

**LUCKY SUPER SOFT ANTI CAVITY WITH FREE TOOTHBRUSH- sodium monofluorophosphate paste, dentifrice
Delta Brands 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.

Lucky Toothpaste/Toothbrush Sodium Monofluorophosphate

Active Ingredient

Sodium monofluorophosphate 0.76% (Total fluoride content-1000 ppm approx.)

Purpose

Anticavity

Uses

Regular brushing with fluoride toothpaste helps protect against cavities

**Keep out of the reach of children
under 6 years of age**

Warnings

In case of accidental overdose, 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 brushing until good habits are established. children under 2 years: ask a dentist or physician

Inactive ingredients

calcium carbonate, flavor, methyl paraben, polyethylene glycol 400, precipitated silica, propyl paraben, sodium carboxymethyl cellulose, sodium lauryl sulphate, sodium saccharin, sodium silicate, sorbitol, tetra sodium pyrophosphate, titanium dioxide, water

Package Label



LUCKY SUPER SOFT ANTI CAVITY WITH FREE TOOTHBRUSH

sodium monofluorophosphate paste, dentifrice

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:20276-551 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--------------------------------------------------------------------------------|-------------------|---------------|
| SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 7.6 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------------------------|----------|
| CALCIUM CARBONATE (UNII: H0G9379FGK) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |

SODIUM SILICATE (UNII: IJF18F77L3)

SORBITOL (UNII: 506T60A25R)

SODIUM PYROPHOSPHATE (UNII: O352864B8Z)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

WATER (UNII: 059QF0K00R)

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:20276-551-64 | 181 g in 1 TUBE; Type 1: Convenience Kit of Co-Package | 02/27/2014 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph final | part355 | 02/27/2014 | |

Labeler - Delta Brands Inc (102672008)

Revised: 12/2020

Delta Brands Inc