

DETTOL FIRST AID ANTISEPTIC- chloroxylenol liquid
Fresh N Clear 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. Isopropyl Alcohol (75%, 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)



Chloroxylenol 4.8% w/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use



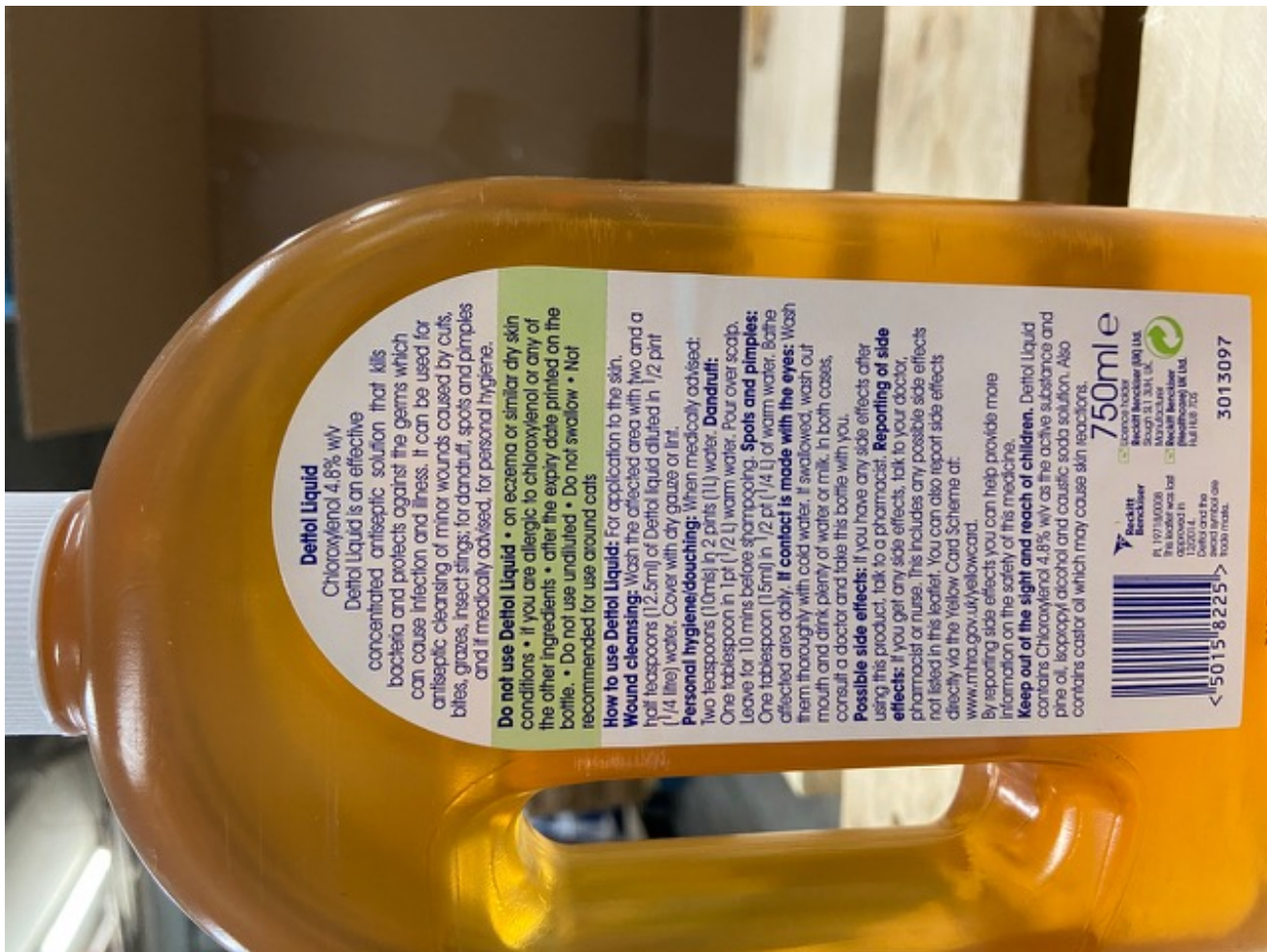
Warnings

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

First Aid to help prevent infection of minor cuts, scrapes, burns



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.

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



750ml NDC 79567-875-4

DETTOL FIRST AID ANTISEPTIC

chloroxylenol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79567-875
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	4.8 g in 15 mL

Inactive Ingredients

Ingredient Name	Strength
CARAMEL (UNII: T9D99G2B1R)	
WATER (UNII: 059QF0KO0R)	
WHITE PINE OIL (UNII: HA5CX6676U)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79567-875-04	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/03/2020	

Labeler - Fresh N Clear LLC (064116345)

Establishment

Name	Address	ID/FEI	Business Operations
Fresh N Clear LLC		064116345	manufacture(79567-875)

Revised: 7/2020

Fresh N Clear LLC