

JACK BLACK THE TRIPLE PLAY- avobenzone, octinoxate lotion

Jack Black L.L.C

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

Avobenzone 2.2%

Octinoxate 7.5%

Purpose

Sunscreen

Use

Moisturizes and helps prevent sunburn

Warnings

For external use only.

Do not use on damaged or broken skin.

Stop use and ask doctor if rash occurs.

When using this product keep out of eyes. Rinse with water to remove

Keep out of reach of children.

- If swallowed, get medical help or contact Poison Control Center right away.

Directions

Apply liberally after cleansing and shaving and 15 minutes before sun exposure. • Use a water-resistant sunscreen if swimming or sweating. • Reapply at least every two hours. • Children under 6 months: 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, use sunscreen with a broad spectrum SPF 15 or higher. • Limit time in the sun, especially from 10 a.m. – 2 p.m. • Wear long-sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients

Water, Cyclopentasiloxane, Octyldodecyl Neopentanoate, Phenethyl Benzoate, Dimethicone, Glycereth-26, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate

Copolymer, Phenoxyethanol, Hydroxypropyl Starch Phosphate, Cetearyl Glucoside, Carbomer, Pyrus Malus (Apple) Fruit Extract, Butylene Glycol, Sodium Hydroxide, Disodium EDTA, Sodium Hyaluronate, Lavandula Angustifolia (Lavender) Oil, Iodopropynyl Butylcarbamate, Pelargonium Graveolens Flower Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Lecithin, Melissa Officinalis Extract, Haslea Ostrearia Extract, Palmaria Palmata Extract, Calendula Officinalis Flower Extract*, Glycerin, Leontopodium Alpinum (Edelweiss) Extract*, Retinyl Palmitate, Tocopheryl Acetate, Anthemis Nobilis Flower Oil, Peucedanum Ostruthium Leaf Extract*, Buddleja Davidii Leaf Extract*, Artemisia Umbelliformis Extract*.

* Certified Organic

Other information

- Protect product from excessive heat and direct sunlight
- You may report a serious adverse reaction from using this product to Jack Black at 1-877-766-3388.

Questions?

1-877-766-3388 www.getJackBlack.com

Printed Date:

DO NOT SCALE DRAWING

PO#: _____
 Name: _____
 Code: _____
 Spec: D30x99mm

Jack Black
Authentic and Original

Date: 03/29/2019
 Retailer: US (United States)
 Art #: 02-2004-08
 UPC #: 6 82223 02004 3
 Product name: Double-Duty Face Moisturizer SPF 20
 Package size: 1.5 oz (D30x99mm)
 File name: 02-2004-08_US_Double-Duty_1.5oz_400-30x99mm.ai

Drug Facts

Active Ingredients	Purpose
Avobenzone 3.0%, Octinoxate 7.0%	Sunscreen

Use - Moisturizes and helps prevent sunburn.

Warnings - For external use only - Do not use on damaged or irritated skin - Change use and avoid direct sunlight when using - When using, be protected from direct sunlight - If you experience a rash or irritation, discontinue use and consult your physician - If you experience a severe allergic reaction, get medical help or contact Poison Control Center right away.

Directions - Apply liberally to clean, moisturized skin before sun exposure.

- Use a water resistant sunscreen if swimming or sweating.

- Reapply often, especially after sweating.

- Children under 6 months - Ask a doctor - See Pediatric Medicines - Caution: This is for use in children 6 months of age and older only. Use only if recommended by your doctor. Do not use in children under 6 months of age. Do not use in children under 2 years of age. Do not use in children under 2 years of age. Do not use in children under 2 years of age.

Other Ingredients - Aqua (Water), Cyclopentasiloxane, Propylparaben, Isopropyl Alcohol, Glycerin, Phenoxyethanol, Hydroxypropyl Starch Phosphate, Cetearyl Glucoside, Carbomer, Pyrus Malus (Apple) Fruit Extract, Butylene Glycol, Sodium Hydroxide, Disodium EDTA, Sodium Hyaluronate, Lavandula Angustifolia (Lavender) Oil, Iodopropynyl Butylcarbamate, Pelargonium Graveolens Flower Oil, Rosmarinus Officinalis (Rosemary) Leaf Oil, Lecithin, Melissa Officinalis Extract, Haslea Ostrearia Extract, Palmaria Palmata Extract, Calendula Officinalis Flower Extract*, Glycerin, Leontopodium Alpinum (Edelweiss) Extract*, Retinyl Palmitate, Tocopheryl Acetate, Anthemis Nobilis Flower Oil, Peucedanum Ostruthium Leaf Extract*, Buddleja Davidii Leaf Extract*, Artemisia Umbelliformis Extract*, Carbomer.

Other Information - Product tested free of parabens and other irritants. For more information, visit www.getJackBlack.com.

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www.getJackBlack.com 1-877-766-3388

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02-2004-08

MADE IN CHINA

JACK BLACK THE TRIPLE PLAY
 avobenzone, octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66738-661
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
PALMARIA PALMATA (UNII: 7832HOY4ZQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CORN OIL (UNII: 8470G57WFM)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
GLYCERETH-26 (UNII: NNE56F2N14)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ALCOHOL (UNII: 3K9958V90M)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
MELISSA OFFICINALIS (UNII: YF70189L0N)	
LEONTOPODIUM ALPINUM FLOWERING TOP (UNII: QQC1AK06RK)	
BUDDLEJA DAVIDII LEAF (UNII: X380815D32)	
HASLEA OSTREARIA (UNII: Y87200QHN9)	
APPLE (UNII: B423VGH5S9)	
ARTEMISIA UMBELLIFORMIS FLOWER (UNII: 91OLL9AJ7D)	
PHOSPHATIDYLCHOLINE, SOYBEAN (UNII: 1T6N4D9YV6)	
PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEUCEDANUM OSTRUTHIUM LEAF (UNII: 86P27YRR6Y)	
WATER (UNII: 059QF0KO0R)	

HYDROXYPROPYL DISTARCH PHOSPHATE, HIGH AMYLOSE CORN (UNII: 9F8ET54T05)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66738-661-40	44 mL in 1 KIT; Type 1: Convenience Kit of Co-Package	09/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/30/2020	

Labeler - Jack Black L.L.C (847024036)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss American CDMO		080170933	manufacture(66738-661)

Revised: 7/2021

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