**HAND SANITIZER- alcohol gel**
**Beattie's Distillers 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.*

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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) (70%, 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. Carbomer 940 (0.5% v/v)
e. 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 kills harmful bacteria or germs.

## Warnings

For external use only. Keep out of reach of children. Flammable. Keep away from fire, open flame or other sources of heat.

## Do not use

- in children less than 2 years of age

When using this product avoid contact with eyes. If contact occurs, rinse thoroughly

with water.

If irritation develops, discontinue use and consult a health care professional.

Keep out of reach of children.

Stop use and ask a doctor if irritation occurs.

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

**Directions**

- Occasional use only.
- Rub thoroughly into hands for 30 seconds and allow to dry.

**Other information**

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

**Inactive ingredients**

glycerin, hydrogen peroxide, purified water, carbomer 940

**Package Label - Principal Display Panel**


DISTILLERS
HAND
SANITIZER
GEL FORMULA
GEL DÉSINFECTANT
POUR LES MAINS
PRODUCT OF CANADA
PRODUIT DU CANADA
FOR EXTERNAL USE ONLY.
FLAMMABLE.
POUR USAGE EXTERNE UNIQUEMENT
INFLAMMABLE
500ml / 16.9 oz
NPN:80100942


BEATTIE'S
HAND SANITIZER KILLS HARMFUL BACTERIA OR GERMS.
LE DÉSINFECTANT POUR LES MAINS TUE LES BACTÉRIES OU LES GERMES NOCIFS
DIRECTIONS: OCCASIONAL USE ONLY. RUB THOROUGHLY INTO HANDS FOR AT LEAST
30 SECONDS AND ALLOW TO DRY.
DIRECTIVES : USAGE OCCASIONNEL SEULEMENT BIEN SE FROTTER LES MAINS
PENDANT AU MOINS 30 SECONDES ET LAISSER SÉCHER.
WARNING: FOR EXTERNAL USE ONLY. KEEP OUT OF REACH OF CHILDREN. WHEN
USING THIS PRODUCT, AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE
THOROUGHLY WITH WATER. IF IRRITATION DEVELOPS, DISCONTINUE USE AND
CONSULT HEALTH CARE PROFESSIONAL.
MISE EN GARDE : POUR USAGE EXTERNE UNIQUEMENT. TENIR HORS DE PORTÉE DES
ENFANTS. LORS DE L'UTILISATION DE CE PRODUIT, ÉVITER TOUT CONTACT AVEC LES
YEUX. EN CAS DE CONTACT, RINCER ABONDAMMENT À L'EAU. EN CAS D'IRRITATION
CESSER TOUTE UTILISATION ET CONSULTER UN PROFESSIONNEL
DE LA SANTÉ.
FLAMMABLE, KEEP AWAY FROM FIRE, OPEN FLAME OR OTHER SOURCES OF HEAT
INFLAMMABLE: TENIR À L'ÉCART DU FEU, D'UNE FLAMME NUE OU D'AUTRES
SOURCES DE CHALEUR.
DO NOT USE ON CHILDREN/INFANTS LESS THAN 2 YEARS OF AGE
UNLESS DIRECTED BY A HEALTH CARE PROFESSIONAL)
NE PAS UTILISER SUR DES ENFANTS/NOURRISSONS ÂGÉS DE MOINS DE 2 ANS SAUF
INDICATION CONTRAIRE D'UN PROFESSIONNEL DE LA SANTÉ)
MEDICINAL INGREDIENTS/ INGRÉDIENTS MÉDICINAUX: Ethyl Alcohol (Ethanol) 70%v/v
NON-MEDICINAL INGREDIENTS/ INGRÉDIENTS NON MÉDICINAUX: Water (Aqua),
Glycerin, Carbomer, Triethanolamine.
8 74303 00001 8
MANUFACTURED BY / FABRIQUÉ PAR:
BEATTIE'S DISTILLERS INC.
6673 LINE 13, ALLISTON, ON L9R 1V4
MADE IN CANADA / FABRIQUÉ AU CANADA

500 mL

NDC: 77427-6311-5

# HAND SANITIZER

alcohol gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:77427-6311 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ALCOHOL** (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 mL in 100 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **CARBOMER 940** (UNII: 4Q93RCW27E) | 0.5 mL in 100 mL |
| **GLYCERIN** (UNII: PDC6A3C0OX) | 1.45 mL in 100 mL |
| **HYDROGEN PEROXIDE** (UNII: BBX060AN9V) | 0.125 mL in 100 mL |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:77427-6311-5 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/01/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333A | 07/01/2020 | |

## Labeler - Beattie's Distillers Inc. (203589130)

## Registrant - Beattie's Distillers Inc. (203589130)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Beattie's Distillers Inc. | | 203589130 | manufacture(77427-6311) |

Revised: 1/2022

Beattie's Distillers Inc.