SUN SAVVY SOLAR SHIELD SPF 20- zinc oxide titanium dioxide lotion
APPLIED SKIN TECHNOLOGY LLC

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.

SUN SAVVY SOLAR SHIELD SPF 20

ACTIVE INGREDIENTS:
ZINC OXIDE 5% TITANIUM DIOXIDE 5%

PURPOSE:
SUNSCREEN

USES: PREVENTION OF SUNBURN, REDUCTION OF SKIN DAMAGE AND PREMATURE AGING CAUSED BY SUN EXPOSURE.

WARNING: FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT: KEEP OUT OF EYES, RINSE WITH WATER TO REMOVE.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS: APPLY A SMALL AMOUNT EVENLY BEFORE SUN EXPOSURE AND AS NEEDED. ASK A DOCTOR BEFORE USE ON CHILDREN UNDER 6 MONTHS OF AGE. REAPPLY AFTER TOWEL DRYING, SWIMMING OR PERSPIRING.

OTHER INFORMATION: LIMITING SUN EXPOSURE, WEARING PROTECTIVE CLOTHING AND USING SUNSCREEN MAY REDUCE THE RISKS OF SKIN AGING, SKIN CANCER AND OTHER HARMFUL AFFECTS OF THE SUN. MAY STAIN FABRIC.

INACTIVE INGREDIENTS: PURIFIED WATER, CETYL DIMETHICONE COPOLYOL, POLYGLYCERYL-4 ISOSTEARATE, HEXYL LAURATE, ETHYLHEXYL PALMITATE, ISOHEXADECANE, CAPRIC CAPRYLIC TRIGLYCERIDES, DIMETHICONE, CETYL DIMETHICONE, SODIUM CHLORIDE, SODIUM PCA, PHENOXYETHANOL, ISOPENTYLDIOL, CAPRYLYL GLYCOL, ALLANTOIN.

DERMAGENICS
PHYSICIAN FORMULATED

SUN SAVVY
SOLAR SHIELD

FACIAL SUNSCREEN
WITH REVERSE EMULSION
TECHNOLOGY

PHYSICAL BARRIER
95% UVA/UVB
PROTECTION

SPF 20
4 FL OZ

BACK

95% UVA/UVB Protection

Reflective Barrier Technology
Does Not Penetrate Skin Surface

Hypoallergenic • Non-Comedogenic

Water Resistant • Long Lasting Protection

Drug Facts	
Active Ingredients: Zinc Oxide 5% Titanium Dioxide 5%	***Purpose:*** Sunscreen
Use: Prevention of sunburn, reduction of skin damage and premature aging caused by sun exposure.	
Warning: For external use only.	
When Using This Product: Keep out of eyes, rinse with water to remove.	
Keep Out of Reach of Children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions: Apply a small amount evenly before sun exposure and as needed. Ask a doctor before use on children under 6 months of age. Reapply after towel drying, swimming or perspiring.	
Other Information: Limiting sun exposure, wearing protective clothing and using sunscreen may reduce the	

protective clothing and using sunscreen may reduce the risks of skin aging, skin cancer and other harmful effects of the sun. May stain fabric.

Inactive Ingredients: Purified Water, Cetyl Dimethicone Copolyol, Polyglyceryl-4-Isostearate, Hexyl Laurate, Ethylhexyl Palmitate, Isohexadecane, Capric Caprylic Triglycerides, Dimethicone, Glycerin, Cetyl Dimethicone, Sodium Chloride, Sodium PCA, Phenoxyethanol, Isopentyldiol, Caprylyl Glycol, Allantoin.

