

**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.*

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Active Ingredient: Sodium Monofluorophosphate (0.76%)

Purpose: Anticavity

Uses: Aids in the prevention of dental cavities

For external use only. Keep out of reach of children

Keep out of reach of children under six years of age

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

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, Carboxymethylcellulose Sodium, Flavour, Glycerin, Purified Water, Sodium Benzoate, Sodium Lauryl Sulfate, Hydrated Silica, Saccharin Sodium, Sorbitol, Sodium Pyrophosphate

**Mega Fresh™**  
**fluoride toothpaste**

Net Wt. 7 oz (200 g)

Reorder NO. TP-700P

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active Ingredient</b> Sodium Monofluorophosphate (0.76%) (0.1% w/v fluoride ion)	<b>Purpose</b> Anticavity	<b>Directions</b> 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). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.	
<b>Uses</b> Aids in the prevention of dental cavities.		<b>Inactive Ingredients</b> Calcium Carbonate, Carboxymethylcellulose Sodium, Flavour, Glycerin, Hydrated Silica, Purified Water, Sodium Benzoate, Sodium Lauryl Sulfate, Saccharin Sodium, Sorbitol, Sodium Pyrophosphate.	
<b>Warning</b> 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.			
Manufactured for American Amenities, Inc. Woodhull, WA 98072 Made in China.			

**MEGAFRESH FLUORIDE TOOTH**  
sodium monofluorophosphate paste, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54157-103
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:54157-103-01	17 g in 1 TUBE		
2	NDC:54157-103-02	24 g in 1 TUBE		
3	NDC:54157-103-03	35 g in 1 TUBE		
4	NDC:54157-103-04	43 g in 1 TUBE		
5	NDC:54157-103-05	50 g in 1 TUBE		
6	NDC:54157-103-06	70 g in 1 TUBE		
7	NDC:54157-103-07	78 g in 1 TUBE		
8	NDC:54157-103-08	90 g in 1 TUBE		
9	NDC:54157-103-09	100 g in 1 TUBE		
10	NDC:54157-103-10	120 g in 1 TUBE		
11	NDC:54157-103-11	130 g in 1 TUBE		
12	NDC:54157-103-12	150 g in 1 TUBE		
13	NDC:54157-103-13	181 g in 1 TUBE		
14	NDC:54157-103-14	200 g in 1 TUBE		
15	NDC:54157-103-15	3 g in 1 POUCH		
16	NDC:54157-103-16	5 g in 1 POUCH		
17	NDC:54157-103-17	10 g in 1 POUCH		
18	NDC:54157-103-18	4.25 g in 1 POUCH		
19	NDC:54157-103-19	71 g in 1 TUBE		
20	NDC:54157-103-20	85 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/04/2013	

**Labeler** - American Amenities, Inc. (181454026)

**Registrant** - American Amenities, Inc. (181454026)

Revised: 1/2015

American Amenities, Inc.