

UGLY DUCK MIRACLE MULTI SHIELD SUN GEL- octinoxate, octisalate, titanium dioxide, gel
EREPH CO., LTD

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.

Ugly Duck Miracle Multi Shield Sun Gel

Active Ingredients

Ethylhexyl Methoxycinnamate (Octinoxate) (7%)

Ethylhexyl Salicylate (Octisalate)(3%)

Titanium Dioxide (1.494%)

Purpose

Sunscreen

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Warnings

For external use only

Do not use when skin is red, inflamed, irritated, or painful

When using this product

- do not apply on other parts of the body
- do not use on damaged or broken skin
- avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water
- do not apply directly to wound or open cut

Stop use and ask a doctor if

- Rash or irritation on skin develops and lasts

Uses

Helps prevent sunburn

Directions

- Apply liberally 15 minutes before sun exposure.
 - Reapply at least every 2 hours.
 - Use a water-resistant sunscreen if swimming or sweating.
 - Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 a.m. - 2 p.m.
 - Wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months of age: ask a doctor

Inactive Ingredients

Water, Homosalate, Pentylene Glycol, Methylpropanediol, Caprylyl Methicone, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Isononyl Isononanoate, Ethylhexyl Triazone, Lauryl Methacrylate/Glycol Dimethacrylate Crosspolymer, Cyclopentasiloxane, Phenoxyethanol, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Aluminum Hydroxide, Stearic Acid, Dimethicone/Vinyl Dimethicone Crosspolymer, Tocopheryl Acetate, Sorbitan Isostearate, Ammonium Acryloyldimethyltaurate/VP Copolymer, Allantoin, Polysorbate 80, Butylene Glycol, Sorbitan Oleate, BHT, Xanthan Gum, Biosaccharide Gum-4, Sodium Hyaluronate, Moringa Oleifera Seed Oil, Ethylhexylglycerin, Camellia Sinensis Leaf Extract, Vaccinium Macrocarpon (Cranberry) Fruit Extract,

Ugly Duck Miracle Multi Shield Sun Gel



UGLY DUCK MIRACLE MULTI SHIELD SUN GEL			
octinoxate, octisalate, titanium dioxide, gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71624-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	4.2 g in 60 mL
Octisalate (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	1.8 g in 60 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	0.8964 g in 60 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
Homosalate (UNII: V06SV4M95S)	
Pentylene Glycol (UNII: 50C1307PZG)	
Methylpropanediol (UNII: N8F53B3R4R)	
CAPRYLYL TRISILOXANE (UNII: Q95M2PIKJL)	
BEMOTRIZINOL (UNII: PWZ1720CBH)	
Isononyl Isononanoate (UNII: S4V5BS6GCX)	
Ethylhexyl Triazone (UNII: XQN8R9SAK4)	
LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EX0F4CZ66H)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)	
Isohexadecane (UNII: 918X1OUF1E)	
Aluminum Hydroxide (UNII: 5QB0T2IUN0)	
Stearic Acid (UNII: 4ELV7Z65AP)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
Allantoin (UNII: 344S277G0Z)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
Butylene Glycol (UNII: 3XUS85K0RA)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
TRIS-BHT MESITYLENE (UNII: 51DM34B894)	
Xanthan Gum (UNII: TTV12P4NEE)	
BIO SACCHARIDE GUM-4 (UNII: 9XRL057X90)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
MORINGA OLEIFERA SEED OIL (UNII: REM6A5QMC0)	
Ethylhexylglycerin (UNII: 147D247K3P)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CRANBERRY (UNII: 0MVO31Q3QS)	
Blackberry (UNII: 8A6OMU3I8L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71624-100-02	1 in 1 PACKAGE	07/26/2017	
1	NDC:71624-100-01	60 mL in 1 CONTAINER; Type 0: Not a Combination		

1	NDC: 71624-100-01	Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	07/26/2017		

Labeler - EREPH CO., LTD (690038933)

Registrant - EREPH CO., LTD (690038933)

Establishment

Name	Address	ID/FEI	Business Operations
EREPH CO., LTD		690038933	relabel(71624-100)

Establishment

Name	Address	ID/FEI	Business Operations
EYESOME. Co.,Ltd.		557795360	manufacture(71624-100)

Revised: 7/2017

EREPH CO., LTD