

TONYMOLY MAGIC FOOD MANGO MILD SUN BLOCK- octinoxate, octisalate, avobenzene, ensulizole, homosalate cream

TONYMOLY 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: Ethylhexyl Methoxycinnamate 6.9%, Ethylhexyl Salicylate 4.5%, Butyl Methoxydibenzoylmethane 3.5%, Phenylbenzimidazole Sulfonic Acid 3.5%, Homosalate 3.0%

INACTIVE INGREDIENT

Inactive ingredients: Water, Butylene Glycol, Alcohol Denat., Octocrylene, Phenethyl Benzoate, Aminomethyl Propanol, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Tricetareth-4 Phosphate, Glycol Stearate, Ammonium Acryloyldimethyltaurate/VP Copolymer, Carbomer, PEG-2 Stearate, Fragrance(Parfum), Phenoxyethanol, Glyceryl Caprylate, Caprylyl Glycol, Mangifera Indica (Mango) Seed Butter, Disodium EDTA, Citrus Limon (Lemon) Fruit Extract, Musa Sapientum (Banana) Fruit Extract, Propylene Glycol, 1,2-Hexanediol, Citrus Aurantium Dulcis (Orange) Fruit Extract, Mangifera Indica (Mango) Fruit Extract, Psidium Guajava Fruit Extract, Citrus Paradisi (Grapefruit) Fruit Extract, Cocos Nucifera (Coconut) Fruit Extract, Actinidia Chinensis (Kiwi) Fruit Extract, Carica Papaya (Papaya) Fruit Extract, Ethylhexylglycerin

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings: For external use only

Do not use on damaged or broken skin

Stop use and ask a doctor if irritation occurs

Keep out of reach of children

DESCRIPTION

Uses: - helps prevent sunburn - If used as directed with other sun protection measures

Directions: decreases the risk of skin cancer and early skin aging caused by the sun

Directions:

For sunscreen use: - apply liberally 15 minutes before sun exposure - use a water resistant sunscreen if swimming or sweating - reapply at least every 2 hours - 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: Ask a doctor

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



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octinoxate, octisalate, avobenzone, ensulizole, homosalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59078-210
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.10 g in 45 g

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.02 g in 45 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.57 g in 45 g
ENSULIZOLE (UNII: 9YQ9D11W42) (ENSULIZOLE - UNII:9YQ9D11W42)	ENSULIZOLE	1.57 g in 45 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	1.35 g in 45 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Butylene Glycol (UNII: 3XUS85K0RA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59078-210-01	45 g in 1 CARTON; 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	12/01/2015	

Labeler - TONYMOLY CO.,LTD (688216798)

Registrant - TONYMOLY CO.,LTD (688216798)

Establishment

Name	Address	ID/FEI	Business Operations
TONYMOLY CO.,LTD		688216798	manufacture(59078-210)

Revised: 1/2016

TONYMOLY CO.,LTD