

SUNSCREEN- octinoxate, oxybenzone lipstick Humphreyline

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

Octinoxate (7.5%)

Oxybenzone (4%)

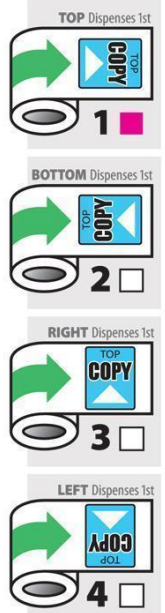
Sunscreen

Helps prevent sunburn and chapped lips

Petrolatum, Octyl Palmitate, Beeswax, Paraffin, Mineral Oil, Ceresin, Cetyl Alcohol, Fragrance, Aloe Barbadensis Leaf Extract, Tocopheryl Acetate (Vitamin E), Propylparaben



UNWIND
LABEL
SIDE OUT



DIELINE DOES NOT PRINT

Humphrey Line
Description: Extended Lip Balm
PN 1614-271



REVISIONS	
STATUS	DATE
NEW	06-05-13

- Carefully proof your artwork.
- It is the client's responsibility to ensure that all copy (ingredients, nutrition, domicile, and all legally required copy) is accurate prior to releasing this artwork for premedia and printing.
- This proof is not intended to show accurate color. A matchprint can be provided at an additional cost (Process color printing only).
- Please refer to Pantone® color swatches for spot color printing.
- Clearly indicate any changes needed.

- OK PER PROOF
- SEE ATTACHED
- OK WITH CHANGES INDICATED
- PLEASE SUBMIT ANOTHER PROOF

Signature _____ Date _____

Please examine it carefully and indicate any corrections needed, if not please sign off and return. Remember... we cannot schedule production until approved and returned. Your Approval Of This Proof Is Our Authority To Proceed. Delay in returning your proof could delay your delivery. Customer assumes full responsibility for compliance with local, state, and federal laws, rules, and regulations.

SUNSCREEN octinoxate, oxybenzone lipstick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:19392-300

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
PARAFFIN (UNII: I9O0E3H2ZE)	
MINERAL OIL (UNII: T5L8T28FGP)	
CERESIN (UNII: Q1LS2UJO3A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	TROPICAL FRUIT PUNCH (tropical flavor) , SPEARMINT (spearmint flavor) , BUBBLE GUM (bubble gum flavor) , VANILLA (vanilla flavor) , CHERRY (cherry flavor) , STRAWBERRY (strawberry flavor) , BERRY (berry flavor) , WATERMELON (watermelon flavor)		Imprint Code
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:19392-300-01	4 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/08/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2010	

Labeler - Humphreyline (122539042)