

TAKO PORE SEBUM SUN- octocrylene, homosalate, octisalate, avobenzone, octinoxate stick
TONY MOLY 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.

ACTIVE INGREDIENT

Active ingredients: Octocrylene 5.00%, Homosalate 5.00%, Ethylhexyl Salicylate 4.50%, Butyl Methoxydibenzoylmethane 4.00%, Ethylhexyl Methoxycinnamate 3.50%

INACTIVE INGREDIENT

Inactive ingredients:

Dimethicone, Polyethylene, Ethylhexyl Palmitate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer, Diphenylsiloxy Phenyl Trimethicone, Microcrystalline Wax, Polysilicone-15, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Fragrance, Tocopheryl Acetate, Caprylyl Glycol, Eclipta Prostrata Extract, Melia Azadirachta Leaf Extract, Moringa Oleifera Seed Oil, Water, Panthenol, Calamine, Nelumbo Nucifera Flower Water, Sea Water, Centella Asiatica Extract, 1,2-Hexanediol, Algae Extract, Chlorella Vulgaris Extract, Hizikia Fusiforme Extract, Hydrolyzed Collagen

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings:

For external use only

Avoid contact with eyes.

Discontinue use if signs of irritation or rashes appear.

Replace the cap after use.

Keep Out of Reach of Children

DESCRIPTION

Uses:

- helps prevent sunburn

- If used as directed with other sun protection measures

Directions:

Take an appropriate amount, evenly apply to face and body anywhere to be exposed to UV rays. Use as the last step of basic skin care.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



TAKO PORE SEBUM SUN

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59 078-326
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	0.47 g in 9.5 g
Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	Homosalate	0.47 g in 9.5 g
Octisalate (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	0.42 g in 9.5 g
Avobenzone (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	Avobenzone	0.38 g in 9.5 g
Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	0.33 g in 9.5 g

Inactive Ingredients

Ingredient Name	Strength
Dimethicone (UNII: 92RU3N3Y1O)	
Ethylhexyl Palmitate (UNII: 2865993309)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59078-326-02	1 in 1 CARTON	03/01/2018	
1	NDC:59078-326-01	9.5 g 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	03/01/2018	

Labeler - TONY MOLY CO.,LTD (688216798)

Registrant - TONY MOLY CO.,LTD (688216798)

Establishment

Name	Address	ID/FEI	Business Operations
TONY MOLY CO.,LTD		688216798	manufacture(59078-326)

Revised: 4/2018

TONY MOLY CO.,LTD