

**HAND SANITIZER- isopropyl alcohol liquid
Evergreen Solutions (USA) 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.

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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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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



Hand Sanitizer

Désinfectant pour les mains

For personal hand hygiene to help prevent the spread of bacteria. Kills harmful bacteria/germs.
Pour l'hygiène personnelle des mains, pour prévenir la propagation des bactéries. Tue les bactéries et les microbes nocifs.

Supervise children when they use this product.
Surveiller les enfants lorsqu'ils utilisent ce produit.

For occasional and personal domestic use.
Pour l'usage domestique occasionnel et personnel.

Rub thoroughly into hands for at least 30 seconds. Allow to dry.
Frottez bien vos mains avec le produit, jusqu'à l'absorption, pendant au moins 30 secondes. Laissez sécher.

- For external use only. Do not ingest.
- Avoid contact with the eyes.
- Discontinue use and consult a health care practitioner if irritation and redness develops.

Medicinal ingredients
1-2 - Propanol (Isopropyl alcohol):
• Isopropyl alcohol
• 70%

Non-medicinal ingredients
1 - Glycerin
2 - Aqua
3 - Hydrogen peroxide
4 - Vitamine E

Recommended use or purpose
Use as part of your daily routine when soap and water washing is not available.

Duration of use
Use as part of your daily routine when soap and water washing is not available.

Recommended dose
Adults 18 years and older: Apply to hands and rub until dry. Children under the age of 6 should be monitored by and adult when using this product.

Cautions and warnings
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 control centre or get medical help right away • Stop use and ask/consult a doctor/physician/health care practitioner/health care provider/health care professional if irritation develops • When using this product avoid contact with eyes • If contact occurs, rinse thoroughly with water.

Contraindications
Do not use on children/infants less than 2 years of age (unless directed by a doctor/physician/health care practitioner/health care provider/health care professional)
• Recommended storage conditions • Store at room temperature away from open flame.

NPN 80098437

Usage ou fin recommandé
Pour l'hygiène personnelle des mains, pour prévenir la propagation des bactéries • Tue les bactéries et les microbes nocifs.

Durée de l'utilisation
Utiliser en tant que de besoin, quand il n'est pas possible de se laver les mains à l'eau et au savon.

Dose recommandée
Pour les adultes de plus de 18 ans: Appliquer sur les mains et se frotter jusqu'à sécher. Les enfants de moins de 6 ans devraient utiliser ce produit seulement sous la supervision d'un adulte.

Précautions et avertissements
Avertissement d'inflammabilité • Tenir à l'écart des flammes nues et des sources de chaleur • Uniquement pour l'usage externe • Garder hors de la portée des enfants • En cas d'ingestion, appeler un Centre Antipoison ou obtenir immédiatement de l'attention médicale • Cesser d'utiliser et consulter un médecin/prestataire de soins/fournisseur de soins/professionnel de santé en cas d'irritation • En utilisant ce produit, éviter le contact avec les yeux. En cas de contact, rincer soigneusement à l'eau.

Contre-indications
Ne pas appliquer aux enfants/bébés de moins de 2 ans (sauf sur les recommandations d'un médecin/prestataire de soins/fournisseur de soins/professionnel de santé) • Conditions recommandées de conservation • Conserver à la température ambiante, à l'écarte des flammes nues.

Supplied by Evergreen Solutions | Fourni par Evergreen Solutions | 64210, 393 Loop East, Okotoks, AB, T1S 0L1 | Toll Free: 800-610-5907

000 ml NDC: 00000-000-00

HAND SANITIZER			
isopropyl alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80164-542
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:80164-542-12	1000 mL in 1 BOTTLE; 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 - Evergreen Solutions (USA) Corp. (122951113)

Establishment

Name	Address	ID/FEI	Business Operations
Evergreen Solutions Corp.		122951113	manufacture(80164-542)

Revised: 8/2020

Evergreen Solutions (USA) Corp.