## MADE BY DENTISTS TOTAL CARE- 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> Total Care 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:**

Cellulose Gum, Cocamidopropyl Betaine, Flavor, Hydrated Silica, Sodium Bicarbonate, Sodium Tripolyphosphate, Sorbitol, Titanium Dioxide, Sodium Saccharin, Water

## Questions or comments?

+1 (646) 980-6461

Product Labeling
Made By Dentists™
Total Care
Toothpaste

Fresh Mint Flavor

Fluoride Anticavity Toothpaste
NET WT 4.2 Oz / 120 g
MADE IN THE USA
90 South Dale, Suite 8, Saint Paul,
Minnesota, USA 55102

## **Carton**





## <u>Tube</u>

# Made By Dentists<sup>™</sup>







Friendly

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

Purpose

Use: Aids in the prevention of dental decay.

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 con-tact a Poison Control Center right away.

- 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 mini-mize swallowing), and only use a pea size amount. • Supervise children as necessary until capable of using without supervision.
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**Total Care Toothpaste** Fluoride Anticavity

NET WT 4.2 Oz / 120 g

Fresh Mint Flavor

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## MADE BY DENTISTS TOTAL CARE

sodium fluoride paste

**Product Information** 

**Product Type** 

HUMAN OTC DRUG

**Item Code (Source)** 

NDC:75065-016

**DENTAL** 

## **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

**SODIUM FLUORIDE** (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | SODIUM FLUORIDE | 0.24 g in 100 g

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

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging				
# Item Co	de Package Description	Marketing Start Date	Marketing End Date	
NDC:75065-	1 in 1 CARTON	07/15/2022		
1	120 g in 1 TUBE; Type 0: Not a Combination Product	n		

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