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## **Product Monograph**

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### **Preface**

The activity of keeping the mouth clean dates all the way back to the religious figure Buddha. It has been recorded that he used a "tooth stick". In 23 - 79 AD the practice of oral hygiene included, drinking goats milk for sweet breath & using ashes etc as they were thought to benefit the gums. The earliest record of an actual toothpaste / mouthwash was in 1780 and included scrubbing the teeth with a formula containing burnt bread, later charcoal became very popular.

Most of the mouthwashes presently in the market contain fluorine, chlorhexidine, triclosan, povidone iodine, sugar, alcohol, etc., that are no more considered safe for daily usage.

Since, lately, Herbal toothpastes / mouthwashes have gained popularity. People are looking for "natural" dental cleansers, which do not include fluoride, sodium lauryl sulphate, or alcohol... in them etc.

Therefore there is a need for some safe, effective & gentle dental cleanser, which is devoid of all the above-mentioned ingredients.

BEFRESH is a mouthwash with an edge over other mouthwashes presently in the market & is completely a natural product containing natural essential oils. BEFRESH mouthwash is completely alcohol & sugar free, hence safe for long-term use.

The product monograph of BEFRESH mouthwash highlights the unique & effective composition of natural essential oils, such as cinnamon oil, spearmint oil, clove oil & eucalyptus oil. BEFRESH mouthwash offers pleasant lingering & refreshing flavor.

Among the various oral problems

It's estimated that 50 to 65 percent of the population suffer from bad breath / halitosis. Chronic halitosis is a more serious and persistent affliction, affecting up to 25% of the population in varying degrees.

More than 30% of the population is estimated to be suffering from periodontitis

About 53% of the adults have some form of gingivitis

With such an enormous rate of sufferers in oral problems, it is a requirement to come up with an innovative product, which is both safe & effective for all oral conditions.

### **Halitosis**

A research performed at California Breath Clinics & also some of the top universities in the world showed that anaerobic bacteria that live beneath the surface of the tongue cause bad breath. These bacteria are not "bad", rather they are a normal part of your oral environment and break down the proteins in foods and in mucus or phlegm. During this process of breaking down these proteins, they extract sulfur from the amino acids, and produce Volatile Sulfur Compounds such as Methyl Mercaptan (which smells sort of like dirty socks) and Hydrogen Sulfide (the "rotten egg" smell).



These are anaerobic bacteria, which breed by the billions, deep within the fibers (papillae) of the tongue, because in normal circumstances, oxygen cannot penetrate beneath the surface of the tongue.

Treatments commonly adopted for these conditions are .....

**Toothpastes-** toothpastes are not effective in treating the bad breath rather they worsen the condition.

Sodium lauryl sulphate dries out the mouth creating an optimal environment for the Bad breath bacteria to produce volatile sulfur content.

**Sugar mints-** Sugar creates an excellent source of food for the bad breath bacteria to thrive, which worsens the conditions.

**Benzyl alkonium chloride-** It can stimulate mucus production by which making breath worse not better

**Mouthwashes** –Mouthwashes are considered the most common & effective remedies in reducing bad breath. But, many of these have limitations & are hazardous to health.

The most commonly found mouthwash formulations contain...

1. Alcohol base
2. Chlorhexidine
3. Triclosan
4. Povidone-Iodine
5. Potassium nitrate
6. Formalin
  
7. Chloroxylonol
8. Benzoic acid

These mouthwashes are no more considered safe or effective for daily usage.

Alcohol base .....

Most of the mouthwashes in the market contain alcohol. But the following study reveals that the use of such mouthwashes can be hazardous.

Industrial alcohol is a major ingredient in mouthwash. The National Cancer Institute of America has found that mouthwashes with an alcohol content of 25% or higher have been implicated in mouth, tongue and throat cancers. The

alcohol acts as a solvent in the mouth, making the skin tissues more vulnerable to carcinogens. The study also showed, men had a 60% higher risk and women a 90% higher risk of these cancers compared to those not using mouthwash.

Blot WJ et al. Oral Cancer and Mouthwash. Journal of the National Cancer Institute. 70. 1983.  
Chlorhexidine.....



