

**KIDS FLOURIDE RINSE- sodium fluoride rinse**  
**WinCo Foods, 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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**Anticavity Fluoride Rinse Winco 004.002/004AE**

**Active ingredient**

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

**Purpose**

Anticavity rinse

**Use**

aids in the prevention of dental cavities

**Warnings**

for this product

**Keep out of reach of children.**

If more than used for rinsing is accidentally swallowed, seek professional assistance or contact a Poison Control Center immediately.

**Directions**

- adults and children 6 years of age and older: use once a day after brushing your teeth with a toothpaste
- remove cap
- pour 10 milliliters (10 mL mark on inside of cap); do not fill above 10 mL mark
- 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**

- store at room temperature

**Inactive ingredients**

benzyl alcohol, calcium disodium EDTA, cetylpyridinium chloride, disodium EDTA, disodium phosphate, flavor, poloxamer 407, polysorbate 80, propylene glycol, red 33, sodium benzoate, sodium phosphate, sodium saccharin, sorbitol, water

## **Questions?**

Or to report an adverse event call 800-824-1706

Monday - Friday 9am - 4pm MST

## **Adverse reaction section**

"The ADA Council on Scientific Affairs' Acceptance of WinCo Food Anticavity Fluoride Rinse is based on its finding that the product is effective in

helping to prevent and reduce tooth decay, when used as directed."

\*This is not manufactured or distributed by Chattem, Inc., distributor of Act Anticavity Kids Fluoride Rinse.

DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704

## **principal display panel**

SEALED WITH PRINTED NECK AND FOR YOUR PROTECTION

Compare to the active ingredient in ACT Anticavity Kids Fluoride Rinse

WinCo

FOODS

ANTICAVITY

Fluoride

Rinse

Strong Cavity Protection

Alcohol Free

Helps Strengthen Teeth

ADA

Accepted

American

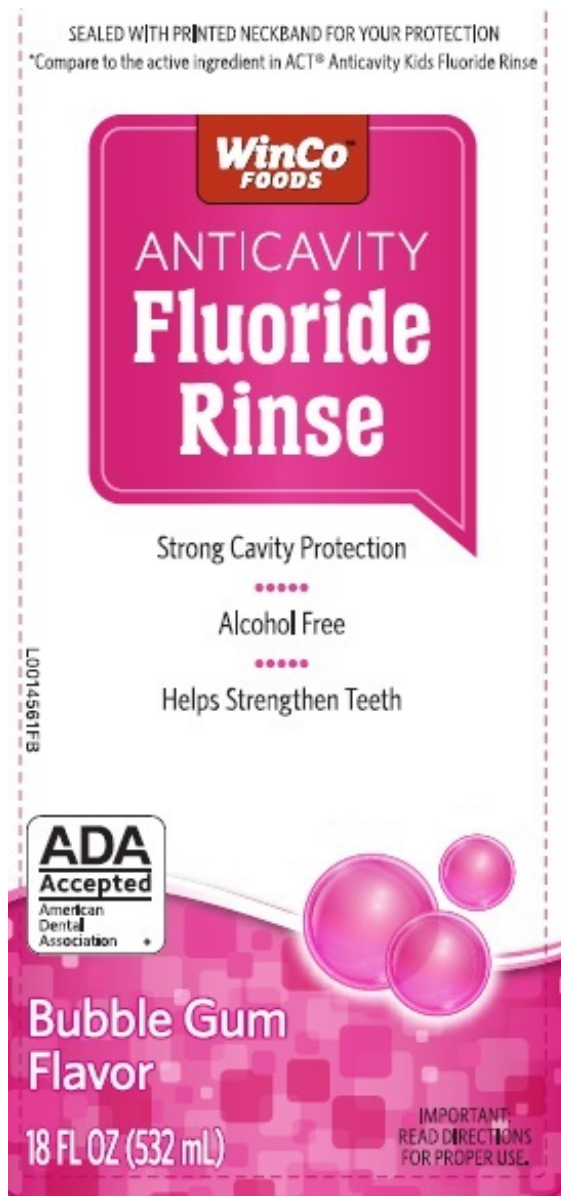
Dental

Association

Bubble Gum

Flavor

18 FL OZ (532 mL)



## KIDS FLOURIDE RINSE

sodium fluoride rinse

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67091-104
<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	0.2 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	

EDETATE CAL CIUM DISODIUM ANHYDRO US (UNII: 8U5D034955)
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)
EDETATE DISODIUM (UNII: 7FLD91C86K)
SODIUM PHOSPHATE, DIBASIC, ANHYDRO US (UNII: 22ADO53M6F)
POLOXAMER 407 (UNII: TUF2IVW3M2)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
D&C RED NO. 33 (UNII: 9DBA0SBB0L)
SODIUM BENZOATE (UNII: OJ245FE5EU)
SODIUM PHOSPHATE (UNII: SE337SVY37)
SACCHARIN SODIUM (UNII: SB8ZUX40TY)
SORBITOL (UNII: 506T60A25R)
water (UNII: 059QF0K00R)

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-104-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/09/2011	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/09/2011	

**Labeler** - WinCo Foods, LLC (056098817)

**Registrant** - Vi-Jon (150931459)

**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon		150931459	manufacture(67091-104)