

SHOPKO ANTIBACTERIAL DEEP CLEANSING HAND- triclosan 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.

bath+body+etc[®] antibacterial deep cleansing hand soap - Ocean Breeze, Cherry Blossom, Warm Vanilla Sugar, Dark Raspberry, and Red Pomegranate

Active ingredient

Triclosan 0.2%

Purpose

Antibacterial

Uses

- handwashing to decrease bacteria on skin

Warnings

For external use only.

When using this product

Avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor

If irritation and redness develop.

Keep out of reach of children.

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

Directions

- wet hands, work into rich lather
- rinse well

Inactive Ingredients

Ocean Breeze

Acrylates copolymer, Aloe Barbadensis Leaf Juice, Benzophenone-4, Blue 1, Cellulose, Cocamide DEA, Cocamidopropyl Betaine, Disodium EDTA, DMDM Hydantoin, Hydroxypropyl methylcellulose, Lactose, Methylchloroisothiazolinone, Methylisothiazolinone, Parfum, PEG-150 Distearate, Polysorbate 20, Retinyl Palmitate, Red 33, Silica, Sodium Chloride, Sodium Hydroxide, Sodium Laureth Sulfate, Tocopheryl Acetate, Ultramarines, Water (Aqua).

Cherry Blossom

Acrylates copolymer, Aloe Barbadensis Leaf Juice, Benzophenone-4, Cellulose, Cocamide DEA, Cocamidopropyl Betaine, Disodium EDTA, DMDM Hydantoin, Hydroxypropyl methylcellulose, Lactose, Methylchloroisoithiazolinone, Methylisothiazolinone, Parfum, PEG-150 Distearate, Polysorbate 20, Red 33, Retinyl Palmitate, Silica, Sodium Chloride, Sodium Hydroxide, Sodium Laureth Sulfate, Tocopheryl Acetate, Ultramarines, Water (Aqua), Yellow 5.

Warm Vanilla Sugar

Acrylates copolymer, Aloe Barbadensis Leaf Juice, Benzophenone-4, Cellulose, Cocamide DEA, Cocamidopropyl Betaine, Disodium EDTA, DMDM Hydantoin, Hydroxypropyl methylcellulose, Lactose, Methylchloroisoithiazolinone, Methylisothiazolinone, Parfum, PEG-150 Distearate, Polysorbate 20, Red 33, Retinyl Palmitate, Silica, Sodium Chloride, Sodium Hydroxide, Sodium Laureth Sulfate, Tocopheryl Acetate, Ultramarines, Water (Aqua), Yellow 5.

Dark Raspberry

Acrylates copolymer, Aloe Barbadensis Leaf Juice, Benzophenone-4, Blue 1, Cellulose, Cocamide DEA, Cocamidopropyl Betaine, Disodium EDTA, DMDM Hydantoin, Hydroxypropyl methylcellulose, Lactose, Methylchloroisoithiazolinone, Methylisothiazolinone, Parfum, PEG-150 Distearate, Polysorbate 20, Red 33, Retinyl Palmitate, Silica, Sodium Chloride, Sodium Hydroxide, Sodium Laureth Sulfate, Tocopheryl Acetate, Ultramarines, Water (Aqua), Yellow 5.

Red Pomegranate

Acrylates copolymer, Aloe Barbadensis Leaf Juice, Benzophenone-4, Cellulose, Cocamide DEA, Cocamidopropyl Betaine, Disodium EDTA, DMDM Hydantoin, Hydroxypropyl methylcellulose, Lactose, Methylchloroisoithiazolinone, Methylisothiazolinone, Parfum, PEG-150 Distearate, Polysorbate 20, Red 33, Retinyl Palmitate, Silica, Sodium Chloride, Sodium Hydroxide, Sodium Laureth Sulfate, Tocopheryl Acetate, Ultramarines, Water (Aqua), Yellow 5.

Questions?

1-800-FDA-1088

Package/Label Principal Display Panel - Bottle Label

bath+body+etc[®]

Ocean Breeze

antibacterial

deep cleansing

hand soap

10.1 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 Bottle Label

Package/Label Principal Display Panel - Bottle Label

bath+body+etc®

Cherry Blossom

antibacterial

deep cleansing

hand soap

10.1 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 Bottle Label

Package/Label Principal Display Panel - Bottle Label

bath+body+etc®

Warm Vanilla Sugar

antibacterial

deep cleansing

hand soap

10.1 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



Warm Vanilla Sugar Bottle Label



Package/Label Principal Display Panel - Bottle Label

bath+body+etc.[®]

Dark Raspberry

antibacterial

deep cleansing

hand soap

10.1 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 Bottle Label



Package/Label Principal Display Panel - Bottle Label

bath+body+etc®

Red Pomegranate

antibacterial

deep cleansing

hand soap

10.1 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



Red Pomegranate Bottle Label

triclosan gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50988-450
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.2 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
LACTOSE (UNII: J2B2A4N98G)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
ULTRAMARINE BLUE (UNII: I39WR998B1)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
SULISOBENZONE (UNII: 1W6L629B4K)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50988-450-00	299 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/22/2012	

SHOPKO ANTIBACTERIAL DEEP CLEANSING HAND

triclosan gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50988-451
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.2 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
LACTOSE (UNII: J2B2A4N98G)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
ULTRAMARINE BLUE (UNII: I39WR998BI)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
SULISOBENZONE (UNII: 1W6L629B4K)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
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:50988-451-00	299 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/22/2012	

SHOPKO ANTIBACTERIAL DEEP CLEANSING HAND

triclosan gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50988-452
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.2 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
LACTOSE (UNII: J2B2A4N98G)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
ULTRAMARINE BLUE (UNII: I39WR998B1)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
SULISOBENZONE (UNII: 1W6L629B4K)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
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:50988-452-00	299 mL in 1 BOTTLE	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/22/2012	

SHOPKO ANTIBACTERIAL DEEP CLEANSING HAND
triclosan gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50988-453
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.2 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
LACTOSE (UNII: J2B2A4N98G)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
ULTRAMARINE BLUE (UNII: I39WR998BI)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
SULISOBENZONE (UNII: 1W6L629B4K)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
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:50988-453-00	299 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/22/2012	

SHOPKO ANTIBACTERIAL DEEP CLEANSING HAND

triclosan gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50988-454
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.2 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
LACTOSE (UNII: J2B2A4N98G)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
ULTRAMARINE BLUE (UNII: B9WR998BI)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
SULISOBENZONE (UNII: 1W6L629B4K)	

VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
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:50988-454-00	299 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/22/2012	

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

Establishment

Name	Address	ID/FEI	Business Operations
Gold Orient International Limited		679905914	MANUFACTURE(50988-450, 50988-451, 50988-452, 50988-453, 50988-454)

Revised: 6/2012

Jets, Sets, & Elephants Beauty Corp.