

HAND SANITIZER- alcohol liquid
3W Healthcare Ltd.

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.

3W Hand Sanitizer 75% 100 mL

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 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, purified water USP, carbomer, aminomethylpropanol, aloe vera leaf, vitamin e

Package Label - Principal Display Panel



NPN:80099044

Extra Strength
Ultra-Puissante
Gel Hand Sanitizer
Gel désinfectant pour les mains

75% Ethyl alcohol / Alcool éthylique

Enriched with moisturising Aloe and Vitamin E
Enrichi en aloe et vitamin E hydratants

Kills harmful bacteria and germs
Tue des bactéries et microbes sensibles

Fragrance free
Sans parfum

100 ml (3 fl oz.)

Drug Facts / Info-médicament

Active Ingredient (v/v) / Ingrédient actif (p/p)	Purpose / Utilité
Ethyl alcohol 75%.....	Antiseptic skin cleanser
Alcool éthylique 75%.....	Nettoyant antiseptique pour la peau


Uses / Usages
For personal hand hygiene to prevent the spread of bacteria. Pour l'hygiène personnelle des mains afin de prévenir la propagation de bactéries.


Warnings / Mises en garde
For external use only. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Stop use and consult a doctor if irritation develops. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Flammability warning Keep away from open flame and sources of heat.
Pour usage externe seulement. Lorsque vous utilisez ce produit éviter tout contact avec les yeux. Le cas échéant, bien rincer avec de l'eau. Cessez d'utiliser et consultez un docteur si une irritation se développe. Garder hors de la portée des enfants. En cas d'ingestion, appeler immédiatement un centre antipoison ou obtenir une assistance médicale. Avertissement – inflammabilité tenir loin des flammes et sources de chaleur.

Directions / Mode d'emploi
Put as much product as needed into your palms. 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.
Déposer une quantité suffisante de produit sur les paumes. Bien frotter pendant au moins 30 secondes. Laisser sécher. Superviser les enfants durant l'utilisation de ce produit. Pour une utilisation occasionnelle pour usage domestique personnel.

Other information / Informations Supplémentaires
Store between 15 - 30C (59-68F). Avoid freezing and excessive heat above 40C (104F)
Conserver entre 15 et 30C. Éviter les conditions de congélation et la chaleur excessive dépassant 40C.


Inactive Ingredients / Ingrédients Inactifs
Water, Glycerine, Carbomer 934, Aloe Barbadosensis Leaf Extract, Vitamin E, 2-amino-2-methyl-1-propanol
Eau, Glycérine, Carbomère 934, Extract de feuille d'Aloe Barbadosensis, Vitamine E, 2-amino-2-méthyl-1-propanol





DANGER

Manufactured for / Fabriqué Pour:
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100 mL NDC: 78144-001-01

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78 144-00 1
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.01 mL in 100 mL
.ALPHA.-TOCOPHEROL SUCCINATE, DL- (UNII: 7VJE08U49E)	0.01 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.53 mL in 100 mL
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	0.4 mL in 100 mL
WATER (UNII: 059QF0K00R)	24.05 mL in 100 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.04 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78144-001-01	100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/19/2020	

Labeler - 3W Healthcare Ltd. (202079498)**Registrant** - 3W Healthcare Ltd. (202079498)**Establishment**

Name	Address	ID/FEI	Business Operations
Guangzhou Rainhome Pharm & Tech Co., Ltd.		547018779	manufacture(78144-001)

Revised: 5/2020

3W Healthcare Ltd.