HAND SANITIZER- is opropyl alcohol spray BCMbio

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.

75% 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. 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)

Isopropyl Alcohol 75% 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)

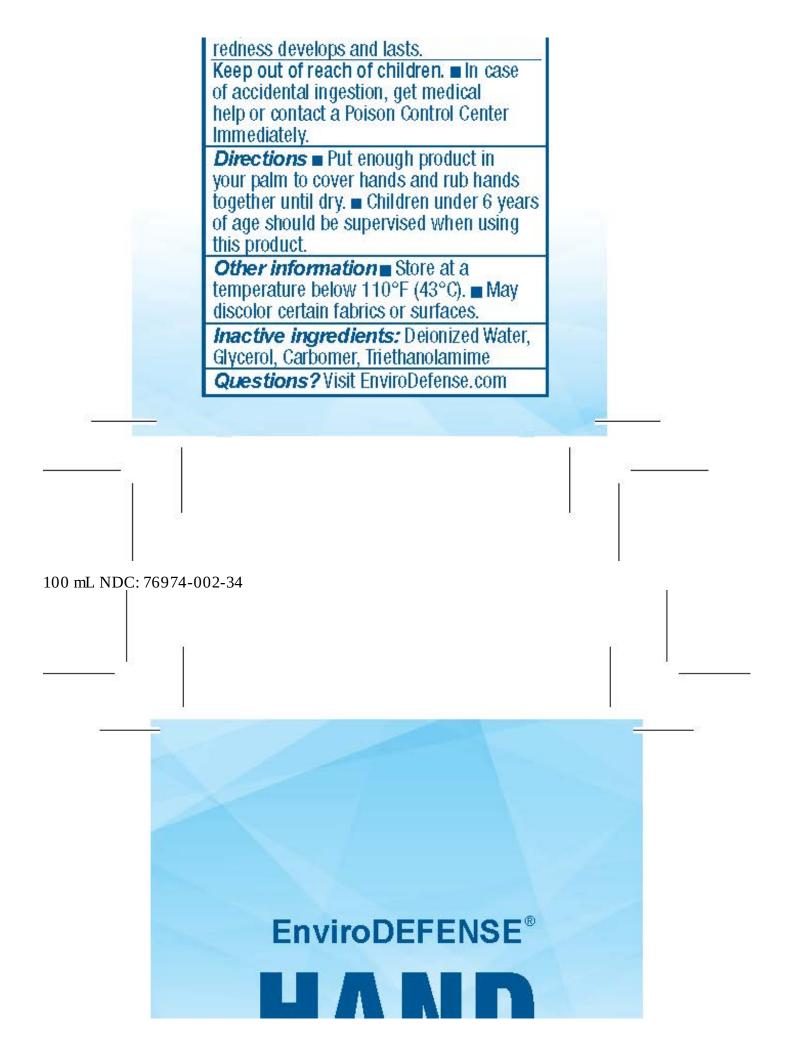
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP 60 mL NDC: 76974-002-02



INSTANTIY KILLS





	EXAMPLE ADVANCED	
	75% Alcohol INSTANTLY KILLS 99.99% OF GERMS	
	ORIGINAL GEL FORMULA	
_	Net: 3.4 fl oz (100 ml)	
100 mL NDC: 76	974-002-34	



250 mL NDC: 76974-002-85

<text>

INSTANTLY KILLS 99.99% OF GERMS

ORIGINAL GEL FORMULA

Net: 8 fl oz (250 ml)

250 mL NDC: 76974-002-85





1893 mL NDC: 76974-002-64

		EnviroDE		283	
	IAND	& S	URF	ACE	
	SAI		17	FR	
	ADVA	NCED	75% AI	cohol	
	NO RINSE Formula	✓ MULTI-SURI	LUTION 🗸 NATUR FACE 🖌 FRAGR TANTLY 🗸 DAILY U	ANCE FREE	
childrei eyes, e water, s of reac	NG: For external use only. Highly Fla 1 under 2 months or on open skin w ars and mouth. In case of contact w Stop use and contact a doctor if irrit o of children. If swallowed contact p GE: Store between 32° F - 104° F	rounds. Keep product on of ith eyes rinse thoroughly with ation or rash occurs. Keep our poison control immediately.	or hands to ensure adequat together until dry.	8 13166 02964 4	
		Net: 64 fl oz	www.EnviroDefense.com	281895 V1 #400005	

3786 mL NDC: 76974-002-75

EnviroDEFENSE®	
	1
HAND & SURFACE	
SANITIZER	
ADVANCED 75% Alcohol	
NO RINSE FORMULA✓ TOPICAL SOLUTION MULTI-SURFACE WORKS INSTANTLY✓ NATURAL PRODUCT FRAGRANCE FREE DAILY USE	
WARNING: For external use only. Highly Flammable. Do not use on children under 2 months or on open skin wounds. Keep product on of eyes, ears and mouth. In case of contact with eyes rinse thoroughly with water. Stop use and contact a doctor if irritation or rash occurs. Keep our of reach of children. If swallowed contact poison control immediately. STORAGE: Store between 32° F - 104° F	
Net: 1 Gal (128 fl oz) 3.78L	

HAND SANITIZER					
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isopropyl alcohol spray					
Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:76974-002	
Route of Administration	TOPICAL				
Active Ingredient/Active Moi	ety				
Ingredient Name H			Basis of Str	ength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL -			ISOPROPYL		75 mL
UNII:ND2M416302) A			ALCOHOL		in 100 mL
Inactive Ingredients					
Ingredient Name		Strength			
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL		

HYDROGEN PEROXIDE (UNII: BBX060AN9V)

WATER (UNII: 059QF0KO0R)

 $0.125\ mL$ in 100 mL

Pa	ckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76974-002-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
2 1	NDC:76974-002-34	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
3 1	NDC:76974-002-85	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
4 1	NDC:76974-002-17	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
5 ľ	NDC:76974-002-64	1893 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
6 1	NDC:76974-002-75	3786 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
Μ	arketing Info	ormation		
N	Aarketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ОТ	C monograph not fin	al part333A	04/29/2020	

Labeler - BCMbio (029272574)

Registrant - BCMbio (029272574)

Revised: 4/2020

BCMbio