

INTENSE THERAPY LIP BALM BLACK CHERRY- sunscreen skin protectant lip balm ointment

Jack Black, LLC

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.

Intense Therapy Lip Balm Black Cherry

Warnings

Stop use and ask doctor if rash occurs

Children under 6 months: Ask a doctor

Active Ingredients

Avobenzone 3.0% Sunscreen

Octinoxate 7.5% Sunscreen

Petrolatum 40.2% Skin Protectant

Directions

Apply liberally and reapply every 2 hours or after eating, drinking, swimming or wiping lips.

Keep out of Reach of Children

Keep out of Reach of Children

Uses

Helps prevent sunburn and chapped lips.

Inactive Ingredients

beeswax, butyrospermum Parkii (shea) butter, C18-38 alkyl hydroxystearol stearate, camellia sinensis (green tea) leaf extract, cyclohexasiloxane, cyclopentasiloxane, flavor, lanolin, microcrystalline wax, ozokerite, persea gratissima (avocado) oil, ployglyceryl 3 beeswax, theobroma cacao (cocoa) seed butter, tocopheryl acetate

Questions

www.getjackblack.com

1-877-766-3388

Label

Printed Date:

DO NOT SCALE DRAWING

PO#: _____

Name: _____

Code: _____

Spec: D19x67mm



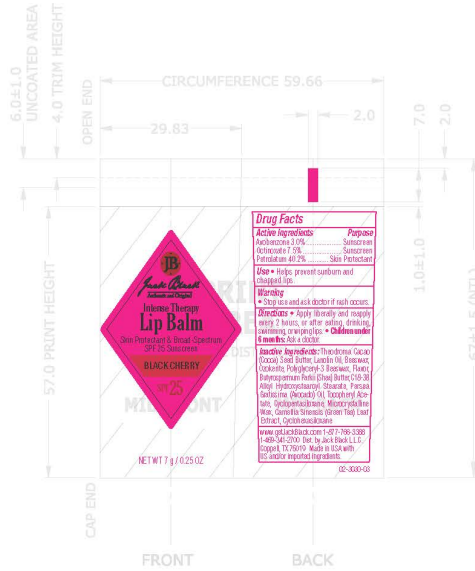
Date: 11/12/2018
 Retailer: US (United States)
 Art #: 02-3030-03
 UPC#: 6 82223 03030 1
 Product name: Intense Therapy Lip Balm (BLACK CHERRY)
 HOLIDAY 2019
 Package size: 0.25 fl oz tube
 File name: 02-3030-03_BLACK_CHERRY_398-19x67mm.ai

US (OTC Products)
 www.getJackBlack.com 1-877-766-3388
 1-469-341-2700 Dist. by Jack Black L.L.C.
 Coppell, TX 75019 Made in USA with US and/or imported ingredients.

- BLACK
- PMS 187
- PMS 1935 (Red 2)
- White

- Updated Distro block
- Moved "Warning" to separate line

Intense Therapy Lip Balm
 Black Cherry & Pomegranate (US Only)
 Updated 11/6/18 Jamie Otlak & Ann Schultheis



Drug Facts

Active Ingredients	Warnings
Avobenzone 3.0% Octinoxate 7.5% Petrolatum 40.2%	Sunscreen Sunscreen Skin Protectant
Use • Help prevent sunburn and tanning.	
Warnings	
• Stop use and seek doctor if rash occurs.	
• Avoid use if you are using or using every 2 hours, or after eating, drinking, swimming, or sweating. • Children under 6 months do not use.	
Other Ingredients: Theobroma Cacao (Cocoa Bean) Butter, Lanolin Oil, Ethanol, Coccolic Acid, Polyglycerol-3, Beeswax, Paraffin, Polypropylene Glycol, Dimethyl Siloxane, Hydroxyethyl Acrylate, Pentaerythrityl Tetraethylhexanoate, Microcrystalline Wax, Candelilla Wax, Polyethylene Glycol, Candelilla Wax.	
www.getJackBlack.com 1-877-766-3388 1-469-341-2700 Dist. by Jack Black L.L.C. Coppell, TX 75019 Made in USA with US and/or imported ingredients. ©S-000-03	

	1	2	3	4	5	6
COLOR						
PMS						

WWP World Wide Packaging 15 Vreeland Road Rutherford Park NJ 07932

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS

LINEAR: .X = ±0.20 .XX = ±0.10

ANGULAR: ±0°30'

EST. Volume (cc, cm³)

EST. Weight (grams)

Material

Project Name: 19mm Cap and Tube

Supplier: WWP Suzhou

Drawn By: Part Name: DECO 19X67

Date: 10/20/16

SHT: A-4

Dwg. No. 398 - 19x67

Rev. Project No.: 398

Status: Production

Part Code:

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SHEET 1 OF 1

INTENSE THERAPY LIP BALM BLACK CHERRY

sunscreen skin protectant lip balm ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66738-031
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 g in 1000 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 g in 1000 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	402 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CERESIN (UNII: Q1LS2UJO3A)	
AVOCADO OIL (UNII: 6VNO72PFC1)	

METHYL SALICYLATE (UNII: LAV5U5022Y)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
SHEA BUTTER (UNII: K49155WL9Y)	
WHITE WAX (UNII: 7G1J5DA97F)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LANOLIN OIL (UNII: OVV5IJJ58F)	
COCOA BUTTER (UNII: 512OYT1CRR)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY (Black Cherry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66738-031-25	7 g in 1 TUBE; Type 0: Not a Combination Product	07/30/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/30/2013	

Labeler - Jack Black, LLC (847024036)

Registrant - Swiss-American CDMO, LLC (080170933)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	manufacture(66738-031)

Revised: 7/2019

Jack Black, LLC