

**BREATHAWAY MOUTH RINSE FRESH MINT- cetylpyridinium chloride mouthwash**  
**Melaleuca, 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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**BreathAway Mouth Rinse Fresh Mint**

**Active ingredient**

Cetylpyridinium chloride 0.07%

**Purpose**

Antigingivitis/Antiplaque

**Uses**

- helps prevent gingivitis
- helps prevent plaque that leads to gingivitis

**Warnings**

**Stop use and ask a dentist if** symptoms persist or condition worsens after regular use.

**Keep out of reach of 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 12 years of age and older: vigorously swish 20 mL (4 teaspoonfuls) between your teeth twice a day for 30 seconds and then spit out. Do not swallow the rinse.
- children 6 years to under 12 years of age: supervise use.
- children under 6 years of age: do not use

**Inactive ingredients**

water, sorbitol, glycerin, PEG-40 hydrogenated castor oil, polysorbate 20, sodium benzoate, flavor, potassium sorbate, citric acid, sodium hydroxide, poloxamer 407, xylitol, zinc citrate, potassium acesulfame, melaleuca alternifolia (tea tree) leaf oil, ethyl menthane carboxamide, commiphora myrrha oil

PULL

Breath-Away® Mouth Rinse is the only mouth rinse that uses pure T40-C3® Melaleuca Oil for freshness plus CPC to kill germs that cause plaque, gingivitis, and bad breath. This formula deeply cleans your mouth for healthier teeth and gums and long-lasting freshness without the burn of alcohol.

**Drug Facts**

<i>Active ingredient</i>	<i>Purpose</i>
Cetylpyridinium chloride 0.07%.....	Antigingivitis/ Anti plaque

**Uses** ■ helps prevent gingivitis  
■ helps prevent plaque that leads to gingivitis

**Warnings**  
**Stop use and ask a dentist if symptoms persist or condition worsens after regular use.**

**Keep out of reach of 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.

NOT FOR RESALE IN CANADA



Melaleuca, Inc., Idaho Falls, ID 83402-6003  
To order : 1-800-282-3000 • www.melaleuca.com  
Dist. by: Melaleuca Southeast Asia (Singapore) Pte Ltd,  
10 Eunos Rd 8, #14-03 Singapore Post Centre,  
Singapore 408600, SG 1800 800 8080  
Product of USA N# 3714 05/11 U/SG

**Drug Facts** (continued)

**Directions** ■ adults and children 12 years of age and older: vigorously swish 20 mL (4 teaspoonfuls) between your teeth twice a day for 30 seconds and then spit out. Do not swallow the rinse. ■ children 6 years to under 12 years of age: supervise use. ■ children under 6 years of age: do not use

**Other information**

■ this rinse is not intended to replace brushing or flossing

**Inactive ingredients**

water, sorbitol, glycerin, PEG-40 hydrogenated castor oil, polysorbate 20, sodium benzoate, flavor, potassium sorbate, citric acid, sodium hydroxide, poloxamer 407, xylitol, zinc citrate, potassium acesulfame, melaleuca alternifolia (tea tree) leaf oil, ethyl menthane carboxamide, commiphora myrrha oil

**\*This product is concentrated. Dilute with water in the *Breath-Away*® Mouth Rinse ready-to-use bottle before using.**

Using this concentrated product undiluted may cause irritation.

**Keep out of reach of children.**

Do not swallow. If swallowed, get medical help or contact a Poison Control Center right away. See ready-to-use bottle for complete Drug Facts, including directions for use and warnings.

## **WHEN USED AS DIRECTED HELPS FIGHT GINGIVITIS AND PLAQUE**

**Diluting Directions:** Pour ½ of the bottle of concentrate into the 16 fl. oz. (473 mL) *Breath Away Mouth Rinse* bottle. Add water to the shoulder of the bottle. Or dilute 1 part concentrate to 3 parts water.

**Ingredients:** Aqua (water/eau), sorbitol, glycerin, PEG-40 hydrogenated castor oil, polysorbate 20, sodium benzoate, flavor, potassium sorbate, citric acid, sodium hydroxide, poloxamer 407, xylitol, zinc citrate, potassium acesulfame, cetylpyridinium chloride, melaleuca alternifolia (tea tree) leaf oil, ethyl menthane carboxamide, commiphora myrrha oil

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Product of USA № 3716 05/11 U/SG



cetylpyridinium chloride mouthwash

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54473-294
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>CETYLPYRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7J10JV3)	CETYLPYRIDINIUM CHLORIDE	0.3394 g in 473 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>ETHYL MENTHANE CARBOXAMIDE</b> (UNII: 6S7S02945H)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MYRRH OIL</b> (UNII: H74221J5J4)	
<b>POLOXAMER 407</b> (UNII: TUF21VW3M2)	
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>ZINC CITRATE</b> (UNII: K72I3DEX9B)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-294-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2018	
2	NDC:54473-294-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2018	09/08/2023

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/02/2011	

**Labeler** - Melaleuca, Inc. (139760102)

## Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc.		079711683	manufacture(54473-294)

Revised: 1/2023

Melaleuca, Inc.