

**ICE SUN BC AIR PUFF- titanium dioxide, octinoxate, zinc oxide, octisalate liquid
POPCO 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.

ICE SUN BC AIR PUFF

Active Ingredients

Titanium Dioxide (2.8%)

Octinoxate (Ethylhexyl Methoxycinnamate) (2.1%)

Zinc Oxide (1.6%)

Octisalate (Ethylhexyl Salicylate) (1.4%)

Purpose

Sunscreen

Keep out of reach of children

Do not swallow. In case of accidental ingestion, seek professional assistance

Warnings

For external use only

Do not use on damaged or broken skin

Do not store at any high or low temperature or sunlight. Product uses high pressure gas and flammable.

Shake well before use

Do not spray over 3 second on same place, face, must use on hand and then spread it on face

If possible spray the product from 20cm or farther from body

Do not inhale spray gas

When using this product

☐ Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

☐ Do not use near fire, heating device, in room that uses flammable device such as heater

☐ Do not store product over 104°F (40°C), and in enclosed place

☐ Do not dispose in to incinerator

☐ Before dispose gas must be removed

Stop use and ask doctor if rash or irritation on skin develops and lasts.

Store at room temperature

Before use, Shake well.

After Use, lid must be sealed in enclosed place, must ventilate room.

Uses

Helps prevent sunburn

Directions

• Turn bottle lid to “ON” state. Shake the bottle well, pump it 4-5 times and take out the puff and apply it

on skin.

- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water-resistant sunscreen if swimming or sweating.
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 a.m. - 2 p.m.
 - Wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months of age: ask a doctor

Inactive Ingredients

Butane, Propane, Water, Cyclopentasiloxane, Alcohol Denat., Propanediol, Bis-Ethylhexyloxyphenol methoxyphenyl triazine, C13-15 Alkane, Niacinamide, Lauryl PEG-9 polydimethylsiloxyethyl dimethicone, Aluminum Hydroxide, Stearic Acid, 1,2-Hexanediol, Lauryl PEG-8 Dimethicone, Polyglyceryl-6 Polyricinoleate, Hydrogen Dimethicone, Parfum, Talc, CI 77492, Polymethyl Methacrylate, Butylene Glycol, CI 77491, Adenosine, Hamamelis Virginiana (Witch Hazel) Water, Disodium EDTA, Alcohol, CI 77499, Ultramarines, Sodium hyaluronate, Glycerin, Triethoxycaprylylsilane, Epilobium Angustifolium Flower/Leaf/Stem Extract, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Lilium Tigrinum Extract, Phenoxyethanol, Camellia Japonica Flower Extract, Melaleuca Alternifolia (Tea Tree) Leaf Extract, Salvia Officinalis (Sage) Leaf Extract, Sodium Hydroxide, Sodium Metabisulfite, Ethylhexylglycerin

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titanium dioxide, octinoxate, zinc oxide, octisalate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71055-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	2.8 g in 100 mL
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1.6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Butane (UNII: 6LV4FOR43R)	
Propane (UNII: T75W9911L6)	
Water (UNII: 059QF0K00R)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
PROPANEDIOL (UNII: 5965N8W85T)	
BEMOTRIZINOL (UNII: PWZ1720CBH)	
C13-15 ALKANE (UNII: 114P5I43UJ)	
Niacinamide (UNII: 25X5118RD4)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
Stearic Acid (UNII: 4ELV7Z65AP)	
1,2-Hexanediol (UNII: TR046Y3K1G)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YO1)	
Talc (UNII: 7SEV7J4R1U)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
Adenosine (UNII: K72T3FS567)	
HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ALCOHOL (UNII: 3K9958V90M)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
ULTRAMARINE BLUE (UNII: I39WR998B1)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
GLYCERIN (UNII: PDC6A3C0OX)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
EPILOBIUM ANGUSTIFOLIUM FLOWERING TOP (UNII: 08H094218D)	
LILIUM LANCIFOLIUM BULB (UNII: 47Z05W73EZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAMELLIA JAPONICA FLOWER (UNII: KUB8101TNF)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	

SAGE (UNII: 065C5D077J)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
Sodium Metabisulfite (UNII: 4VON5FNS3C)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71055-100-02	1 in 1 PACKAGE	10/21/2016	
1	NDC:71055-100-01	100 mL in 1 BOTTLE; 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	10/21/2016	

Labeler - POPCO CO.,LTD. (689851927)

Registrant - POPCO CO.,LTD. (689851927)

Establishment

Name	Address	ID/FEI	Business Operations
POPCO CO.,LTD.		689851927	manufacture(71055-100)

Revised: 10/2016

POPCO CO.,LTD.