HAND SANITIZER- alcohol gel Khrysos Industries, Inc.

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.

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

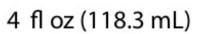
glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-sterile Solution

FOR EXTERNAL USE ONLY





NDC 74577-402-01 Lot No. HS Manufactured By: Khrysos Industries, Inc. 4121 SW 34th St., Orlando, FL 32811

118.3 mL

NDC: 74577-402-01

HAND SANITIZER

alcohol gel

Product Information HUMAN OTC DRUG **Product Type**

Item Code (Source)

NDC:74577-402

Route of Administration

TOPICAL

Active Ingredient/Active Moiety									
	Ingredient Name Basis of Stree				gth	Strength			
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCO						80 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)									
н	YDRO XYPRO PYI								
Р	ackaging								
P #			Package Description	Marketing St Date	art	Marketing End Date			
#	Item Code	1 mL i Produ	n 1 BOTTLE, DISPENSING; Type 0: Not a Combination	0	art	0			
#	Item Code NDC:74577-402-		n 1 BOTTLE, DISPENSING; Type 0: Not a Combination	Date	art	0			
#	Item Code NDC:74577-402-		n 1 BOTTLE, DISPENSING; Type 0: Not a Combination	Date	art	0			
#	Item Code NDC:74577-402-	Pro du	n 1 BOTTLE, DISPENSING; Type 0: Not a Combination ct	Date	art	0			
# 1	Item Code NDC:74577-402- 01	Produ 1fori	n 1 BOTTLE, DISPENSING; Type 0: Not a Combination ct	Date		0			
# 1	Item Code NDC:74577-402- 01 /arketing In	Produ 1fori gory	n 1 BOTTLE, DISPENSING; Type 0: Not a Combination ct mation Application Number or Monograph Citation	Date 08/11/2020		Date			

Labeler - Khrysos Industries, Inc. (117007580)

Establishment						
Name	Address	ID/FEI	Business Operations			
Khrysos Industries, Inc.		117007580	manufacture(74577-402), pack(74577-402), label(74577-402)			

Revised: 8/2020

Khrysos Industries, Inc.