

**SHU UEMURA UV UNDERBASE SPF 20 SUNSCREEN- octinoxate titanium dioxide liquid  
Cosmelor 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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**Drug Facts**

**Active Ingredients**

OCTINOXATE 3%; TITANIUM DIOXIDE 5.09%

**Uses: Directions:**

USES: Helps prevent sunburn.

DIRECTIONS: For sunscreen benefits, apply evenly before sun exposure.

**Storage:**

Please store at room temperature.

**Warnings**

**WARNINGS:** FOR EXTERNAL USE ONLY, NOT TO BE SWALLOWED. AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE EYES THOROUGHLY WITH WATER. DISCONTINUE USE IF SIGNS OF IRRITATION OR RASH APPEAR. IF IRRITATION OR RASH PERSISTS, CONSULT A DOCTOR. KEEP OUT OF REACH OF CHILDREN.



**SHU UEMURA UV UNDERBASE SPF 20 SUNSCREEN**

octinoxate titanium dioxide liquid

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:68570-704 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b>   |
|---|--------------------------|-------------------|
| <b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)             | Octinoxate               | 0.84 mL in 28 mL  |
| <b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP) | Titanium Dioxide         | 1.428 mL in 28 mL |

**Packaging**

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|----------------------------|-----------------------------|---------------------------|
| 1        | NDC:68570-704-01 | 1 in 1 CARTON              |                             |                           |
| 1        |                  | 28 mL in 1 TUBE            |                             |                           |

**Marketing Information**

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final   | part352   | 10/01/2009                  |                           |

**Labeler** - Cosmelor Ltd (690725908)**Establishment**

| <b>Name</b>  | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|--------------|----------------|---------------|----------------------------|
| Cosmelor Ltd |                | 690725908     | manufacture                |

Revised: 2/2010

Cosmelor Ltd