

**MEDIKOO BIO SAFE HAND REFRESHING- alcohol gel
THERANOTICS 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.

Drug Facts

ACTIVE INGREDIENTS

ALCOHOL 62% v/v

INACTIVE INGREDIENTS

Water, Ecklonia Cava Extract, Sophora Flavescens Extract, Centaurea Cyanus Flower Extract, Borago Officinalis Extract, Lavandula Angustifolia (Lavender) Flower Extract, Chamomilla Recutita (Matricaria) Flower Extract, Salvia Sclarea (Clary) Extract, Hyacinthus Orientalis (Hyacinth) Extract, Carbomer, Butylene Glycol, Tromethamine, 1,2-Hexanediol, Fragrance

PURPOSE

ANTISEPTIC

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.

Uses

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


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)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

 <p>MEDIKOII</p> <p>Containing 62% Ethyl Alcohol, it helps your hand stay clean without soap and water and herb extract complex keeps feeling skin soft and moisturized after use.</p> <p>Bio-Safe Hand Refreshing Gel</p> <p>100ml / 3.38 fl. oz.</p>	<p>Drug Facts</p>	
	<p>Active ingredients</p> <p>ALCOHOL 62% v/v</p>	<p>Purpose</p> <p>ANTISEPTIC</p>
	<p>Uses</p> <p>Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p>	
	<p>Warnings</p> <p>For external use only. Flammable. Keep away from heat or flame.</p> <p>Do not use</p> <ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds <p>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.</p>	
	<p>Directions</p> <ul style="list-style-type: none"> • 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. 	
	<p>Other information</p> <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
	<p>Inactive ingredients</p> <p>Water, Ecklonia Cava Extract, Sophora Flavescens Extract, Centaurea Cyanus Flower Extract, Borago Officinalis Extract, Lavandula Angustifolia (Lavender) Flower Extract, Chamomilla Recutita (Matricaria) Flower Extract, Salvia Sclarea (Clary) Extract, Hyacinthus Orientalis (Hyacinth) Extract, Carbomer, Butylene Glycol, Tromethamine, 1,2-Hexanediol, Fragrance</p>	
	<p>Distributor: NUYU, Inc. 99 Gorge Road, #201 Edgewater, NJ 07020</p> <p>Manufacturer: Bio-FD&C Co., Ltd. A-510, Songdo BRC Smart Valley, 30 Songdomirae-ro, Yeonsu-gu, Incheon, Korea</p>	
	<p>Net Wt: 100mL / 3.38 Fl. Oz.</p>	

MEDIKOII BIO SAFE HAND REFRESHING

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72695-0014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
ECKLONIA CAVA (UNII: UXX2N5V39P)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
CENTAUREA CYANUS FLOWER (UNII: QZ239038YC)	
BORAGO OFFICINALIS SEED (UNII: 2GXJ790US0)	
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	

CHAMOMILE (UNII: FGL3685T2X)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
Butylene Glycol (UNII: 3XUS85K0RA)	
TROLAMINE (UNII: 9O3K93S3TK)	
1,2-Hexanediol (UNII: TR046Y3K1G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72695-0014-1	100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/01/2020	

Labeler - THERANOTICS CO.,LTD. (694963085)

Registrant - THERANOTICS CO.,LTD. (694963085)

Establishment

Name	Address	ID/FEI	Business Operations
BIO-FD&C. Co., Ltd.		688203268	manufacture(72695-0014)

Revised: 6/2020

THERANOTICS CO.,LTD.