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.

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).

Non-medicinal ingredients

Sorbitol, aqua, glycerin, hydrated silica, sodium lauryl sulfate, gaultheria procumbens (wintergreen) leaf oil ¹, xanthan gum, citric acid, sodium bicarbonate, stevia rebaudiana leaf / stem extract, sodium benzoate, carica papaya leaf extract, camellia sinensis (green tea) leaf extract, titanium dioxide, potassium sorbate.

1 Naturally contains : D-limonene.

QUESTIONS?

+1 (514) 509-7225

PRINCIPAL DISPLAY PANEL - 120 g Tube Label

ATTITUDE ® bio spectra

natural care

anticavity • with fluoride

toothpaste ENAMEL CARE Spearmint

• EWG VERIFIED • FOR YOUR HEALTH • EWG.ORG™

NPN 80104880

GEL • 120 g e 4.2 OZ.

DRUG FACTS / RENSEIGNEMENTS

Active ingredient Purpose
Sodium fluoride (0.243% w/w) Anti-cavity
Ingrédients médicinaux Utilisation
Fluorure de sodium (0,243 % p/p) Anticaries

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. / Utilisation: ■ Prévient, combat et protège contre la carie. ■ Protection efficace au fluorure. ■ Protège les dents contre l'érosion causée par l'acidité. ■ Pénètre l'émail de la dent et aide à la régénération des points faibles.

Warnings / Attention :

Keep out of reach of children. / Garder hors de la portée des enfants,

If swallowed, call a poison control centre or get medical help right away. / En cas d'ingestion, appeler immédiatement un centre antipoison ou obtenir une assistance médicale.

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). Mode d'emploi: Ne pas avaler. Devrait être utilisé dans le cadre d'un programme d'hygiène bucco-dentaire comprenant l'utilisation régulière de la soie dentaire et des examens dentaires. Se brosser soigneusement les dents durant au moins une minute 2 fois par jour, de préférence après chaque repas, ou selon les directives d'un dentiste. Les enfants âgés de moins de 6 ans devraient utiliser une quantité de dentifrice équivalente à un pois. Un adulte devrait s'assurer de l'efficacité du brossage et vérifier que l'enfant n'avale pas le produit. Consulter un dentiste ou un professionnel de la santé avant l'emploi chez les enfants âgés de moins de 2 ans. À conserver à température ambiante (15-30 °C).

Non-medicinal ingredients / Ingrédients non médicinaux :

Sorbitol, aqua, glycerin, hydrated silica, sodium lauryl sulfate, gaultheria procumbens (wintergreen) /eaf oil*, xanthan gum, citric acid, sodium bicarbonate, stevia rebaudiana leaf / stem extract, sodium benzoate, carica papaya leaf extract, camellia sinensis (green tea) leaf extract, titanium dioxide, potassium sorbate. *Naturally contains / contient naturellement : D-limonene.

QUESTIONS? +1 (514) 509-7225
MADE IN CANADA / FAIT AU CANADA
ATTITUDEliving.com / labonneATTITUDE.com





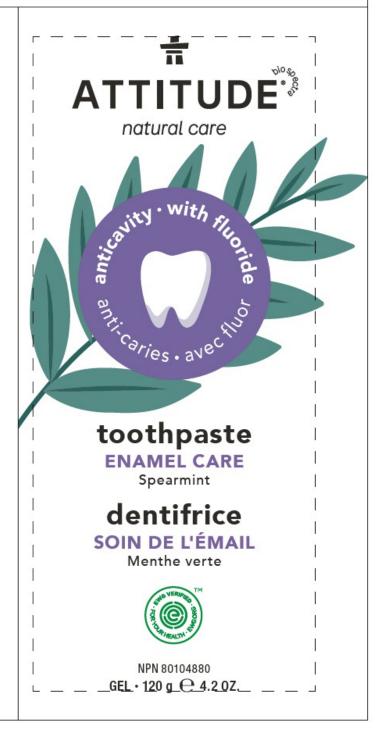






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BIO SPECTRA ATTITUDE

sodium fluoride gel, dentifrice

Product In	formation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:61649-734

Route of Administration DENTAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII: Q80VPU4080)	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)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARICA PAPAYA LEAF (UNII: 66J7636Z2I)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

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

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:61649-734- 01	120 g in 1 TUBE; Type 0: Not a Combination Product	05/15/2021	

Start Marketing End Date
J :

Labeler - Attitude DBA 9055-7588 Québec Inc. (201137051)

Establishment

Name	Address	ID/FEI	Business Operations
Attitude DBA 9055-7588 Québec Inc.		204307099	manufacture(61649-734), label(61649-734), pack(61649-734), analysis(61649-734)

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