DAWNMIST - toothbrush, toothpaste and floss kit paste Donovan Industries, 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.

DawnMist Toothbrush, Toothpaste and Floss Kit

DRUG FACTS

Active Ingredient: Purpose: SMFP 0.76% Anticavity

Use: Aids in the prevention of dental cavities

Warning: Keep out of reach of children under 6 years of age.

If you accidentally swallow more than used for brushing seek

professional assistance or contact a Poison Control Center Immediately.

Directions: Adults and children 2 yrs. and older. Brush teeth thoroughly after

meals or at least twice a day or use as directed by a dentist or physician.

Children under 6 yrs.: To minimize swallowing use a pea sized amount and

supervise brushing until good habits are established.

Children Under 2 years: Ask a dentist or physician.

Sorbitol, Silica, Water, Sodium Lauryl Sulfate,

Xanthan Gum, Sodium Benzoate, Titanium Dioxide,

Peppermint Oil, Sodium Saccharin

Expiration Date: Expiration Date and Batch No. on Primary Package

Manufactured for:

Donovan Industries, Inc.

Tampa, FL 33626-3061

www.dawnmist.com

1-800-334-4404

MADE IN MALAYSIA

DawnMist

Cavity Fighting

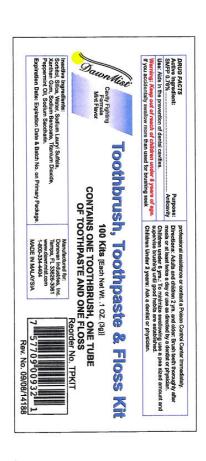
Formula

Mint Flavor

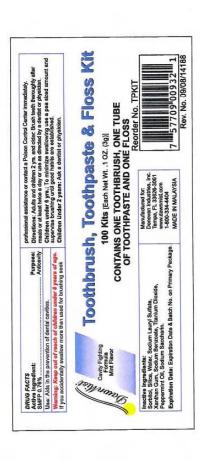
Toothbrush, Toothpaste and Floss Kit

100 Kits Each Net Wt .1 OZ 3g

CONTAINS ONE TOOTHBRUSH, ONE TUBE OF TOOTHPASTE AND ONE FLOSS







Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55504-0540
Route of Administration	DENTAL		

l	Active Ingredient/Active Moiety		
l	Ingredient Name	Basis of Strength	Strength
	SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80 VPU408O)	SODIUM MONOFLUOROPHOSPHATE	0.76 g in 3 g

Inactive Ingredients				
Ingredient Name	Strength			
SORBITOL (UNII: 506T60A25R)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
WATER (UNII: 059QF0KO0R)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
XANTHAN GUM (UNII: TTV12P4NEE)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
SACCHARIN (UNII: FST467XS7D)				

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55504-0540-1	2.83 g in 1 KIT		
2	NDC:55504-0540-2	2.83 g in 1 KIT		
3	NDC:55504-0540-3	3 g in 1 TUBE		
3	NDC:55504-0540-3	3 g in I TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	09/01/2009		

Labeler - Donovan Industries, Inc. (096662267)

Registrant - Fulijaya Manufacturing SDN. BHD. (652087115)

Establishment			
Name	Address	ID/FEI	Business Operations
Fulijaya Manufacturing SDN. BHD.		652087115	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations

Donovan Industries, Inc.	096662267	import

Revised: 8/2009 Donovan Industries, Inc.