

TROPICSURF EXTREME PROTECTION SPF50- octocrylene, zinc oxide lotion
PALMER SURF LLC (DBA X3EMBRANDS)

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.

ACTIVE INGREDIENT

- OCTOCRYLENE 7.5%
- ZINC OXIDE 10.5%

DIRECTIONS

- APPLY LIBERALLY 15 MINUTES PRIOR TO SUN EXPOSURE. REAPPLY AFTER 80 MINUTES OF SWIMMING OR SWEATING; IMMEDIATELY AFTER TOWEL DRYING; AND, AT LEAST EVERY 2 HOURS.

SUN PROTECTION MEASURES:

- SPENDING TIME IN THE SUN INCREASES YOUR RISK OF SKIN CANCER AND EARLY SKIN AGING. TO DECREASE THIS RISK, REGULARLY USE A SUNSCREEN WITH A BROAD SPECTRUM SPF VALUE OF 15 OR HIGHER AND OTHER SUN PROTECTION MEASURES INCLUDING: LIMIT TIME IN THE SUN, ESPECIALLY FROM 10 AM TO 2 PM; WEAR LONG-SLEEVE SHIRTS, PANTS, HATS AND SUNGLASSES; CHILDREN UNDER 6 MOS. OF AGE, ASK A DOCTOR

PURPOSE:

- SUNSCREEN

Uses:

- HELPS PREVENT SUNBURN
- IF USED AS DIRECTED WITH OTHER SUN PROTECTION MEASURES (SEE DIRECTIONS), DECREASES THE RISK OF SKIN CANCER AND EARLY SKIN AGING CAUSED BY THE SUN.

WARNINGS

FOR EXTERNAL USE ONLY

DO NOT USE ON DAMAGED OR BROKEN SKIN

WHEN USING THIS PRODUCT

- KEEP OUT OF THE EYES.
- RINSE WITH WATER TO REMOVE

STOP USE AND ASK A DOCTOR IF

- IF RASH OCCURS

KEEP OUT OF REACH OF CHILDREN.

- IF PRODUCT IS SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

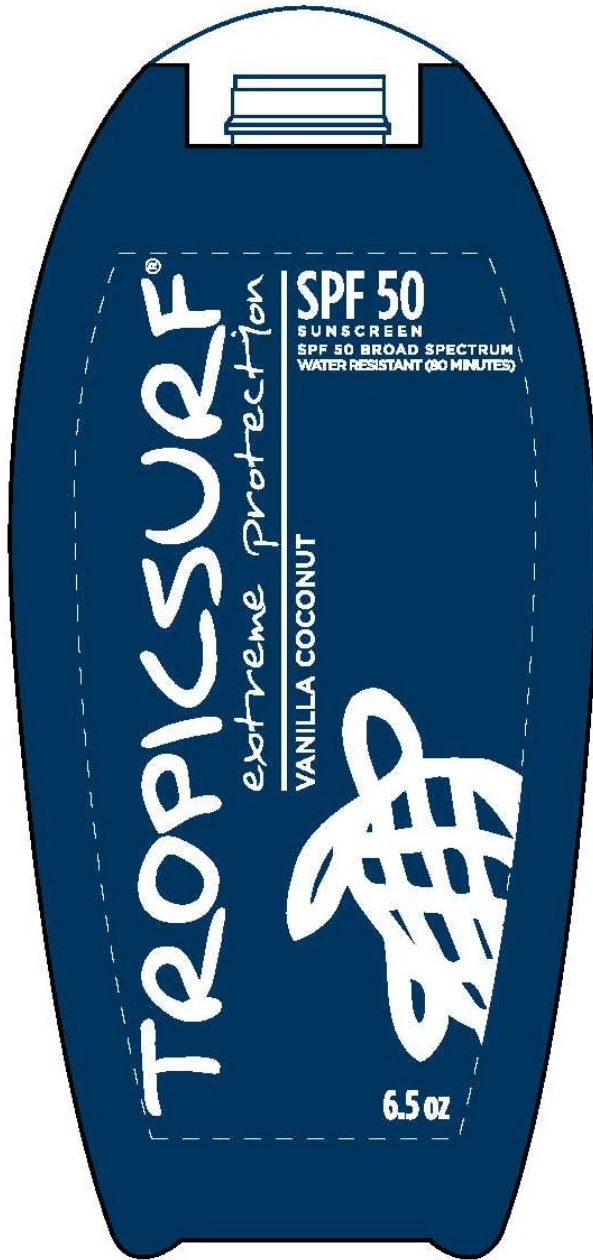
INACTIVE INGREDIENTS:

WATER/AQUA/EAU, OCTYLDODECYL NEOPENTANOATE, DIMETHICONE, CETEARYL ALCOHOL, ACRYLATES COPOLYMER,

PEG-100 STEARATE, GLYCERYL STEARATE, PENTYLENE GLYCOL, PHENYL TRIMETHICONE, GLYCERIN, CYCLOPENTASILOXANE,
TRIMETHYLSILOXYSILICATE, PEG-40 STEARATE, ALOE BARBADENSIS LEAF JUICE, CAMELLIA OLEIFERA LEAF JUICE,
ASTROCARYUM TUCUMA SEED BUTTER, MACADAMIA TERNIFOLIA SEED OIL, ADANSONIA DIGITATA SEED OIL, MANGIFERA
INDICA (MANGO) SEED BUTTER, COCO GLUCOSIDE, TOCOPHERYL ACETATE, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL
TAURATE COPOLYMER, SQUALANE, POLYSORBATE 60, POLYSILICONE-11, SODIUM POLYACRYLATE, XANTHAN GUM,
DICETYL PHOSPHATE, CETTH-10 PHOSPHATE, AMINOMETHYLPROPANOL, DISODIUM EDTA, CAPRYLYL GLYCOL, PHENOXYETHANOL,
CHLOPHENESIN, BENXYL CINNAMATE, COUMARIN, LIMONENE, HEXYL CINNAMAL, FRAGRANCE (PARFUM)

FRONT - 6.5 OZ

BACK- 6.5 OZ



TROPICSURF EXTREME PROTECTION SPF50

octocrylene, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70884-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	7.5 g in 100 mL

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)

ZINC CATION

10.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
ASTROCARYUM ACULEATUM SEED OIL (UNII: JUP28JXP3K)	
MACADAMIA OIL (UNII: 515610SU8C)	
ADANSONIA DIGITATA SEED OIL (UNII: 77MKL7AR5I)	
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
COCO GLUCOSIDE (UNII: ICS790225B)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPAS AT 1.5%) (UNII: 86FQE96TZ4)	
SQUALANE (UNII: GW89575KF9)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
SODIUM POLYACRYLATE (250000 MW) (UNII: 05115JN12J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BENZYL CINNAMATE (UNII: V67O3RO97U)	
COUMARIN (UNII: A4VZ22K1WT)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
.ALPHA.-HEXYL CINNAMALDEHYDE (UNII: 7X6O37OK2I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70884-102-11	45 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/04/2016	
2	NDC:70884-102-03	90 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/04/2016	

3	NDC:70884-102-16	195 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/04/2016	
4	NDC:70884-102-13	390 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/04/2016	
5	NDC:70884-102-30	960 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/04/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/04/2016	

Labeler - PALMER SURF LLC (DBA X3EMBRANDS) (080315280)

Registrant - PALMER SURF LLC (DBA X3EMBRANDS) (080315280)

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PALMER SURF LLC (DBA X3EMBRANDS)