Made in USA

dermagenics.com

Mfd. for Applied Skin Technology
Santa Barbara, CA

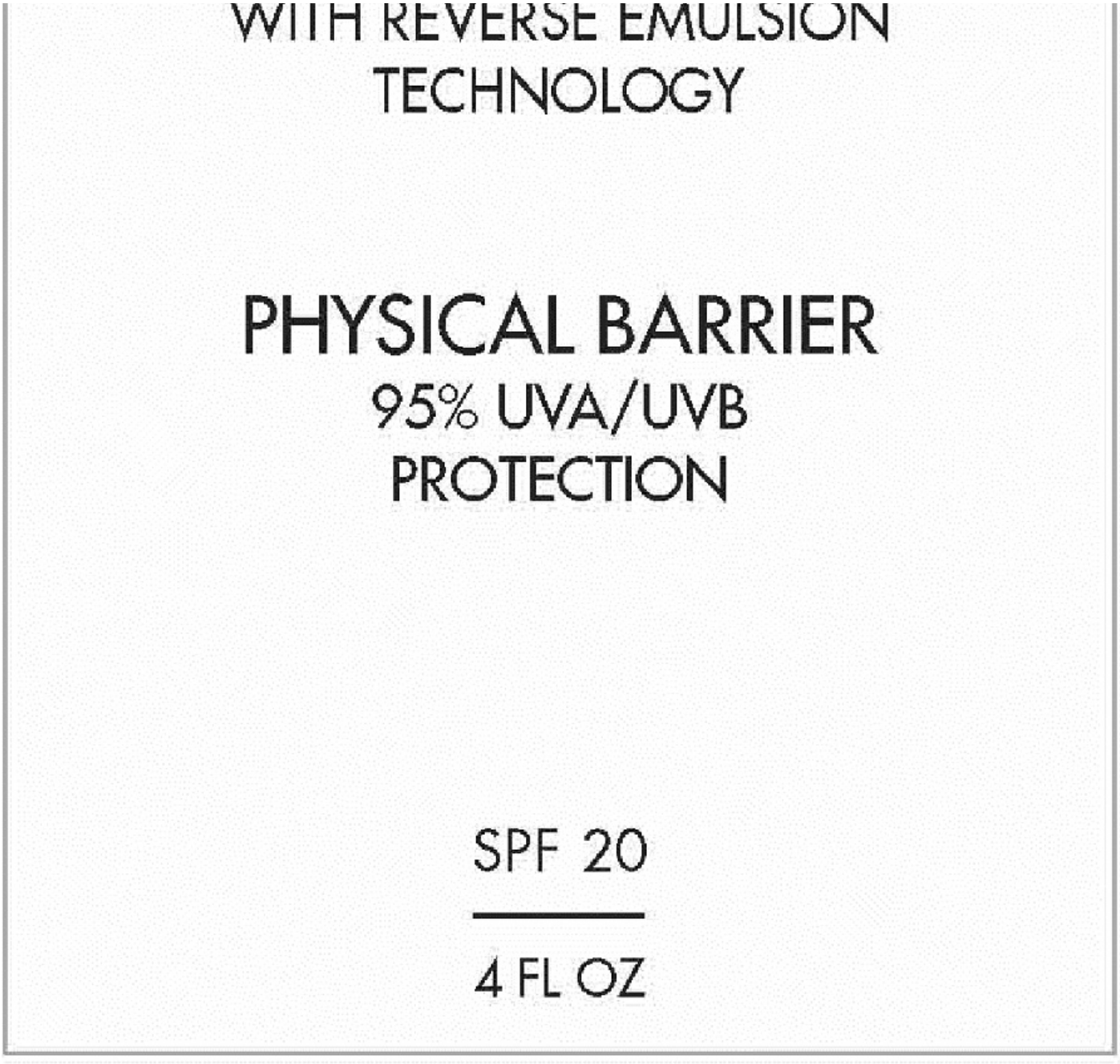
FDA12345

FRONT

DERMAGENICS®
PHYSICIAN FORMULATED

SUN SAVVY
SOLAR SHIELD

FACIAL SUNSCREEN



SUN SAVVY SOLAR SHIELD SPF 20

zinc oxide titanium dioxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55071-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ISOPENTYLDIOL (UNII: 19NOL5474Q)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ALLANTOIN (UNII: 344S277G0Z)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55071-001-04	118 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/26/2011	

Labeler - APPLIED SKIN TECHNOLOGY LLC (036766984)

Registrant - CRC (Cosmoceutical Research Center) (160019006)

Establishment

Name	Address	ID/FEI	Business Operations
CRC (Cosmoceutical Research Center)		160019006	manufacture

Revised: 10/2011 APPLIED SKIN TECHNOLOGY LLC