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GERMICIDAL DENTAL PAD

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This application is a continuation-in-part based on application Serial No. 125,391, filed July 20, 1961, now abandoned.

This invention relates to dental cushions for use with artificial dentures in order to compensate for looseness of fit of the denture, due in the main to gum recession.

The primary object of the present invention is to provide a dental cushion such as that described in our prior Patents No. 2,664,631, No. 2,897,592, and No. 2,897,593 in which the fabric is impregnated with a wax-plasticizer-germicide composition which renders the cushion softer and more pliable and hence more adaptable or conformable to the denture.

The cushions of our previous patents have proved to be highly successful and are presently in wide use. The cushions are not only soft and pliable but are also adaptable and conformable to the denture. The cushion of the present invention likewise possesses these properties.

Moreover, a satisfactory cushion should possess a requisite tackiness and should be resistant to fraying, crystallization and flasking at body temperautre. In addition it should possess a satisfactory taste, color and appearance.

It has been noted, however, that the prior cushions sometimes exhibited an unpleasant odor upon prolonged or repeated contact and use in the mouth of the wearer. This odor is due to the ordinary bacteria which is usually to be found in the mouth.

It is accordingly an object of the present invention to provide a dental cushion which possesses the desirable properties of previous dental cushions and which in addition will resist the effect of mouth bacteria and retain a pleasant taste and odor in spite of of repeated and protracted use and contact in the user's mouth.

Still another object of the present invention is to provide a dental cushion in which the fabric is impregnated with a wax-plasticizer-germicide composition which renders the cushion softer and more pliable and hence more adaptable or conformable to the denture.

Another object of the invention is to provide a dental cushion of the character described which is more adherent to the denture because it is tackier. Yet, it is not so tacky as to prevent separation of the cushions one from another when they are nested in packaged form.

A further object of the invention is to provide a dental cushion of the character described which is not only pliable but which is also unusually resistant to fraying and to crystallization or flaking.

And yet a further object of the invention is to provide a novel wax-plasticizer-germicide composition per se which is flake-resistant and pliable at body temperatures and unusually durable, and hence can be applied to fabrics or other fibrous materials for use other than as dental cushions.

The present invention is applicable to dental cushions of varying shapes and especially to the shape and construction as set forth in Patent No. 2,664,631. Hence special drawings are not deemed necessary for inclusion herein.

The aforementioned objects and other objects of the invention are obtained by providing a composition comprising a water-insoluble wax which is combined with a minor amount of a fat or oil plasticizer comprising saturated, unsaturated and partly saturated animal, vegetable and synthetic fats and oils, and an associated germicidal material.

The germicidal material is present in a quantity such that the final composition exhibits the necessary germicidal characteristics. The germicidal material is added to a sufficient quantity of the fat or oil plasticizer, and the resulting mixture is then incorporated into the wax which has been previously liquefied under conditions of heat. In this manner, a composition is prepared which yields a satisfactory product upon solidification at room temperature. This sequence of preparation is usually preferable as the germicidal material is generally soluble in the plasticizer, and the resultant mixture soluble in the wax.

The germicidal material is preferably one which is soluble to the extent necessary in the plasticizer employed and whereby the resultant mixture will be compatible with the wax so that the resultant product exhibits the desired properties including the requisite germicidal activity.

The germicidal compound or composition may be diaphene (ASC4 Brand manufactured by the Stecker Company, Inc., of Ridgewood, New Jersey), acriflavin, chlorophenyl propanol (Millmaster), penicillin, Aureomycin, streptomycin, Terramycin and neomycin, etc.

Another germicidal compound which is used in connection with the present invention is hexachlorophene, a compound sold under the trademark G–11. It is known chemically as 2,2′ - methylenebis - 3,4,6 - trichlorophenol; bis(3,5,6-trichloro-2-hydroxyphenyl)methane; or 2,2′-dihydroxy-3,6,3′,5′,6′-hexachlorodiphenylmethane.

The germicidal compound or composition should be present in such a proportion that the resultant mixture or solution exhibits germicidal properties. The lower limit of the germicidal material is about 0.01% by weight of total solids although somewhat lower amounts may be employed depending upon the germicidal activity desired in the final product.

The upper limit of the germicidal material is also dependent upon the desired germicidal properties of the finished product. An upper limit of .02% by weight of total solids has proved to be satisfactory under severe test conditions although still greater amounts may be employed and is limited only by considerations of compatibility with the other components.

The germicidal material is preferably placed in solution in the plasticizer and the resulting mixture placed in solution with the wax. Heat or solvents may be employed where necessary. In this manner the germicidal material is uniformly and thoroughly distributed throughout the wax.

Where the germicidal material is not soluble in the plasticizer, the germicidal material may be incorporated in the wax and the plasticizer then added to the resultant mixture. With this sequence of preparation, the final product may be a dispersion. Such a product is still satisfactory so long as the desired germicidal properties are exhibited.

