LAND SHARK SPF 45- octocrylene, octinoxate, oxybenzone, homosalate and octisalate lotion Tropical Seas, Inc.

Drug Facts

Active Ingredients

Octocrylene 8.0%

Octinoxate 7.5%

Oxybenzone 6.0%

Homosalate 5.0%

Octisalate 5.0%

Purpose

Sunscreen

Uses

helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown to prevent sunburn, not skin cancer or early skin aging.

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- · children under 6 months: Ask a doctor

Inactive Ingredients

aqueous extracts of: aloe barbadensis leaf extract, algae extract (hawaiian seaplant), chamomilla recutita (matricaria) flower extract, symphytum officinale (comfrey) root & leaf extract, taraxacum officinale (dandelion) leaf extract, echinacea purpurea (coneflower) extract, sambucus nigra (elder) flower extract, panax quinquefolium (ginseng) root extract, macrocystis pyrifera (kelp) extract, lavandula angustifolia (lavender) extract, cymbopogon schoenanthus (lemon grass) extract, althea officinalis (marshmallow) root extract, achillea millefolium (yarrow flower) extract, camellia sinensis (white tea) extract, stearic acid (vegetable derived), glyceryl stearate se (vegetable derived), titanium dioxide, cetyl dimethicone, glycerin (coconut derived), sodium hydroxide, emulsifying wax (vegetable derived), tricontanyl-pvp, polyethylene, acrylates/c10-30 alkyl acrylates cross-polymer, methylparaben, cetyl alcohol (vegetable derived), diazolidinyl urea and propylparaben.

Other Information

• protect this product from excessive heat and direct sun

Questions or comments?

Call toll free 1-800-368-7327

Principal Display Panel - Bottle Label

120 ml NDC: 52854-945-01







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Other Information

protect this product from excessive heat and direct sun

Questions or comments?

Call toll free 1-800-368-7327

Made in the Tropical Seas® Ormond Beach, FL 32173

U.S.A. by:

1-800-368-SEAS (7327)

www.tropicalseas.com





LAND SHARK SPF 45

octocrylene, octinoxate, oxybenzone, homosalate and octisalate lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52854-945	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 g in 100 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	6 g in 100 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL	

