

OCEAN BREEZE SCENTED HAND SANITIZER 01- alcohol 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.

RM0001TA(EN) ocean breeze/ green

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

RM0001TA_PK

2020/12/09 (1)

— DIE LINE—DO NOT PRINT

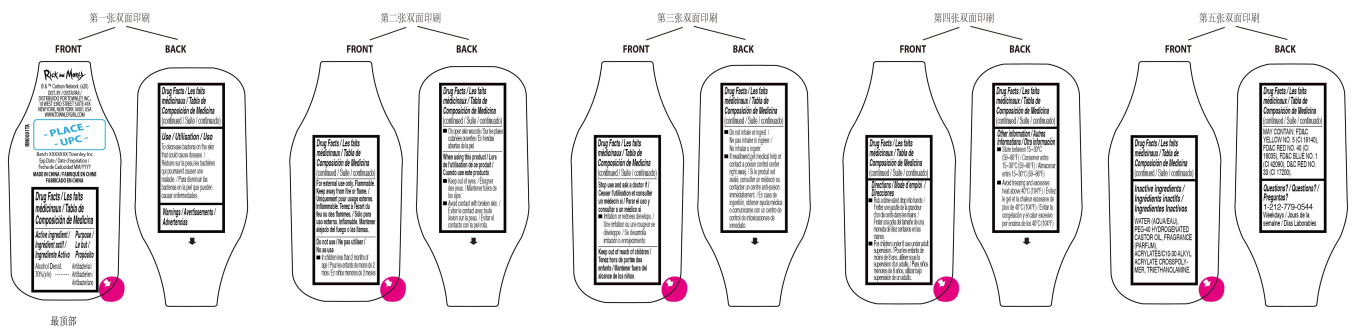
CMYK PROCESS

CLEAR ADHESIVE STOCK
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此灰色代表透明区域,不要印刷为灰色

CONFIRM
WEIGHTS + FLAVORS +
INGREDIENTS +
MAY CONTAINS

Townley
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New York, NY 10016
Call (212) 779-0544 • Fax (212) 779-4192



OCEAN BREEZE SCENTED HAND SANITIZER 01

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74440-060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	0.16 g in 100 mL
WATER (UNII: 059QF0KO0R)	36.2397 g in 100 mL
3-(3,4-METHYLENEDIO XYPHENYL)-2-METHYLPROPANAL (UNII: L65EG8H6PA)	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

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	0.0003 g in 100 mL
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	0.0003 g in 100 mL

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74440-060-01	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.,ltd (544366795)

Establishment

Name	Address	ID/FEI	Business Operations
Jiangxi Iris Chemical Co.,ltd		544366795	manufacture(74440-060)

Revised: 1/2021

Jiangxi Iris Chemical Co.,ltd