The fat or oil plasticizer is present in such proportion as to give the requisite softness, pliability and tackiness and is preferably present in a proportion of about 2% by weight of total solids. In the preferred embodiments, this amount of plasticizer is sufficient to dissolve the germicidal material.

The fat or oil plasticizer is a saturated, unsaturated or partly saturated animal, vegetable or similar synthetic fat or oil basically comprising a mixture of fatty acids and fatty acid esters (usually triglycerides). These fats and oils are usually subdivided into three groups: solid (mainly stearin), semi-solid (mainly palmitin) and liquid (mainly olein). Animal fats and oils which may be used are beef, chicken and mutton fats and lard.

Vegetable fats and oils are generally preferred because of superior taste and odor characteristics. Examples of satisfactory vegetable materials are corn oil, cottonseed oil, peanut oil, olive oil, flaxseed oil, perilla, oiticica and mixtures thereof. In addition certain hydrogenated materials known as "Crisco" and "Spry" have proved to be satisfactory.

Any wax having the desired minimum melting point may be employed in the wax-plasticizer-germicide composition but we have found that the best wax is a 50–50 mixture of Atlantic Refining Company 131 wax and Cities Service Pacemaker D–30.

Atlantic 131 wax is a low melting, fully refined paraffin wax having the following physical properties:

Melting point, ° F. (AMP)	127
Saybolt color (ASTM D–156)	+30
Durometer hardness @ 95° F.	0
Oil percent (ASTM D–721)	0.6
Penetration @ 100° F. (suggested TAPPI Semi-Muro Method)	140
Taste and odor	None

Cities Service Pacemaker D–30 is a low melting refined microcrystalline wax having the following physical properties:

Melting point, ° F. (AMP)	128–130
Saybolt color, min.	28
Tensile, min. @ 73° F. p.s.i.	300
Heat stability min. @ 180° F. days	10
Oil content, max. percent	0.25
Carbonizable substance	Pass
Taste and odor	Nil

Although the fat or oil plasticizer is preferably present in a proportion of 2% by weight of total solids, the percentage may vary depending upon the degree of softness and pliability desired in the finished product. In employing the plasticizer in proportion less than 2%, it is preferable that enough plasticizer still be employed so as to completely dissolve the germicidal material. If this is not done, it will be necessary to disperse the germicidal material in the wax. In this connection a **50–50** mixture of Atlantic **131** wax and Cities Service **D–30** as well as other varied blends may be employed.

In use, the plasticizer and the germicidal material are preferably initially combined and the resulting mixture added to the melted wax with constant agitation and heat where necessary until thorough dispersion or solution is obtained. A relatively thin piece of cloth, such as flannel, is dipped in the composition while the latter is still hot and under continuous agitation. The coated cloth while hot is conveyed between plates which remove the excess to the desired coating thickness. The coated cloth is then air cooled until the composition hardens. The excess composition may be manually removed by rolling the cloth while it is impregnated with the hot composition. The cloth is then stamped, cut or otherwise formed into U-shaped upper and lower denture cushions as illustrated in Patent No. 2,664,631. The cushions are then nested and packaged for storage and shipment.

The final product is a cushion which readily conforms

to the denture with good adherence thereto while possessing, at the same time, unusual resistance to flaking, fraying and disintegration in the mouth. Attention is called to the fact that while the cushions are sufficiently tacky to adhere to the dentures, they are not so tacky as to adhere one to another during nesting.

The following examples relating to the preparation and testing of various compositions and pads within the scope of the present invention is merely exemplary thereof and is not to be construed in a limiting manner.

Example I

The following tests were run using corn oil as an exemplary fat or oil plasticizer:

The Alantic and Cities Service waxes used herein are as previously indicated. The diaphene employed is Stecker Company ASC4. The B–16 employed is Santicizer B–16 disclosed in Patent No. 2,897,593 for use as a plasticizer for wax. B–16 is the trade designation of butyl phthalyl butyl glycollate.

The following were employed.

Mix #1:
124 gms. Atlantic
123 gms. Cities Service
6 gms. corn oil, 0.05 gm. diaphene (0.02%)
No B–16

Mix #2:
124 gms. Atlantic
123 gms. Cities Service
6 gms. corn oil, 0.05 gms. diaphene (0.02%)
3 gms. B–16

Mix #3:
124 gms. Atlantic
123 gms. Cities Service
0.05 gm. diaphene (0.02%) added to paraffin
3 gms. B–16
No corn oil

Mix #3A:
247 gms. Atlantic paraffin only
0.05 gm. diaphene (0.02%) added to paraffin
3 gms. B–16
No corn oil

Mix #4:
124 gms. Atlantic
123 gms. Cities Service
3 gms. corn oil, 0.025 gm. diaphene (0.01%)
No B–16

Mix #5:
124 gms. Atlantic
123 gms. Cities Service
3 gms. oil, 0.025 gm. Diaphene (0.01%)
3 gms. B–16

