

SPARKLEFRESH FLOURIDE TOOTHPASTE- sodium monofluorophosphate paste, dentifrice

Medline Industries, LP

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.

083 SparkleFresh Fluoride Toothpaste

Active ingredient

Sodium Monofluorophosphate 0.76%

Purpose

Anticavity toothpaste

Use

aids in the prevention of dental cavities

Warnings

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

If you accidentally swallow more than used for brushing, seek medical help or contact a Poison Center immediately.

Directions

- adults and children 2 yrs. and older: brush teeth thoroughly after meals or at least twice a day or as directed by a dentist or physician
- 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 physician

Inactive ingredients

calcium carbonate, treated water, sorbitol, precipitated silica, sodium lauryl sulfate, flavor, sodium carboxymethyl cellulose, sodium silicate, tetrasodium pyrophosphate, sodium saccharin, methylparaben, titanium dioxide, polyethylene glycol 400, propylparaben

Manufacturing Information

Manufactured for:

Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093 USA

Made in India

www.medline.com

1-800-MEDLINE (633-5463)

REF: NONTP15I

RH22NWI

Package Label



Drug Facts

Active Ingredient	Purpose
Sodium Monofluorophosphate 0.76%.....	Anticavity toothpaste

Use Aids in the prevention of dental cavities

Warnings

Keep out of the reach of children under 6 yrs. of age. If you accidentally swallow more than used for brushing, seek medical help 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 as directed by a dentist or physician. • instruct children under 6 yrs. of age in good brushing and rinsing habits (to minimize swallowing) • supervise children as necessary until capable of using without supervision • children under 2 yrs. of age: Consult a dentist or physician

Inactive Ingredients: calcium carbonate, treated water, sorbitol, precipitated silica, sodium lauryl sulfate, flavor, sodium carboxymethyl cellulose, sodium silicate, tetrasodium pyrophosphate, sodium saccharin, methylparaben, titanium dioxide, polyethylene glycol 400, propylparaben

1222101995 C.No. DNH/COS/DNH/52

Exp. ▼

Exp. ▼

www.medline.com ©2019 Medline Industries, LP

Made in India for: Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093 USA 1-800-MEDLINE RH22NWI

SPARKLEFRESH FLOURIDE TOOTHPASTE

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-083
---------------------	----------------	---------------------------	---------------

Route of Administration	DENTAL
--------------------------------	--------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM SILICATE (UNII: IJF18F77L3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SORBITOL (UNII: 506T60A25R)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-083-21	42.5 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2019	
2	NDC:53329-083-92	17 g in 1 PACKET; Type 0: Not a Combination Product	08/01/2019	
3	NDC:53329-083-93	24 g in 1 PACKET; Type 0: Not a Combination Product	08/01/2019	
4	NDC:53329-083-94	78 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part355	01/01/2007	
---------------------	---------	------------	--

Labeler - Medline Industries, LP (025460908)

Registrant - Medline Industries, LP (025460908)

Revised: 6/2023

Medline Industries, LP