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Chewable dental product

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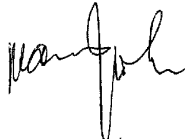
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Abstract

A chewable dental composition of compressed fine solid particles of non cariogenic food or other edible material in a tablet, confection, stick or small bar shape that is convenient and easy to chew before and after every meal or snack displacing previously trapped food between teeth and inside deep pits and fissures in grooves on chewing surfaces under chewing pressure and is hard to displace helping prevent any food being trapped and any carbohydrate changed to acid while eating and helping saliva displace trapped food, neutralise acid, and repair demineralised tooth after eating.


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CHEWABLE DENTAL PRODUCT

This invention relates to a chewable dental care product.

Background to the Invention

- 5 Many foods and confections are trapped inside pits and fissures in teeth and in gaps between teeth to cause acid attack and eventually develop cavities. Almost all cavities occur between teeth and inside pits and fissures where the toothbrush cannot reach food and plaque to prevent sugar being changed to acid, which causes demineralisation of tooth resulting in cavities.
- 10 Co pending patent application WO 2004/039282 discloses a dental foam which can remove food and plaque from gum margins more efficiently than a toothbrush, or dental floss because it is able to force saliva and dental agents inside pits and fissures to prevent acid attack. However a cleaning agent is preferably used with this chewable strip. Conventional toothpaste is not effective with this form of
- 15 cleaning because it does not persist long enough in the mouth and cannot form a barrier or sealant on the teeth.
- Alternatives to conventional tooth paste have been previously proposed. Active agents such as antibacterial agents have been incorporated into a long lasting tablet or jube for delivery to the oral cavity.
- 20 USA patent 4157386 discloses a soft chewable lozenge which includes a fluoride source, a starch adhesive, a polishing agent a viscosity agent and artificial sweeteners. The sticky material is hard to remove and encourages better brushing habits.
- USA patent 4828820 incorporates an abrasive material into chewing gum.
- 25 Colgate USA patent 4814164 discloses a sorbitol and carrageenan lozenge containing zinc and mint and deposits a barrier on the teeth to prevent tartar buildup.
- USA 5156845 discloses a dry mouth lozenge of similar formula to 4157386.
- USA patent 59809868 discloses the application of a barrier material to teeth
- 30 including pits and fissures. The material is not applied by chewing but rather by use of an applicator.
- USA 6177097 discloses a sucking tablet containing isomalt, carbonate, citrate and phosphates.

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It is an object of this invention to modify toothpaste formulae to produce a convenient solid chewy tablet that will seal pits and fissures or otherwise inactivate bacteria in plaque before eating. A compact seal of relatively insoluble particles prevents sugar and starch being changed to acid while eating.

- 5 It is another object of this invention to produce a convenient chewy tablet to penetrate and help remove trapped food from pits and fissures after eating.

Brief Description of the Invention

- To this end the present invention provides a method of cleaning teeth which consists of chewing a composition of fine compressed particles which
- 10 includes a combination of a carrier material which is not readily soluble or dispersible in the oral cavity and a non foaming cleansing agent so that the composition is dispersed in the oral cavity and penetrates into deep cracks and fissures in the teeth.

- In another aspect this invention provides a dental cleaning composition which
- 15 includes

- a) a chewable carrier material that is not a gum or foam and which is not readily soluble or dispersible in the mouth
 - b) a cleansing agent which is non foaming
 - c) optionally a barrier material
- 20 d) optionally an anticariogenic agent, a mineralising agent or antibacterial agents.

- This invention is partly predicated on tests which show that a toothbrush, toothpaste, mouthwash, chewing gum, can not remove food or plaque from inside
- 25 pits and fissures. In assessing the efficacy of various materials to provide sufficient force to the saliva to force it quickly into the deep cracks and fissures a glass model of a fissured tooth has been studied using food dye to indicate penetration. This methodology has reduced the time needed to ascertaining if a procedure will benefit teeth from years (based on clinical trials) to a matter of hours. The glass
- 30 model shows that a solid chewable tablet formed a saliva mix on the outside of the

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bolus which forced the saliva mix between teeth and inside pits and fissures displacing other foods.

The non gum carrier material used as a binder may be selected from gelatin, sodium caseinate, methyl cellulose, milk powder or finely powdered treated foods
5 such as nuts cocoa or coffee that have been de-oiled, crushed and roasted. The cleaning agent may be any abrasive agent such as dental grade silica, feldspar, calcium carbonate, calcium phosphate(hydroxyapatite), instant coffee or an anticariogenic agent such as a mixture of acid neutralizing compounds or an anti bacterial agent. The particle size of all components in the formulation need to be
10 small enough to fit into the cracks and fissures of teeth and are generally from 0.01mm to 0.5mm or preferably finer.

