

**WET N WILD MEGASHIELD- octinoxate 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.*

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**Active Ingredients**

Octinoxate 7.5%

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:** Ozokerite, Pentaerythrityl Tetraisostearate, Octyldodecanol, Bis-Diglyceryl Polyacyladipate-2, Neopentyl Glycol Dicaprylate/Dicaprate, Tridecyl Stearate, Propylheptyl Caprylate, Caprylic/Capric Triglyceride, VP/Hexadecene Copolymer, Microcrystalline Wax/Cire microcristalline, Polysilicone-6, Tridecyl Trimellitate, Caprylyl Glycol, Sorbic Acid, Oryza Sativa (Rice) Germ Oil, Persea Gratissima (Avocado) Oil, Tocopheryl Acetate, Alumina, Stearic Acid (MAY CONTAIN/PEUT CONTENIR): Carmine/CI 75470, Iron Oxides/CI 77491, CI 77492, CI 77499, Mica, Red 7 Lake/CI 15850, Red 28 Lake/CI 45410, Red 30 Lake/CI 73360, Titanium Dioxide/CI 77891, Yellow 5 Lake/CI 19140, Yellow 6 Lake/CI 15985, Zinc Oxide/CI 77947)

Package Label

0 77802 59650 5

Peel Here/Peler ici

**360S**  
Birthday Suit/  
Costume d'Ève

Net wt. 0.10 oz./  
Poids net 3.1 g

**Drug Facts**

Active Ingredients	Purpose
Octinoxate 7.5%.....	Sunscreen
Oxybenzone 2.0%.....	Sunscreen

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



0 77802 53722 5

Peel Here/Peler ici

**372S**  
Within These Adobe  
Walls/Briques-à-brac

Net wt. 0.10 oz./  
Poids net 3.1 g

**Drug Facts**

Active Ingredients	Purpose
Octinoxate 7.5%.....	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
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**

Ozokerite, Pentaerythrityl Tetraisoostearate, Octyldodecanol, Bis-Diglyceryl Polyacyladipate-2, Neopentyl Glycol Dicaprylate/Dicaprate, Tridecyl Stearate, Propylheptyl Caprylate, Caprylic/Capric Triglyceride, VP/Hexadecene Copolymer, Microcrystalline Wax/Cire microcristalline, Polysilicone-6, Tridecyl Trimellitate, Caprylyl Glycol, Sorbic Acid, Oryza Sativa (Rice) Germ Oil, Persea Gratissima (Avocado) Oil, Tocopheryl Acetate, Alumina, Stearic Acid [+/- (MAY CONTAIN/PEUT CONTENIR): Carmine/CI 75470, Iron Oxides/CI 77491, CI 77492, CI 77499, Mica, Red 7 Lake/CI 15850, Red 28 Lake/CI 45410, Red 30 Lake/CI 73360, Titanium Dioxide/CI 77891, Yellow 5 Lake/CI 19140, Yellow 6 Lake/CI 15985, Zinc Oxide/CI 77947]

**Other Information**

- protect this product from excessive heat and direct sun

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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

MADE IN CHINA/FABRIQUÉ EN CHINE



**WET N WILD MEGASHIELD**

octinoxate oxybenzone lipstick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:12027-100
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	2 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
CERESIN (UNII: Q1LS2UJO3A)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
PROPYLHEPTYL CAPRYLATE (UNII: 991Z19V2OD)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBIC ACID (UNII: X045WJ989B)	
RICE GERM OIL (UNII: D4H5GGS5JF)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINUM OXIDE (UNII: LM26O6933)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
COCHINEAL (UNII: TZ8Z31B35M)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12027-100-10	3.1 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