VILLAGE11FACTORY HYDRA SUN FLUID- octinoxate, homosalate, octisalate cream PFD Co.,Ltd.

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 INGREDIENT

Active ingredients: Ethylhexyl Methoxycinnamate 7.0%, Homosalate 6.0%, Ethylhexyl Salicylate 4.5%

INACTIVE INGREDIENT

Inactive ingredients:

Water, Glycerin, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Propanediol, Alcohol, Methyl Methacrylate Crosspolymer, Niacinamide 1,2-Hexanediol, Polymethylsilsesquioxane, Salvia HispanicaSeed Extract, Centella Asiatica Extract, Houttuynia Cordata Extract, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Tromethamine, Fructooligosaccharides, Saccharide Hydrolysate, Pullulan, Ethylhexylglycerin, Xanthan Gum, Octyldodecanol, Adenosine, EchiumPlantagineum Seed Oil, Butylene Glycol, Cardiospermum Halicacabum Flower/Leaf/Vine Extract, Helianthus Annuus (Sunflower) SeedOil Unsaponifiables, Origanum Vulgare Leaf Extract, Chamaecyparis Obtusa Leaf Extract, Salix Alba (Willow) Bark Extract, GlycerylStearate, Dimethicone, Carbomer, Polyglyceryl-3 Methylglucose Distearate, Polysorbate 20, Polyacrylate Crosspolymer-6, TitaniumDioxide (CI 77891), C12-15 Alkyl Benzoate, Lactobacillus/Soybean Ferment Extract, Portulaca Oleracea Extract, CinnamomumCassia Bark Extract, Scutellaria Baicalensis Root Extract, Tocopherol, Moringa Pterygosperma Seed Extract, Polyglyceryl-2 Caprate, Aluminum Stearate, Polyhydroxystearic Acid, Alumina, Sucrose Stearate, Simmondsia Chinensis (Jojoba) Seed Oil, t-Butyl Alcohol, Stearic Acid, Glyceryl Caprylate, Squalane, Fragrance

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings:

- 1) In case of swelling, redness, itching or any severe allergic reactions while using the product, discontinue use and consult with a specialist.
- 2) Do not apply on broken skin or wounded areas.
- 3) Precautions for storage and handling A) Keep out of reach of children. B) Store away from direct sunlight.
- 4) For external use only

DESCRIPTION

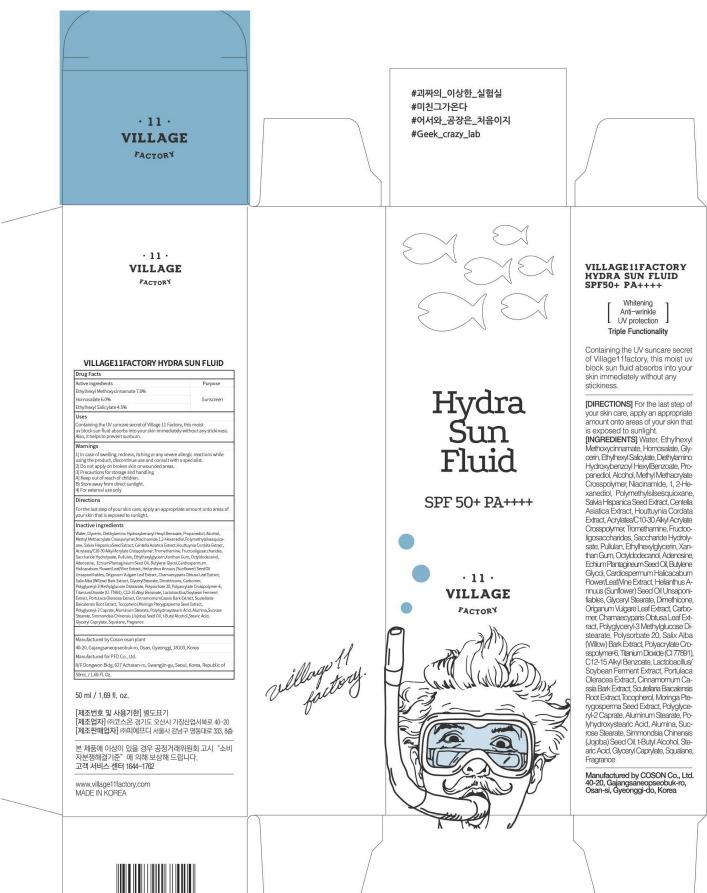
Uses:

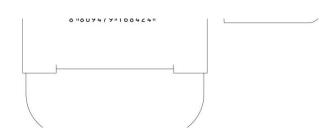
Containing the UV suncare secret of Village 11 Factory, this moist uv block sun fluid absorbs into your skin immediately without any stickiness. Also, it helps to prevent sunburn.

Directions:

For the last step of your skin care, apply an appropriate amount onto areas of your skin that is exposed to sunlight.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





VILLAGE11FACTORY HYDRA SUN FLUID

octinoxate, homosalate, octisalate cream

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:72470-020

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) Octinoxate (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) Homosalate (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) Octisalate 2.25 g in 50 mL

Inactive Ingredients				
Ingredient Name	Strength			
Water (UNII: 059QF0KO0R)				
Glycerin (UNII: PDC6A3C0OX)				

l	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:72470-020- 02	1 in 1 CARTON	07/01/2018		
	1 NDC:72470-020-01	50 mL in 1 CONTAINER; Type 0: Not a Combination Product			

Marketing Inform			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/01/2018	

Labeler - PFD Co.,Ltd. (694522499)

Registrant - PFD Co.,Ltd. (694522499)

Establishment

Name	Address	ID/FEI	Business Operations
Coson Co., LtdOsan Plant		689847210	manufacture(72470-020)

Revised: 8/2018 PFD Co.,Ltd.