

**SALIVEA- fluoride toothpaste paste, dentifrice  
Laclede, 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.*

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**Salevia**

**ACTIVE INGREDIENT**

Sodium Monofluorophosphate (0.14% w/v fluoride ion)

**PURPOSE**

Anticavity

**USES**

Aids in the prevention of dental cavities.

**WARNINGS**

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

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

**KEEP OUT OF REACH OF CHILDREN**

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

**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.
- To minimize swallowing for children under 6, use a pea-size amount and supervise brushing until good habits are established. Children under 2 years ask a dentist or physician.

**OTHER INFORMATION**

Store at Room Temperature.

**INACTIVE INGREDIENTS**

Sorbitol, Glycerin, Calcium Pyrophosphate, Water, Hydrated Silica, Xylitol, Silica,



# SALIVEA

fluoride toothpaste paste, dentifrice

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54897-701
<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	1.4 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CALCIUM PYROPHOSPHATE</b> (UNII: X69NU20D19)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%)</b> (UNII: 8136Y38GY5)	
<b>ISOCETETH-20</b> (UNII: O020065R7Z)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>MINT</b> (UNII: FV98Z8GITP)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>LACTOPEROXIDASE BOVINE</b> (UNII: 01UIN5OC49)	
<b>POTASSIUM THIOCYANATE</b> (UNII: TM7213864A)	
<b>GLUCOSE OXIDASE</b> (UNII: 0T8392U5N1)	
<b>LYSOZYME</b> (UNII: 968JKA7T33)	
<b>LACTOFERRIN, BOVINE</b> (UNII: KG21X1090A)	
<b>DEXTRANASE PENICILLIUM</b> (UNII: N2161X105O)	
<b>CALCIUM LACTATE</b> (UNII: 2URQ2N32W3)	

## 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
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<b>1</b>	NDC:54897-701-13	121.9 g in 1 TUBE; Type 0: Not a Combination Product	02/19/2018	
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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/19/2018	

**Labeler** - Laclede, Inc. (098835994)

**Registrant** - Laclede, Inc. (098835994)

## Establishment

Name	Address	ID/FEI	Business Operations
Laclede, Inc.		098835994	manufacture(54897-701)

Revised: 2/2023

Laclede, Inc.