

**SOOM GREEN MOUTHWASH- sodium fluoride liquid**  
**TECOZYME 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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**ACTIVE INGREDIENT**

Sodium Fluoride 0.02%

**PURPOSE**

Anticavity

**Uses**

- Help teeth whitening and reduce of bad breath
- Aids in the prevention of gingivitis, periodontitis

**WARNINGS**

Do not use in Children under 6 years of age  
If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**KEEP OUT OF REACH OF CHILDREN**

Do not use in Children under 6 years of age  
If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

Adults and children 6 years of age and older

- Vigorously swish 11 mL between teeth twice a day for 30 seconds then spit out.
- Do not swallow
- Children under 6 years of age: do not use

**Other Information**

- Read the directions and warnings before use
- Store at room temperature
- This rinse is not intended to replace brushing or flossing

## QUESTIONS

■ [www.tecozyme.com](http://www.tecozyme.com) or [contact@tecozyme.com](mailto:contact@tecozyme.com)

## INACTIVE INGREDIENTS

Water, Erythritol, Xylitol, Sodium Benzoate, Glycerin, Allantoin, Propylene Glycol, PEG-40 Hydrogenated Caster Oil, L-Menthol, Zinc Gluconate, Sodium Citrate, Fragrance

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



## SOOM GREEN MOUTHWASH

sodium fluoride liquid

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:79717-0010

**Route of Administration** DENTAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.02 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Erythritol</b> (UNII: RA96B954X6)	
<b>Xylitol</b> (UNII: VCQ006KQ1E)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79717-0010-2	20 in 1 CARTON	08/01/2021	
1	NDC:79717-0010-1	11 mL in 1 POUCH; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/01/2021	

**Labeler** - TECOZYME INC (694613703)

**Registrant** - TECOZYME INC (694613703)

### Establishment

Name	Address	ID/FEI	Business Operations
BD TECH CO LTD		695005161	manufacture(79717-0010)

Revised: 8/2021

TECOZYME INC