

POWDER- zinc oxide, titanium dioxide powder
Oxygen Development

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.

Touch Behold SPF FINISHING POWDER BROAD SPECTRUM SPF 25

Active ingredient

Titanium Dioxide 15%

Zinc oxide 17%

Purpose

Sunscreen

Uses

Help 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

Warnings

For external use only

Do not use

Do not use on damaged or broken skin

When using

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

Stop use

Stop use and ask a doctor if rash occurs

Keep out of the reach of children

If swallowed, get medical help or contact a poison control center right away

Directions

Apply generously 15 minutes before sun exposure. Children under 6 months of age: ask a doctor.

Reapply: immediately after towel drying. 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 time in the sun, especially from 10 a.m-2p.m. wear long-sleeved shirts, pants, hats, and sunglasses

Other information

protect the product in this container from excessive heat and direct sun

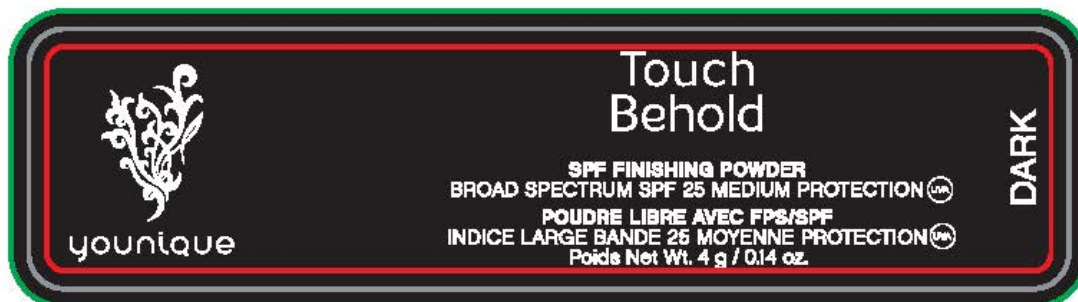
Ininactive ingredient

polymethylsilsesquioxane, silica, jojoba esters, alumina, oryza sativa (rice)extract, caprylyl glycol, phenoxyethanol, hexylene glycol, aluminum dimyristate, triethoxycaprylylsilane, disodium stearyl glutamate, iron oxides, mica.

