SHEER SUNSCREEN SPF 30 MEIJER- avobenzone 3.00% homosalate 8.00% octisalate 5.00% octocrylene 4.00% oxybenzone 4.00% lotion Meijer

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.

Drug Facts

Active ingredients Purpose

Avobenzone - 3.00% Homosalate - 8.00% Octisalate - 5.00% Octocrylene - 4.00% Oxybenzone - 4.00%

Sunscreen

- helps prevent sunburn

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 occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

applyliberally and spread evenly by hand 15 minutes before sun exposure

- 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 this risk, regularly use a sunscreen with a 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive ingredients

Behenyl Alcohol BHT Butyloctyl Salicylate Caprylyl Methicone Dimethicone Dimethyl Capramide Disodium EDTA
Ethylhexyl Stearate
Ethylhexylglycerin
Fragrance
Glyceryl Stearate
Hydrated Silica
PEG-100 Stearate
Phenoxyethanol
Polyester-8
Sodium Polyacrylate
Styrene/Acrylate Copolymer
Trideceth-6
Trimethylsiloxysilicate
VP/Hexadecene Copolymer
Water

Xanthan Gum



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avobenzone 3.00% homosalate 8.00% octisalate 5.00% octocrylene 4.00% oxybenzone 4.00% lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-783	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Avobenzone (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	Avobenzone	3 g in 100 mL		

Homosalate (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	Homosalate	8 g in 100 mL
Octisalate (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	Octisalate	5 g in 100 mL
Octocrylene (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Octocrylene	4 g in 100 mL
Oxybenzone (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	Oxybenzone	4 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
DOCOSANOL (UNII: 9G10E216XY)			
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)			
Butyloctyl Salicylate (UNII: 2EH13UN8D3)			
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)			
Dimethicone (UNII: 92RU3N3Y1O)			
Dimethyl Capramide (UNII: O29 Y6 X2JEZ)			
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)			
Ethylhexyl Stearate (UNII: EG3PA2K3K5)			
Ethylhexylglycerin (UNII: 147D247K3P)			
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)			
Hydrated Silica (UNII: Y6O7T4G8P9)			
PEG-100 Stearate (UNII: YD01N1999R)			
Phenoxyethanol (UNII: HIE492ZZ3T)			
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296U138P)			
Trideceth-6 (UNII: 3T5PCR2H0C)			
Water (UNII: 059QF0KO0R)			
Xanthan Gum (UNII: TTV12P4NEE)			

F	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-783-04	89 mL in 1 TUBE; Type 0: Not a Combination Product	03/09/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/09/2017	

Labeler - Meijer (006959555)

Registrant - Product Quest Mfg (927768135)

Establishment			
Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(41250-783), label(41250-783)

Revised: 5/2018 Meijer