The most commonly used mouthwashes with Chlorhexidine is no more considered safe and effective for all age groups. The most conspicuous side-effects are the development of yellow-brown stains on the teeth, tongue, and at the margins of anterior restorations, and an alteration in taste sensation.

Spec Care Dentist. 1994 May-Jun;14(3):116-22. A review of chlorhexidine and its use in special populations.

### **Triclosan.....**

Triclosan, a chemical used for its antibacterial properties. It is an ingredient in many detergents, dishwashing liquids, soaps, deodorants, cosmetics, lotions, anti-microbial creams, various toothpastes, and an additive in various plastics and textiles. However, the safety of triclosan has been questioned in regard to environmental and human health. While the companies that manufacture products containing this chemical claim that it is safe, the United States Environmental Protection Agency (EPA) has registered it as a pesticide. The chemical formulation and molecular structure of this compound are similar to some of the most toxic chemicals on earth, relating it to dioxins and PCBs. The EPA gives triclosan high scores both as a human health risk and as an environmental risk.

Reports have suggested that triclosan can combine with chlorine in tap water to form chloroform gas (PMID 15926568), which the U.S. EPA classifies as a probable human carcinogen. As a result, triclosan was the target of a UK cancer alert.

A 2006 triclosan study concluded that low doses of triclosan act as an endocrine disruptor in the North American bullfrog. The hypothesis proposed is that triclosan blocks the metabolism of thyroid hormone, because it

chemically mimics thyroid hormone, and binds to the hormone receptor sites, blocking them, so that normal hormones cannot be utilized.

Triclosan is a chlorophenol, a class of chemicals suspected of causing cancer in humans.

Externally, it can cause skin irritations. "Internally, it can lead to cold sweats, circulatory collapse, convulsions, coma, and even death".

Stored in body fat, it can accumulate to toxic levels, damaging the liver, kidneys, and lungs, and can cause paralysis, sterility, suppression of immune function, brain hemorrhage, decreased fertility and sexual function, heart problems, and coma."

### **Povidine iodine.....**

The effect of povidone-iodine (PVP-I) hand washing and gargling on thyroid function was assessed. In 16 nurses using PVP-I products and 16 control subjects, serum inorganic iodine levels and thyroid functions were investigated. The status of PVP-I use was also surveyed in the nurses. Clinical symptoms considered to be attributable to thyroid dysfunctions were seen in none of the subjects, nor was a goiter observed in any of the subjects. In nurses, serum inorganic iodine levels were slightly increased as compared to those in the control subjects, although the difference was not significant. The iodine incorporated during working hours of nurses appears to be attributable to gargling rather than to hand washing. The long-term use of PVP-I for gargling should be avoided by (1) people with



a high risk of developing thyroid dysfunction due to the excessive intake of iodine, (2) pregnant women and (3) breast-feeding mothers.

Dermatology 2002;204:99-102

Therefore, herbal mouthwash with effective natural essential oils are safer & a better alternative.

#### BEFRESH MOUTHWASH:

- BEFRESH mouthwash treats and prevents Halitosis
- BEFRESH Mouthwash has been clinically studied for treating gingivitis, periodontitis effectively
- BEFRESH restores the oral hygiene.

#### BEFRESH includes: -

- Anti-inflammatory, o Antimicrobial
- Astringent,
- Local anaesthetic and
- Coolant action.
- BEFRESH is completely alcohol free
- BEFRESH is beneficial as gargle in throat infections.
- BEFRESH offers pleasant feeling by its lingering & refreshing flavor.

#### Composition:

Ingredient	Botanical name	Percentage Contains
CINNAMON OIL	<i>Cinnamomum zeylanicum</i>	0.05%
SPEARMINT OIL	<i>Mentha spicata</i>	0.30%
CLOVE OIL	<i>Syzygium aromaticum</i>	0.05%
EUCALYPTUS OIL	<i>Eucalyptus globulus</i>	0.05%

#### Cinnamomum zeylanicum

Various terpenoids found in the volatile oil are the reason for cinnamon's medicinal effects. eugenol and cinnamaldehyde are the principle terpenoids . Cinnamaldehyde and Cinnamon oil vapors are potent anti-fungal compounds.

Singh HB, Srivastava M, Singh AB, Srivastava AK. Cinnamon bark oil, a potent fungitoxicant against fungi causing respiratory tract mycoses. Allergy 1995;50:995-9.

