

WET N WILD JUICY LIP BALM- octinoxate octocrylene oxybenzone lipstick
Markwins Beauty Products, 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.

Active Ingredients

Octinoxate 7.5%

Octocrylene 7%

Oxybenzone 2%

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 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 liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- children under 6 months: Ask a doctor

Inactive Ingredients: Pentaerythrityl Tetraisostearate, Bis-Diglyceryl Polyacyladipate-2, Ethylhexyl Isononanoate, Propylheptyl Caprylate, Ozokerite, Tridecyl Trimellitate, Mineral Oil/Huile minérale, Neopentyl Glycol Dicaprylate/Dicaprate, Tridecyl Stearate, Diisostearyl Malate, Polyethylene, Euphorbia Cerifera (Candelilla) Wax/Cire de candelilla, Beeswax/Cire d'abeille, Ricinus Communis (Castor) Seed Oil, Caprylyl Glycol, Hydrogenated Styrene/Isoprene Copolymer, Caprylic/Capric Triglyceride, Persea Gratissima (Avocado) Oil, Sorbic Acid, Tocopheryl Acetate, Stearic Acid, Alumina, Laminaria Ochroleuca Extract, BHT, Fragrance/Parfum
(MAY CONTAIN/PEUT CONTENIR): Blue 1 Lake/CI 42090, Red 7 Lake/CI 15850, Red 28 Lake/CI 45410, Titanium Dioxide/CI 77891, Yellow 6 Lake/CI 15985, Yellow 10 Lake/CI 47005, Zinc Oxide/CI 77947)

Package Label

0 77802 52802 5

280C
Cherry/
Cerise

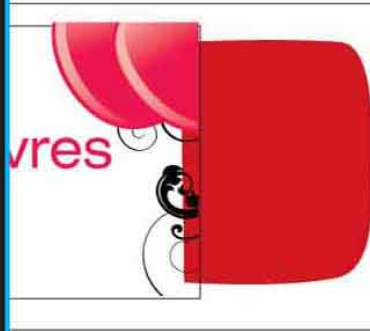
▲ Peel Here/Peler ici

Net wt. 0.26 oz./
Poids net 7.5 g

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5%.....	Sunscreen
Octocrylene 7%.....	Sunscreen
Oxybenzone 2%.....	Sunscreen

Lift for Drug Facts continued/Soulever pour suite des données ▼



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THIS PAGE
STICKS TO
COMPONENT

Données pharmaceutiques

Ingrédients actifs	Type de produit
Octinoxate 7.5 %.....	Écran solaire
Octocrylene 7 %.....	Écran solaire
Oxybenzone 2 %.....	Écran solaire

Utilisation

- Contribue à prévenir les coups de soleil.

Mises en garde

Cancer de la peau et vieillissement de la peau - L'exposition aux rayons du soleil augmente le risque de cancer de la peau et de vieillissement prématuré de la peau. Ce produit est indiqué uniquement pour la prévention des coups de soleil et non pour celle du cancer de la peau et du vieillissement prématuré de la peau.

Pour usage externe seulement

Ne pas appliquer sur une peau éraflée ou abîmée.
Lors de l'utilisation de ce produit, éviter tout contact avec les yeux. En cas de contact, rincer.

- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- children under 6 months: Ask a doctor

**Inactive Ingredients/
Ingrédients inactifs**

Pentaerythrityl Tetraisostearate, Bis-Diglyceryl Polyacyladipate-2, Ethylhexyl Isononanoate, Propylheptyl Caprylate, Ozokerite, Tridecyl Trimellitate, Mineral Oil/Huile minérale, Neopentyl Glycol Dicaprylate/Dicaprate, Tridecyl Stearate, Diisostearyl Malate, Polyethylene, Euphorbia Cerifera (Candelilla) Wax/Cire de candelilla, Beeswax/Cire d'abeille, Ricinus Communis (Castor) Seed Oil, Caprylyl Glycol, Hydrogenated Styrene/Isoprene Copolymer, Caprylic/Capric Triglyceride, Persea Gratissima (Avocado) Oil, Sorbic Acid, Tocopheryl Acetate, Stearic Acid, Alumina, Laminaria Ochroleuca Extract, BHT, Fragrance/Parfum [+/- (MAY CONTAIN/PEUT CONTENIR): Blue 1 Lake/CI 42090, Red 7 Lake/CI 15850, Red 28 Lake/CI 45410, Titanium Dioxide/CI 77891, Yellow 6 Lake/CI 15985, Yellow 10 Lake/CI 47005, Zinc Oxide/CI 77947]

Other Information

- protect this product from excessive heat and direct sun

0911

contact avec les yeux. En cas de contact, rincer avec de l'eau.

Cesser l'utilisation et consulter un professionnel de la santé s'il se produit une irritation.

Tenir hors de la portée des enfants.

En cas d'ingestion, consulter un professionnel de la santé ou contacter immédiatement un centre antipoison.

Mode d'emploi

- Appliquer généreusement 15 minutes avant l'exposition au soleil
- Renouveler l'application au moins toutes les 2 heures
- Utiliser un écran soleil résistant à l'eau en cas de baignade ou de transpiration
- Enfants de moins de 6 mois : consulter un médecin avant l'utilisation

Information complémentaire

- Garder à l'abri d'une chaleur excessive ou d'une exposition directe aux rayons du soleil.

Distributed by/Distribué par:
Markwins Beauty Products, Inc.,
City of Industry, CA 91789 U.S.A.

Markwins Canada Corp.,
Mississauga, ON L5T 2N6 CANADA



NOT TESTED ON ANIMALS/
NON TESTÉ SUR DES ANIMAUX

cruelty free

MADE IN CHINA/FABRIQUÉ EN CHINE

WET N WILD JUICY LIP BALM

octinoxate octocrylene oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12027-101
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
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7.0 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2.0 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYL ISONONANOATE (UNII: I6KB4GE3K4)	
PROPYLHEPTYL CAPRYLATE (UNII: 991Z19V2OD)	
CERESIN (UNII: Q1LS2UJO3A)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
MINERAL OIL (UNII: T5L8T28FGP)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CASTOR OIL (UNII: D5340Y2I9G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
SORBIC ACID (UNII: X045WJ989B)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM OXIDE (UNII: LM26O6933)	
LAMINARIA OCHROLEUCA (UNII: 4R2124HE76)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12027-101-26	7.5 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/01/2011	

Labeler - Markwins Beauty Products, Inc (135407760)

Establishment

Name	Address	ID/FEI	Business Operations
Markwins International Corp.		544845621	manufacture