

**ORDAY MILD SUNCREAM- zinc oxide, titanium dioxide cream**  
**Elisacoy Co., 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.*

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**69013-026**

Zinc Oxide 11.64%

Titanium Dioxide 3.12%

Sunscreen

Helps prevent sunburn

Apply liberally 15 minutes before sun exposure. Reapply at least every two hours

For external use only.

Do not use on damaged or broken skin.

When using this product, keep out of eyes. Rinse with water to remove.

Stop using and ask a doctor if rash occurs.

Keep out of reach of the children. If product is swallowed, get medical help or contact a poison control center right away.

Water, Cyclomethicone, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Glycerin, Calamine, Propanediol, Dibutyl Adipate, Caprylyl Methicone, 1,2-Hexanediol, Disteardimonium Hectorite, Cetyl Ethylhexanoate, Magnesium Sulfate, Hydrogen Dimethicone, Betaine, Trehalose, Aluminum Hydroxide, C30-45 Alkyl Cetaryl Dimethicone Crosspolymer, Sorbitan Sesquioleate, Styrene/Acrylates Copolymer, Stearic Acid, Dipotassium Glycyrrhizate, Tranexamic Acid, Inositol, Citrus Aurantium Dulcis (Orange) Peel Oil, Pentylene Glycol, Ethylhexylglycerin, Octyldodecanol, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Lavandula Angustifolia (Lavender) Oil, Rosa Damascena Flower Water, Litsea Cubeba Fruit Oil, Echium Plantagineum Seed Oil, Pelargonium Graveolens Oil, Ocimum Basilicum (Basil) Oil, Butylene Glycol, Cardiospermum Halicacabum Flower/Leaf/Vine Extract, Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables, Methyl Methacrylate Crosspolymer, Glyceryl Stearate, Xanthan Gum, Tocopherol



# ORDAY MILD SUNCREAM

zinc oxide, titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69013-026
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	116.4 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	31.2 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
PROPANEDIOL (UNII: 5965N8W85T)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CETYL ETHYLHEXANOATE (UNII: 134647WMX4)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
BETAINE (UNII: 3SCV180C9W)	
TREHALOSE (UNII: B8WCK70T7I)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
TRANEXAMIC ACID (UNII: 6T84R30KC1)	
INOSITOL (UNII: 4L6452S749)	
ORANGE OIL (UNII: AKN3KSD11B)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
OCTYLDODECANOL (UNII: 461N10614Y)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ROSA X DAMASCENA FLOWER OIL (UNII: 18920M3T13)	
LITSEA OIL (UNII: 2XIW34BN6O)	
ECHIUM PLANTAGINEUM SEED OIL (UNII: PIB7XBU8XW)	
GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)	
BASIL OIL (UNII: Z129UMU8LE)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CARDIOSPERMUM HALICACABUM FLOWERING TOP (UNII: MZP2508BRR)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: 657L0NC5MT)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TOCOPHEROL (UNII: R0ZB2556P8)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69013-026-02	1 in 1 CARTON	04/18/2019	
1	NDC:69013-026-01	50 mL in 1 CONTAINER; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/18/2019	

**Labeler** - Elishacoy Co., Inc (631138567)

**Registrant** - Elishacoy Co., Inc (631138567)

## Establishment

Name	Address	ID/FEI	Business Operations
COSON Co., Ltd._Osan Plant		689847210	manufacture(69013-026)

Revised: 4/2019

Elishacoy Co., Inc