

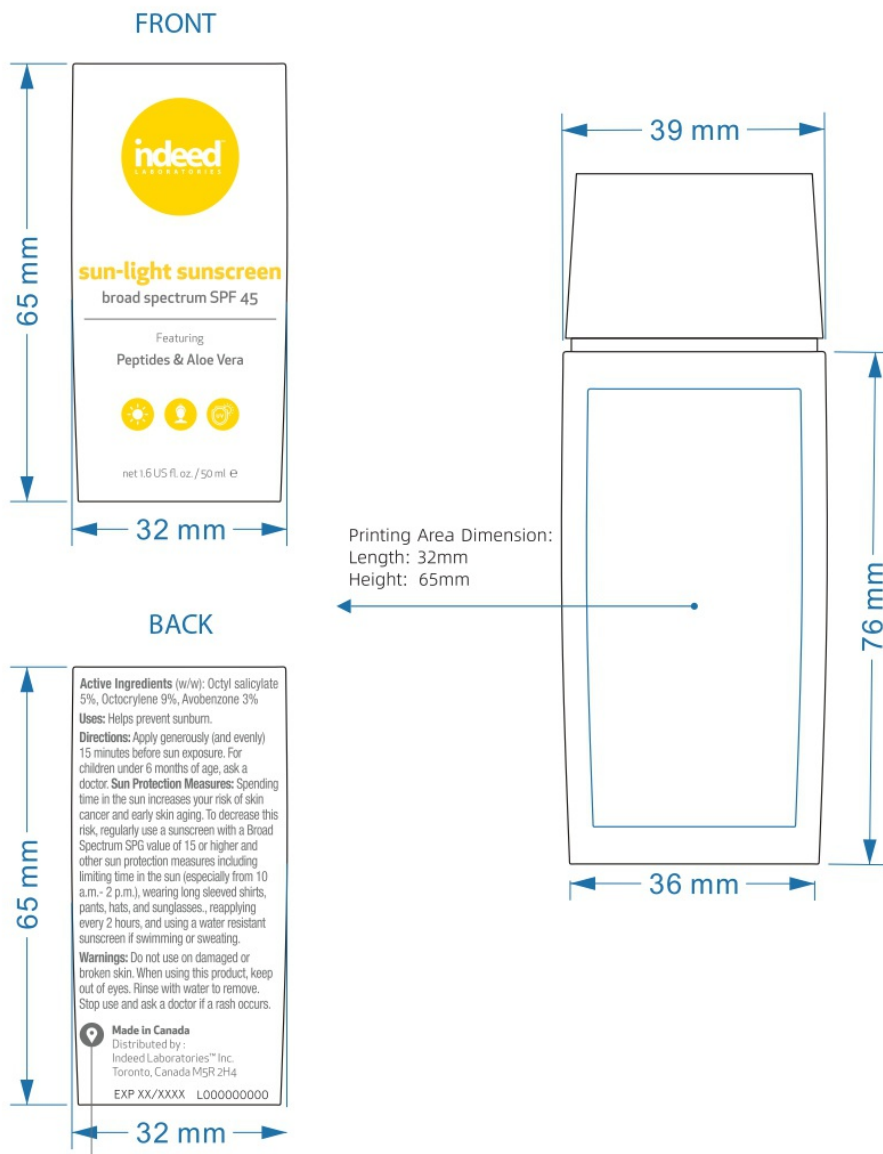
SUN-LIGHT SUNSCREEN BROAD SPECTRUM SPF 45- octyl salicylate, octocrylene, avobenzone lotion

