ORANGE BLOSSOM SCENTED HAND SANITIZER 01- alochol gel Jiangxi Iris Chemical Co., ltd

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.

FZ2097TA(EN) light purple, orange blossom (new label) Jiangxi Iris

Active ingredient Purpose

Alcohol Denat. 70%(v/v)..... Antibacterial

Use

To decrease bacteria on the skin that could cause disease.

Warnings

For external use only.

Flammable. Keep away from fire or flame.

When using this product

- · Keep out of eyes.
- · Avoid contact with broken skin.

Stop use and ask a doctor if

· Irritation or redness develops.

Keep out of reach of children

- Do not inhale or ingest
- if swallowed, get medical help or contact a poison control center right away.

Direction

Rub a dime sized drop into hands.

For children under 8 use under adult supervision

Inactive ingredients

WATER(AQUA/EAU), PEG-40 HYDROGENATED CASTOR OIL, FRAGRANCE(PARFUM), ACRYLATES/ C10-30 ALKYL ACRYLATE CROSSPOLYMER, TRIETHANOLAMINE.

MAY CONTAIN: FD&C YELLOW NO. 5(CI19140), FD&C RED NO. 40(CI16035), FD&C BLUE NO.1(CI 42090), D&C RED NO. 33(CI 17200).

Questions?

1-212-779-0544 weekdays

ORANGE BLOSSOM SCENTED HAND SANITIZER 01

alochol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74440-041	
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			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	0.0003 g in 100 mL			
WATER (UNII: 059QF0KO0R)	36.2397 g in 100 mL			
FD&C RED NO. 40 (UNII: WZB9127XOA)	0.0003 g in 100 mL			
TROLAMINE (UNII: 903K93S3TK)	0.16 g in 100 mL			
ORANGE OIL (UNII: AKN3KSD11B)	0.2 g in 100 mL			
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	0.2 mL in 100 mL			
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	0.2 mL in 100 mL			

Product Characteristics		
Color	purple	Score
Shape		Size
Flavor	ORANGE	Imprint Code
Contains		

	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
ı	1 NDC:74440-041-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2020			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	06/19/2020			

Labeler - Jiangxi Iris Chemical Co.,ltd (544366795)

Registrant - Jiangxi Iris Chemical Co., Itd (544366795)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jiangxi Iris Chemical Co.,ltd		544366795	manufacture(74440-041)	

Revised: 8/2020 Jiangxi Iris Chemical Co.,ltd