

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 - Ocean Breeze, Cherry Blossom, Red Pomegranate, Dark Raspberry, and Warm Vanilla Sugar

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 (Ocean Breeze)

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

Inactive ingredients (Cherry Blossom)

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

Hydroxypropyl Methylcellulose, Lactose, Parfum, Polysorbate 20, Propylene Glycol, Red 40, Retinyl Palmitate, Tocopheryl Acetate, Triethanolamine, Ultramarines, Yellow 5

Inactive ingredients (Red Pomegranate)

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

Inactive ingredients (Dark Raspberry)

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

Inactive ingredients (Warm Vanilla Sugar)

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Aqua, Cellulose, Hydroxypropyl Methylcellulose, Lactose, Parfum, Polysorbate 20, Propylene Glycol, Red 40, Retinyl Palmitate, Tocopheryl Acetate, Triethanolamine, Ultramarines, Yellow 5

QUESTIONS?

1-800-FDA-1088

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

bath·body·etc[®]

Ocean Breeze

anti-bacterial hand gel

1 fl. oz.

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



Ocean Breeze

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

bath·body·etc®

Cherry Blossom

anti-bacterial hand gel

1 fl. oz.

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



Cherry Blossom

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

bath·body·etc®

Red Pomegranate

anti-bacterial hand gel

1 fl. oz.

Made in China

Distributed by Jets, Sets & Elephants Beauty Corp,
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Green Bay, WI 54307, U.S.A

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Red Pomegranate

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

bath·body·etc®

Dark Raspberry

anti-bacterial hand gel

1 fl. oz.

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



Dark Raspberry

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

bath·body·etc®

Warm Vanilla Sugar

anti-bacterial hand gel

1 fl. oz.

Made in China

Distributed by Jets, Sets & Elephants Beauty Corp,

For ShopKo Stores Operating Co., LLC

Green Bay, WI 54307, U.S.A

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Warm Vanilla Sugar

SHOPKO ANTIBACTERIAL HAND SANITIZER

ethyl alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50988-288 |
| 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 BLUE NO. 1 (UNII: H3R47K3TBD) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------|----------------------|--------------------|
| 1 | NDC:50988-288-00 | 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 | 06/21/2012 | |

SHOPKO ANTIBACTERIAL HAND SANITIZER

ethyl alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50988-289 |
| 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 YELLOW NO. 5 (UNII: I753WB2F1M) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------|----------------------|--------------------|
| 1 | NDC:50988-289-00 | 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 | 06/21/2012 | |

SHOPKO ANTIBACTERIAL HAND SANITIZER

ethyl alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50988-400 |
| 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: 059QF0K00R) | |
| 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: H3R47K3TBD)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------|----------------------|--------------------|
| 1 | NDC:50988-400-00 | 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 | 06/21/2012 | |

SHOPKO ANTIBACTERIAL HAND SANITIZER

ethyl alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50988-401 |
| 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 MPAS) (UNII: 59TL3WG5CO) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) | |
| LACTOSE (UNII: J2B2A4N98G) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| HYPROMELLOSE 2208 (100 MPAS) (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: H3R47K3TBD) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------|----------------------|--------------------|
| 1 | NDC:50988-401-00 | 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 | 06/21/2012 | |

SHOPKO ANTIBACTERIAL HAND SANITIZER

ethyl alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50988-402 |
| 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 YELLOW NO. 5 (UNII: I753WB2F1M) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------|----------------------|--------------------|
| 1 | NDC:50988-402-00 | 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 | 06/21/2012 | |

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------------|---------|-----------|--|
| Gold Orient International Limited | | 679905914 | MANUFACTURE(50988-288, 50988-289, 50988-400, 50988-401, 50988-402) |

Revised: 6/2012

Jets, Sets, & Elephants Beauty Corp.