# BIO SPECTRA ATTITUDE- sodium fluoride gel, dentifrice Attitude DBA 9055-7588 Québec 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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BIO SPECTRA ATTITUDE DRUG FACTS

## **Active ingredient**

Sodium fluoride (0.243% w/w)

## **Purpose**

Anti-cavity

#### Uses

- Prevents, fights and protects against cavities and tooth decay.
- Effective fluoride protection.
- Protects teeth from acid erosion.
- Penetrates tooth enamel to help rebuild weak spots.

## **Warnings**

# Keep out of reach of children.

If swallowed, call a poison control centre or get medical help right away.

#### **Directions**

Do not swallow. Should be used as part of an oral health program that includes regular flossing and dental check-ups. Brush teeth thoroughly for at least 1 minute twice a day, preferably after each meal, or as directed by a dentist. Children under 6 years of age should use only a pea-sized amount and be supervised to brush properly and to not swallow. Consult a dentist or health care professional before using with children under 2 years of age. Store at room temperature (15-30 °C).

# **Inactive ingredients**

sorbitol, aqua, glycerin, hydrated silica, sodium lauryl sulfate, xanthan gum, citric acid, stevia rebaudiana leaf / stem extract, sodium benzoate, carica papaya leaf extract, camellia sinensis (green tea) leaf extract, potassium sorbate, caprylic/capric triglyceride\*, ethyl butyrate\*, ethyl 2-methylbutyrate\*, ethyl acetate\*, dimethyl heptenal\*, \*flavour

(arôme) <sup>1</sup>.

1 Contains limonene

# **QUESTIONS?**

+1 (514) 509-7225

## PRINCIPAL DISPLAY PANEL - 120 g Tube Label

ATTITUDE™ natural care

for kids • with fluoride

toothpaste WATERMELON Prevents cavities

**ECO-CONSCIOUS** 

**VEGAN** 

NPN 80104880

GEL • 120 g  $\oplus$  4.2 OZ.





### **BIO SPECTRA ATTITUDE**

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sodium fluoride gel, dentifrice

#83 GREEN LANES, LONDON, N13 4BS, UK

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61649-724
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII: Q80VPU408O)	SODIUM FLUORIDE	0.243 g in 100 g	

Inactive Ingredients				
Ingredient Name	Strength			
SORBITOL (UNII: 506T60A25R)				
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
HYDRATED SILICA (UNII: Y6O7T4G8P9)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
XANTHAN GUM (UNII: TTV12P4NEE)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
CARICA PAPAYA LEAF (UNII: 66J7636Z2I)				
GREEN TEA LEAF (UNII: W2ZU1RY8B0)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
ETHYL BUTYRATE (UNII: UFD2LZ005D)				
ETHYL 2-METHYLBUTYRATE (UNII: L1T4AB29DS)				
ETHYL ACETATE (UNII: 7684508NMZ)				
2,6-DIMETHYL-5-HEPTENAL (UNII: Z331YX9EL9)				

Product Characteristics			
Color	white (Opaque)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:61649-724- 01	120 g in 1 TUBE; Type 0: Not a Combination Product	05/15/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/15/2021	

Establishment				
Name	Address	ID/FEI	Business Operations	
Attitude DBA 9055-7588 Québec Inc.		204307099	manufacture(61649-724) , label(61649-724) , pack(61649-724) , analysis(61649-724)	

Revised: 7/2023 Attitude DBA 9055-7588 Québec Inc.