

IRIS HAND SANITIZER- alcohol spray

Iris 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.

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



Nourishing and Strengthening
formula

8 FL OZ (237 ML)



WARNING
Extremely flammable.
Keep away from flame.

Unscented



Active Ingredients: Purpose
Ethyl alcohol 80% v/v ... antiseptic

Uses:
Hand sanitizer to help reduce bacteria
that potentially can cause disease.
For use when soap and water are
unavailable.

Warnings:
For external use only. Flammable.
Keep away from heat and flame, avoid
contact with eyes. In case of contact
with eyes, flush thoroughly with water.
Avoid contact with broken skin.
Stop use and ask doctor if irritation
or redness develops, or if condition

persists for more than 72 hours.
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.
For children under 6, use with adult
supervision. Not recommended for infants.

Other Info:

Store between 15-30C (59-86F).
Avoid freezing and excessive heat above
40C (104F)

Inactive Ingredients:

Glycerin, hydrogen peroxide, water USP



237 mL NDC: 74052-338-08

IRIS HAND SANITIZER

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74052-238
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
GLYCERIN (UNII: PDC6A3C0OX)		1.45 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74052-238-10	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74052-238-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74052-238-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74052-238-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74052-238-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:74052-238-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:74052-238-28	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:74052-238-38	18927.1 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:74052-238-55	208198 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
10	NDC:74052-238-99	1041000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
11	NDC:74052-238-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
12	NDC:74052-238-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
13	NDC:74052-238-34	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
14	NDC:74052-238-17	500 mL in 1 BOTTLE; 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 - Iris LLC (114973408)

Establishment

Name	Address	ID/FEI	Business Operations
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