

SPF 15 PROTECTIVE BALM WITH UVA/UVB SUNSCREENS - octinoxate octisalate oxybenzone stick

Laboratoire Dr Renaud inc.

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 (Octyl Methoxycinnamate) à 7.5 % w/w, Octisalate (Octyl Salicylate) à 3% w/w, Oxybenzone à 3% w/w.

Inactive ingredients

RICINUS COMMUNIS (CASTOR) SEED OIL • LANOLIN OIL • OCTYLDODECANOL • RED PETROLATUM • ISOPROPYL PALMITATE • OZOKERITE • EUPHORBIA CERIFERA (CANDELILLA) WAX / CIRE DE CANDELILLA • BEESWAX / CIRE D'ABEILLE • COPERNICA CERIFERA (CARNAUBA) WAX / CIRE DE CARNAUBA • TOCOPHERYL ACETATE • BISABOLOL • PANTHENOL • TOCOPHEROL • ZEA MAYS (CORN) OIL • VEGETABLE OIL / HUILE VEGETALE • GLYCERYL OLEATE • BETA-CAROTENE • PROPYLENE GLYCOL • TBHQ • CITRIC ACID • ISOPROPYLPARABEN • ISOBUTYLPARABEN • BUTYLPARABEN •

Helps protect from sunburn. Formulated to minimize allergic risks.

Apply liberally and evenly 15 to 30 minutes before exposure to the sun. Reapply every 2 hours and after swimming perspiring heavily.

image of cartridge label

NON-MÉDICINAUX / INACTIVE INGREDIENTS: RICINUS COMMUNIS (CASTOR) SEED OIL • LANOLIN OIL • UNOL • RED PETROLATUM • ISOPROPYL PALMITATE • OZOKERITE • EUPHORBIA CERIFERA (CANDELLILLA) WAX / CIRE DE BEESWAX / CIRE D'ABEILLE • COPERNICA CERIFERA (CARNAUBA) WAX / CIRE DE CARNAUBA • TOCOPHERYL ACETATE • PHANTHENOL • TOCOPHEROL • ZEA MAYS (CORN) OIL • VEGETABLE OIL / HUILE VÉGÉTALE • GLYCERYL OLEATE • JE • PROPYLENE GLYCOL • TBHQ • CITRIC ACID • ISOPROPYL PARABEN • ISOBUTYL PARABEN • BUTYL PARABEN •

DR DR RENAUD INC. Laval (Québec) Canada H7V 0A3 Idrenaud.com

C40420ET-03-L4

DIN 02086328

Baume Protecteur

FPS 15

avec filtres

UVA / UVB

SPF 15

Protective Balm

with UVA / UVB

Sunscreens

LÈVRES
LIPS

Soins
 Soleil

Cell' Defense*

*Combat l'apparence
des rides

*Fights the look
of wrinkles



Laboratoire
Dr Renaud

édicinaux : Octinoxate (Méthoxycinnamate d'octyle) à 7,5 % p/p, Octisalate (Salicylate d'octyle) à 3 % p/p, Oxybenzone à 3 %
is coups de soleil. Formulé pour minimiser les risques d'allergies. MODE D'EMPLOI : De 15 à 30 minutes avant l'exposition au
quer généreusement et uniformément. Répéter l'application aux 2 heures et après la baignade ou transpiration excessive.

EN GARDE : Pour usage externe seulement. Garder hors de portée des enfants. Éviter tout contact direct avec les yeux.

l'utilisation si des signes d'éruption ou d'irritation se manifestent. Enfant de moins de 6 mois, consulter un médecin.

nts: Octinoxate (Octyl Methoxycinnamate) 7.5% w/w, Octisalate (Octyl Salicylate) 3% w/w, Oxybenzone 3% w/w. Helps protect
formulated to minimize allergic risks. WARNINGS: For external use only. Keep out of reach of children. Avoid direct contact with
use if signs of rash or irritation appear. Children under 6 months, ask a doctor. DIRECTIONS FOR USE: Apply liberally and evenly
15 to 30 minutes before exposure to the sun. Reapply every 2 hours and after swimming or perspiring heavily.

