LIVESTS MOIST FOUNDATION 122- titanium dioxide liquid ARSOA HONSHA CORPORATION

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.

Drug Facts

Active ingredients

Titanium dioxide 10.2%

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.
- higher SPF gives more sunburn protection.
- provides moderate protection against sunburn and tanning.

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 or irritation develops and lasts.

• side effects occur. You may report side effects to FDA at 1-800-FDA-1088.

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

Directions

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 10a.m.-2p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses.
- Shake well before use.
- Use a normal foundation.
- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply as needed or after towel drying, swimming or perspiring.
- Children under 6 months of age: ask a doctor.

Inactive ingredients

water, cyclopentasiloxane, butylene glycol, Cl 77891, titanium dioxide, octyldodecyl neopentanoate, glycerin, talc, phenyl trimethicone, peg-9 olydimethylsiloxyethyl dimethicone, cetyl ethylhexanoate, neopentyl glycol diethylhexanoate, dimethicone, mica, Cl 77492, acrylates/dimethicone copolymer, aluminum hydroxide, betaine, polymethylsilsesquioxane, phytosteryl/isostearyl/cetyl/stearyl/behenyl dimer dilinoleate, dimethicone/vinyl dimethicone crosspolymer, stearic acid, sodium chloride, phenoxyethanol, Cl 77491, polyglyceryl-2 triisostearate, triethoxycaprylylsilane, Cl 77499, tocopherol, hydrogen dimethicone, hydroxyapatite, stearyl glycyrrhetinate, squalane, hydroxyproline, phytosteryl/octyldodecyl lauroyl glutamate, phytosteryl macadamlate, zinc oxide, palmitoyl proline, glycyrrhiza glabra (licorice) root extract, sodium palmitoyl sarcosinate, magnesium palmitoyl glutamate, palmitic acid, alumina, saxifraga sarmentosa extract, cynara scolymus (artichoke) leaf extract

Other Information

• protect the product in this container from excessive heat and direct sun.

Principal Display Panel - 20 mL Carton Label

LIVEST'S

MOIST LIQUID FOUNDATION 122

Liqud Foundation SUNSCREEN

BROAD SPECTRUM

SPF 15

Warnings:

The safety of this product has not been determined.

NET 0.67 FL.OZ.

(20 ML)



LIVESTS MOIST FOUNDATION 122

titanium dioxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55655-270
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Titanium dioxide (UNII: 15FIX9 V2JP) (Titanium dioxide - UNII:15FIX9 V2JP)	Titanium dio xide	2.31 g in 20 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TALC (UNII: 7SEV7J4R1U)	
O CTYLDO DECYL NEO PENTANO ATE (UNII: X8725R883T)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENYL TRIMETHICO NE (UNII: DR0 K5NO J4R)	
PEG-9 POLYDIMETHYLSILO XYETHYL DIMETHICONE (UNII: TYP8 1E471F)	
CETYL ETHYLHEXANO ATE (UNII: 134647WMX4)	
NEOPENTYL GLYCOL DIETHYLHEXANOATE (UNII: U68ZV6W62C)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
MICA (UNII: V8A1AW0880)	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
BETAINE (UNII: 3SCV180C9W)	
PHYTOSTERYL/ISOSTEARYL/CETYL/STEARYL/BEHENYL DIMER DILINOLEATE (UNII: 8 N725H4EFN)	
DIMETHICO NE/VINYL DIMETHICO NE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SO DIUM CHLO RIDE (UNII: 451W47IQ8 X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-2 TRIISOSTEARATE (UNII: 68 DUY2D39 A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TRIETHO XYCAPRYL YLSILANE (UNII: LDC331P08E)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
TOCOPHEROL (UNII: R0ZB2556P8)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
HYDRO XYPRO LINE (UNII: RMB44WO89X)	
STEARYL GLYCYRRHETINATE (UNII: 3YYE6 VJS0P)	
SQUALANE (UNII: GW89575KF9)	
TRIBASIC CALCIUM PHO SPHATE (UNII: 91D9 GV0 Z28)	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)	
PHYTOSTERYL MACADAMIATE (UNII: 233VSF903M)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
PALMITO YL PROLINE (UNII: 149727TDYF)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
SODIUM PALMITOYL SARCOSINATE (UNII: 7297LY09YF)	
MAGNESIUM PALMITO YL GLUTAMATE (UNII: DH37YM1F48)	
PALMITIC ACID (UNII: 2V16EO95H1)	
ALUMINUM O XIDE (UNII: LMI26O6933)	
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)	

CYNARA SCOLYMUS LEAF (UNII: B71UA545DE)

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:55655-270- 01	1 in 1 BOX	12/09/2016	
1	20 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/09/2016	

Labeler - Arsoa Honsha Corporation (694245452)

Establishment			
Name	Address	ID/FEI	Business Operations
NIPPON SHIKIZAI, INC		694869178	ANALYSIS(55655-270), LABEL(55655-270), MANUFACTURE(55655-270), PACK(55655-270), PARTICLE SIZE REDUCTION(55655-270), RELABEL(55655-270), REPACK(55655-270), STERILIZE(55655-270)

Revised: 12/2016 ARSOA HONSHA CORPORATION