

IRIS HAND SANITIZER GEL- alcohol gel

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.

Alcohol 70% v/v. Purpose: Antiseptic

Antiseptic, Hand Sanitizer

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

For external use only. Flammable. Keep away from heat and flame.

In children less than two 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.

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.

Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C (104F)

Glycerin, propylene glycol, carbomer, aminomethylpropanol, purified water USP



Hand Sanitizer gel

Nourishing and Strengthening
formula

8 FL OZ (237 ML)



WARNING
Extremely flammable.
Keep away from flame.

Unscented



Active Ingredients: Purpose
Ethyl alcohol 70% 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, propylene glycol, carbomer, 2-amino methyl-1 propanol solution water USP



8 FL OZ (237 ML)

IRIS HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74052-337
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74052-337-10	296 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	
2	NDC:74052-337-02	59 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	
3	NDC:74052-337-04	118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	
4	NDC:74052-337-08	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	
5	NDC:74052-337-12	355 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	
6	NDC:74052-337-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	
7	NDC:74052-337-28	3785.41 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	
8	NDC:74052-337-38	18927.1 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	
9	NDC:74052-337-55	208198 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	
10	NDC:74052-337-99	1041000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	

11	NDC:74052-337-01	30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	
12	NDC:74052-337-03	100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	
13	NDC:74052-337-34	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/03/2020	

Labeler - Iris LLC (114973408)

Establishment

Name	Address	ID/FEI	Business Operations
Iris LLC		114973408	manufacture(74052-337)

Revised: 5/2020

Iris LLC