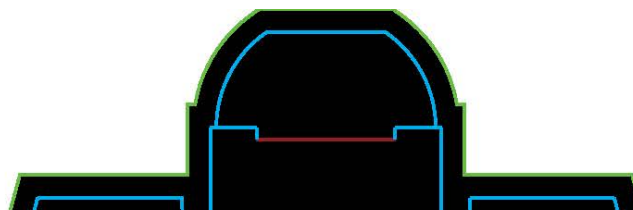
Questions or Comments

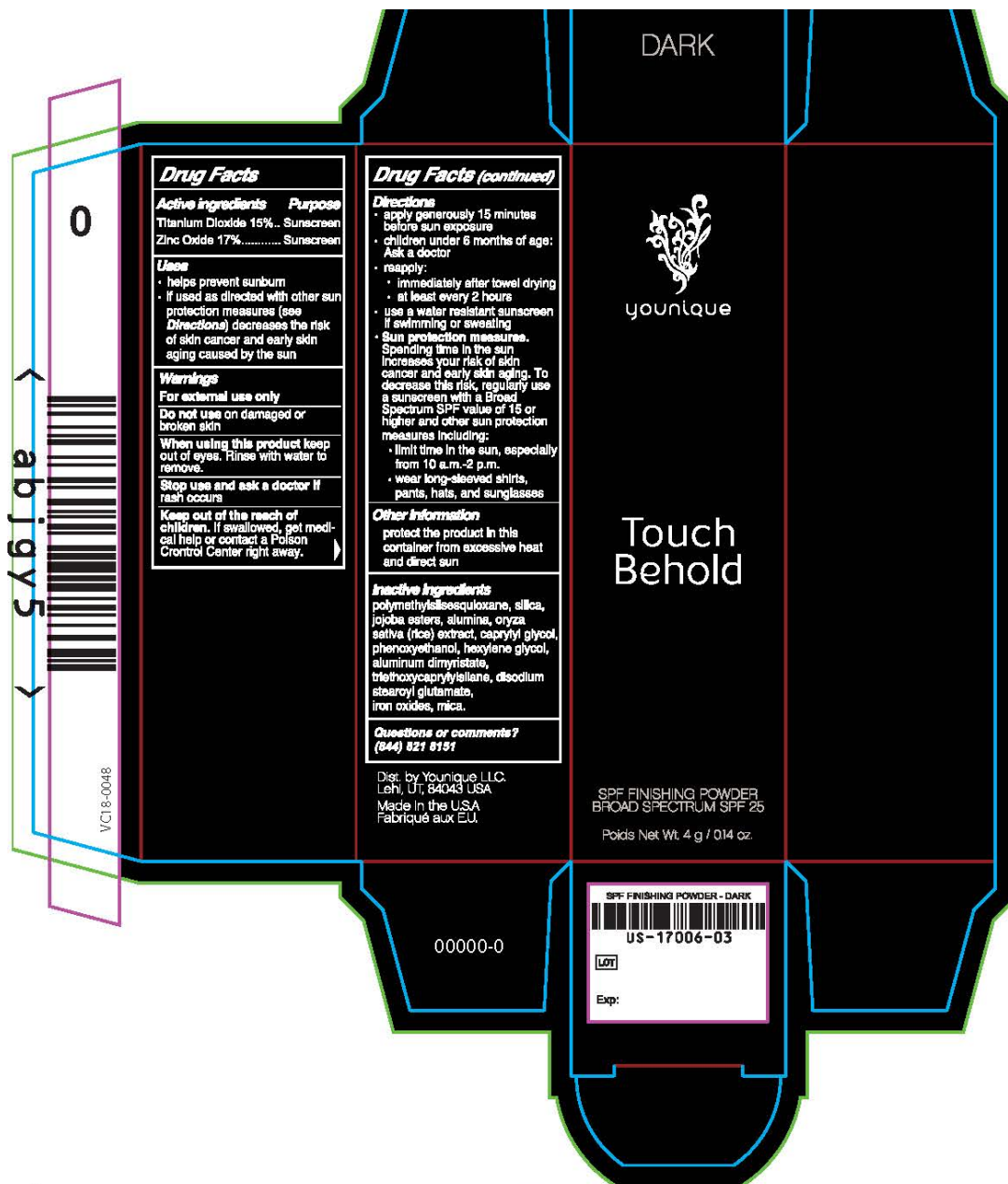
(844) 821 8151


Primary package



Secondary package





 VISTA COLOR®											
Company		Component size	7.684" X 5.579"								
Oxygen Development LLC		Colors									
Part Number OXYDE-050_UNI_861_PDR3342_Pro		<table border="1"> <tr> <td>Black</td> <td>Black</td> </tr> <tr> <td>%</td> <td>%</td> </tr> </table>		Black	Black	%	%				
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%	%										
Overs/Unders		Spot Coatings									
Caller		Special Finishes									
Stock		<table border="1"> <tr> <td><input type="checkbox"/> Blanket</td> <td><input type="checkbox"/> Cyrel</td> <td><input type="checkbox"/> Hybrid</td> <td><input type="checkbox"/> Foll</td> <td><input type="checkbox"/> Emboss</td> <td><input type="checkbox"/> Braille</td> </tr> </table>		<input type="checkbox"/> Blanket	<input type="checkbox"/> Cyrel	<input type="checkbox"/> Hybrid	<input type="checkbox"/> Foll	<input type="checkbox"/> Emboss	<input type="checkbox"/> Braille		
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Comments (Reason for the change)		<table border="1"> <tr> <td><input type="checkbox"/> PDF Uploaded WebCenter</td> <td><input type="checkbox"/> PDF Approved</td> </tr> </table>		<input type="checkbox"/> PDF Uploaded WebCenter	<input type="checkbox"/> PDF Approved						
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Proof Number	Date	<table border="1"> <tr> <td>OPERATOR mruiz</td> <td>Date 3/27/2018 14:40:16</td> <td>QC acuevas</td> <td>Date 3/27/2018 14:40:06</td> </tr> <tr> <td>REP / CSR</td> <td>Date</td> <td>Customer Approval</td> <td>Date</td> </tr> </table>		OPERATOR mruiz	Date 3/27/2018 14:40:16	QC acuevas	Date 3/27/2018 14:40:06	REP / CSR	Date	Customer Approval	Date
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<input type="checkbox"/> Samples Mock-Up	Operator: _____	Date: _____									

POWDER

zinc oxide, titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61354-061
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	15.09 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	17.55 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
JOJOBA OIL (UNII: 724GKU717M)	
MICA (UNII: V8A1AW0880)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-061-03	1 in 1 CARTON	02/23/2021	02/10/2023
1		4 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/23/2021	

Labeler - Oxygen Development (137098492)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen development		137098492	manufacture(61354-061)