LABO DE DERMAFIRM SUN DEFENSE FLUID- ethylhexyl methoxycinnamate, zinc oxide, ethylhexyl salicylate, titanium dioxide liquid
Dermafirm INC.

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

ETHYLHEXYL METHOXYCINNAMATE, ZINC OXIDE, ETHYLHEXYL SALICYLATE, TITANIUM DIOXIDE

Water, Glycerin, ETC

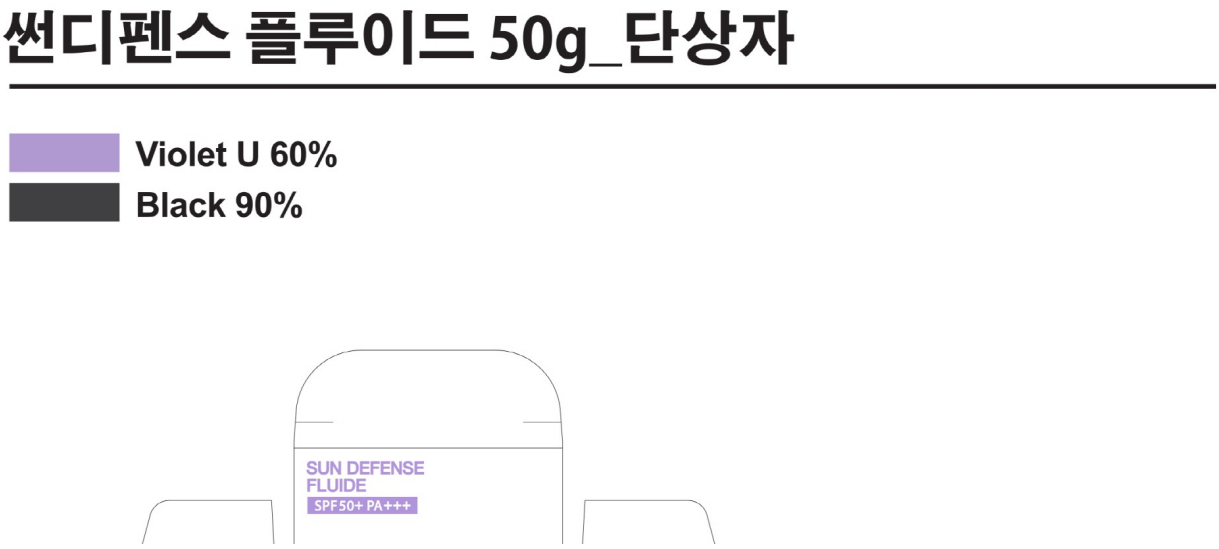
Sunscreen

keep out of reach of the children

 After basic skin care, apply on entire face and neck.
 Apply before sun exposure.
 Apply often to sun-sensitive areas

1. Do not use in the following cases(Eczema and scalp wounds)
2.Side Effects
1)Due to the use of this druf if rash, irritation, itching and symptopms of hypersnesitivity occur dicontinue use and consult your phamacisr or doctor
3.General Precautions
1)If in contact with the eyes, wash out thoroughty with water If the symptoms are servere, seek medical advice immediately
2)This product is for exeternal use only. Do not use for internal use
4.Storage and handling precautions
1)If possible, avoid direct sunlight and store in cool and area of low humidity
2)In order to maintain the quality of the product and avoid misuse
3)Avoid placing the product near fire and store out in reach of children

for external use only



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ethylhexyl methoxycinnamate, zinc oxide, ethylhexyl salicylate, titanium dioxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71638-0012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5.52 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.15 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71638-0012-1	50 g in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/01/2018	

Labeler - Dermafirm INC. (690171603)

Registrant - Dermafirm INC. (690171603)

Establishment

Name	Address	ID/FEI	Business Operations
Dermafirm INC.		690171603	label(71638-0012) , pack(71638-0012) , manufacture(71638-0012)

Revised: 5/2018 Dermafirm INC.