Antibacterial actions have also been demonstrated for cinnamon.

Azumi S, Tanimura A, Tanamoto K. A novel inhibitor of bacterial endotoxin derived from cinnamon bark. Biochem Biophys Res Commun 1997;234:506-10.

Cinnamon is an efficient natural essence for neutralizing halitosis.

International Rap session on Oral malodor Study in Chicago. (September 18th, 2007)

Spearmint oil



A Volatile essential oil from mint, rich in menthol. obtained by steam distillation of mint leaves. An esteemed stimulant & febrifuge with local anesthetic action. Generally used as an external application in congestive headaches, neuralgia & rheumatism etc. Locally, the oil is a powerful anodyne, anesthetic, antiseptic and germicide.

(Nadkarni, Vol I, P 788-790 )

### **Eucalyptus oil**

Eucalyptus oil contains 70-85% 1,8-cineole (eucalyptol), a potent antiseptic that kills bacteria responsible for bad breath. This is also present in other plant oils. Eucalyptol is used as an ingredient in some mouthwash and dental preparations, as an endodontic solvent, and may possess antimicrobial properties.

Eucalyptus leaf and its extracts have antimicrobial and antifungal activity

Takahashi T, Kokubo R, Sakaino M. Antimicrobial activities of eucalyptus leaf extracts and flavonoids from *Eucalyptus maculata*. Lett Appl Microbiol 2004;39:60-4.

Experimental research shows that eucalyptus oil is bactericidal against 5 types of pathogenic oral bacteria.

**(Takarada K et al. A comparison of the antibacterial efficacies of essential oils against oral pathogens. Oral Microbial Immunol 2004 Feb;19(1):61-4.)**

### **Clove oil**

Clinical trials assessing monotherapy of clove are limited, although the expert panel German Commission E has approved the use of clove as a topical antiseptic and anesthetic.

Alqareer A, Alyahya A, Andersson L. The effect of clove and benzocaine versus placebo as topical anesthetics. J Dentistry. November 2006;34(10):747-750.

Clove is antiseptic, antibacterial, antifungal, antiviral, spasmolytic and a local anaesthetic.

(Source: PDR for herbal medicine, first edition, page

1167.)

The cinnamon & clove are potentially effective against species belonging to *Eurotium*, *Aspergillus* and *Penicillium* genus.

Journal of Applied Microbiology, Volume 94 Issue 5 Page 893-899, May 2003

### **Indications & Dosage**

- Halitosis / Bad breath
- Gingivitis
- Periodontitis
- Mild throat infections
- Oral fungal & Bacterial Infections
- Prevents Plaque & Tartar



**Directions for use:** Rinse 10 ml of BEFRESH mouthwash vigorously around teeth & gums, for at least 30 seconds then gargle & spit. Follow the same twice daily, once in the morning & before going to bed.

USE WITHIN 15 DAYS AFTER OPENING.

### **Why Essential oils.....?**

Various ingredients are used in oral rinses for therapeutic and cosmetic purposes. Three common therapeutic agents are chlorhexidine, high cetylpyridinium chloride (CPC), and essential oils. All three agents have been clinically shown to produce significant gingival and plaque control benefits when formulated at therapeutic concentrations.

Chlorhexidine is the most effective therapeutic prescription rinse approved for clinical use as an antiplaque and antigingivitis agent. High bioavailable CPC and essential oils are the only two antimicrobial systems for over-the-counter rinses that are classified by the Food and Drug Administration (FDA) Dental Plaque Subcommittee as safe and effective for the treatment of plaque-induced gingivitis.

The FDA Dental Plaque Subcommittee recommended essential oils as a safe and effective active system for over-the-counter antiplaque / antigingivitis rinses when formulated as a combination of 0.092% eucalyptol, 0.042% menthol, 0.06% methyl salicylate, and 0.064% thymol in a hydroalcoholic vehicle containing 21.6% to 26.9% alcohol.

Essential oil mouthwashes work by disrupting the bacterial cell wall and inhibiting its enzyme activity. <http://www.dimensionsofdentalhygiene.com/ddhright.asp?id=801>

Long-term trials of these essential mouthwashes, showed reductions in gingivitis from 12% to 30% and plaque reductions from 21% to 56% when compared to a placebo. The safety of essential oils were also well-established.

