

BODY BUTTER BROAD SPECTRUM SUNSCREEN SPF 40- avobenzone, octisalate, octocrylene cream
Taylor James Ltd.

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.

Body Butter SPF 40

Active Ingredients Purpose

Avobenzone 3% Sunscreen

Octisalate 5% Sunscreen

Octocrylene 10% Sunscreen

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.

Keep out of reach of children

If swallowed, get medical help or contact a poison Control Center right away

Stop use and ask a doctor if rash occurs

Warnings

- **For external use only**
- **Do not use** on damaged or broken skin
- **When using this product** keep out of eyes. Rinse with water to remove

Directions

- Apply generously and evenly 15 minutes before sun exposure
 - Reapply at least every 2 hours.
 - Use a water-resistant sunscreen if swimming or sweating
- **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 your time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses
 - Children under 6 months of age: ask a doctor.

Inactive Ingredients

Water, Isododecane, Glycerin, Trimethoxybenzylidene Pentanedione, Polyester-8, Poly C10-30 Alkyl Acrylate, Cetearyl Oliviate, Oryza Sativa (Rice) Bran Extract, Sucrose Stearate, Diisopropyl Sebacate, Hydroxyacetophenone, Isodecyl Neopentanoate, Lauryl Lactate, Sodium Polyacrylate Starch, Diethylhexyl Syringlidenemalonate, Sodium Stearoyl Glutamate, C18-38 Alkyl Hydroxystearoyl Stearate, Chlorphenesin, Ethylhexylglycerin, 1,2 Hexanediol, Caprylyl Glycol, Helianthus Annuus(Sunflower) Extract, Trisodium Ethylenediamine Disuccinate, Xanthan Gum, Tocopherol, Romarinus Officinalis (Rosemary) Leaf Extract, Caprylic/Capric Triglyceride, Citric Acid, Hippophae Rhamnoides Seed Oil, Citrus Nobilis (Manadarin Orange) Peel Oil, Cymbopogon Schoenanthus Oil, Elettaria Cardamomum Seed Oil, Eugenia Caryophyllus (Clove) Leaf Oil, Cinnamomum Cassia, Vanillin, Eucalyptus Globulus Leaf Oil, Lavandula Hybrida Oil

Supergoop!

