

**MALIE ORGANICS REEF SAFE SUNSCREEN SPF-30- homosalate, octisalate, zinc oxide cream**

**Malie, 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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**MALIE ORGANICS REEF SAFE SUNSCREEN SPF-30**

***Drug Facts***

***Active-Ingredients***

Homosalate 10%

Octisalate 5%

Zinc-Oxide 5%

***Purpose***

Sunscreen

***Uses***

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Retains SPF for 80 minutes of swimming or sweating
- If used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun.

***Warnings***

**For external use only** not intended for ingestion.

**Do not use**

on damaged or broken skin.

**When using this product**

- keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor if**

rash or irritation develops and lasts.

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

- Apply liberally 15 minutes before sun exposure and as needed.
- Children under 6 months of age: ask a doctor.
- Reapply: After 80 minutes of swimming or sweating. Immediately after towel drying. 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 the risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures including: Limit time in the sun, especially from 10 am.m -2 p.m. Wear long-sleeved shirts, pants, hats and sunglasses.

### ***Other Information***

- Protect the product in this container from excessive heat & direct sun.
- This sustainable packaging is Earth-friendly & made in the USA using sugar cane derived resin, **please Recycle this tube.**

### ***Inactive Ingredients:***

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Bixa Orellana (Annatto) Extract, Bromelain (Pineapple), Butyloctyl Salicylate, Butyrospermum Parkii (Shea) Butter, Camellia Sinensis (Green Tea) Extract, Carnauba Wax, Caprylyl/Capryl Glucoside, Carthamus Tinctorius (Safflower) Oil, Cocos Nucifera (Coconut) Oil, Curcuma Longa (Turmeric) Extract, Glycerin, Glycyrrhiza Glabra (Licorice) Extract, Glyceryl Caprylate, Glyceryl Stearate Citrate, Glyceryl Undecylenate, Helianthus Annuus (Sunflower) Oil, Lecithin, Parfum (Fragrance), Persea Gratissima (Avocado) Oil, Polyhydroxystearic Acid, Punica Granatum (Pomegranate) Extract.

### **Package Labeling:**



**MALIE ORGANICS REEF SAFE SUNSCREEN SPF-30**  
 homosalate, octisalate, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73731-082

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	50 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	
ANNATTO (UNII: 6PQP1V1B6O)	
BROMELAINS (UNII: U182GP2CF3)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SHEA BUTTER (UNII: K49155WL9Y)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CAPRYLYL/CAPRYL OLIGOGLUCOSIDE (UNII: E00JL9G9K0)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
COCONUT OIL (UNII: Q9L0O73W7L)	
TURMERIC (UNII: 856YO1Z64F)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
POMEGRANATE (UNII: 56687D1Z4D)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73731-082-05	150 mL in 1 TUBE; Type 0: Not a Combination Product	03/20/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/20/2020	

Labeler - Malie, Inc. (164892056)