# MADE BY DENTISTS WHITENING- sodium fluoride paste Oral Spotlight Care 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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### Made By Dentists<sup>™</sup> Whitening Toothpaste

**Drug Facts** 

Active ingredient: Sodium Fluoride 0.24%

Purpose: Anticavity

**Use**: Aids in the prevention of cavities.

Warnings:

**Keep out of reach of children under 6 years of age.** If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.
- Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing), and only use a pea size amount.
- Supervise children as necessary until capable of using without supervision.
- Children under 2 years of age: Consult a dentist or doctor.

### **Inactive Ingredients:**

Questions or comments?

+1 (646) 980-6461

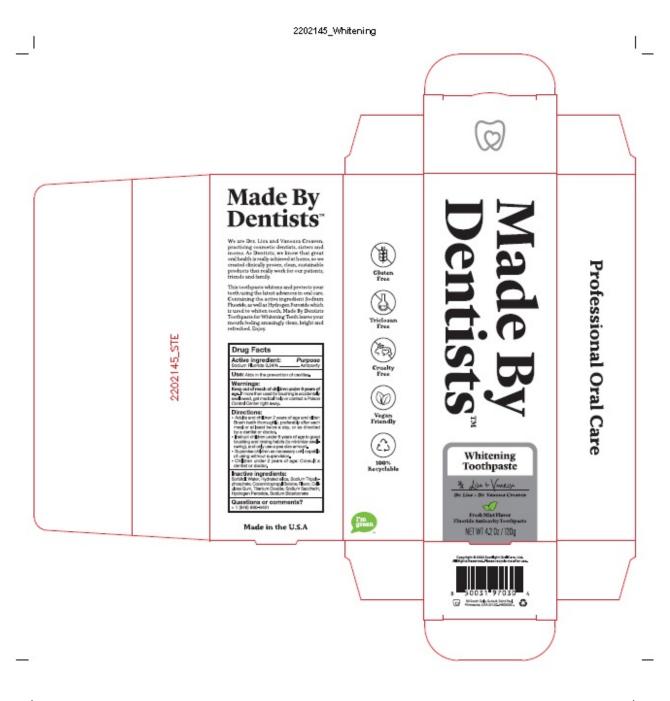
Product Labeling
Made By Dentists™
Whitening
Toothpaste

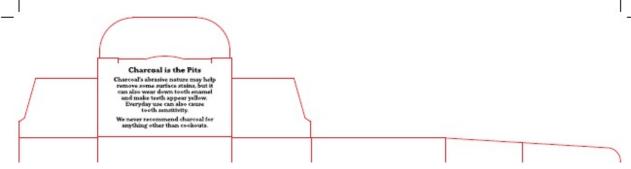
Fresh Mint Flavor

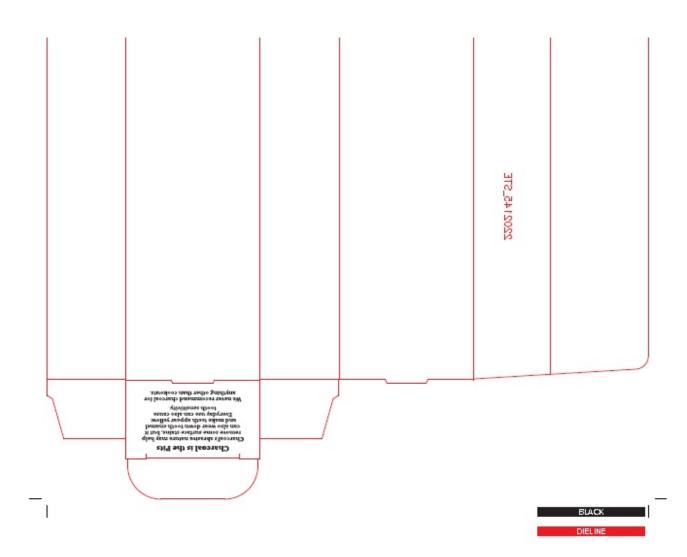
Fluoride Anticavity Toothpaste

NET WT 4.2 Oz / 120 g

### **Carton**







# <u>Tube</u>





# Made By Dentists<sup>\*</sup>







Vegan Friendly

Cruelty

Me

Active ingredient: Purpose Sodium Fluoride 0.24% ...... Anticavity

Use: Aids in the prevention of dental decay.

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#### Directions:

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dentist or doctor.



Whitening Toothpaste Fluoride Anticavity

NET WT 4.2 Oz / 120 g

#### Fresh Mint Flavor

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### MADE BY DENTISTS WHITENING

sodium fluoride paste

#### **Product Information**

**Product Type** HUMAN OTC DRUG Item Code (Source) NDC:75065-015

**Route of Administration** DENTAL

#### **Active Ingredient/Active Moiety**

**Basis of Strength** Strength **Ingredient Name** 

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) SODIUM FLUORIDE 0.24 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM TRIPOLYPHOSPHATE (UNII: 5HK03SA80J)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				

F	Packaging							
#	tem Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:75065-015- 06	1 in 1 CARTON	07/15/2022					
1		120 g in 1 TUBE; Type 0: Not a Combination Product						

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part355	07/15/2022			

# **Labeler -** Oral Spotlight Care Inc (117405870)

# **Registrant -** Oral Spotlight Care Inc (117405870)

Revised: 7/2022 Oral Spotlight Care Inc