

UPC 801803 00203 MEGAFRESH FLUORIDE TOOTH- sodium monofluorophosphate paste, dentifrice

American Amenities, 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.

Active Ingredient: Sodium Monofluorophosphate (0.76%)

Purpose: Anticavity

Uses: Aids in the prevention of dental cavities

If more than used for brushing is accidentally swallowed, get medical help or contact a poison control center immediately.

Keep out of reach of children under six years of age

Adults and children of two 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 a doctor. Instruct children under six years of age in good brushing and rinsing habit (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: consult a dentist or doctor.

Calcium Carbonate, Purified Water, Sorbitol, Polyethylene Glycol, Sodium Lauryl Sulfate, Hydrated Silica, Carboxymethylcellulose Sodium, Flavor, Guar Gum, Saccharin Sodium, Methylisothiazolinone

Mega Fresh™ fluoride toothpaste

Net Wt. 0.85 oz (24 g)

Product NO TP-0858

UPC: 801803 00203

Drug Facts		Drug Facts (continued)	
Active Ingredient Sodium Monofluorophosphate (0.75%)	Purpose Anticavity	Directions Adults and children 2 years of age and older: Brush thoroughly, pain reliever each meal or at least twice a day, or as directed by a dentist or doctor. Rinse with water after brushing. For good brushing and rinsing, use a fluoride mouthwash. Supplies of fluoride are necessary for children of 2 years of age and older. Children under 2 years of age: Consult a dentist or doctor.	
Uses Aids in the prevention of dental cavities.		Inactive Ingredients Casein Calcium, Fluorochloride, Glycerin, Polyethylene Glycol, Sodium Lauryl Sulfate, Hydroxyethyl Cellulose, Calcium Hydroxide, Sodium Fluoride, Glycerin, Saccharin Sodium, Methylparaben.	
Warning Keep out of reach of children under 6 years of age. If swallowed, stop brushing & seek medical attention. Get medical help or contact a Poison Control Center right away.			
Manufactured by American Dental, Inc. Kirkland, WA 98033 Made in China.			

UPC 801803 00203 MEGAFRESH FLUORIDE TOOTH

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54157-108
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
GUAR GUM (UNII: E891I637KE)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54157-108-01	17 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
2	NDC:54157-108-02	24 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
3	NDC:54157-108-03	43 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
4	NDC:54157-108-04	78 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
5	NDC:54157-108-05	85 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
6	NDC:54157-108-06	130 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
7	NDC:54157-108-07	181 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
8	NDC:54157-108-08	200 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
9	NDC:54157-108-09	4.25 g in 1 POUCH; Type 0: Not a Combination Product	06/03/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/03/2017	

Labeler - American Amenities, Inc. (181454026)

