 6 ans doivent être surveillés pendant l'utilisation. Ne pas stocker au-dessus de 110°F. Peut décolorer certains tissus.
ATTENTION: Inflammable. Tenir loin du feu et des flammes. Seulement pour usage externe. Gardez hors des yeux. En cas de contact avec les yeux, rincer immédiatement à l'eau.
Appeler un médecin.
En cas d'ingestion, appeler un médecin. Arrêtez l'utilisation en cas d'irritation ou de rougeur.
Si la condition persiste pendant plus de 72 heures, consultez un médecin.
GARDER HORS DE LA PORTEE DES ENFANTS

NPN: 80100161

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BEAPCO HAND SANITIZER

isopropyl alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79376-001 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 75 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------------|--------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 1.45 mL in 100 mL |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | 0.125 mL in 100 mL |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:79376-001-04 | 430 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/29/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 07/29/2020 | |

Labeler - SIM INC (080208966)

Registrant - SIM INC (080208966)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------|---------|-----------|------------------------|
| SIMINC | | 080208966 | manufacture(79376-001) |

Revised: 7/2020

SIM INC