INGRÉDIENTS
OCTYLDODECA
CANDELILLA • F
BISABOLOL • F
BETA-CAROTEN

LABORATOI



Poids net 3.8 g
Net Wt. 0.13 OZ.

Ingrédients mé
p/p. Protège de
soleil, applic
MISES I
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Active ingredier
from sunburn. F
the eyes. Stop u

image of carton label

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LABORATOIRE DR RENAUD INC. Laval (Québec) Canada HTV OA3 ldrenaud.com

VENTE RÉSERVÉE
EXCLUSIVEMENT AUX
DÉPOSITAIRES AGRÉÉS
LABORATOIRE DR RENAUD
SOLD EXCLUSIVELY BY
LABORATOIRE DR RENAUD
CERTIFIED AGENTS



40420-05
L4

Ingrédients médicinaux : Octinoxate (Méthoxycinnamate d'octyle) à 7,5 % p/p, Octisalate (Salicylate d'octyle) à 3 % p/p, Oxybenzone à 3 % p/p.

Protège des coups de soleil. Formulé pour minimiser les risques d'allergies.

MODE D'EMPLOI : De 15 à 30 minutes avant l'exposition au soleil, appliquer généreusement et uniformément. Répéter l'application aux 2 heures et après la baignade ou transpiration excessive.

MISES EN GARDE : Pour usage externe seulement. Garder hors de portée des enfants. Éviter tout contact direct avec les yeux. Cesser l'utilisation si des signes d'éruption ou d'irritation se manifestent. Enfant de moins de 6 mois, consulter un médecin.

15

15

DIN 02086328

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FPS 15
avec filtres
UVA / UVB
SPF 15
Protective Balm
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LÈVRES / LIPS
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Laboratoire
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Laboratoire
Dr Renaud

Active ingredients: Octinoxate (Octyl Methoxycinnamate) 7.5% w/w, Octisalate (Octyl Salicylate) 3% w/w, Oxybenzone 3% w/w.

Helps protect from sunburn. Formulated to minimize allergic risks.

WARNINGS: For external use only. Keep out of reach of children. Avoid direct contact with the eyes. Stop use if signs of rash or irritation appear. Children under 6 months, ask a doctor.

DIRECTIONS FOR USE: Apply liberally and evenly 15 to 30 minutes before exposure to the sun. Reapply every 2 hours and after swimming or perspiring heavily.

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SPF 15 PROTECTIVE BALM WITH UVA/UVB SUNSCREENS

octinoxate octisalate oxybenzone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62499-420
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 g in 100 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
RICINUS COMMUNIS SEED (UNII: 7EK4SFN1TX)	
LANOLIN (UNII: 7EV65EAW6H)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PETROLATUM (UNII: 4T6H12BN9U)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
CERESIN (UNII: Q1LS2UJO3A)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
ACETATE ION (UNII: 569DQM74SC)	
LEVOMENOL (UNII: 24WE03BX2T)	
PANTHENOL (UNII: WV9CM0O67Z)	
ISOPROPYL PARABEN (UNII: A6EOX47QK0)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
BUTYL PARABEN (UNII: 3QPII03FV8)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
CORN OIL (UNII: 8470G57WFM)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
T-BUTYLHYDROQUINONE (UNII: C12674942B)	
GLYCERYL MONOOLEATE (UNII: 4PC054V79P)	
BETA CAROTENE (UNII: 01YAE03M7J)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	red (dark red)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62499-420-11	1 in 1 BOX		
1	NDC:62499-420-02	3.8 g in 1 CARTRIDGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/21/2011	

Labeler - Laboratoire Dr Renaud inc. (202501565)**Registrant** - Laboratoire Dr Renaud inc (202501565)**Establishment**

Name	Address	ID/FEI	Business Operations
Laboratoire Dr Renaud inc		202501565	manufacture

Revised: 3/2011

Laboratoire Dr Renaud inc.