Ingredient Name	Inactive Ingredients			
ALOE VERA LEAF (UNII: ZY81Z83HOX) CARRAGEENAN (UNII: 5C69YCD2YJ) CHAMOMILE (UNII: FGL3685TZX) SYMPHYTUM UPLANDICUM LEAF (UNII: D05HXK6R3G) COMFREY ROOT (UNII: M9VVZ 08EKQ) TARAXACUM OFFICINALE LEAF (UNII: 0022LFJ74Y) ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T) AMERICAN GINSENG (UNII: 8W75VCV53Q) MACROCYSTIS PYRIFERA (UNII: X31S3OG5C4) LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4871U8P) CYMBOPOGON SCHOENANTHUS TOP (UNII: 9YT4871U8P) CYMBOPOGON SCHOENANTHUS TOP (UNII: 9YT4871U8P) CYMBOPOGON SCHOENANTHUS TOP (UNII: YQR8R0SQEA) GREEN TEA LEAF (UNII: WZZU1RYB80) STEARIC ACID (UNII: 4ELV7Z65AP) GLYCERYL STEARATE SE (UNII: FCZ5MH785I) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) CETYL DIMETHICONE 150 (UNII: 5L694Y0T22) GLYCERIN (UNII: PDC6A3COOX) SODIUM HYDROXIDE (UNII: 5DMT128M1S) POLYSORBATE 60 (UNII: CAL22UVI4M) TRICONTANYL POVIDONE (UNII: NOSS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: WGOKM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: 45RIZ 3MPW4)	Ingredient Name	Strength		
CARRAGEENAN (UNII: 5C69YCD2YJ) CHAMOMILE (UNII: FGL3685T2X) SYMPHYTUM UPLANDICUM LEAF (UNII: D05HXK6R3G) COMFREY ROOT (UNII: M9VVZ08EKQ) TARAXACUM OFFICINALE LEAF (UNII: 0022LFJ74Y) ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T) AMERICAN GINSENG (UNII: 8W75VCV53Q) MACROCYSTIS PYRIFERA (UNII: K181530G5C4) LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4871U8P) CYMBOPOGON SCHOENANTHUS TOP (UNII: 9SJILLW39W) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H) ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA) GREEN TEA LEAF (UNII: WZZU1RY8B0) STEARIC ACID (UNII: 15FIX9VZ)P) CETYL DIMETHICONE 150 (UNII: 5L694Y0T22) GLYCERYL STEARATE SE (UNII: 5SX04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UVI4M) TRICONTANYL POVIDONE (UNII: NOSS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A218C7HIST) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: HSRIZ3MPW4)	WATER (UNII: 059QF0KO0R)			
CHAMOMILE (UNII: FGL3685T2X) SYMPHYTUM UPLANDICUM LEAF (UNII: D05HXK6R3G) COMFREY ROOT (UNII: MYV/Z 08EKQ) TARAXACUM OFFICINALE LEAF (UNII: 0022LFJ74Y) ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T) AMERICAN GINSENG (UNII: 8W75VCV53Q) MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4) LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P) CYMBOPOGON SCHOENANTHUS TOP (UNII: 9SJILW39W) ALTHAEA OFFICINALIS ROOT (UNII: TRV2FUF47H) ACHILLEAM ILLEFOLIUM FLOWER (UNII: YQR8R0SQEA) GREEN TEA LEAF (UNII: WZZU1RY8B0) STEARIC ACID (UNII: 4ELV7Z65AP) GLYCERYL STEARATE SE (UNII: FCZ5MH785I) TITANIUM DIOXIDE (UNII: 15FIX9VZJP) CETYL DIMETHICONE 150 (UNII: 55K04Y0722) GLYCERIN (UNII: PDC6A3COOX) SODIUM HYDROXIDE (UNII: 55X04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UV14M) TRICONTANYL POVIDONE (UNII: MOSS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UGOOKM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A218C7HIST) CETYL ALCOHOL (UNII: 936JST6JCN)	ALOE VERA LEAF (UNII: ZY81Z83H0X)			
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COMFREY ROOT (UNII: M9VVZ 08EKQ) TARAXACUM OFFICINALE LEAF (UNII: 0022LFJ74Y) ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T) AMERICAN GINSENG (UNII: 8W75VCV53Q) MACROCYSTIS PYRIFERA (UNII: K31530G5C4) LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P) CYMBOPOGON SCHOENANTHUS TOP (UNII: 9SJILLW39W) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H) ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA) GREEN TEA LEAF (UNII: W2ZU1RY8B0) STEARIC ACID (UNII: 4ELV7Z65AP) GLYCERYL STEARATE SE (UNII: FCZ5MH785I) TITANIUM DIOXIDE (UNII: 55X04QC32I) CETYL DIMETHICONE 150 (UNII: 55X04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL2ZUVI4M) TRICONTANYL POVIDONE (UNII: W3S3Q238D) MIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A218C7H19T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	CHAMOMILE (UNII: FGL3685T2X)			
TARAXACUM OFFICINALE LEAF (UNII: 0022LFJ74Y) ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T) AMERICAN GINSENG (UNII: 8W75VCV53Q) MACROCYSTIS PYRIFERA (UNII: K3153OG5C4) LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P) CYMBOPOGON SCHOENANTHUS TOP (UNII: 9SJJ1LW39W) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H) ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA) GREEN TEA LEAF (UNII: WZZU1RY8B0) STEARIC ACID (UNII: 4ELV7Z65AP) GLYCERYL STEARATE SE (UNII: FCZ5MH785I) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) CETYL DIMETHICONE 150 (UNII: 55K04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UV4M) TRICONTANYL POVIDONE (UNII: NOSS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UGO0KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: 42I8C7HI9T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ 3MPW4)	SYMPHYTUM UPLANDICUM LEAF (UNII: D05HXK6R3G)			
