CRIMSON HAND SAN- alcohol liquid Chemical Distributors, 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.

Crims on Hand San - Hand Sanitizer

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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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

Crimson Hand San labels



CRIMSON HAND SAN

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HIGHLY FLAMMABLE LIQUID AND VAPOR, CAUSES SERIOUS EYE

precautionary statements - prevention

wash face, Hands and any exposed skin thoroughly after Handling

keep away from Heat Hot Surfaces, sparks, open Flames and other Ignition sources, no smoking keep container tightly closed

ground/Bond container and receiving equipment

USE explosion-proof electrical/ventilating/lighting/

таке precautionary measures against static discharge

wear protective of overveye protection/gace protection

IF IN EYES: RINSE CAUTIOUSLY WITH WATER FOR SEVERAL MINUTES. REMOVE CONTROL LENSES, IF PRESENT AND EASY TO DO. CONTINUE FINSING IF EYE IFFITATION PERSISTS: GET MEDICAL ADVICE/ATTENTION.

IF ON SKIN (OF HAIF): TAKE OFF IMMEDIATELY ALL CONTAMINATED CLOTHING. RINSE SKIN WITH WATER/ SHOWER

In case of fire: Use bry chemical, co2, water spray or alcohol-resistant foam to extinguish

precautionary statements - storage

store in a well-ventilated place, keep cool

precautionary statements - disposal

DISPOSE OF CONTENTS/CONTAINER TO AN APPROVED WASTE DISPOSAL PLANT

KEEP OUT OF THE REACH OF CHILDREN. FOR INDUSTRIAL OR FOOD PLANT USE ONLY

ingredients: Denatured Ethanol, GLycerine and Hydrogen Peroxide

Alcohol Antiseptic 80% **Topical Solution**

Hand Sanitizer Non-sterile Solution

18.93L

18.93L NDC: 75022-001-05

DRUG FACTS LABEL

Drug Facts

Use[s]

Warnings For external use only, Flammable, Keep away from heat or flame

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Manufactured By: CHEMICAL DISTRIBUTORS, INCORPORATED 80 Metcalfe street BUFFALO, NY 14206

716.856.2300 / Sales@cdiBuffalo.com

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Ingredients: Denatured Ethanol, GLycerine and Hydrogen Peroxide

Alcohol Antiseptic 80% **Topical Solution**

Hand Sanitizer Non-sterile Solution

208L

208L NDC: 75022-001-55

DRUG FACTS LABEL

Drug Facts

Use[s]

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CRIMSON HAND SAN

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75022-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 L in 100 L	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 L in 100 L		
WATER (UNII: 059QF0KO0R)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75022-001-05	18.93 L in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75022-001-55	208 L in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75022-001-27	1022 L in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75022-001-01	3.78 L in 1 JUG; 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 - Chemical Distributors, Incorporated (013711338)

Registrant - Chemical Distributors, Incorporated (013711338)

Establishment				
Name	Address	ID/FEI	Business Operations	
Chemical Distributors, Incorporated		013711338	manufacture(75022-001)	

Revised: 4/2020 Chemical Distributors, Incorporated