

**CLEAR-N-SMOOTH- skin lightening cream cream**  
**Hawknad Manufacturing Industries, 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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**Listing for Clear-N-Smooth Skin Lightening Cream**

**Indications for Use**

**Drug Facts**  
 Hydroquinone 2% Skin Bleaching Agent  
 Octinoxate 2.5% Sunscreen

**Active Ingredients Purpose**  
 Hydroquinone 2% Skin Bleaching Agent  
 Octinoxate 2.5% Sunscreen

**USES**  
 ■ Lightens dark discolorations in the skin such as freckles, age and liver spots.  
 ■ Contains a sunscreen to help prevent darkening from re-occurring.

**Warnings**  
**Do not use** ■ On children under 12 years of age unless directed by a doctor.  
 ■ This product is not for use in the prevention of sunburn.

**For external use only**

**Drug Facts: (Continued)**  
 ■ When using this product  
 ■ Avoid contact with eyes  
 ■ Some users of this product may experience a mild skin irritation. If irritation becomes severe, stop use and consult a doctor.

**Directions** ■ **Adults:** Apply a small amount as a thin layer on the affected area twice daily or use as directed by a doctor. If no improvement is seen after 3 months of treatment, use of this product may not be effective. Lightening effect of this product may not be noticeable when used on very dark skin.  
 ■ **Children under 12 years of age:** do not use unless directed by a doctor.  
 ■ Sun exposure should be limited by using a sunscreen agent or sun blocking agent, or protective clothing to cover bleached skin after treatment is completed in order to prevent darkening from re-occurring.

**Drug Facts: (Continued)**  
**Inactive Ingredients:**  
 Ascorbic acid, Cetyl Alcohol, Citric Acid, Disodium Urea, Dimethicone, Disodium EDTA, Fragrance, Glycerin Stearate, Isopropyl Myristate, Lanolin Alcohol, Methyl Paraben, Mineral Oil, Propyl Paraben, Propylene Glycol, Sodium Lauryl Sulfate, Stearyl Alcohol, Stearic Acid, Stearyl Stearate, Tocopherol, Acetate, Water.

Clear-N-Smooth contains a gentle skin lightening ingredient in a rich moisturizing base to lighten your complexion, and help give your skin a smoother, lovelier, even tone.  
 Manufactured by Hawaiian Mfg. Industries, Inc., Alexandria, VA 22312, USA



**CLEAR-N-SMOOTH**  
 SKIN LIGHTENING CREAM  
 CRÈME ÉCLAIRCISSANT POUR LA PEAU  
 With Vitamin E and Sunscreen  
 NET WT 4.0 oz  
 CONTENU 113.04 ml

- Lightens dark colorations in the skin such as freckles, age, and liver spots
- Contains a sunscreen to help prevent darkening from re-occurring.

**Purpose**

Skin Lightening Cream

**Dosage**

Moisten a cotton ball and apply a thin layer over the entire affected area.

**Keep Out of Reach of Children**

Children under 12 years of age: do not use unless directed by a doctor.

**Warnings**

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When using this product avoid contact with eyes.

Some users of this product may experience a mild skin irritation. If irritation becomes severe, stop use and consult a doctor.

**Instructions for Use**

Apply a small amount as a thin layer on the affected area twice daily, or use as directed by a doctor. If no improvement is seen after 3 months of treatment, use of this product should be discontinued. Lightening effect of this product may not be noticeable when used on very dark skin. Sun exposure should be limited by using a sunscreen agent, a protective clothing to cover bleached skin after treatment is completed in order to prevent darkening from re-occurring.

**Inactive Ingredients**

ascorbic acid, cetyl alcohol, citric acid, diazolidinyl urea, dimethicone, disodium EDTA, Fragrance, glyceryl stearate, isopropyl myristate, lanolin alcohol, methyl paraben, propyl paraben, mineral oil, propylene glycol, sodium lauryl sulfate, sodium metabisulfite, stearyl alcohol, stearyl stearate, tocopherol acetate, water.

