

**CRAYOLA ANTICAVITY WATERMELON FLAVOR- sodium fluoride paste,
dentifrice
Ashtel Studios, 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.

Crayola ANTICAVITY FLUORIDE TOOTHPASTE - WATERMELON FLAVOR

Drug Facts

Active ingredient

Sodium fluoride 0.243%
(Fluoride ion content 1100 ppm)

Purpose

Anticavity

Uses

helps protect teeth and roots against cavities.

Warnings

Keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately.

Directions

- **Adults and children 2 years and older:** brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist.
- **Do not swallow.**
- **Children 2 to 6 years:** to minimize swallowing use a pea-sized amount and supervise children's brushing and rinsing until good habits are established.
- **Children under 2 years of age:** Consult a dentist or doctor.

Inactive ingredients

Sorbitol, Silica, Aqua, PEG -32, Xylitol, Sodium Lauryl Sulphate, Flavor, Cellulose Gum, Benzyl Alcohol, Sodium Benzoate, Sodium Saccharin, Trisodium Phosphate, FD & C Yellow # 5, FD & C Blue # 1

Questions or comments?

Call toll free **1-877-274-8358**

BrushBuddies®

Silly scents

HELPS PREVENT CAVITIES

WATERMELON FLAVOR

CAUTION:

AVOID EXCESSIVE INGESTION.
NOT FOR PETS.

NOT TESTED ON ANIMALS.

OFFICIAL LICENSED PRODUCT

DESIGNED IN U.S.A. • MADE IN INDIA

QUALITY GUARANTEE

Ashtel Studios Inc. guarantees the quality of this Crayola product. If this product does not perform properly, please contact us at 1-877-274-8358, Monday-Friday 8AM-5PM. PST

ABOUT US

Crayola A Hallmark Company

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make brushing fun!®

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• **1-909-434-0911 INTERNATIONAL**

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Packaging

INNER TUBE LABEL





OUTER BOX LABEL





CRAYOLA ANTICAVITY WATERMELON FLAVOR

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70108-081
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)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS (UNII: SX01TZO3QZ)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor	WATERMELON	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70108-081-01	1 in 1 BOX	09/06/2023	
1		113 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	M021	09/06/2023	

Labeler - Ashtel Studios, Inc. (148689180)

Revised: 9/2023

Ashtel Studios, Inc.