VIDA- virucidal disinfectant rtu gel Isochem Australia PTY 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.

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 80% 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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away.

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



75% Alcohol

Kills 9.99% of Germs

No Water Required

•	ALCOHOL	75%
•	WATER	21.98%
•	GLYCERIN	2.0%
•	DL-ALPHA TOCOPHERYL ACETATE	0.10%
•	ALOE VERA LEAF EXTRACT	0.10%
•	GUARSAFE JK-303	0.10%
	CIRTIC ACID	0.02%

Product description:

- · Antiseptic hand rub
- Kills 99.9% of most of common germs
- Use in the absence of water or towels
- With natural Aloe Vera extract

Directions for use:

Hand Sanitiser to help reduce bacteria that potentially can cause a disease. For when soap and water are not available. Apply sufficient amount of 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.

Warnings:

For external use only. Flammable. Keep away from heat or flame. Keep out of eyes, ears and mouth.

Discontinue use if skin irritation or rash occurs.

Keep out of reach of children.

If swallowed, seek medical help immediately.

Store below 30 °C.

Date of manufacture: 01/04/2020

Do Not Use:

in children less than 2 months of age. On Open skin wounds

Storage:

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

Quad 3, Suite 1.07 102 Bennelong Pkwy, Sydney Olympic Park, NSW 2127 Australia +61 2 9060 7400 www.isochem.com.au









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VIDA

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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78182-0075
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients				
Ingredient Name	Strength			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	0.1 g in 100 g			
HYDROXYPROPYL GUAR (2500-4500 MPA.S AT 1%) (UNII: 3A1I7376TC)	0.8 g in 100 g			
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	0.02 g in 100 g			
WATER (UNII: 059QF0KO0R)	21.98 g in 100 g			
.ALPHATO COPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	0.1 g in 100 g			
GLYCERIN (UNII: PDC6A3C0OX)	2 g in 100 g			

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:78182-0075-9	100 g in 1 PACKAGE; Type 0: Not a Combination Product	05/27/2020			
2	NDC:78182-0075-1	150 g in 1 PACKAGE; Type 0: Not a Combination Product	05/27/2020			
3	NDC:78182-0075-2	250 g in 1 PACKAGE; Type 0: Not a Combination Product	05/27/2020			
4	NDC:78182-0075-5	500 g in 1 PACKAGE; Type 0: Not a Combination Product	05/27/2020			
5	NDC:78182-0075-3	375 g in 1 PACKAGE; Type 0: Not a Combination Product	05/27/2020			
6	NDC:78182-0075-0	50 g in 1 PACKAGE; Type 0: Not a Combination Product	05/27/2020			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/27/2020		

Labeler - Isochem Australia PTY LTD (740451042)

Registrant - Isochem North America Inc (080431615)

Establishment			
Name	Address	ID/FEI	Business Operations
Isochem Australia Pty Ltd		740451042	manufacture(78182-0075)

Revised: 9/2020 Isochem Australia PTY LTD