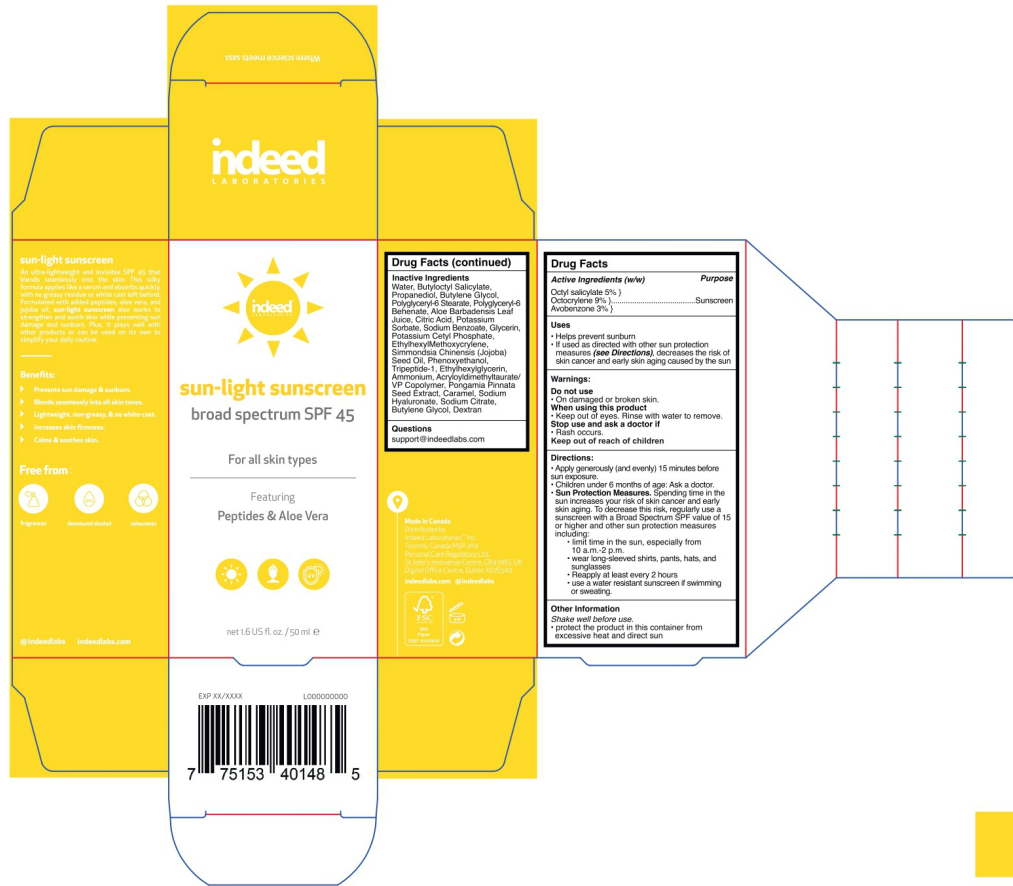
Indeed Laboratories Inc.

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.

Sun-light Sunscreen SPF 45 Indeed

Inner Package





PANTONE 012 C



PANTONE 424 C

Active Ingredient

Octyl salicylate 5%

Octocrylene 9%

Avobenzone 3%

Purpose

Sunscreen

Warnings

Warnings:
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

Keep out of reach of children.

Directions

- Apply generously (and evenly) 15 minutes before sun exposure.

- Children under 6 months of age: Ask a doctor.

- 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.-2p.m.

- wear long sleeve shirts, pants, hats and sunglasses.

- reapply at least every 2 hours

- use a water resistant sunscreen if swimming or sweating.

Indications and Usage

Uses

- Helps prevent sunburn.

- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Inactive ingredients

Water, Butyloctyl salicylate, propanediol, butylene glycol, polyglyceryl-6 stearate, polyglyceryl-6 behenate, aloe barbadensis leaf juice, citric acid, potassium sorbate, sodium benzoate, glycerin, potassium cetyl phosphate, ethylhexylmethoxycrylene, Simmondsia chinensis (jojoba) seed oil, phenoxyethanol, tripeptide-1, ethylhexylglycerin, ammonium, acryloyldimethyltaurate/VP copolymer, Pongamia pinnata seed extract, caramel, sodium hyaluronate, sodium citrate, butylene glycol, dextran.

SUN-LIGHT SUNSCREEN BROAD SPECTRUM SPF 45

octyl salicylate, octocrylene, avobenzene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83407-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPANEDIOL (UNII: 5965N8W85T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
JOJOBA OIL (UNII: 724GKU717M)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
POLYGLYCERYL-6 BEHENATE (UNII: 4T2L7QI313)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PONGAMIA PINNATA SEED (UNII: C2BRV53B1V)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POLYGLYCERYL-6 STEARATE (UNII: ETY9Q81E2T)	
DEXTRAN 110 (UNII: 05Q25F6XJ3)	
CARAMEL (UNII: T9D99G2B1R)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PREZATIDE (UNII: 39TG2H631E)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
AMMONIUM ACRYLOYLDIMETHYLTAAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83407-001-01	1 in 1 BOX	09/05/2023	
1		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	09/05/2023	

Labeler - Indeed Laboratories Inc. (245225615)

Registrant - Indeed Laboratories Inc. (245225615)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetica Laboratories		255080491	manufacture(83407-001)

Revised: 5/2023

Indeed Laboratories Inc.