

MINERALIUM HDRA SOURCE MOISTURIZING PROTECTOR SPF 25- octinoxate, octocrylene, octisalate, avobenzone, homosalate cream cream
Peer Pharm 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.

Mineralium Hdra Source Moisturizing Protector SPF 25



MINERALIUM HDRA SOURCE MOISTURIZING PROTECTOR SPF 25			
octinoxate, octocrylene, octisalate, avobenzone, homosalate cream cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69435-1606
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H)	
SHEA BUTTER (UNII: K49155WL9Y)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
NIACINAMIDE (UNII: 25X51I8RD4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SEA SALT (UNII: 87GE52P74G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PANTHENOL (UNII: WV9CM0O67Z)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
POMEGRANATE SEED OIL (UNII: 0UI45XV0T6)	
CAMELINA SATIVA WHOLE (UNII: W42JFE4HON)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69435-1606-1	50 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/24/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/24/2016	

Labeler - Peer Pharm Ltd. (514678390)

Registrant - Peer Pharm Ltd. (514678390)

Establishment

Name	Address	ID/FEI	Business Operations
Peer Pharm Ltd.		5146 78 390	manufacture(69435-1606)

Revised: 3/2016

Peer Pharm Ltd.