

STEEL CITY SANITIZER- alcohol gel
Eco Solution Distributing LLC

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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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

STEEL CITY SANITIZER

HAND SANITIZER GEL

ALCOHOL ANTISEPTIC 80%

TOPICAL SOLUTION | NON-STERILE SOLUTION

FOR EXTERNAL USE ONLY

12 FL OZ (355 ML)

Drug Facts

Active ingredient(s) Purpose

Alcohol 80% v/v.....Antiseptic

Use(s)

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Drug Facts (continued)

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Other information

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

Inactive ingredients fragrance, glycerin, *hydroxypropyl cellulose, *hydroxypropyl methylcellulose, water

***May or may not include**

Proudly packaged and distributed by:
Eco Solution Distributing
Pittsburgh, PA 15220

steelcitysanitizer.com

UPC
Here

STEEL CITY SANITIZER

HAND SANITIZER GEL

ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION | NON-STERILE SOLUTION

FOR EXTERNAL USE ONLY

16 FL OZ (473 ML)

Drug Facts

Active ingredient(s) Purpose
Alcohol 80% v/v.....Antiseptic

Use(s)

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ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION | NON-STERILE SOLUTION

FOR EXTERNAL USE ONLY

128 FL OZ (3.79 L)

Drug Facts

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STEEL CITY SANITIZER

HAND SANITIZER GEL

ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION | NON-STERILE SOLUTION

FOR EXTERNAL USE ONLY

5 GAL (18.93 L)

Drug Facts

Active ingredient(s) Purpose
Alcohol 80% v/v.....Antiseptic

Use(s)

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HAND SANITIZER GEL

ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION | NON-STERILE SOLUTION

FOR EXTERNAL USE ONLY

55 GAL (208.2 L)

Drug Facts

Active ingredient(s) Purpose
Alcohol 80% v/v.....Antiseptic

Use(s)

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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Drug Facts (continued)

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STEEL CITY SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78338-400(NDC:75512-002)	
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: PDC6A3C00X)			0.4 L in 100 L	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)			0.75 L in 100 L	
WATER (UNII: 059QF0KO0R)			18.85 L in 100 L	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			0.75 L in 100 L	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78338-400-55	208.2 L in 1 DRUM; Type 0: Not a Combination Product	05/28/2020	
2	NDC:78338-400-05	18.93 L in 1 PAIL; Type 0: Not a Combination Product	05/28/2020	
3	NDC:78338-400-01	3.79 L in 1 JUG; Type 0: Not a Combination Product	05/28/2020	
4	NDC:78338-400-16	0.473 L in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	05/28/2020	
5	NDC:78338-400-12	0.355 L in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	05/28/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/28/2020		

Labeler - Eco Solution Distributing LLC (038022733)

Registrant - Eco Solution Distributing LLC (038022733)

Establishment

Name	Address	ID/FEI	Business Operations
Eco Solution Distributing LLC		038022733	relabel(78338-400) , repack(78338-400)

Establishment

Name	Address	ID/FEI	Business Operations
Three Rivers Marine & Rail Terminals, LLC		117645884	repack(78338-400) , relabel(78338-400)

Revised: 12/2021

Eco Solution Distributing LLC