# CRYSTAL MIRACLE MULTI- octinoxate cream Coson 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

Actve Ingredient: ETHYLHEXYL METHOXYCINNAMATE 7.5%

### INACTIVE INGREDIENT

**Inactive Ingredients:** 

WATER, GLYCERIN, TITANIUM DIOXIDE, TRIETHOXYCAPRYLYLSILANE, BIS-ETHYLHEXYLOXYPHENOL METHOXYPHENYL TRIAZINE, CETYL ETHYLHEXANOATE, ISOAMYL p-METHOXYCINNAMATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, CYCLOPENTASILOXANE, HEXYL LAURATE, PEG-10 DIMETHICONE, STEARIC ACID, ALUMINA, BUTYLENE GLYCOL, CETEARYL ALCOHOL, POLYSORBATE 20, CAPRYLYL GLYCOL, ETHYLHEXYL GLYCERIN, TROPOLONE, TRIETHANOLAMINE, METHYLMETHACRYLATE CROSSPOLYMER, SILICA, ACRYLATES/C10-30 ALKLY ACRYLATE CROSSPOLYMER, CARBOMER, GLUTATHIONE, ARGANIA SPINOSA KERNEL OIL, OENOTHERA BIENNIS (EVENING PRIMROSE) OIL, TOCOPHEROL, ASCORBYL PALMITATE, CAMELLIA JAPONICA SEED OIL, OLEA EUROPAEA (OLIVE) FRUIT OIL, LIMNANTHES ALBA (MEADOWFOAM) SEED OIL, PEARL POWDER, SODIUM HYALURONATE, SCLEROTIUM GUM, PAEONIA LACTIFLORA ROOT EXTRACT, CONVALLARIA MAJALIS BULB/ROOT EXTRACT, MAGNOLIA LILIFLORA FLOWER EXTRACT, LILIUM CANDIDUM FLOWER EXTRACT, LEONTOPODIUM ALPINUM FLOWER/LEAF EXTRACT, BIOSACCHARIDE GUM-1, SODIUM PCA, BETAIN, SORBITOL, GLYCINE, ALANINE, PROLINE, SERINE, THREONINE, ARGININE, LYSINE, GLUTAMIC ACID, ARNICA MONTANA FLOWER EXTRACT, ARTEMISIA ABSINTHIUM EXTRACT, ACHILLEA MILLEFOLIUM EXTRACT, GENTIANA LUTEA ROOT EXTRACT, GLYCYRRHIZA GLABRA(LICORICE)ROOT EXTRACT, BROUSSONETIA KAZINOKI ROOT EXTRACT, PORTULACA OLERACEA EXTRACT, VACCINIUM MYRTILLUS FRUIT/LEAF EXTRACT, SACCHARUM OFFICINARUM (SUGAR CANE) EXTRACT, ACER SACCHARUM (SUGAR MAPLE) EXTRACT, CITRUS AURANTIUM DULCIS (ORANGE) FRUIT EXTRACT, CITRUS MEDICA LIMONUM (LEMON) FRUIT EXTRACT, DISODIUM EDTA, FRAGRANCE

#### **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:

In the last step of skin care, spread and tap it softly on the whole face.

## DOSAGE AND ADMINISTRATION

Dosage and Administration:

Release an appropriate amount and evenly spread over face and body with gentle patting.

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



## CRYSTAL MIRACLE MULTI

octinoxate cream

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:62171-040 |
| Route of Administration | TOPICAL        |                    |               |
|                         |                |                    |               |

| Active Ingredient/Active Moiety                              |                   |                  |  |
|--|-------------------|------------------|--|
| Ingredient Name  | Basis of Strength | Strength         |  |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 3.75 mg in 50 mL |  |

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

| Packaging |                  |                     |                      |                    |
|-----------|------------------|---------------------|----------------------|--------------------|
| #         | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1         | NDC:62171-040-01 | 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 2/0 1/20 14        |                    |  |
|                         |  |                      |                    |  |

## **Labeler -** Coson Co., Ltd. (689835593)

## **Registrant -** Coson Co., Ltd. (689835593)

| Establishment   |         |           |                        |  |
|-----------------|---------|-----------|------------------------|--|
| Name            | Address | ID/FEI    | Business Operations    |  |
| Coson Co., Ltd. |         | 689835593 | manufacture(62171-040) |  |

Revised: 4/2014 Coson Co., Ltd.