

ANATIZER- ethanol gel

Anat Incorporated

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)

Ethyl 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

1 gal. (3.78L)/70% ALC

ANATIZER™
Hand Sanitizer
Désinfectant Pour Les Mains
70% alcohol/70% d'alcool

www.sossanitizer.ca

NPN# 80099271
Manufacturer's License 0054-SL-619

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LOT#AN012 EXP MA 2023

USE HAND SANITIZER

Product of Canada / Produit du Canada
Manufactured by/Fabriqué par Anat Inc.

RECOMMENDED USE: Kills harmful bacteria/germs. **DIRECTION FOR USE:** Adolescents 12-17 years; Adults 18 years and older; Children 2-11 years: Supervise children when they use this product. For occasional and personal domestic use. Rub thoroughly into hands for at least 30 seconds. Allow to dry. **MEDICINAL INGREDIENTS:** Ethyl Alcohol, 70% (technical grade alcohol). **NON-MEDICINAL INGREDIENTS:** Water, Glycerin, Hydrogen Peroxide, Hydroxy Ethyl Cellulose. This product does not contain mercury. **WARNING:** Adults only. Do not use on broken or damaged skin; Do not use if you are pregnant or breastfeeding. Do not inhale. 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/healthcare practitioner/healthcare provider/healthcare professional if irritation develops. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. **FLAMMABILITY WARNING:** Keep away from open flame and source of heat. **CONTRAINDICATION:** Do not use on children/infants less than 2 years of age (unless directed by a doctor/physician/healthcare practitioner/healthcare provider/healthcare professional). **RECOMMENDED STORAGE CONDITION:** Keep in a cool dry place.

USAGE RECOMMANDÉ: Tue les bactéries/germes nocifs. **MODE D'EMPLOI:** Adolescents 12-17 ans; Adultes 18 ans et plus; Enfants 2-11 ans: Surveillez les enfants lorsqu'ils utilisent ce produit. Pour un usage occasionnel et personnel, frottez soigneusement les mains pendant au moins 30 secondes. Laissez sécher. **INGRÉDIENTS MÉDICINAUX:** Alcool éthylique à 70% (alcool de qualité technique). **INGRÉDIENTS NON MÉDICINAUX:** Eau, glycérine, peroxyde d'hydrogène, cellulose hydroxy éthylique. Ce produit ne contient pas de mercure. **AVERTISSEMENT:** Adultes seulement. Ne pas utiliser sur une peau abîmée ou endommagée; Ne pas utiliser si vous êtes enceinte ou si vous allaitez; Ne pas inhaler. Usage externe seulement; Tenir hors de portée des enfants. En cas d'ingestion, appeler un centre antipoison ou obtenir une aide médicale immédiatement. Arrêter l'utilisation et demander/consulter un médecin/un professionnel de la santé si une irritation se développe. Lors de l'utilisation de ce produit, éviter le contact avec les yeux, en cas de contact, rincer abondamment à l'eau. **AVERTISSEMENT D'INFLAMMABILITÉ:** Tenir à l'écart des flammes et des sources de chaleur. **CONTRE-INDICATION:** Ne pas utiliser sur des enfants/nouveaux-nés de moins de 2 ans (sauf sur indication consulté d'un médecin/professionnel de la santé). **CONDITIONS DE STOCKAGE RECOMMANDÉES:** Conserver dans un endroit frais et sec.

1 Gallon NDC: 75171-111-

40

ANATIZER

ethanol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:75171-111

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
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:75171-111-40	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020	
2	NDC:75171-111-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020	
3	NDC:75171-111-03	234 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/23/2020	

Labeler - Anat Incorporated (243784795)

Establishment

Name	Address	ID/FEI	Business Operations
Anat Incorporated		243784795	manufacture(75171-111)

Revised: 5/2020

Anat Incorporated