# UV BOUNCE MIST- octinoxate, octisalate spray MIZON 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.

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#### ACTIVE INGREDIENT

Active Ingredients: Ethylhexyl Methoxycinnamate 7%, Ethylhexyl Salicylate 4%

## INACTIVE INGREDIENT

**Inactive Ingredients:** 

Water, Butylene Glycol, Caprylic/Capric Triglyceride, Phenylbenzimidazole Sulfonic Acid, Disiloxane, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Ceteareth-6 Olivate, Niacinamide, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Tromethamine, Dimethicone, Tocopheryl Acetate, Benzyl Alcohol, Microcrystalline Cellulose, Fragrance, Portulaca Oleracea Extract, Phenoxyethanol, Sodium Benzoate, Disodium EDTA, Potassium Sorbate, Glycerin, Cetearyl Olivate, Sorbitan Olivate, Adenosine, Cellulose Gum, Alpinia Officinarum Root Extract, Lactobacillus/Nelumbo Nucifera Seed Ferment Filtrate, Citrullus Lanatus (Watermelon) Fruit Extract, Terminalia Chebula Fruit Extract, Abies Koreana Leaf Extract, Aloe Barbadensis Leaf Juice

## **PURPOSE**

Purpose: UVA/UVB Protection

### **WARNINGS**

Warnings:

- 1. If following symptoms occur, stop use and consult a doctor: red spots, swelling, itcihng, irritation, or symtoms on applied skin under direct sunlight.
- 2. Do not use on scarred skin, or if you have dermatitis or eczema
- 3. Keep the cap close on its product
- 4. Keep away from direct sunlight or heat.

## KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children:

Keep out of reach of babies and children

## INDICATIONS AND USAGE

Indication and Usage:

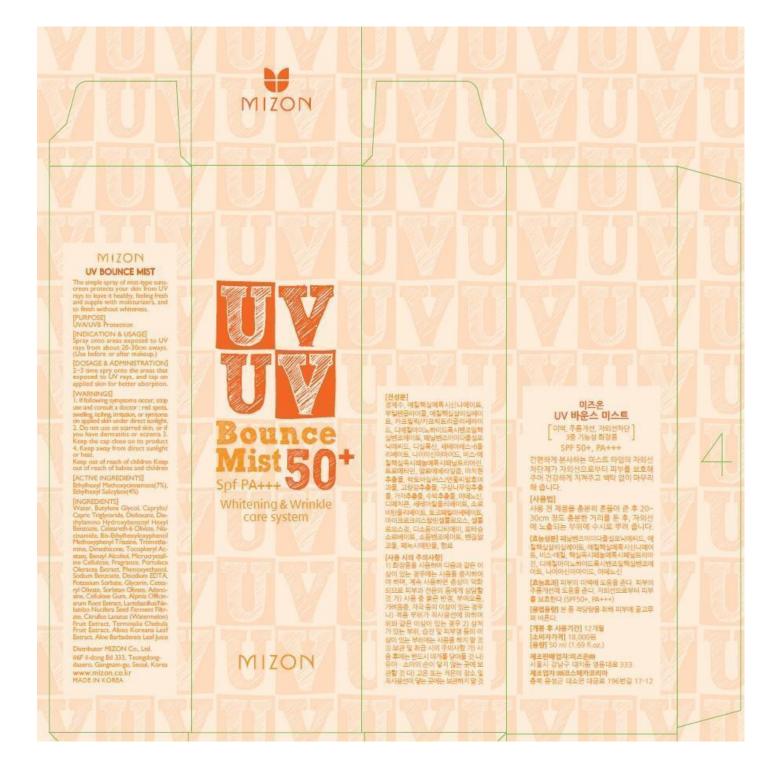
Spray onto areas exposed to UV rays from about 20-30cm aways. (Use before or after makeup.)

### DOSAGE AND ADMINISTRATION

Dosage and Administration:

2-3 time spry onto the areas that exposed to UV rays, and tap on applied skin for better aborption.

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



## **UV BOUNCE MIST**

octinoxate, octisalate spray

HUMAN OTC DRUG	Item Code (Source)	NDC:57718-030
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TOPICAL		
	HUMAN OTC DRUG TOPICAL	nem coue (cource)

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.5 mg in 50 mL
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	2 mg in 50 mL

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
Butylene Glycol (UNII: 3XUS85K0RA)		

	Packaging			
	# Item Code	Package Description	Marketing Start Date	<b>Marketing End Date</b>
ı	1 NDC:57718-030-01	50 mL in 1 CARTON		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	0 3/0 1/20 14		

## Labeler - MIZON CO., LTD. (557815570)

## Registrant - MIZON CO., LTD. (557815570)

Establishment				
Name	Address	ID/FEI	Business Operations	
MIZON CO., LTD.		557815570	manufacture(57718-030)	

Revised: 4/2014 MIZON CO., LTD.