PURPOSE- octinoxate, octisalate and oxybenzone lotion
Bausch Health US LLC

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

Octinoxate 7.5%
Octisalate 5%
Oxybenzone 3%

Purpose

Sunscreen

Use

helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

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

- apply generously and evenly 15 minutes before sun exposure
- apply to all skin exposed to the sun
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months of age:

  Ask a doctor

Other information

- protect this product from excessive heat and direct sun

■ may stain or damage some fabrics or surfaces

Inactive ingredients

water, octyldodecyl neopentanoate, glycerin, emulsifying wax NF, glyceryl stearate, PEG-100 stearate, dimethicone, triethanolamine, diazolidinyl urea, carbomer, methylparaben, ethylparaben, propylparaben, bisabolol, farnesol, citric acid

Questions/comments?

1-800-321-4576

Package/Label Principal Display Panel – 118 ml Carton

PURPOSE®

Dual Treatment
Moisture Lotion

Sunscreen
SPF 10

Oil-Free

Fragrance Free

Provides

Long-Lasting

Moisture

Developed with

Dermatologists

4 FL. OZ. (118 mL)

PURPOSE

octinoxate, octisalate and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0187-5500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	76 mg in 1 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Octyldodecyl Neopentanoate (UNII: X8725R883T)	
Glycerin (UNII: PDC6A3C0OX)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
PEG-100 Stearate (UNII: YD01N1999R)	
Dimethicone (UNII: 92RU3N3Y1O)	
Trolamine (UNII: 9O3K93S3TK)	
Diazolidinyl Urea (UNII: H5RIZ3MPW4)	
Methylparaben (UNII: A2I8C7HI9T)	
Ethylparaben (UNII: 14255EXE39)	
Propylparaben (UNII: Z8IX2SC1OH)	
Levomenol (UNII: 24WE03BX2T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0187-5500-04	1 in 1 CARTON	10/07/2013	
1		118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/07/2013	

Labeler - Bausch Health US LLC (831922468)

Establishment

Name	Address	ID/FEI	Business Operations
KIK Custom Product - Rexdale Plant		243547333	MANUFACTURE(0187-5500)