

**TheraBreath Healthy Smile Oral Rinse- sodium fluoride rinse**  
**Dr. Harold Katz, LLC**

*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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***Active Ingredient***

Sodium fluoride 0.05% (0.02% w/v fluoride ion)

***Purpose***

Anticavity

***Uses***

Aids in the prevention of dental cavities

***Warnings***

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

***Warnings***

***Directions***

Adults and Children 6 years of age and older:

- Use once a day after brushing your teeth with a toothpaste.
- Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out.
- Do not swallow the rinse.
- Do not eat or drink for 30 minutes after rinsing.
- Instruct children under 12 years of age in good rinsing habits (to minimize swallowing).
- Supervise children as necessary until capable of using without supervision.
- Children under 6 years of age: consult a dentist or doctor.

***Other Information***

Do not use if safety seal is broken or missing.

***Inactive Ingredients***

Water, Glycerin, PEG-40 Hydrogenated Castor Oil, Citric Acid, Sodium Hydroxide, Sodium Chlorite, Menthol, Citrus Lemon Peel Oil, Mentha Piperita Oil, Sodium Benzoate, Sucralose, Xylitol, Sodium Bicarbonate.

**TheraBreath Healthy Smile Oral Rinse**

ANTICAVITY ORAL RINSE
Made just for you by THERABREATH



PROFESSIONAL FORMULA

**TheraBreath**

DENTIST FORMULATED

**HEALTHY SMILE**

**ORAL RINSE**

FIGHTS CAVITIES FOR **24 HOURS\***

STRENGTHENS TEETH + IMPROVES THEIR APPEARANCE

FRESHENS BREATH

Helps rebuild weakened tooth enamel and reverse early tooth decay

No Alcohol, No Artificial Flavors or Colors



**SPARKLE MINT**

**Here's Our Story:**

A healthy smile looks radiant. As a dentist who has treated thousands of patients, Dr. Katz has learned there is nothing better for your appearance than a well-maintained smile and great smelling breath. This new Healthy Smile Remedy breaks breath so it returns the goodness of fresh breath and natural luminance of healthy teeth.

**Our Guarantee To You:**

Your satisfaction with every TheraBreath product is guaranteed or your money back. If you are not completely satisfied, please contact us for refund instructions.

**Keep out of the reach of children. A spill or splash, use as directed. Use immediately after brushing and rinsing.**

\*For 24 Hr Cavity Protection, use daily after brushing and flossing.

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PHONE: 1-800-973-7174  
WEB: THERABREATH.COM



**Dr. Harold Katz**  
Dentist & Endodontist

**Drug Facts**

**Active Ingredients** Purpolene (Polychlorophenol) 0.15%, 1,12,12,12-tetrafluoroethane  
**Purpose** Anticavity

**Directions**  
Keep out of the reach of children. If used from child to teenager, thoroughly wash, spit, and brush teeth. If used by teenager to adult, brush teeth. Use as directed. For more information, see back of product.

**Warnings**  
Do not use if you are pregnant or breastfeeding.  
Do not use if you are allergic to any of the ingredients.  
Do not use if you have a known sensitivity to any of the ingredients.  
Do not use if you have a known sensitivity to any of the ingredients.

**Other Information**  
Do not use if you are pregnant or breastfeeding.  
Do not use if you are allergic to any of the ingredients.

16 fl. oz.  
473 mL






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ORAL RINSE

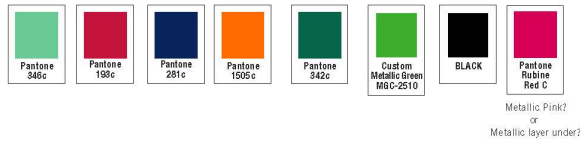
**Healthy Smile Travel Size**



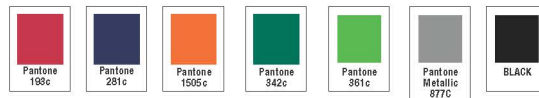
115.0 mm



HPerf  
24mm



Healthy Smile Travel Pouch 0.25 oz



## THERABREATH HEALTHY SMILE ORAL RINSE

sodium fluoride rinse

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72551-246
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0005 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
LEMON OIL (UNII: 19GRO824LL)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>PEG-40 CASTOR OIL</b> (UNII: 4ERD2076EF)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>SODIUM CHLORITE</b> (UNII: G538EBV4VF)	
<b>MENTHA PIPERITA</b> (UNII: 79M2M2UDA9)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	

### Product Characteristics

<b>Color</b>	white (Clear)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Clean Mint)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72551-246-01	473 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	
2	NDC:72551-246-02	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	
3	NDC:72551-246-03	7 g in 1 POUCH; Type 0: Not a Combination Product	03/19/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/02/2018	

**Labeler** - Dr. Harold Katz, LLC (965507767)

Revised: 3/2019

Dr. Harold Katz, LLC