# MELAN SPF-30 BROAD SPECTRUM- avobenzone, homosalate, octisalate lotion MELAN INC.

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### **MELAN SPF-30 Broad Spectrum Lotion**

# **Drug Facts**

#### **Active Ingredients**

Avobenzone 3.00%

Homosalate 8.00%

Octisalate 5.00%

# **Purpose**

Sunscreen

#### Uses

- Helps prevent sunburn.
- higher SPF gives more sunburn protection
- retains SPF after 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

#### 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.

# If pregnant or breast-feeding,

ask a health professional before use

#### **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 a.m. 2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses.

#### Other Information

• Protect the product in this container from excessive heat and direct sun.

# Inactive Ingredients

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Ammonium Acryloyldimethyltaurate/VP Copolymer, Aqua (Deionized Water), Behenyl Alcohol Butyloctyl Salicylate, Caprylyl Glycol, Cetearyl Olivate, Cetyl Alcohol, Citrullus Lanatus (Watermelon) Extract, Citrus Aurantium Dulcis (Orange) Oil, Citrus Grandis (Grapefruit) Oil, Cocos Nucifera (Coconut) Oil, Diisopropyl Adipate, Dodecane, Ethylhexylglycerin, Eucalyptus Globulus Oil, Glycerin, Glyceryl Laurate, Glyceryl Undecylenate, Helianthus Annuus (Sunflower) Oil, 1-2 Hexanediol, Lauryl Lactate, Mentha Piperita (Peppermint) Oil, Ocimum Basilicum (Basil) Extract, Oryza Sativa (Rice) Bran Oil, dl-Panthenol, Pentylene Glycol, Phenoxyethanol, Polycrylene, Polysorbate-20, Potassium Cetyl Phosphate, Rosmarinus Officinalis (Rosemary) Extract, Sodium Hydroxide, Sorbitan Olivate, Tocopherol (Vitamin E), Xanthan Gum.

**Questions?** 

1-888-676-3890

Package Labeling:



### **MELAN SPF-30 BROAD SPECTRUM**

avobenzone, homosalate, octisalate lotion

<b>Product Information</b>	luct Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84294-484	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	80 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
WATER (UNII: 059QF0KO0R)	
DOCOSANOL (UNII: 9G10E216XY)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATERMELON (UNII: 231473QB6R)	
ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)	
GRAPEFRUIT (UNII: O82C39RR8C)	
COCONUT OIL (UNII: Q9L0O73W7L)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
DODECANE (UNII: 11A386X1QH)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL LAURATE (UNII: Y98611C087)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
LAURYL LACTATE (UNII: G5SU0BFK7O)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
BASIL (UNII: 2U0KZP0FDW)	
RICE BRAN OIL (UNII: LZO6K1506A)	
PANTHENOL (UNII: WV9CM0067Z)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
ROSEMARY (UNII: IJ67X351P9)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
TOCOPHEROL (UNII: R0ZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84294- 484-00	100.55 mL in 1 TUBE; Type 0: Not a Combination Product	05/06/2024	

Marketing In	larketing Information		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/06/2024	

Revised: 5/2024 MELAN INC.