

**FLUORIDE SOFT MINT- sodium monofluorophosphate paste, dentifrice
Swiss Shine Beauty AG**

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.

Fluoride Toothpaste Soft Mint

Active Ingredients

Sodium monofluorophosphate 0.88% (0.115% W/V fluoride Ion)

Purpose Anticavity

Use

- Aids in the prevention of dental cavities.

Keep out of reach of children under 6 years age.

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Use

Aids in the prevention of dental cavities.

Warnings

Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.
- 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 doctor.

Inactive Ingredients

water, hydrated silica, hydrogenated starch hydrolysate, glycerin, hydroxyapatite, xylitol, sodium coco-sulfate, calcium carbonate, flavor, xanthan gum, citric acid, potassium sorbate, sodium benzoate, leontopodium alpinum flower/leaf extract, rhododendron ferrugineum extract, oligopeptide-104, lactic acid

Other Information

You may report serious side effects to : Swiss Shine Beauty, Inc.

651 N. Broad St., Middletown, DE 19709

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SWITZERLAND

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79763-003
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.88 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM COCO-SULFATE (UNII: 3599J29ANH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
LACTIC ACID (UNII: 33X04XA5AT)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0KO0R)	
HYDROGENATED STARCH HYDROLYSATE (UNII: 27F77DSJ5V)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
LEONTOPODIUM ALPINUM FLOWERING TOP (UNII: QQC1AK06RK)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
RHODODENDRON FERRUGINEUM WHOLE (UNII: FO6B1S7BZU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79763-003-01	65 g in 1 TUBE; Type 0: Not a Combination Product	07/22/2020	
2	NDC:79763-003-02	6.5 g in 1 TUBE; Type 0: Not a Combination Product	07/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/22/2020	

Labeler - Swiss Shine Beauty AG (480422958)

Establishment

Business

Name	Address	ID/FEI	Business Operations
System Kosmetik Produktionsgesellschaft für kosmetische Erzeugnisse mbH		328825757	manufacture(79763-003)

Establishment

Name	Address	ID/FEI	Business Operations
Marvinpac SA		482060329	pack(79763-003)

Revised: 8/2021

Swiss Shine Beauty AG