



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁶ : A61F 2/02</p>	<p>A1</p>	<p>(11) International Publication Number: WO 00/06050</p> <p>(43) International Publication Date: 10 February 2000 (10.02.00)</p>						
<p>(21) International Application Number: PCT/US99/17069</p> <p>(22) International Filing Date: 28 July 1999 (28.07.99)</p> <p>(30) Priority Data:</p> <table border="0"> <tr> <td>09/123,646</td> <td>28 July 1998 (28.07.98)</td> <td>US</td> </tr> <tr> <td>09/152,151</td> <td>11 September 1998 (11.09.98)</td> <td>US</td> </tr> </table> <p>(71)(72) Applicant and Inventor: FUST, Charles, A. [US/US]; 3828 Chaumont Circle, Ocean Springs, MS 39564 (US).</p> <p>(74) Agent: KAYDEN, James, W.; Thomas, Kayden, Horstemeyer & Risley, LLP, Suite 1500, 100 Galleria Parkway, N.W., Atlanta, GA 30339 (US).</p>		09/123,646	28 July 1998 (28.07.98)	US	09/152,151	11 September 1998 (11.09.98)	US	<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p>
09/123,646	28 July 1998 (28.07.98)	US						
09/152,151	11 September 1998 (11.09.98)	US						
<p>(54) Title: COMPOSITION FOR FRESHENING NOSTRILS AND SINUS CAVITIES</p>								
<p>(57) Abstract</p> <p>A composition for freshening nostrils and sinus cavities is disclosed for masking or eliminating objectionable odors in the breath. The composition is typically administered from a squeeze or pump-type bottle or the like and includes a carrier such as saline solution and a masking agent such as oil of peppermint or other flavoring.</p>								

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakistan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

**COMPOSITION FOR
FRESHENING NOSTRILS AND SINUS CAVITIES**

FIELD OF INVENTION

5 This invention relates to a composition that is applied to a person's nostrils and sinus cavities, using an inhaler or other suitable means, for freshening and deodorizing the named areas for controlling halitosis.

BACKGROUND OF THE INVENTION

10 Conventional control of halitosis or "bad breath", as it is often termed, is presently accomplished through the use of mouthwashes, breath mints, candy, chewing gum, brushing and flossing teeth, and other such means that are taken by mouth. Recent developments in this field have focused on the theory that the digestive organs can be responsible for objectionable odors that are produced from consuming certain foods or liquids.

15 Mouthwash rinses are used to flush the mouth with bacteria killing agents and, in most cases, with additives of various types designed to freshen the mouth and mask odors. Bacterial elimination is normally accomplished by the use of alcohol and/or various dilutions of saline solution. The use of alcohol in these products often causes the intrusive effect experienced by many persons as a burning sensation. Saline
20 solutions are very effective bacteria killing agents and do not cause the burning sensation; however, the taste is not well received by most consumers. While effective in many cases, mouthwashes and other oral means of controlling breath odors can be supplemented with the composition that is the subject matter of the present invention.

SUMMARY OF THE INVENTION

It is, therefore, one of the principal objects of the present invention to freshen breath and eliminate or mask objectionable breath odors by introducing the present invention into the nostrils and therethrough, into the sinus cavities.

5 Another object of the present invention is to provide a composition which may be conveniently introduced through the nose with, for example, an inhaler or atomizer - type container and which causes no discomfort to the user.

A further object of the present invention is to provide an effective means of breath odor control as a substitute or supplement to conventional therapies and which
10 has both immediate and residual effect.

These and additional objects are attained by the present invention which, in the broadest sense, comprises a carrier means, such as water or a dilute saline solution, and an odor masking agent. The odor masking agent can be an essential oil or flavoring means such as those used in conventional mouthwashes. Other additives
15 may include a small quantity of alcohol for acting on bacteria and an adherent means such as glycerine for maintaining the composition in place in the nostrils and sinus cavities for a sufficient length of time to produce the desired effect. Other means such as preserving agents may also be employed.

