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(54) Title: DENTURE CLEANSER

(57) Abstract

A denture cleanser tablet or other cleaning composition comprises a synergistic combination of a hexametaphosphate, such as sodium hexametaphosphate, and an ethylenediamine tetraacetic acid (Versene Acid or EDTA) or a salt thereof. The cleaning composition can be prepared without peracids or peracid salts, which leads to a milder, but highly effective, cleaning composition.

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DENTURE CLEANSER

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to a denture cleanser tablet composition and to methods of making and using a denture cleanser tablet composition.

2. Description of Related Art

Full or partial dentures are intended to be worn in the mouth to replace missing teeth. Like teeth, dentures should be cleaned regularly to maintain good oral health. Like teeth, dentures should also be cleaned regularly for cosmetic reasons.

Unlike teeth, dentures can be removed for cleaning. Dentures are also made of durable materials, such as acrylic polymers, that can withstand harsher cleaning conditions than teeth. As a result, dentures can be, and are, exposed to harsher cleaning conditions than teeth. Dentures are typically cleaned in one of two ways: either the dentures are soaked for some time in a cleansing bath or dentures are brushed with dentifrices or specially formulated cleansing creams.

Brushing with creams has the advantage of supplementing the cleaning formulation with mechanical action. Unfortunately, as with teeth, spots on the dentures can be missed or overlooked during the brushing process. As a result, the denture material can degrade over time, and remaining teeth and gums of the user may be exposed to disease agents and undesirable cosmetic consequences.

Soaking in a cleansing bath offers the advantage of reaching every part of a denture for cleaning. Full immersion of the denture in the bath allows the cleansing composition to reach areas that cannot be reached by ordinary brushing with creams.

Cleansing baths are not usually sold as such. Typically, the active ingredients are sold in solid form, as a denture cleanser powder or tablet, or in concentrated liquid form. The active ingredients are then dissolved in a water bath to form the cleansing bath. Unfortunately, soaking surrenders the advantage of mechanical scrubbing found with creams and dentifrices. To compensate for this loss of mechanical cleaning, denture

cleansing tablets and powders usually contain an effervescent system and strong chemical cleaning agents.

Strong chemical cleaning agents, such as bleaches, can impart an unpleasant taste or odor to soaked dentures, however. Thus, denture cleanser manufacturers face a trade off between efficacy and cosmetic and organoleptic considerations. Finding strong denture cleanser agents that do not impart unpleasant qualities to the dentures is an ongoing task. Acceptable agents must be nontoxic, nonstaining, and water soluble. Although not a strict requirement, the cleanser should not precipitate in the bath during cleaning to coat the denture or leave an unsightly residue in the bath.

U.S. Patent No. 2,409,718 was an early approach to the denture cleanser agent dilemma, disclosing a water soluble salt of 2, 2' dihydroxy-3, 5, 6, 3', 5', 6' hexachlorodiphenylmethane as a disinfectant, combined with sodium perborate as an oxidizing agent, tetrasodium pyrophosphate as a scale disintegrating material, sodium lauryl sulfo-acetate as a surface tension lowering agent, tricalcium phosphate as an anticaking agent, oil of peppermint and sodium chloride to make a denture cleanser material.

U.S. Patent No. 5,571,519 teaches a two-layer tablet with a bleaching agent, such as perborate and persulfate, in combination with a flavoring agent. U.S. Patent No. 2,498,343 reports oxidizing agents, such as sodium perborate and sodium percarbonate, in denture cleanser formulations. U.S. Patent Nos. 4,217,234 and 4,256,599 are directed to denture cleansing tablets, containing sodium bicarbonate containing ingredients such as sodium hexametaphosphate, acid disodium pyrophosphate, amidosulfonic acid, ethylenediamine tetraacetic acid, polyethylene glycol, sodium polyacrylate, a surfactant, dye, dibasic calcium phosphate and other optional ingredients.

U.S. Patent No. 5,055,305 is directed to a denture cleansing tablet with an inorganic persalt bleaching agent and an organic peroxyacid bleach precursor in combination with an effervescent system. U.S. Patent Nos. 5,476,607 and 5,015,408 disclose combinations of perborate and persulfate in a denture cleanser. U.S. Patent No.

4,701,223 is directed to a spray-on denture cleanser having a detergent, a chelating agent, such as EDTA, and water.

U.S. Reissue Patent No. 32,771 discloses a combination of perborates, a fluorocarbon, and a phosphate salt. U.S. Patent No. 5,120,460 uses a solution of EDTA in combination with a carboxyvinyl polymer, which thixotropically gels the solution, and an antibacterial agent.

Variants of EDTA have also been used as disclosed in U.S. Patent No. 4,851,146. Enzymes are another material that can be used in denture cleansers as shown in U.S. Patent No. 4,486,330.