In another study ...

A mouthwash combination that includes sage oil, mentha piperita oil, cinnamon tincture, clove oil, and caraway oil, echinacea has been used successfully to treat gingivitis. This was studied in comparison with a chlorhexidine containing mouthwash. The natural herbal mouthwash was significantly effective than the mouthwash with Chlorhexidine.

**(Comparative clinical trial with natural herbal mouthwash versus chlorhexidine in gingivitis. Serfaty R, Itic J.)**

### **Why mouthwash & not toothpaste.....?**

**Toothpastes-** toothpastes are not effective in treating the bad breath rather they worsen the condition. SLS (sodium lauryl sulphate) used in toothpastes, are detergent and are responsible for the foam formation. SLS, dry out the mouth creating an optimal environment for the Bad breath bacteria to produce volatile sulfur content & worsen the condition.

Moreover mouthwash could be used in any oral condition comfortably, even in attrition of teeth.

Attrition – Is wearing out of the teeth is called attrition. This creates gaps on top of the teeth, causing them to become sensitive to hot and cold stimuli. These patients are generally advised to replace



brushing with applications, mouthwashes & gum massage or replace the original teeth with that of dentures.

There are a few treatmental procedures. Which aren't accessible by all patients, due to cost factors. Although, these treatments could never substitute the healthy teeth.

BEFRESH Mouthwash was found very effective in halitosis & hypersensitivity due to dental attrition also

**Comparative study**

A comparative study on Antimicrobial activity of Befresh mouthwash in comparison with chlorhexidine (c) & alcohol based (L) mouthwashes was conducted at "MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES,

MANIPAL". The study was conducted mainly on 4 varieties of micro-organisms in various media. Observations of the study were as follows.

Mic.  Org.	Zone of Inhibition (in mm)					
	Chlohexidine mouthwash (C)		Befresh mouthwash		Alcohol based mouthwash (L)	
	Undiluted	1:1	Undiluted	1:1	Undiluted	1:1
E. Coli	22	18	12	6	10	5
	20	17	15	8	12	4
	19	15	16	8	15	8
	Avg. ± SEM 20.33 ± 0.88	Avg. ± SEM 16.66 ± 0.88	Avg. ± SEM 14.33 ± 1.20	Avg. ± SEM 6.66 ± 0.81	Avg. ± SEM 12.33 ± 1.45	Avg. ± SEM 5.66 ± 1.20
<i>Bacillus Subtilis</i>	14	12	10	5	12	5
	13	11	11	6	11	4
	12	10	10	4	14	8
	Avg. ± SEM 13.00 ± 0.57	Avg. ± SEM 11.00 ± 0.58	Avg. ± SEM 10.33 ± 0.33	Avg. ± SEM 5.00 ± 0.58	Avg. ± SEM 12.33 ± 0.88	Avg. ± SEM 5.66 ± 1.20
<i>Pseudomonas aeruginosa</i>	19	15	12	5	13	5
	19	16	15	8	14	8
	17	15	14	7	16	7
	Avg. ± SEM 18.33 ± 0.66	Avg. ± SEM 15.33 ± 0.33	Avg. ± SEM 13.66 ± 0.88	Avg. ± SEM 6.66 ± 0.88	Avg. ± SEM 14.33 ± 0.88	Avg. ± SEM 6.66 ± 0.88
<i>Staphylococcus aureus</i>	32	22	35	31	28	21
	30	19	34	30	31	20



	29	21	34	29	29	21
	Avg. $\pm$ SEM					
	30.33 $\pm$ 0.88	20.66 $\pm$ 0.88	34.33 $\pm$ 0.33	30.00 $\pm$ 0.58	29.33 $\pm$ 0.88	20.66 $\pm$ 0.33

**Inference:** Although Chlorhexidine mouthwash (C) exhibited superior antimicrobial activity; all the readings of Befresh mouthwash are not significantly different from either chlorhexidine mouthwash or alcohol-based mouthwash (L) in undiluted form, in which the patients use it. This indicates that Befresh mouthwash possesses good antimicrobial activity against the above microorganisms. In diluted form (1:1), Befresh and alcohol-based mouthwash (L) did not show a good activity except Staphylococcus aureus; whereas chlorhexidine mouthwash retained almost the same activity.

