DD TZ FORTE- titanium dioxide, zinc oxide, octinoxate, octisalate lotion
LINEX HEALTH & BEAUTY

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.

Linex (as PLD) - TZ FORTE (69769-102)

ACTIVE INGREDIENTS

TITANIUM DIOXIDE 2%

ZINC OXIDE 8%

OCTINOXATE 7.5%

OCTISALATE 5%

PURPOSE

SUNSCREEN

USES

- HELPS PREVENT SUNBURN.
- IF USED AS DIRECTED WITH OTHER SUN PROTECTION MEASURES (SEE DIRECTION), 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 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 BEFORE SUN EXPOSURE.
- REAPPLY -
- AFTER 40 MINUTES OF SWIMMING
- AT LEAST EVERY 2 HOURS
- CHILDREN UNDER 6 MONTHS; ASK A DOCTOR.

OTHER INFORMATION

PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN.

INACTIVE INGREDIENTS

WATER, CYCLOPENTASILOXANE, GLYCERIN, PEG-10 DIMETHICONE, DIMETHICONE, POLYMETHYL METHACRYLATE, CETEARYL ISONONANOATE, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, ACRYLATES/DIMETHICONE COPOLYMER, METHYL METHACRYLATE CROSSPOLYMER, SODIUM CHLORIDE, POLYGLYCERYL-3 POLYRICINOLEATE, GINKGO BILOBA LEAF EXTRACT, JOJOBA ESTERS, ALOE BARBADENSIS LEAF JUICE, PHENOXYETHANOL, DISTEARDIMONIUM HECTORITE, GLYCYRRHIZA GLABRA (LICORICE) ROOT EXTRACT, BUTYLENE GLYCOL, SORBITAN SESQUIOLEATE, ALUMINUM HYDROXIDE, STEARIC ACID, CETYL RICINOLEATE, CAPRYLYL GLYCOL, TRIETHOXYCAPRYLYLSILANE, ETHYLHEXYLGLYCERIN, GLYCERYL CAPRATE, MAGNESIUM STEARATE, ALUMINUM TRISTEARATE, SILICA SILYLATE, HEXYLENE GLYCOL, TOCOPHEROL, BEESWAX, VINYL DIMETHICONE/METHICONE SESQUIOXANE CROSSPOLYMER, LYCIUM BARBARUM FRUIT EXTRACT, FRAGRANCE. MAY CONTAIN: MICA, IRON OXIDES (CI 77491, CI 77492, CI 77499)

DD TZ FORTE

titanium dioxide, zinc oxide, octinoxate, octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69769-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	8 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
DIMETHICONE 100 (UNII: RO266O364U)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
METHYL METHACRYLATE (UNII: 196OC77688)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6)	
GINKGO BILOBA WHOLE (UNII: 660486U6OI)	
MICA (UNII: V8A1AW0880)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
LICORICE (UNII: 61ZBX54883)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL RICINOLEATE (UNII: 1P677500YD)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL CAPRATE (UNII: 197M6VFC1W)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ALUMINUM STEARATES (UNII: O4D7U3B46U)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
TOCOPHEROL (UNII: R0ZB2556P8)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
LYCIUM BARBARUM FRUIT (UNII: 930626MWDL)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69769-102-51	1 in 1 BOX	04/29/2015	
1	NDC:69769-102-11	50 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/29/2015	

Labeler - LINEX HEALTH & BEAUTY (050219996)

Revised: 12/2022 LINEX HEALTH & BEAUTY