

**SEI BELLA FLAWLESS LIQUID FOUNDATION 540 W- octinoxate 6% octisalate  
5% titanium dioxide 2% lotion  
Melaleuca 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.*

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**Sei Bella Flawless Liquid Foundation - 540 W**

**Active Ingredient**

Octinoxate 7.5%

**Purpose**

Sunscreen

**Use**

■ helps prevent sunburn

**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.

**Stop use and ask a doctor** if rash occurs

**Keep out of reach of children.**

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

**Directions**

■ apply after cleanser, toner, and foundation primer. Blend outward with Sei Bella foundation brush or fingers.

■ apply liberally 15 minutes before sun exposure

■ use a water-resistant sunscreen if swimming or sweating

■ reapply at least every 2 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, regularly use a sunscreen with a broad-spectrum SPF value of 15 or higher and other sun protection measures including:

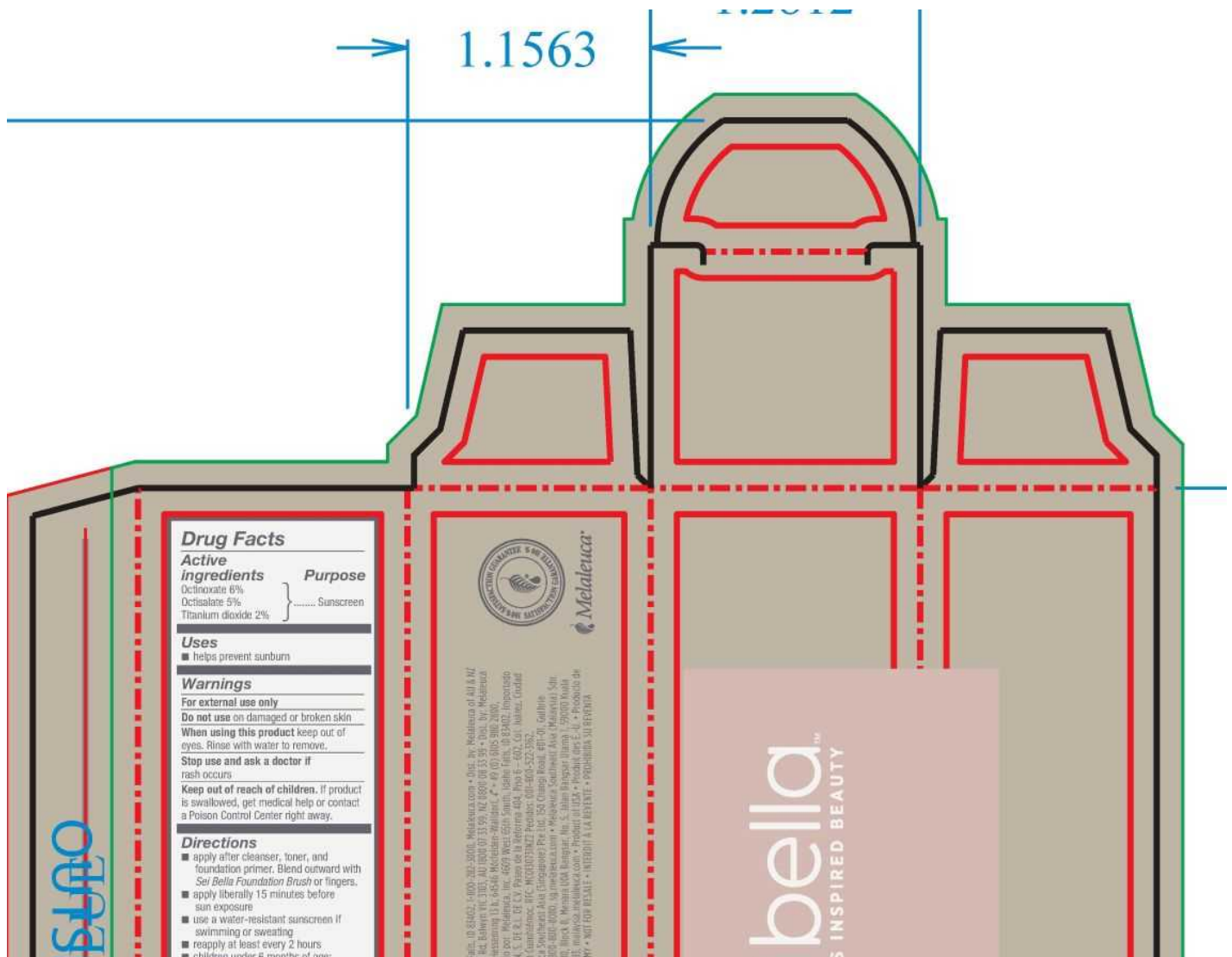
- limit time in the sun, especially from 10 a.m.-2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses

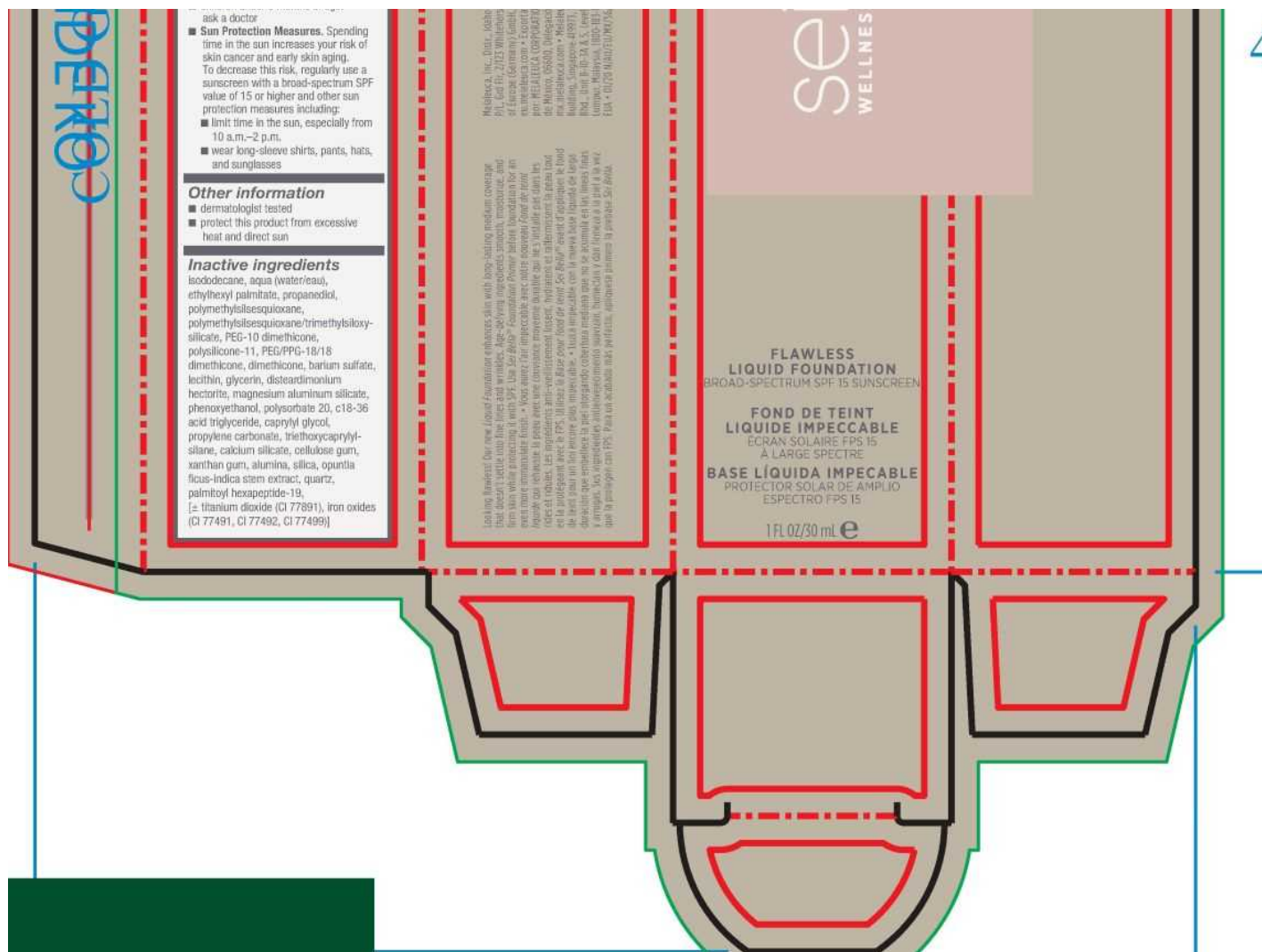
### Other information

- dermatologist and allergy tested
- protect this product from excessive heat and direct sun

### Inactive ingredients

isododecane, water, titanium oxide, dodecane, ethylhexyl palmitate, propanediol, polymethylsilsesquioxane, trimethylsiloxysilicate, peg-10 dimethicone, polysilicone-11, peg/ppg-18/18 dimethicone, dimethicone, barium sulfate, lecithin, glycerin, disteardimonium hectorite, magnesium aluminum silicate, phenoxyethanol, polysorbate 20, c18-36 acid triglyceride, caprylyl glycol, propylene carbonate, triethoxycaprylylsilane, calcium silicate, xanthum gum, cellulose gum, ouptnia ficus-indica stem extract, quartz, palmitoyl hexapeptide-19, may contain: iron oxide CI 77492, iron oxide 77491, iron oxide 77499





## SEI BELLA FLAWLESS LIQUID FOUNDATION 540 W

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### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54473-327
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	1.5 g in 30 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.8 g in 30 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.6 g in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>FERRIC OXIDE YELLOW</b> (UNII: EX43802MRT)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	

<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>ISODODECANE</b> (UNII: A8289P68Y2)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>C18-36 ACID TRIGLYCERIDE</b> (UNII: ZRA72DR3R7)
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)
<b>OPUNTIA FICUS-INDICA STEM</b> (UNII: MUD8892KHL)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)
<b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)
<b>CALCIUM SILICATE</b> (UNII: S4255P4G5M)
<b>PALMITOYL HEXAPEPTIDE-12</b> (UNII: HO4ZT5S86C)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)
<b>DODECANE</b> (UNII: 11A386X1QH)
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.66)</b> (UNII: 5041RX63GN)
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V15VM0)
<b>POLYSILICONE-15</b> (UNII: F8DRP5BB29)
<b>PEG/PPG-18/18 DIMETHICONE</b> (UNII: 9H0AO7T794)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>BIARIUM SULFATE</b> (UNII: 25BB7EKE2E)

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-327-01	1 in 1 BOX	06/01/2020	
1		30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2020	

**Labeler** - Melaleuca Inc. (139760102)

**Registrant** - Melaleuca Inc. (139760102)

## Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies & Packaging LLC.		809172885	manufacture(54473-327)

Revised: 1/2023

Melaleuca Inc.