

**CROC BLOC BROAD SPECTRUM SPF 50 FPS ECRAN SOLAIRE- homosalate, octisalate, octocrylene, oxybenzone, and avobenzone lotion
Degil Safety Products (1989) 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

Homosalate 13.0% w/w

Octocrylene 7.0% w/w

Octisalate 5.0% w/w

Oxybenzone 4.0% w/w

Avobenzone 3.0% w/w

Purpose

- Sunscreen

Uses

- Helps prevent sunburn

Warnings

For external use only

Do not use on damaged or broken skin

Keep out of reach of children

- May stain or damage some fabrics or surfaces

When using this product

- Avoid contact with eyes. Rinse with water to remove.

Stop use and ask doctor if

- Rash or irritation develops and lasts

Directions

- Apply liberally and evenly to dry skin 15 minutes before exposure to the sun. Reapply every 2 hours to insure adequate UV protection or 80 minutes after swimming,

perspiring heavily, or immediately after washing and towel drying.

- For children under 6 months of age: Ask a doctor

Other Information

- Protect the product from excessive heat and direct sun

Inactive Ingredients

Aqua, Sorbitol, Aluminum Starch Octenylsuccinate VP/Eicosene Copolymer, Stearic Acid, Triethanolamine, Sorbitan Isostearate, Benzyl Alcohol, Dimethicone, Tocopherol, Polyglyceryl-3 Distearate, Methylparaben, Carbomer, Propylparaben, Disodium EDTA.



**BROAD SPECTRUM • LARGE SPECTRE
UVA / UVB PROTECTION
CONTRE LES RAYONS UVA ET UVB**

Dermatologist Tested • Gentle Lotion Formula
Unscented • Water Resistant (80 Minutes)
Testé par les dermatologues • Formule écran solaire
Douce • Non Parfumée • Résistant à l'eau

Net Contents/Contenu : 4 fl. oz. (120 mL)

Sunscreen
SPF 50 FPS
Écran Solaire

Distributed by/Distribué par:
Croc Bloc Products Inc.
200 Zenway Blvd., Unit 1 Vaughan, Ontario, Canada
1-800-332-1810
E-mail: degil@degilsafety.com
Website: www.degilsafety.com

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58331-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TOCOPHEROL (UNII: R0ZB2556P8)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	

SORBITOL (UNII: 506T60A25R)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CARBOXPOLYMETHYLENE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58331-050-01	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/21/2022	
2	NDC:58331-050-03	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/21/2022	
3	NDC:58331-050-02	10 mL in 1 PACKET; Type 0: Not a Combination Product	11/21/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/18/2020	

Labeler - Degil Safety Products (1989) Inc. (247083686)

Revised: 11/2022

Degil Safety Products (1989) Inc.