

**SPARKLEFRESH FLOURIDE TOOTHPASTE- sodium monofluorophosphate paste, dentifrice**

**Medline Industries, LP**

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**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



**SparkleFresh™**  
Fluoride Toothpaste

REF NONTP275I Net Wt 2.75 oz (78 g)

**Drug Facts**

|   |   |
|---|---|
| <b>Active Ingredient</b><br>Sodium Monofluorophosphate 0.76%..... | <b>Purpose</b><br>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

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

| <b>SPARKLEFRESH FLOURIDE TOOTHPASTE</b>      |                |                           |               |
|--|----------------|---------------------------|---------------|
| sodium monofluorophosphate paste, dentifrice |                |                           |               |
| <b>Product Information</b>                   |                |                           |               |
| <b>Product Type</b>                          | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:53329-083 |
| <b>Route of Administration</b>               | DENTAL         |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength       |
|---|-------------------|----------------|
| <b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION      | 1 mg<br>in 1 g |

## Inactive Ingredients

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

## Product Characteristics

|                 |       |                     |  |
|-----------------|-------|---------------------|--|
| <b>Color</b>    | white | <b>Score</b>        |  |
| <b>Shape</b>    |       | <b>Size</b>         |  |
| <b>Flavor</b>   | MINT  | <b>Imprint Code</b> |  |
| <b>Contains</b> |       |                     |  |

## 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 Drug | M021                                     | 01/01/2007           |                    |

**Labeler** - Medline Industries, LP (025460908)

**Registrant** - Medline Industries, LP (025460908)

Revised: 11/2024

Medline Industries, LP