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T) AMERICAN GINSENG (UNII: 8W75VCV53Q) MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4) LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P) CYMBOPOGON SCHOENANTHUS TOP (UNII: 9SJILLW39W) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H) ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA) GREEN TEA LEAF (UNII: WZZU1RY8B0) STEARIC ACID (UNII: 4ELV7Z65AP) GLYCERYL STEARATE SE (UNII: FCZ5MH785I) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) CETYL DIMETHICONE 150 (UNII: 55K04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UV14M) TRICONTANYL POVIDONE (UNII: NOSS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UGOOKM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A2IBC7H19T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ 3MPW4)	COMFREY ROOT (UNII: M9VVZ 08EKQ)			
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MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4) LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P) CYMBOPOGON SCHOENANTHUS TOP (UNII: 9SJILLW39W) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H) ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8ROSQEA) GREEN TEA LEAF (UNII: W2ZU1RY8B0) STEARIC ACID (UNII: 4ELV7Z65AP) GLYCERYL STEARATE SE (UNII: FCZ5MH785I) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) CETYL DIMETHICONE 150 (UNII: 5L694Y0T22) GLYCERIN (UNII: PDC6A3C0OX) SODIUM HYDROXIDE (UNII: 25X04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UVI4M) TRICONTANYL POVIDONE (UNII: NOSS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: 4218C7H19T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T)			
LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P) CYMBOPOGON SCHOENANTHUS TOP (UNII: 9SJI1LW39W) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H) ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA) GREEN TEA LEAF (UNII: W2Z U1RY8B0) STEARIC ACID (UNII: 4ELV7Z65AP) GLYCERYL STEARATE SE (UNII: FCZ5MH785I) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) CETYL DIMETHICONE 150 (UNII: 5L694Y0T22) GLYCERIN (UNII: PDC6A3C0OX) SODIUM HYDROXIDE (UNII: 25X04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UVI4M) TRICONTANYL POVIDONE (UNII: NOSS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A2I8C7H19T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ 3MPW4)	AMERICAN GINSENG (UNII: 8W75VCV53Q)			
CYMBOPOGON SCHOENANTHUS TOP (UNII: 9SJI1LW39W) ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H) ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA) GREEN TEA LEAF (UNII: W2ZU1RY8B0) STEARIC ACID (UNII: 4ELV7Z65AP) GLYCERYL STEARATE SE (UNII: FCZ5MH785I) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) CETYL DIMETHICONE 150 (UNII: 5L694Y0T22) GLYCERIN (UNII: PDC6A3C0OX) SODIUM HYDROXIDE (UNII: 55X04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UVI4M) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A2I8C7HI9T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)			
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H) ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8ROSQEA) GREEN TEA LEAF (UNII: WZZU1RY8B0) STEARIC ACID (UNII: 4ELV7Z65AP) GLYCERYL STEARATE SE (UNII: FCZ5MH785I) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) CETYL DIMETHICONE 150 (UNII: 5L694Y0T22) GLYCERIN (UNII: PDC6A3COOX) SODIUM HYDROXIDE (UNII: 55X04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UVI4M) TRICONTANYL POVIDONE (UNII: NOSS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A2I8C7H19T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)			
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA) GREEN TEA LEAF (UNII: W2ZU1RY8B0) STEARIC ACID (UNII: 4ELV7Z65AP) GLYCERYL STEARATE SE (UNII: FCZ5MH785I) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) CETYL DIMETHICONE 150 (UNII: 5L694Y0T22) GLYCERIN (UNII: PDC6A3C0OX) SODIUM HYDROXIDE (UNII: 55X04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UVI4M) TRICONTANYL POVIDONE (UNII: NOSS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A2I8C7HI9T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ 3MPW4)	CYMBOPOGON SCHOENANTHUS TOP (UNII: 9SJI1LW39W)			