U.S. Patent Nos. 3,590,121 and 4,753,792 disclose a chewable effervescent tablet for cleaning teeth. U.S. Patent No. 5,437,856 is directed to oral gels, toothpastes and mouthwashes containing an enzyme, a surfactant, a chelating agent and a fluoride ion source. U.S. Patent No. 5,529,788 discloses a water soluble effervescent tablet for use in water baths of ultrasonic cleaning equipment, containing a proteolytic enzyme and helps ultrasonic equipment clean dental and medical instruments.

Tablets, concentrates and powders can also be used in fields other than oral health care in cleaning systems where water can be supplied independently of the cleaning agent. Cleaning systems that are not designed for oral health care, however, have very different operating constraints, and great care should be taken before adapting such cleaning systems for oral health care use.

Cleaning agents in the form of tablets, concentrates or powders are usually found outside the oral health care field as cleaners for various household uses, i.e., as laundry detergents, dishwashing detergents and hard surface cleaners. There are many formulations for carrying out various cleaning tasks. One example is U.S. Patent No. 5,306,439, disclosing a jewelry cleaner having tetra sodium ethylenediamine tetraacetic acid (EDTA), sodium lauryl sulfate, and an alkyl aryl sulfate in a compressed effervescent tablet. A fabric cleaner is addressed in U.S. Patent No. 4,299,717, which discloses an alkaline detergent for fabric washing containing a detergent surfactant, an

alkali metal carbonate, a pyrophosphate and phosphate builder salts. U.S. Patent No. 5,482,646 discusses a laundry detergent for cold water with a reduced detergent residue.

Tablet or powder cleaning systems may also be used in place of traditional aqueous solution cleaners, as in U.S. Patent No. 4,502,892, which is directed to a pelleted windshield cleaner that is dissolved in water before use. A liquid laundry detergent with enzymes is the subject of U.S. Patent No. 4,169,817, which is directed to a stabilized enzyme system that is derived from *Bacillus subtilis* and that increases the effectiveness of the detergent against proteinaceous and carbohydraceous soils.

Despite the efforts in the oral health care field to develop highly effective denture cleanser systems, the search for ways to maximize the effectiveness of cleaning systems while avoiding the unpleasant consequences of strong chemical agents continues.

SUMMARY OF THE INVENTION

The inventors have surprising found a cleaning material which has strong cleaning properties without the problems caused by strong chemicals, such as oxidants, and does not tarnish or corrode metal surfaces often found in partial dental prostheses and orthodontic appliances.

The invention provides a cleaning material containing a synergistic combination of hexametaphosphate (or a salt thereof) and ethylenediamine tetraacetic acid (EDTA) or a salt thereof in the absence of an oxidizing agent.

The invention further provides a method for cleaning an object or surface comprising the steps of preparing a liquid cleaning material comprising a synergistic combination of hexametaphosphate (or a salt thereof) and ethylenediamine tetraacetic acid (EDTA) or a salt thereof in the absence of an oxidizing agent and bringing the liquid cleaning material in contact with the object, thereby cleaning the object or surface.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The cleaning agent of the invention may be in any form useful for carrying out the cleaning purpose, i.e., aqueous solution, liquid concentrate, powder, tablet or other

solid system. Preferably, the form is a tablet or other solid delivery system, and more preferably, the solid delivery system is an effervescent tablet or powder that is substantially water soluble.

The cleaning agent comprises an effective amount of sequestering / chelating agents to clean the desired material or surface. In the most preferred embodiment, the amount of sequestering/chelating agents in the tablet should be sufficient to cleanse dentures in a moderate volume of water, i.e., in about eight ounces of room temperature water. Cleansing does not contemplate complete and permanent removal of all contaminants from dentures, rather, the formulation should be sufficient to remove a substantial amount of plaque deposits from dentures, partial dentures, orthodontic materials and other oral health care materials formed during ordinary use. Properly applied, however, the invention provides superior plaque removal cleaning efficacy.

The sequestering/chelating agents of the invention comprise a synergistic combination of hexametaphosphate and ethylenediamine tetraacetic acid (EDTA). This synergistic combination of sequestering/chelating agents allows for a more thorough removal of plaque on dentures with conventional levels of hexametaphosphate and EDTA. Alternatively, low amounts of hexametaphosphate and EDTA may be used together to achieve levels of cleaning that would otherwise be unattainable.

