TROPICSURF EXTREME PROTECTION SPF30-ULTRA- titanium dioxide, 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 INGREDIENTS

- TITANIUM DIOXIDE 4.5%
- ZINC OXIDE 8.7%

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 RISKI 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, CAPRYLIC/CAPRIC TRIGLYCERIDE, GLYCERIN, CETEARYL ALCOHOL, STEARETH-2, VP/HEXADECENE COPOLYMER,

STEREATH-21, DIMETHICONE, POLYHYDROXYSTEARIC ACID, ALOE BARBADENSIS LEAF EXTRACT, CAMELLIA OLEIFERA

LEAF EXTRACT, PLEIOGYNIUM TIMORIENSE FRUIT EXTRACT, PODOCARPS ELATUS FRUIT EXTRACT, TERMINALIA FERDINANDIANA

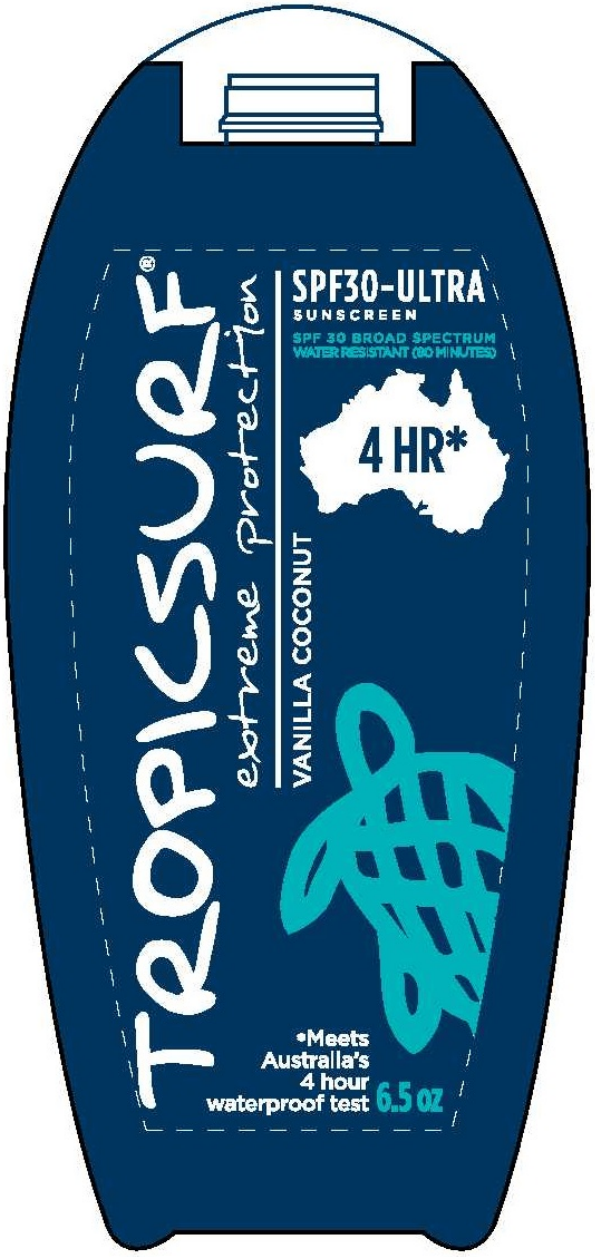
FRUIT EXTRACT, ADANSONIA DIGITATA SEED OIL, ASTROCARYUM TUCUMA SEED BUTTER, MADACAMIA TERNIFOLIA NUT OIL,

DIPOTASSIUM GLYCYRRHIZATE, ALUMINA, STEARIC ACID, SODIUM STEAROYL GLUTAMATE, TRIETHOXYCAPRYLYLSILANE,

PROPANEDIOL, CAPRYLHYDROXAMIC ACID, DISODIUM EDTA, XANTHAN GUM, CAPRYLYL GLYCOL, ALCOHOL DENAT.,

FRAGRANCE (PARFUM)

FRONT - 6.5 OZ



BACK- 6.5 OZ

TROPICSURF EXTREME PROTECTION SPF30-ULTRA

titanium dioxide, zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70884-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.5 g in 100 mL

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	8.7 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
STEARETH-2 (UNII: V56DFE46J5)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
STEARETH-21 (UNII: 53J3F32P58)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
PLUM (UNII: 67M3EQ6BE1)	
PODOCARPUS ELATUS WHOLE (UNII: H38807Y47G)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
ADANSONIA DIGITATA SEED OIL (UNII: 77MKL7AR5I)	
ASTROCARYUM ACULEATUM SEED OIL (UNII: JUP28JPX3K)	
MACADAMIA OIL (UNII: 515610SU8C)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PROPANEDIOL (UNII: 5965N8W85T)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70884-101-11	45 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2016	
2	NDC:70884-101-03	90 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2016	
3	NDC:70884-101-16	195 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2016	
4	NDC:70884-101-13	390 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2016	
5	NDC:70884-101-32	960 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/03/2016	

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

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

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