Mix #6:
124 gms. Atlantic
123 gms. Cities Service
0.025 gm. diaphene added to paraffin (0.01%)
3 gms. B–16
No corn oil

The foregoing mixtures including a control preparation were placed in tubes which were in turn placed in an autoclave, heated to 250° F. for 15 minutes, cooled to 98° F. and then inoculated with one loop each of a 24 hour broth culture *Staphylococcus aureus.*

Other well known test cultures are:

(a) *M. pyogenes aureus*
(b) *M. pyogenes aurgus*
(c) *M. pyogenes varians aureus* (F.D.A. Strain No. 209)

The test culture is embodied in a test broth prepared in accordance with the standard F.D.A. procedure. The test culture has a 24 hour broth culture, sub-cultured at least six times prior to the test. The inoculated loop employed is a 4 mm. I.D. loop of platinum wire U.S. No. 23 B. & S. guage.

The test culture, prior to use, must be tested for resistance to phenol and must resist 1–80 phenol for 5 minutes exposure and 1–90 phenol for 15 minutes' exposure.

The results of the tests are as follows:

	Observations		
	24 Hrs.	40 Hrs.	70 Hrs.
Control	++	+++	+++
Mix #1	–	–	–
Mix #2	–	–	–
Mix #3	–	–	–
Mix #3A	–	–	–
Mix #4	–	–	–
Mix #5	–	–	–
Mix #6	+	++	+++

– No growth visible.
+ Fair growth.
++ Moderate growth.
+++ Prolific growth.

Cloth such as flannel as previously described of a substantially U-shape was dipped in all of the foregoing mixes including the control to form pads and antiseptic test repeated. Substantially the same results were obtained. Where no corn oil was employed (Mixes 3, 3A, and 6), the diaphene was first incorporated in the wax and the B–16 added thereafter.

The foregoing tests establish that a product of satisfactory color, taste, softness, pliability and tackiness can be prepared which will also exhibit satisfactory germicidal activity.

These pads were checked several weeks of actual use in the mouth and the test pads were found to possess the essential properties of a newly prepared pad.

Example II

The tests of Example I were run using cotton seed oil, peanut oil and olive oil, and satisfactory results similar to those of Example I were obtained. These pads were checked after several weeks of actual use in the mouth and the test pads were found to possess the essential properties of a newly prepared pad.

Example III

Mixes Nos. 1 and 4 of Example I were employed using lard, chicken fat, "Crisco" and "Spry" as the plasticizer in place of corn oil. The diaphene readily dissolved in the plasticizer upon agitation and heat, and the resultant mixture readily dissolved in the wax. The final products when applied to flannel exhibit satisfactory germicidal properties under antiseptic testing. The use of animal fats and oils is, however, restricted because these materials possess an inherent taste or flavoring.

Example IV

Example I was repeated using .01 and .02% by weight acriflavin, 25 p.p.m. Aureomycin, .01 and .02% by weight penicillin and chlorophenyl propanol. Antiseptic tests on these compositions were also quite satisfactory.

It is further to be noted that a control was run in conjunction with tests of Examples II, III and IV. The control indicated that the normal growth of bacteria under test conditions is prolific.

Example V

Example IV was repeated using .01, .02, .05% by weight hexachlorophene. Antiseptic tests on this formulation yielded excellent results. A control was run in conjunction with the tests of this example, and indicated that the normal growth of bacteria under test conditions is prolific for the control. However, the formulations containing the hexachlorophene exhibited essentially an absence of bacteria growth.

Obviously many modifications and variations of the present invention are possible in the light of the above teachings. It is, therefore, to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.

What is claimed as the invention is:

1. A cushion for an artificial denture comprising a relatively thin layer of cloth of a substantially U-shape, and impregnated with a composition including a water-insoluble paraffin wax which does not melt at body temperature a fat or oil plasticizer and an effective amount of a germicidal material compatible with said wax and said plasticizer.

2. The invention of claim **1** wherein said fat or oil plasticizer is a vegetable oil.

3. The invention of claim **2** wherein said vegetable oil is selected from the group consisting of corn oil, cotton seed oil, olive oil and peanut oil.

4. The invention of claim **2** wherein said germicidal material is selected from the group consisting of hexachlorophene, diaphene, acriflavin, chlorophenyl propanol, penicillin and Aureomycin.

5. A cushion for an artificial denture comprising a relatively thin layer of cloth of a substantially U-shape and impregnated with a composition including a major portion of water-insoluble paraffin wax which does not melt at body temperature, two per cent by weight of total solids of corn oil and 0.02 percent by weight of total solids of diaphene.

6. A cushion for an artificial denture comprising a relatively thin layer of cloth of a substantially U-shape, and impregnated with a composition including a major portion of water-insoluble paraffin wax which does not melt at body temperature, two percent by weight of total solids of corn oil and 0.02 percent by weight of total solids of hexachlorophene.

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