MINT FLUORIDE TOOTH- sodium monofluorophosphate paste, dentifrice Yangzhou SION Commodity Co.,Ltd

70766-011 Mint Fluorine Toothpaste

Active ingredients

SODIUM FLUORIDE 0.243%(0.11 w/v Fluoride ion)

Purpose

Anti-cavity toothpaste

Uses

aids in the prevention of cavities.

Warnings

Keep out of the reach of children under 6 years of age. If accidently swallow more than used for brushing, get medical help or contact a Poison Control Center immediately.

Do not use if the inner foil is torn, cut, or missing

Keep out of reach of children.

Directions

Brush teeth thoroughly, preferrably after each meal or at least twice a day, or as directed by a dentist or a physician

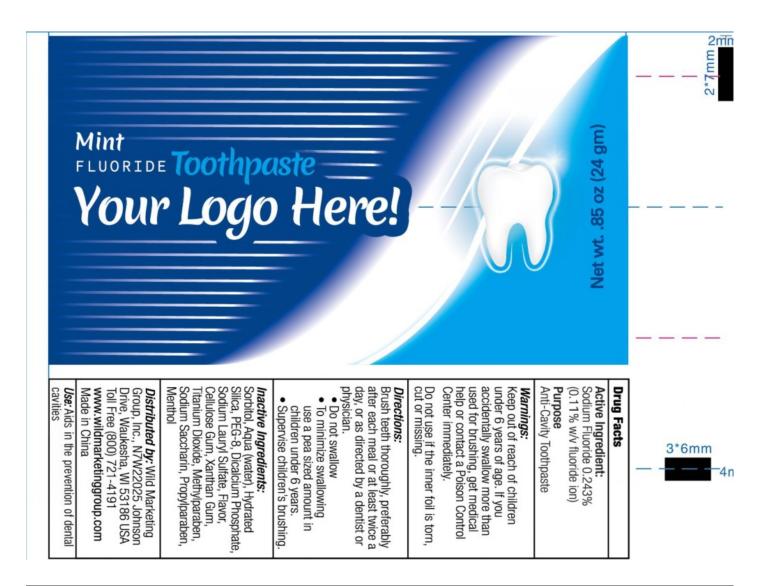
Do not swallow

To minimize wallowing, use a pea sizes amount in children under 6 years

Supervise children's brushing

INACTIVE INGREDIENT

Sorbitol, Hydrated silica, Water, PEG-8, Sodium lauryl sulfate, Cellulose gum, Xanthan gum, flavor, Menthol, Dicalcium Phosphate, Methylparaben, Propylparaben, Titanium Dioxide, sodium sacharine



MINT FLUORIDE TOOTH

sodium monofluorophosphate paste, dentifrice

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70766-011 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety Ingredient Name Basis of Strength SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE ION 0.11 g in 100 g

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| WATER (UNII: 059QF0KO0R) | | |
| SORBITOL (UNII: 506T60A25R) | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | | |

| MENTHOL (UNII: L7T10EIP3A) | | |
|--|--|--|
| CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J) | | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | | |
| PROPYLPARABEN (UNII: Z8IX2SC10H) | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | | |

| P | Packaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:70766-011- 07 | 4 in 1 BOX | 12/10/2022 | |
| 1 | | 12 in 1 POUCH | | |
| 1 | | 24 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:70766-011- 02 | 12 in 1 BOX | 12/10/2022 | |
| 2 | | 12 in 1 POUCH | | |
| 2 | | 24 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 3 | NDC:70766-011- 03 | 24 in 1 BOX | 12/10/2022 | |
| 3 | | 12 in 1 POUCH | | |
| 3 | | 24 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 4 | NDC:70766-011- 04 | 144 in 1 BOX | 12/10/2022 | |
| 4 | | 24 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 5 | NDC:70766-011- 05 | 288 in 1 BOX | 12/10/2022 | |
| 5 | | 24 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 6 | NDC:70766-011- 06 | 576 in 1 BOX | 12/10/2022 | |
| 6 | | 24 g in 1 TUBE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M021 | 11/13/2022 | |
| | | | |

Labeler - Yangzhou SION Commodity Co.,Ltd (546806042)

Registrant - Yangzhou SION Commodity Co.,Ltd (546806042)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------|---------|-----------|----------------------------|
| Yangzhou SION Commodity Co.,Ltd | | 546806042 | manufacture(70766-011) |

Revised: 12/2023 Yangzhou SION Commodity Co.,Ltd