Body Butter

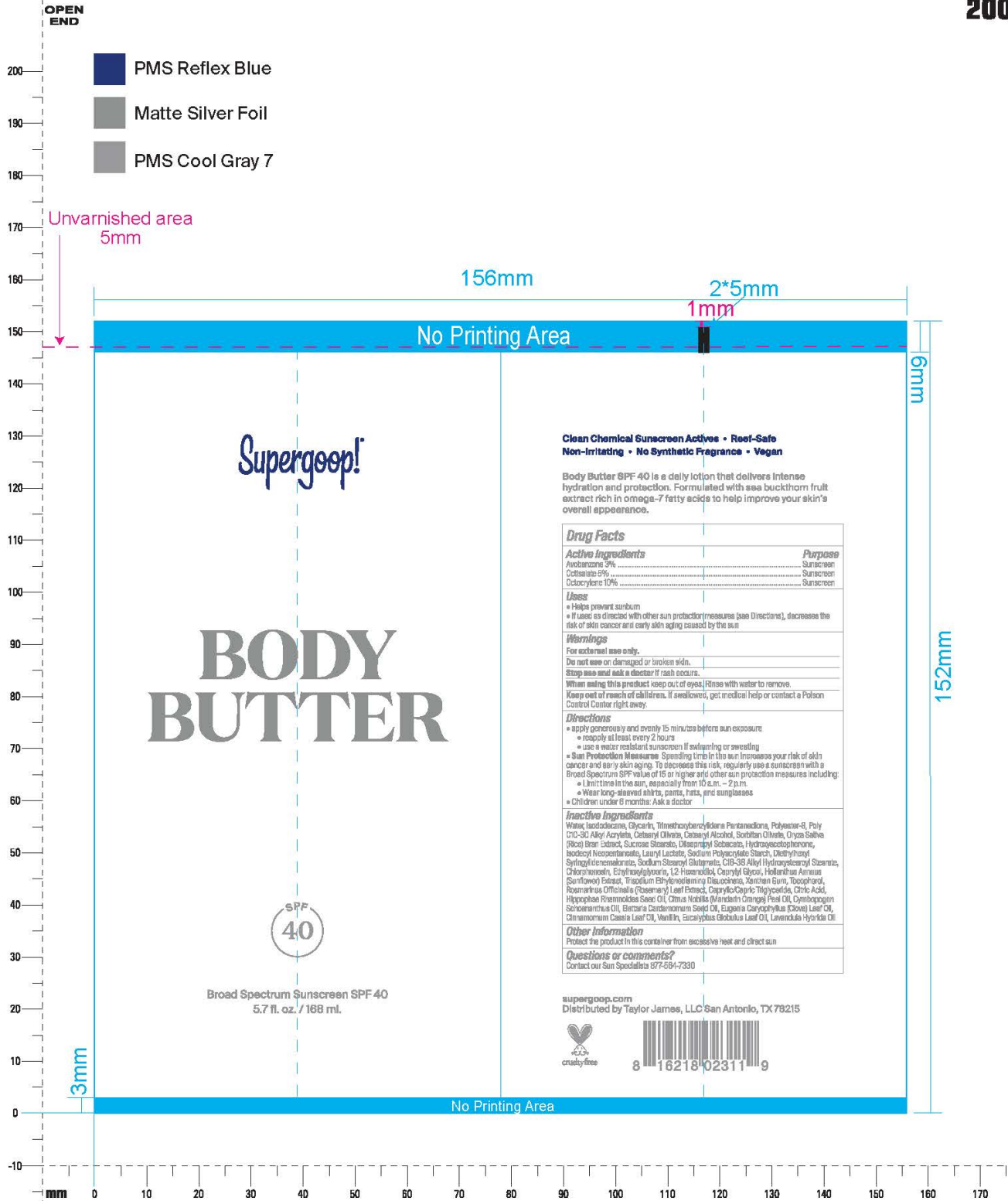
SPF 40

Broad Spectrum Sunscreen SPF 40

5.7 fl. oz./168 ml

PARTIAL LARGE SIZE

200%



FILE INFORMATION

PROJECT INFORMATION

CLIENT APPROVAL CHECKLIST

TM Hot Stamping Diecut Coev Colors UPC



FILE NAME	TUBE DIMENSION <input checked="" type="checkbox"/> 30 mm	<input type="checkbox"/> Silver <input type="checkbox"/> Gold	<input type="checkbox"/> Photography <input type="checkbox"/> Illustration <input type="checkbox"/> Eye Mark
	TUBE LENGTH 152 mm	<input type="checkbox"/> Other Metallic Color	
CLIENT B	PRINT INFORMATION		client signature _____
STARTED CGP	OFFSET COLOR	5 mm unvarnished from bottom	date _____
MODIFIED 00/00/00 CGP		INTERNAL APPROVAL	
SOFTWARE ai by Illustrator CS cdr by Coreldraw 9	SILK-SCREEN COLOR	Design <i>Chel</i> Proof _____	
EXPORT PDF	<input type="checkbox"/> TUBE COLOR	UPC Test _____ Verify _____	
		RELEASE DATE	IMPORTANT: This art has been checked and proofed for accuracy. It is the responsibility of the client to make all final approvals before the release of this art. PLEASE DOUBLE CHECK FOR ACCURACY.
		DIELINE DOES NOT PRINT	

BODY BUTTER BROAD SPECTRUM SUNSCREEN SPF 40

avobenzone, octisalate, octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75936-256
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISODODECANE (UNII: A8289P68Y2)	
GLYCERIN (UNII: PDC6A3C0OX)	
TRIMETHOXYBENZYLIDENE PENTANEDIONE (UNII: 322V0ACF25)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
RICE BRAN (UNII: R60QEP13IC)	
SUCROSE STEARATE (UNII: 274KW0O50M)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
LAURYL LACTATE (UNII: G5SU0BFK7O)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	

XANTHAN GUM (UNII: TTV12P4NEE)
TOCOPHEROL (UNII: R0ZB2556P8)
ROSEMARY (UNII: IJ67X351P9)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)
MANDARIN OIL (UNII: NJO720F72R)
CYMBOPOGON SCHOENANTHUS OIL (UNII: XE7K568ILO)
CARDAMOM OIL (UNII: JM0KJ091HZ)
CLOVE LEAF OIL (UNII: VCA5491KVF)
CHINESE CINNAMON LEAF OIL (UNII: 4U4V2F2E4Y)
VANILLIN (UNII: CHI530446X)
EUCALYPTUS OIL (UNII: 2R04ONI662)
LAVANDIN OIL (UNII: 9RES347CKG)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75936-256-01	168 mL in 1 PACKAGE; Type 0: Not a Combination Product	03/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/01/2020	

Labeler - Taylor James Ltd. (033381850)

Establishment

Name	Address	ID/FEI	Business Operations
Cosway Company		620899877	manufacture(75936-256)