GREEN TEA LEAF (UNII: WZZU1RY8B0) STEARIC ACID (UNII: 4ELV7Z65AP) GLYCERYL STEARATE SE (UNII: FCZ5MH785I) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) CETYL DIMETHICONE 150 (UNII: 5L694Y0T22) GLYCERIN (UNII: PDC6A3C0OX) SODIUM HYDROXIDE (UNII: 55X04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UVI4M) TRICONTANYL POVIDONE (UNII: NOSS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A2I8C7HI9T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)			
STEARIC ACID (UNII: 4ELV7Z65AP) GLYCERYL STEARATE SE (UNII: FCZ5MH785I) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) CETYL DIMETHICONE 150 (UNII: 5L694Y0T22) GLYCERIN (UNII: PDC6A3C0OX) SODIUM HYDROXIDE (UNII: 55X04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UVI4M) TRICONTANYL POVIDONE (UNII: NOSS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A2I8C7HI9T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA)			
GLYCERYL STEARATE SE (UNII: FCZ5MH785I) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) CETYL DIMETHICONE 150 (UNII: 5L694Y0T22) GLYCERIN (UNII: PDC6A3C0OX) SODIUM HYDROXIDE (UNII: 55X04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UVI4M) TRICONTANYL POVIDONE (UNII: NOSS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A2I8C7HI9T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) CETYL DIMETHICONE 150 (UNII: 5L694Y0T22) GLYCERIN (UNII: PDC6A3C0OX) SODIUM HYDROXIDE (UNII: 55X04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UVI4M) TRICONTANYL POVIDONE (UNII: NOSS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A2I8C7HI9T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	STEARIC ACID (UNII: 4ELV7Z65AP)			
CETYL DIMETHICONE 150 (UNII: 5L694Y0T22) GLYCERIN (UNII: PDC6A3C0OX) SODIUM HYDROXIDE (UNII: 55X04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UVI4M) TRICONTANYL POVIDONE (UNII: N0SS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A218C7H19T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	GLYCERYL STEARATE SE (UNII: FCZ5MH785I)			
GLYCERIN (UNII: PDC6A3C0OX) SODIUM HYDROXIDE (UNII: 55X04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UVI4M) TRICONTANYL POVIDONE (UNII: NOSS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A2I8C7HI9T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
SODIUM HYDROXIDE (UNII: 55X04QC32I) CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UVI4M) TRICONTANYL POVIDONE (UNII: N0SS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A2I8C7HI9T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	CETYL DIMETHICONE 150 (UNII: 5L694Y0T22)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) POLYSORBATE 60 (UNII: CAL22UVI4M) TRICONTANYL POVIDONE (UNII: NOSS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A2I8C7HI9T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	GLYCERIN (UNII: PDC6A3C0OX)			
POLYSORBATE 60 (UNII: CAL22UVI4M) TRICONTANYL POVIDONE (UNII: N0SS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A2I8C7HI9T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	SODIUM HYDROXIDE (UNII: 55X04QC32I)			
TRICONTANYL POVIDONE (UNII: N0SS3Q238D) HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A218C7H19T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
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CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) METHYLPARABEN (UNII: A2I8C7HI9T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	TRICONTANYL POVIDONE (UNII: NOSS3Q238D)			
METHYLPARABEN (UNII: A2I8C7HI9T) CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)			
CETYL ALCOHOL (UNII: 936JST6JCN) DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)			
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	METHYLPARABEN (UNII: A2I8C7HI9T)			
	CETYL ALCOHOL (UNII: 936JST6JCN)			
PROPYLPARABEN (UNII: Z8IX2SC10H)	DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)			
	PROPYLPARABEN (UNII: Z8IX2SC1OH)			

I	Packaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	,	NDC:52854-	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a	07/22/2020	

945-01	Combination Product	01/22/2020		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Dru	g M020	07/22/2020		

Labeler - Tropical Seas, Inc. (627865660)

Establishment				
Name	Address	ID/FEI	Business Operations	
Tropical Seas, Inc.		627865660	manufacture(52854-945)	

Revised: 10/2023 Tropical Seas, Inc.