

**CLOSYS- sodium fluoride paste, dentifrice**  
**Rowpar Pharmaceuticals, Inc.**

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**CloSYS Fluoride Toothpaste**

**ACTIVE INGREDIENT:**

Sodium fluoride 0.24% (0.13% w/v fluoride ion)

**PURPOSE:**

Anticavity

**USE:**

Aids in the prevention of dental decay.

**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.

**children under 6 years of age:**

- instruct in good brushing and rinsing habits (to minimize swallowing).
- supervise children as necessary until capable of using without supervision.
- do not swallow

**children under 2 years of age:**

consult a dentist or doctor

**INACTIVE INGREDIENTS:**

water, hydrated silica, stabilized chlorine dioxide, sarkosyl (coconut derived), disodium hydrogen phosphate, cellulose gum, titanium dioxide, peppermint oil, sodium dihydrogen phosphate, sucralose, menthol crystals

Use of stabilized chlorine dioxide is protected under U.S. & foreign patents-see [CloSYS.com/patents](http://CloSYS.com/patents)

***Questions or comments?***

**Call 1-800-643-3337**

**Principal Display Panel**

Closys®  
Anticavity Fluoride Toothpaste

SULFATE-FREE

NEW LOOK!

A CLEANER MOUTH  
A HEALTHIER YOU®

CLOSYS®  
Anticavity Fluoride Toothpaste

SENSITIVE  
TOOTHPASTE  
WITH FLUORIDE

NON-IRRITATING  
SULFATE-FREE

HELPS REBUILD WEAKEND  
TOOTH ENAMEL

Protects Against  
Cavities

Freshens Breath

Non-Irritating  
Formula

Gentle Mint

7oz (196g)

NON-IRRITATING  
SULFATE-FREE

pH balanced

Fights  
Cavities

Strengthens  
Enamel

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Gentle Mint

3.4oz (96g)

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Gentle Mint 3.4oz (96g)



sodium fluoride paste, dentifrice

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58578-0749
<b>Route of Administration</b>	ORAL, DENTAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS</b> (UNII: KH7I04HPUU)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>CARBOXYMETHYLCELLULOSE</b> (UNII: 05JZI7B19X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>CHLORINE DIOXIDE</b> (UNII: 8061YMS4RM)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	

## 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

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:58578-0749-1	1 in 1 BOX	10/20/2017	
1		96 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:58578-0749-2	1 in 1 BOX	10/20/2017	
2		198 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:58578-0749-3	1 in 1 BOX	10/20/2017	06/01/2025
3		21 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	10/20/2017	

**Labeler** - Rowpar Pharmaceuticals, Inc. (783704661)

## Establishment

Name	Address	ID/FEI	Business Operations
Transom Symphony OPCO, LLC		117501991	manufacture(58578-0749)

Revised: 12/2024

Rowpar Pharmaceuticals, Inc.