The term sodium hexametaphosphate is intended to encompass a broad class of compounds having the general formula $(NaPO_3)_x$, wherein x is an integer. These salts are known as Graham's salt and may comprise a mixture of polymeric metaphosphates. The term is not limited to a specific mixture, nor is it limited to hexamers. The compounds are available commercially and are usually sold as mixtures in powders, flakes or particles. Sodium hexametaphosphate may comprise any amount by weight of a denture cleanser that forms a synergistic combination with EDTA in use. Preferably, however, sodium hexametaphosphate may comprise from about 1% by weight to about 10% by weight of a denture cleanser made in accordance with the invention, preferably from about 2% to about 10% by weight and most preferably from about 5% to about 8% by weight of the denture cleanser.

EDTA, also known as Versene Acid, edetic acid or ethylenediamine tetraacetic acid, is intended to encompass not only the acid but also salts thereof. Such salts may be full or partial salts, may be monovalent or divalent salts and may even be mixed salts. Non-limiting examples of such salts are the sodium, disodium, trisodium and calcium disodium salts of EDTA. The acid itself is preferred in the invention, but the salts thereof, especially the partial salts, and more especially the alkali partial salts of EDTA may also be used. EDTA may comprise any amount of a denture cleanser made in accordance with the invention that makes a synergistic combination with sodium hexametaphosphate. Preferably, however, EDTA comprises from about 1% by weight to about 15% by weight of the denture cleanser, more preferably from about 5% to about 12% by weight and most preferably from about 8% to about 10% by weight of the denture cleanser.

Harsh chemicals, such as bleaching or oxidizing agents, can be avoided using the synergistic combination of the invention. Thus, agents such as perborates, including anhydrous sodium perborates, sodium perborate monohydrates and monopersulfates need not be present in the formulation, especially for denture cleansers. The absence of such agents is a strong advantage of the invention, because these agents can cause tarnish or corrosion on metal surfaces, an important factor for partial denture prostheses and orthodontic materials. In addition, certain flavors, such as citrus and fruity flavors, can be adversely affected by bleaching or oxidizing agents, so conventional denture cleansers have limited flavors available. Oxidants are also strong chemicals that must be carefully handled during manufacturing and transport. The invention works well at any pH, although denture cleansers, especially effervescent tablets, usually operate in a neutral or slightly basic pH. Preferred is a range of from about 6.5 to about 8.5. Higher pH values tend to increase the cleaning effect of the combination of the invention, and there is no reason to expect that lower pH values detract meaningfully from the invention, so the invention is not limited in operation to any specific pH range.

A denture cleanser tablet in accordance with the invention may further comprise known effervescent systems, such as sodium bicarbonate and citric acid, additional

sequestering / chelating agents, binders, surfactants, flavor oils, enzymes, foam stabilizing agents and lubricant systems known in the art. The formulation is preferably compressible at the high speeds necessary for commercial production, yet preferably retains its efficacy and stability. In addition, the formulation of the invention may comprise other agents known in the art for cleaning purposes including, but not limited to, enzymes.

The currently preferred embodiments of the invention are set forth in the following examples. These examples are intended to illustrate the invention and demonstrate its benefits. No limitation on the full scope and spirit of the invention is, however, to be inferred from these examples alone.

EXAMPLES 1-4

Denture cleanser tablets were prepared having the formulations set forth in Table 1. Example 1 is in accordance with the invention, while Examples 2-4 are comparative. The tablets were prepared by adding a granulation of sodium bicarbonate, sodium hexametaphosphate, polyvinyl pyrrolidone and a dye to a mixing vessel. Liquid ingredients, i.e., the fluorochemical surfactant, peppermint oil and spearmint oil, were added to the vessel, and the resulting powder blend was mixed. The remaining solid ingredients, EDTA, citric acid, sodium lauryl sulfoacetate, sodium perborate and sodium benzoate were then added to the mixing vessel, and the resulting blended powder was compressed into tablets using a Stokes tablet press with a compression force of about 8-10 tons.

Example 1 contains sodium hexametaphosphate and EDTA in synergistic amounts. Example 2 contains sodium hexametaphosphate and disodium EDTA, but not enough EDTA is present to establish a synergistic cleaning effect with the sodium hexametaphosphate. Example 3 contains EDTA but no sodium hexametaphosphate, and Example 4 contains sodium hexametaphosphate but no EDTA.

Plaque removal analyses were conducted in accordance with the t test as follows: sterilized acrylic slides were placed in Todd Hewitt broth medium with pooled human saliva and incubated overnight for plaque growth. Some slides were set aside as controls

and stained using a disclosing dye solution. Reflectance readings were taken on these slides to establish controls. Other control slides were cleaned before staining. Reflectance readings were also taken on the cleaned slides as well as on unstained slides.