Various additional objects and advantages of the present invention will
20 become apparent from the following detailed description.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention is a liquid composition that is inhaled through the nostrils and into the sinus cavities. It is of particular utility for use by persons who smoke cigarettes, cigars, and the like as the smoke necessarily invades the nostrils and sinus cavities when it is inhaled.

The composition includes a carrier means, which can be water or a mild or dilute saline solution. The saline solution is preferred and provides a mild antibacterial effect. Saline solutions are also commonly used as moisturizers at present and are safely used in the nasal passages and sinuses. While the concentration may vary between 50% and 75%, a solution of 65% saline has been found to be effective and non-objectionable for the user.

Control and/or elimination of objectionable odors is accomplished using masking agents such as oil of peppermint, spearmint, etc., or agents having a fruity or citrus essence. Other agents include, but are not limited to eucalyptol, methyl salicylate, and various other flavoring means.

A small quantity of alcohol may be used to provide an antibacterial effect. The alcohol is not necessary but may facilitate mixing of the other components. A further component which may be added is a preserving agent such as benzalkonium chloride which is used to extend shelf life. The use of the preserving agent or agents depends on whether or not some or any of the other components are stable in storage.

The delivery method used for the present composition can vary, with spray bottles, droppers, and/or atomizers - type squeeze or pump bottles, all being suitable, among other delivery means. Experimentation with a one-half (1/2 oz.) pump atomizer spray bottle proved to be an effective delivery means. Containers of this

type are currently used by several pharmaceutical companies for introducing sinus medication into the nostrils and sinus cavities. The atomizer - type bottles reduce the contents of the bottle to a very fine mist, thus making the delivery of the composition minimally intrusive.

5 No discomfort for the user was experienced in testing of the product. In addition, no harmful effects on the nostrils or sinus cavities were caused by any of the components of the present composition. The composition effectively eliminated or masked odors associated with smoking and with eating various foods such as onion, garlic and other spices, and certain liquids, particularly alcoholic beverages, coffee,
10 tea, etc.

Example 1

The following formula provides a representative example of a composition prepared according to the present invention.

	Sodium Chloride	0.65%
15	Benzalkonium Chloride	0.002%
	Thimerosal	0.001%
	Eucalyptol	0.03%
	Methyl Salicylate	0.02%
	Menthol	0.015%
20	Alcohol	0.07%
	PEG or Glycerin	Trace (Optional)

	Sodium Chloride	Base ingredient also acting as a moisturizer
	Benzalkonium Chloride	Preservative
25	Thimerosal	Preservative
	Eucalyptol	Flavoring Agent, also containing antiseptic effect
	Methyl Salicylate	Counterirritant, (Local Analgesic containing flavor similar to Wintergreen)
30	Menthol	Counterirritant

Alcohol

Aids in solubility effect of other ingredients also containing antibacterial effect.

The above listed formula has undergone testing and has proved effective for its stated purpose. The composition was dispensed from a one-half (1/2 oz.) pump atomizer bottle and was successful in eliminating and/or masking odors which could be considered offensive in certain circumstances or by certain people, i.e. odors from smoking, consuming onions etc.

Based on experiments that have been conducted, the eucalypton, methyl salicylate and menthol can be replaced by other similar acting ingredients to completely change the flavor. The base ingredient, preservative(s) and alcohol percentages will remain relatively constant. The solution of the invention is prepared according to known techniques and excipients, as described in "Remington's Pharmaceutical Sciences handbook," Hack Publ. Co., N.Y., U.S.A.

It should be stated, the compositions of my invention are not limited to the ingredients stated in original application or the CIP formulation. Substitution ingredients are widely available for each of the essential components, as described in Remington's Pharmaceutical Sciences.

The first intrinsic ingredients of my invention are the Antiseptic and Anti-Infective agents. The elimination of certain types of bacteria, which are known to cause offensive odors, will aid in the freshening of the breath and are selected and formulated to produce the results as described.