**Active Ingredient**

Hydroquinone - 2%

**Principal Display Panel**

**Drug Facts**  
 Active Ingredients Purpose  
 Hydroquinone 2% Skin Bleaching Agent  
 Cetrizoxate 2.5% Sunscreen

**USES**  
 Lightens dark discolorations in the skin such as freckles, age and liver spots.  
 Contains a sunscreen to help prevent tanning from recurring.

**Warnings**  
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**Directions**  
 Adults: Apply a small amount of the affected area twice daily, or use as directed by a doctor. If no improvement is seen after 3 months of treatment, use of this product should be discontinued. Lightening effect of this product may not be noticeable when used on very dark skin.  
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**Drug Facts: (continued)**  
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**Drug Facts: (continued)**  
 Inactive Ingredients:  
 Ascorbic acid, Cetyl Alcohol, Citric Acid, Diazolidinyl Urea, Dimethylolurea, Disodium EDTA, Fragrance, Glycerol Stearate, Alcohol, Methyl Paraben, Isopropyl Myristate, Lanolin, Mineral Oil, Propyl Paraben, Propylene Glycol, Sodium Lauryl Sulfate, Sodium Metabisulfite, Stearyl Alcohol, Stearyl Stearate, Tocopherol Acetate, Water.

Clear-N-Smooth contains a gentle skin lightening ingredient in a non-irritating base to lighten your complexion and help give your skin a smoother, lovelier, even-tone.  
 Manufactured by Hawkwind Mfg. Industries, Inc., Alexandria, VA 22312, USA.



**CLEAR-N-SMOOTH**  
 SKIN LIGHTENING CREAM  
 CRÈME ÉCLAIRCISSANT POUR LA PEAU  
 With Vitamin E and Sunscreen  
 NET WT 4.0 oz  
 CONTENU 113.64 ml

skin lightening cream cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76445-0043
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	2 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	8.1 g in 100 g
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	0.3 g in 100 g
STEARYL STEARATE (UNII: 5WX2EGD0DK)	1.5 g in 100 g
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	3.5 g in 100 g
CETYL ALCOHOL (UNII: 936JST6JCN)	3.5 g in 100 g
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	4 g in 100 g
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	1 g in 100 g
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.25 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51)	3 g in 100 g
LIGHT MINERAL OIL (UNII: N6K5787QVP)	4 g in 100 g
ETHYLHEXYL PALMITATE (UNII: 2865993309)	2 g in 100 g
PEG-100 STEARATE (UNII: YD01N1999R)	2 dL in 100 g
ASCORBIC ACID (UNII: PQ6CK8PD0R)	0.1 g in 100 g
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	0.1 g in 100 g
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	0.3 g in 100 g
METHYLPARABEN (UNII: A2I8C7HI9T)	0.1 g in 100 g
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.1 g in 100 g
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	0.2 g in 100 g
WATER (UNII: 059QF0K00R)	57.6 g in 100 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	5.6 g in 100 g
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.1 g in 100 g

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76445-0043-4	118 g in 1 JAR; Type 0; Not a Combination Product	01/15/2001	

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 SKIN LIGHTENING CREAM  
 CRÈME ÉCLAIRCISSANT POUR LA PEAU  
 With Vitamin E and Sunscreen  
 AVEC VITAMINE E ET ECRAN SOLAIRE  
 NET WT 4.0 oz  
 CONTENU 113.64 ml

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part358A	01/02/1992	
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**Labeler** - Hawknad Manufacturing Industries, Inc. (618892426)

**Registrant** - Hawknad Manufacturing Industries, Inc. (618892426)

**Establishment**

Name	Address	ID/FEI	Business Operations
EMS Acquisition Group		048602791	manufacture(76445-0043)

Revised: 12/2019

Hawknad Manufacturing Industries, Inc.