BBCREAM - titanium dioxide, ethylhexyl methoxycinnamate cream E-House Korea Holdings International

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.

Directions: Apply on a clean, toned face

Active Ingredients: Titanium Dioxide 10.14%, Ethyhexyl Methoxycinnamate 4.5%

Uses: Apply prior to sun exposure. Re-Apply as required

Purpose: Sunscreen

Inactive Ingredients: Water, Cyclopentasiloxane, Dimethicone, Talc, Arbutin, Dimethyl Sulfone, Aloe Barbedensis Leaf Juice, Silica

Caution: Do not apply to broken skin. Avoid using on pimples and irritated skin. Discontinue use if sun irritation develops or increases.

If irritation persists, consult a health care practitioner. Avoid contact with eyes

KEEP OUT OF REACH OF CHILDREN

Store in a cool dry place

Do not use other than directed. For external use only

Sun alert warning: Sun may cause sunburn, premature aging of the skin and skin cancer. Avoiding the sun, wearing protective clothing and regular use of sunscreens over the years may reduce the chance of these harmful effects





BBCREAM

titanium dioxide, ethylhexyl methoxycinnamate cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50387-300	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	3.04 mL in 30 mL		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.35 mL in 30 mL		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
TALC (UNII: 7SEV7J4R1U)		
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)		
SQUALENE (UNII: 7QWM220FJH)		
ARBUTIN (UNII: C5INA23HXF)		
POLYSORBATE 60 (UNII: CAL22UVI4M)		
LICORICE (UNII: 61ZBX54883)		
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
WHEAT (UNII: 4J2I0 SN84Y)		
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
APRICOT (UNII: 269CJD5GZ9)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
ADENO SINE (UNII: K72T3FS567)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:50387-300-30	30 mL in 1 TUBE			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/20/2011	

Labeler - E-House Korea Holdings International (688527548)

Registrant - E-House Korea Holdings International (688527548)

Establishment				
Name	Address	ID/FEI	Business Operations	
E-House Korea Holdings International		688527548	relabel	

Establishment				
Name	Address	ID/FEI	Business Operations	
Enbioscience Co Ltd		687650226	manufacture	

Revised: 4/2011 E-House Korea Holdings International