

FLUORIDE STRONG MINT- sodium monofluorophosphate paste
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 Strong Mint

Active Ingredients Purpose

sodium monofluorophosphate 0.88% Anticavity
(0.115% W/V fluoride)

Use

- Aids in the prevention of dental cavities

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.

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Directions

- Adults and children 2 years of age and older: Brush teeth thoroughly, preferable 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, sorbitol, glycerin, hydroxyapatite, xylitol, sodium coco-sulfate, xanthan gum, calcium carbonate, citric acid, flavor, zinc lactate, menthol, potassium sorbate, sodium benzoate, leontopodium alpinum flower/leaf extract, rhododendron ferrugineum extract, oligopeptide-104

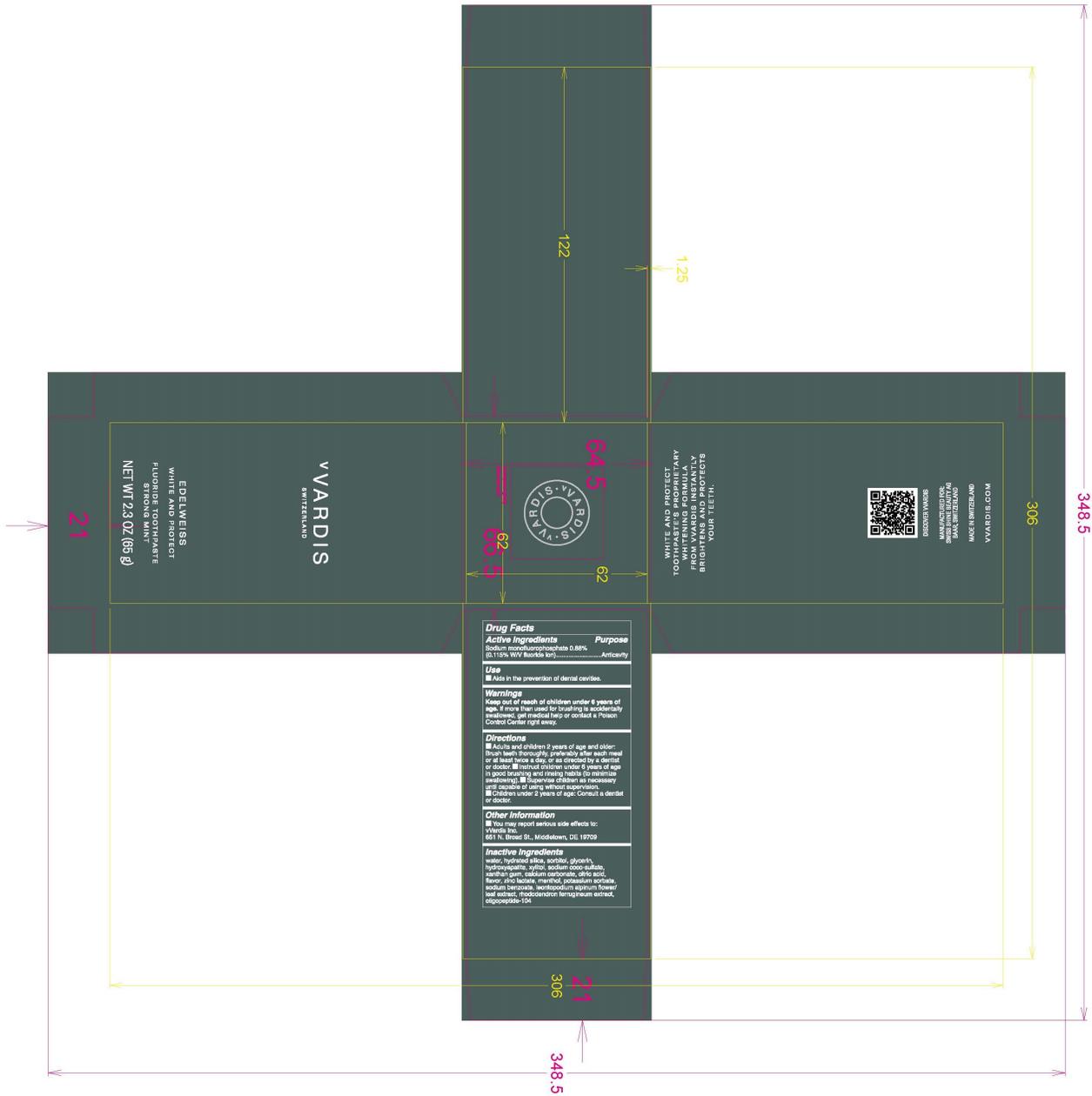
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Fluoride Toothpaste Strong Mint

NET WT 2.3 OZ (65 g)



FLUORIDE STRONG MINT

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79763-007
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Ingredient Name	Strength
ZINC LACTATE (UNII: 2GXR25858Y)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM COCO-SULFATE (UNII: 3599J29ANH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
XYLITOL (UNII: VCQ006KQ1E)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
LEONTOPODIUM NIVALE SUBSP. ALPINUM FLOWERING TOP (UNII: QQC1AK06RK)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
RHODODENDRON FERRUGINEUM WHOLE (UNII: FO6B1S7BZU)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79763-007-01	65 g in 1 TUBE; Type 0: Not a Combination Product	10/14/2020	
2	NDC:79763-007-02	6.5 g in 1 TUBE; Type 0: Not a Combination Product	01/17/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	10/14/2020	

Labeler - Swiss Shine Beauty AG (480422958)

Establishment

Name	Address	ID/FEI	Business Operations
System Kosmetik Produktionsgesellschaft für kosmetische Erzeugnisse mbH		328825757	manufacture(79763-007)

Establishment

Name	Address	ID/FEI	Business Operations
Marvinpac SA		482060329	pack(79763-007)

Revised: 1/2022

Swiss Shine Beauty AG