### FAQ's

#### 1) What is new in “Befresh mouthwash”?

“Befresh mouthwash” is first mouthwash in the market with natural essential oils in it such as – cinnamon oil, spearmint oil, clove oil & eucalyptus oil.

#### 2) How effective is Befresh mouthwash?

Befresh mouthwash contains natural essential oils. Essential oils are tested & proven effective in plaque & gingivitis for long-term use. Befresh mouthwash contains:

Cinnamon oil & spearmint oil – which are effective in Halitosis  
Clove oil – is found to be very effective in Gingivitis & Periodontitis,  
Eucalyptus oil – is effective in mild throat infections &

Cinnamon oil & spearmint oil - Removes & prevents plaque / tartar formation.

#### 3) How safe is “Befresh mouthwash” for prolonged use?

Most of the mouthwash in the market contains alcohol, chlorhexidine, triclosan, povidone iodine or sugar base etc. These mouthwashes are not considered safe for daily usage, due to their hazardous side effects.

Befresh mouthwash is devoid of these ingredients & contains natural essential oils, which are safe for long-term use.

#### 4) Why is alcohol-based mouthwash harmful?

Alcohol base is used as a solvent in mouthwashes to dissolve the active ingredients. It is also considered to prevent bacteria from growing, especially in the opened pack. Hence, keeps the product stable. Alcohol also helps to provide - clean, refreshing feeling in mouth after the rinse



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But, Alcohol based mouthwashes act as a solvent in the mouth & they make the skin tissues more vulnerable to carcinogens / oral cancers.

**5) Why is chlorhexidine-based mouthwash harmful?**

Chlorhexidine is considered effective therapeutic prescription rinse approved for clinical usage as an - antiplaque and antigingivitic agent.

But, the most conspicuous side effect of Chlorhexidine based mouthwashes is the development of yellow-brown stains on the teeth, tongue, and at the margins of anterior restorations. Chlorhexidine also alters the taste sensation.

**6) Why is mouthwash with Triclosan harmful?**

Triclosan is used in mouthwashes, for its antibacterial properties. It is an ingredient in many detergents, dishwashing liquids, soaps, various toothpastes, etc

But, Triclosan based mouthwash is carcinogenic & endocrine disruptor ie affects the endocrine functions.

**7) Why is povidone iodine based mouthwash harmful?**

Povidone iodine in mouthwashes is used to treat infections of the mouth and throat, such as gingivitis (inflammation of the gums) and mouth ulcers. It is also used for oral hygiene, to kill microorganisms before, during and after dental and oral surgery and hence prevent infections.

But, Povidone iodine based mouthwashes are considered to bring thyroid disturbances on long-term usage.

**8) How is sugar-based mouthwash harmful?**

Sugar base in mouthwashes is added as a sweetening agent. But, the Dentists do not recommend these mouthwashes, as they promote the development of oral bacteria & tooth decay.

**9) Does “Befresh mouthwash” reduce plaque?**

Yes. Active ingredients in “Befresh mouthwash” have shown significant reduction of plaque index in human studies.

**10) Can we dilute “Befresh mouthwash” with water?**

No, “Befresh mouthwash” should not be diluted with water as it reduces the effectiveness of the essential oils performance. Therefore, we recommend using it in full strength.

**11) What is the shelf life for “Befresh Mouthwash?”**



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“Befresh mouthwash” has the shelf life of 3years. But, has to be used within 15 days, after opening of the pack.

**12) How do I use “Befresh mouthwash”?**

Rinse 10 ml of BEFRESH mouthwash vigorously around teeth & gums, for at least 30 seconds then gargle & spit. Follow the same twice daily, once in the morning & before going to bed.

**13) Does Befresh mouthwash have any contraindications?**

Yes! It should be avoided in children below 6 yrs of age, because they tend to swallow the content after rinsing & gargling.

**14) Befresh mouthwash is an ayurvedic mouthwash then, what is the risk of swallowing the content?**

Though Befresh mouthwash is an ayurvedic / herbal mouthwash & is devoid of side effects, swallowing the content after squishing & gargling means swallowing the morbid oral collection in to the stomach, which on regular habit leads to digestive disturbances