

SHOPKO ANTIBACTERIAL HAND SANITIZER- ethyl alcohol gel
Jets, Sets, & Elephants Beauty Corp.

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.

SHOPKO® Antibacterial Hand Sanitizer - Frosted Vanilla, Merry Berry, and Winter Gumdrop

Active Ingredient

Ethyl Alcohol 62% w/w

Purpose

Anti-bacterial

Use

- To decrease bacteria on the skin and clean hands.
- Recommended for repeated use.

Warnings

For external use only.

Flammable, keep away from fire or flame.

Keep out of reach of children.

If accidentally swallowed, get medical help or contact a Poison Control Center right away.

Do not get into eyes.

If contact occurs, rinse thoroughly with water.

Discontinue use

if irritation or redness develop. If irritation persists for more than 72 hours, consult a doctor.

Directions

- Apply to hands until thoroughly wet.
- Rub vigorously until dry.
- Supervise children in the use of this product.

Inactive ingredients (Frosted Vanilla)

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Blue 1, Cellulose, Fragrance (Parfume), Hydroxypropyl Methylcellulose, Lactose, Parfum, Polysorbate 20, Propylene Glycol, Red 33, Retinyl Palmitate, Tocopheryl Acetate, Triethanolamine, Ultramarines, Water (Aqua), Yellow 5

Inactive ingredients (Merry Berry)

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Cellulose, Fragrance

(Parfume), Hydroxypropyl Methylcellulose, Lactose, Parfum, Polysorbate 20, Propylene Glycol, Red 33, Red 40, Retinyl Palmitate, Tocopheryl Acetate, Triethanolamine, Ultramarines, Water (Aqua)

Inactive ingredients (Winter Gumdrops)

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadosensis Leaf Juice, Blue 1, Cellulose, Fragrance (Parfume), Hydroxypropyl Methylcellulose, Lactose, Parfum, Polysorbate 20, Propylene Glycol, Red 33, Retinyl Palmitate, Tocopheryl Acetate, Triethanolamine, Ultramarines, Water (Aqua), Yellow 5

QUESTIONS?

1-800-FDA-1088

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

bath·body·etc®

Frosted Vanilla

anti-bacterial hand gel

1 fl. oz.

SATISFACTION GUARANTEED BY REFUND OR EXCHANGE

Made in China

Distributed by Jets, Sets & Elephants Beauty Corp,

For ShopKo Stores Operating Co., LLC

Green Bay, WI 54307, U.S.A

©2012 ShopKo Stores Operating Co., LLC



Bottle Label

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

bath·body·etc®

Merry Berry

anti-bacterial hand gel

1 fl. oz.

SATISFACTION GUARANTEED BY REFUND OR EXCHANGE

Made in China

Distributed by Jets, Sets & Elephants Beauty Corp,

For ShopKo Stores Operating Co., LLC

Green Bay, WI 54307, U.S.A

©2012 ShopKo Stores Operating Co., LLC



Bottle Label

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

bath·body·etc®

Winter Gumdrop

anti-bacterial hand gel

1 fl. oz.

SATISFACTION GUARANTEED BY REFUND OR EXCHANGE

Made in China

Distributed by Jets, Sets & Elephants Beauty Corp,

For ShopKo Stores Operating Co., LLC

Green Bay, WI 54307, U.S.A

©2012 ShopKo Stores Operating Co., LLC



Bottle Label

SHOPKO ANTIBACTERIAL HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50988-405
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	0.62 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TROLAMINE (UNII: 9O3K93S3TK)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
LACTOSE (UNII: J2B2A4N98G)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ULTRAMARINE BLUE (UNII: I39WR998B1)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50988-405-00	30 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/02/2012	

SHOPKO ANTIBACTERIAL HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50988-406
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.62 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TROLAMINE (UNII: 9O3K93S3TK)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
LACTOSE (UNII: J2B2A4N98G)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ULTRAMARINE BLUE (UNII: I39WR998B1)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50988-406-00	30 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/02/2012	

SHOPKO ANTIBACTERIAL HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50988-407
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.62 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TROLAMINE (UNII: 9O3K93S3TK)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
LACTOSE (UNII: J2B2A4N98G)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ULTRAMARINE BLUE (UNII: B9WR998B1)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50988-407-00	30 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/02/2012	

Labeler - Jets, Sets, & Elephants Beauty Corp. (243254039)

Establishment

Name	Address	ID/FEI	Business Operations
Gold Orient International Limited		679905914	MANUFACTURE(50988-405, 50988-406, 50988-407)

Revised: 6/2012

Jets, Sets, & Elephants Beauty Corp.