

**TANNERS TASTY OOH LA LA ORANGE- sodium fluoride paste, dentifrice
Sheffield Pharmaceuticals LLC**

Tanners Tasty Paste Ooh La La Orange

Drug Facts:

Active Ingredient:

Sodium fluoride - 0.243%

Anticavity toothpaste

Uses:

- Aids in the prevention of dental decay

Warnings:

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

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.
- Instruct children 6 years of age in good brushing and rinsing habits (to minimize swallowing), and and only use a pea size amount.
- Supervise children as necessary until capable of using without supervision.
- Children under 2 years of age: Consult a dentist or doctor.

Inactive ingredients:

Inactive Ingredients: Sorbitol, Purified Water, Hydrated Silica, Xylitol, Glycerin, Cocamidopropyl Betaine, Flavor, Cellulose Gum, Titanium Dioxide, Disodium Phosphate, Sucralose

Principal Panel 4.2 OZ Tube

Tanner Tasty Paste NDC 11527-045-42

0.243% Sodium Fluoride Toothpaste

Ooh La La Orange

NET WT. 4.2 oz (119g)



As a pediatric dentist, Dr. Janelle Holden knows how important it is for children to brush their teeth regularly. As a mom, she also knows how difficult it can be to get children to brush. So she worked in collaboration with formulation experts to create this safe, effective and delicious flavored toothpaste.

Your child is going to love to brush!

Drug Facts

Active ingredient	Purpose
Sodium fluoride 0.243%	Anticavity

Use aids in the prevention of dental cavities

Warning

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

Sorbitol, Water (Purified), Hydrated Silica, Xylitol, Glycerin, Cocamidopropyl Betaine, Flavor, Disodium Phosphate, Titanium Dioxide, Cellulose Gum, Sucralose

Distributed by: **Sheffield Pharmaceuticals**
170 Broad Street, New London, CT 06320
Questions? 1.800.222.1087
www.tannerstastypaste.com

Made in the USA of U.S. & Imported Parts



TANNERS TASTY OOH LA LA ORANGE

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11527-045
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	2.43 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
XYLITOL (UNII: VCQ006KQ1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM PHOSPHATE DIBASIC DIHYDRATE (UNII: 94255I6E2T)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11527-045-42	119 g in 1 TUBE; Type 0: Not a Combination Product	03/25/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	03/25/2021	

Labeler - Sheffield Pharmaceuticals LLC (151177797)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(11527-045)