

WET N WILD ULTIMATE SHEER- octinoxate oxybenzone liquid
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 6%
Oxybenzone 2%

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/Ingredients inactifs Water/Eau, Butylene Glycol, Isopropyl Myristate, Isododecane, Glyceryl Stearate SE, Triethanolamine, Neopentyl Glycol Dicaprylate/Dicaprate, Tridecyl Stearate, Talc, Stearic Acid, Sorbitan Sesquioleate, Triacontanyl PVP, Cetyl Palmitate, Alumina, Xanthan Gum, Acrylates Copolymer, Tridecyl Trimellitate, Chlorphenesin, Tocopheryl Acetate, Sodium Laureth Sulfate, Aloe Barbadensis Leaf Juice, Dipotassium Glycyrrhizate, Disodium EDTA, Stearyl Glycyrrhetinate, Sodium Hyaluronate, Methylisothiazolinone
(MAY CONTAIN/PEUT CONTENIR): Iron Oxides/CI 77491, CI 77492, CI 77499, Titanium Dioxide/CI 77891, Ultramarines/CI 77007 77891, Yellow 6 Lake/CI 15985, Yellow 10 Lake/CI 47005, Zinc Oxide/CI 77947)

Package Label



Drug Facts (continued)
 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/ Ingrédients inactifs
 Water/Eau, Betylene Glycol, Isopropyl

Myristate, Isododecane, Glyceryl Stearate SE, Triethanolamine, Neopentyl Glycol Diacrylate/Diacrylate, Tridecyl Stearate, Talc, Stearic Acid, Sorbitan Sesquioléate, Triaccontanyl PVP (WP-660), Alumina, Xanthan Gum, Acrylates Copolymer, Tridecyl Trimellitate, Chlorphenesin, Tocopheryl Acetate, Sodium Lauryl Sulfate, Aloe Barbadensis Leaf Juice, Dipotassium Glycyrrhizate, Disodium EDTA, Stearyl Glycyrrhizate, Sodium Hydroxide, Methylisothiazolinone [+/-] (MAY CONTAIN/PEUT CONTENIR: Iron Oxides/CI 77491, CI 77492, CI 77499, Titanium Dioxide/CI 77891, Ultramarines/CI 77007)
Other Information
 • protect this product from excessive heat and direct sun
 LRI for Drug Facts continued/Solveur pour suite des données

Données pharmaceutiques
Ingrédients actifs Type de produit
 Octinoxate 6%.....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 éraillée ou abîmée.

Lors de l'utilisation de ce produit, éviter tout 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.

(STICKS TO COMPONENT)

WET N WILD ULTIMATE SHEER

octinoxate oxybenzone liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12027-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6 mL in 100 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	2 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISODODECANE (UNII: A8289P68Y2)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TROLAMINE (UNII: 9O3K93S3TK)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
TALC (UNII: 7SEV7J4R1U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
TRIACONTANYL PVP (WP-660) (UNII: N0SS3Q238D)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
ALUMINUM OXIDE (UNII: LM26O6933)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
CHLORPHENESIN (UNII: I670DAL4S2)	

ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12027-104-01	29.6 mL in 1 BOTTLE, GLASS		

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

Revised: 11/2011

Markwins Beauty Products, Inc