Slides containing plaque were then placed in a denture bath comprising a tablet from Examples 1-4 in warm water. After 5-10 minutes, the slides were removed, and plaque was disclosed with a disclosing dye solution. The percent cleaning was calculated from reflectance readings on these slides when compared to controls using computerized statistical analysis (a At test@) that has a 95% confidence level. The results are summarized in Table 2. Plaque removal of Formula 1 was statistically significant at the 95% confidence level according to the t test when compared with the comparative examples.

It will be apparent to those skilled in the art that various modifications and variations may be made in the apparatus or procedure of the invention without departing from the scope or spirit of the invention.

Table 1 -- Formulations of Examples 1-4				
	Weight percent			
Ingredient	Ex. 1	Ex. 2	Ex. 3	Ex. 4
Sodium Hexametaphosphate	6.93	9.02	0	4.75
Versene Acid (EDTA)	9.60	0	9.60	0
Disodium EDTA	0	0.93	0	0
Sodium Bicarbonate	39.27	9.15	46.32	26.90
Soda Ash, Light	10.00	12.90	10.00	8.10
Citric Acid	16.00	15.14	16.00	18.17
Fluorochemical Surfactant	0.05	0	0.05	0.05
Proteolytic Enzyme	1.50	1.61	1.50	0
Peppermint Oil	0	0	0.30	0.80
Spearmint Oil	0.40	0.40	0	0
Sodium Lauryl Sulfoacetate	4.00	0.93	4.00	4.00
Sodium Sulfate	0	11.65	0	0
Potassium Monopersulfate	0	22.20	0	25.00
Sodium Perborate	0	13.20	0	5.00
Sodium Stearate	0.50	0	0.50	0.50
Polyethylene Glycol 8000	5.00	0	5.00	2.88
Sodium Benzoate	5.00	0	5.00	2.88
Polyvinylpyrrolidone	1.71	2.85	1.71	0.90
FD&C Blue No. 2	0.02	0.01	0.02	0.03
FD&C Yellow No. 5	0.02	0.01	0	0.04
Total	100.00	100.00	100.00	100.00

Table 2 -- Percent Plaque Removal, Examples 1-4				
Test	Ex.1	Ex. 2	Ex. 3	Ex. 4
1	82%	19%	20%	69%
2	75%	20%	7%	--
3	67%	11%	--	--

What is claimed is:

1. A cleaning composition free of peracids and salts thereof,comprising a synergistic combination of a hexametaphosphate and EDTA.

2. The cleaning composition of claim 1, wherein said alkali hexametaphosphate is sodium hexametaphosphate.

3. The cleaning composition of claim 1, wherein said EDTA is selected from the group consisting of monovalent and divalent salts of ethylenediamine tetraacetic acid.

4. The cleaning composition of claim 3, wherein said EDTA is an alkali ethylenediamine tetraacetic acid salt.

5. A denture cleanser composition substantially free of peracids or salts thereof,comprising a synergistic combination of a hexametaphosphate and EDTA.

6. The denture cleanser composition of claim 5, wherein said hexametaphosphate is sodium hexametaphosphate.

7. The denture cleanser composition of claim 5, wherein said ethylenediamine tetraacetic acid is selected from the group consisting of monovalent and divalent salts of EDTA.

8. The denture cleanser composition of claim 7, wherein said EDTA is an alkali ethylenediamine tetraacetic acid salt.

9. A method for cleaning materials comprising the steps of preparing a cleaning liquid free of peracids and salts thereof comprising a synergistic combination of sodium

hexametaphosphate and ethylenediamine tetraacetic acid, and applying said cleaning liquid to said material for a time sufficient to clean said material.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/14878

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A 61K 7/16
US CL :424/49
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. : 424/49

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)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3,483,033 A (CASEY) 09 December 1969, entire document.	1-9
X	US 3,751,372 A (ZECHER) 07 August 1973, entire document.	1-9
X	US 4,344,932 A (GORDON) 17 August 1982, entire document.	1-9
X	US 4,357,318 A (SHAH et al.) 02 November 1982, entire document.	1-9
X	US 4,395,346 A (KLEIST) 26 July 1983, entire document.	1-9
X	US 4,747,880 A (BERRIDO et al.) 31 May 1988, entire document.	1-9
X	US 4,762,638 A (DOLLMAN et al.) 09 August 1988, entire document.	1-9
X	US 5,460,802 A (ASAMI) 24 October 1995, entire document.	1-9

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

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INTERNATIONAL SEARCH REPORT

International application No.
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,217,234 A (KRISP et al.) 08 December 1980, entire document.	1-9
X	US 4,256,599 A (KRISP et al.) 17 March 1981, entire document.	1-9
X	US 3,821,117 A (BREECE et al.) 28 June 1974, entire document.	1-9
X	US 3,793,211 A (KOHLHEPP et al.) 19 February 1974, entire document.	1-9