The second intrinsic ingredient of my invention is the Aromatic Components which aid in the freshening and deodorizing of the nasal and sinus cavities. These ingredients are selected and formulated to produce the results as described in Claim 6.

The third intrinsic ingredient of my invention is the isotonic, aqueous solution acting as an Osmotic Agent. This ingredient is selected and formulated for the isotonic value and fully disclosed in Remington's Pharmaceutical Sciences, 17th edition. This ingredient is selected and formulated to produce the results further
5 described herein.

Example 2

The following formula provides a second representative example of An Isotonic, Sterile, Aqueous Solution prepared according to the present invention. In this formula, the function of the ingredients is given under "Application".

<u>RANGE</u>	<u>INGREDIENT</u>	<u>APPLICATION</u>	<u>PERCENTAGE</u>
0.1. to 2%	Sodium Chloride	Osmotic Agent	0.650
0.1 to 5%	Sodium Borate	Buffering Agent	0.100
0.1 to 9%	Alcohol SD	Solubilizing Agent	0.090
0.001 to 2%	Edetate Disodium	Preservative	0.050
0.1 to 3%	Glycerin	Solubilizing Agent	0.001
0.001 to 5%	Polysorbate 80	Surfactant	0.045
0.001 to 5%	Poloxamer 407	Antiseptic	0.030
0.001 to 5%	Domiphen Bromide	Antiseptic	0.030
0.001 to 5%	Cetylpyridinium Chloride	Anti-Infective	0.040
0.1 to 2%	Sorbitol	Sweetener	0.002
0.1 to 2%	Sodium Saccharin	Sweetener	0.002
0.1 to 5%	Aromatic Component	Masking Agent	0.005
	Deionized Water	Solvent (Vehicle)	<100% (W/W%)

The examples I have given, both in the parent application and the CIP filing are representative of preferred embodiments. However, the range of my invention should not be limited to these examples in terms of ingredients and administration.

Thus, while an embodiment and various modifications thereof of a
5 composition for freshening nostrils and sinus cavities has been described in detail herein, various additional changes and modifications may be made without departing from the scope of the present invention.

I Claim:

1. A composition for freshening sinus cavities comprising a carrier means
and a masking agent for concealing or eliminating odors emanating from the sinus
5 cavities.
2. A composition as defined in Claim 1 and further including a
preservative.
- 10 3. A composition as defined in Claim 1 and further including a
counterirritant.
4. A composition as defined in Claim 1 and further including a solubility
enhancer.
- 15 5. A composition as defined in Claim 1 and further including an
antiseptic means.
- 20 6. A composition for freshening nostrils and sinus cavities comprising a
saline solution as a moisturizing base component, a flavoring agent for masking or
eliminating odors from the sinuses or nostrils, a preservative means for enhancing the
shelf life of the composition, a counterirritant for facilitating acceptance of the
composition by the nostrils and sinuses, and an alcohol for facilitating solubility of the
components.

7. A composition as defined in Claim 1 and further including an anti-infective means.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/17069

A. CLASSIFICATION OF SUBJECT MATTER
 IPC(6) : A61F 2/02
 US CL : 424/434
 According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
 Minimum documentation searched (classification system followed by classification symbols)
 U.S. : 424/434

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

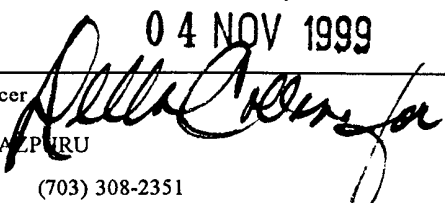
C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,622,992 A (BECK) 22 April 1997, see Abstract; columns 3-6; column 4, lines 4-5.	1-7

Further documents are listed in the continuation of Box C.
 See patent family annex.

* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
---	--

Date of the actual completion of the international search 24 SEPTEMBER 1999	Date of mailing of the international search report 04 NOV 1999
--	---

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer  CARLOS ALPURU Telephone No. (703) 308-2351
---	---