The tooth cleaning composition of this invention can be used in association with the open cell foam strips which are the subject of patent application WO 2004/039282.

15 The composition of this invention omits the usual foaming agent used in conventional toothpastes. This invention is partly predicated on the discovery that the foaming agent ensures that the paste does not persist for sufficient time to ensure that the active agent is delivered into deep pits and fissures.

As well as an active agent the composition may incorporate barrier materials
20 which are non-cariogenic and act as a barrier to cariogenic food stuffs. Even foods that tend to stick like cocoa or cheese are hard to remove even by using the dental foam strip of patent application WO 2004/039282 alone. Some of these food like materials, with no sugar or starch content and other materials like calcium carbonate powder, can be used as barrier foods or materials that can seal pits and
25 fissures preventing acid being formed while eating.

The composition is best presented as a chewable jube that can be forced into pits and fissures and will remain in the mouth and on the teeth for a sufficient time to penetrate the pits and fissures. A range of formulas are conceivable.

Anti bacterial agents such as chlorhexidine may be used as part of a tablet to
30 inhibit the action of plaque bacteria on gums and prevent sugar and starch being changed to acid.

Many foods or materials such salts of calcium including solids from conventional toothpaste formulae, that can be powdered and compacted into a chewy tablet

- under a pressure of one or two tonnes, may be used as components in this invention. Chewy tablets form a thick bolus with an outer saliva mix that breaks up food trapped inside pits and fissures under chewing pressure. Soluble tablets are better for cleaning teeth after eating while insoluble tablets are better for sealing
- 5 fissures.
- Chewy fibre dental foam, enhances delivery of agents to pits and fissures and solid agents achieve better penetration inside pits and fissures than liquid agents utilising foam assistance.
- The new dental foam disclosed in WO 2004/039282 has been designed with outer
- 10 cup shaped half cells that easily fill with any saliva mix, which is expelled under chewing pressure and forced inside pits and fissures. This long acting chewy foam fibre bolus removes most foods even hard to remove barrier type foods and sealants after eating and helps saliva neutralise acid and repair demineralised teeth. A soluble tablet breaks up the barrier helping removal.
- 15 After food and stain is removed it is often desirable to prepare the tooth surfaces for the mineralisation process which occurs when chewing stops stimulation of saliva flow. Dentists often prepare tooth surfaces with an acid like citric acid, which can be incorporated in a tablet. At that point it is suitable to have a mineralising tablet like sodium fluoride while still chewing the same dental foam strip. A
- 20 combination of acid and fluoride may be used. The dental foam strip and tablet system of this will allows greater flexibility to develop the most appropriate formulation with a range of active ingredients, flavours, etc. that can be added according to the specific purpose, consumer interest and dentist advice.
- The tablet can be bulked with calcium salts or sugarless sweeteners such as xylitol
- 25 or breath fresheners such as thymol or a combination of agents. However it is the convenience of chewy tablets that can function as a convenient, versatile, confection like version of toothpaste, mouthwash and fissure sealant. Tablets help remove food after eating, prepare teeth for mineralisation and assist mineralisation and toughening of tooth surfaces particularly when used with a dental foam strip.
- 30 Tablets or suitable confection are a better and more flexible method than toothpaste for delivering dental agents or for cleaning teeth even without a toothbrush or dental foam; even when incorporated in or around the foam. The many varieties of toothpaste can be replicated as chewable tablets by omitting the

foaming agent and providing a suitable non gum carrier material to suit the many tastes of consumers or to deliver the active ingredients required by the dentist. Chewing breaks the tablet into small particles which are held together with the binding agent till significantly diluted with the saliva mix, at which time it can be swished around teeth like a mouth wash.

Detailed Description of the invention

The present invention can be formulated for a variety of uses.

The following examples are chewable tablets for use before and after eating as indicated. These compositions may be used alone or in association with the open cell foam strips which are the subject of patent application PCT/AU2003/01411.

Example 1 – Sealant compositions for use prior to eating

These have the object of

1. acting as a sealant that prevents sugar contacting tooth enamel where plaque bacteria change sugar to acid, and/or
2. an antibacterial agent to inhibit the activity of plaque bacteria changing sugar to acid.

Cocoa powder tableted under one or two tonne pressure forms a chewy tablet that crumbles under chewing pressure forming an outer salivary mix that is forced inside pits and fissures. However the chewy bolus disintegrates quickly. The bolus holds together when a binding agent like sodium caseinate or gelatine is used.

This combination ensures that a good sealing cover is obtained in tooth pits and fissures. When this tablet is used in combination with chewable foam strip the barrier medium is packed inside tooth grooves forming a more lasting seal that is harder to remove. Cocoa is bitter and a sweetener and perhaps a flavour like Xylitol and peppermint make the tablet more acceptable before eating.

Cheese is another effective barrier food, which may be made into a tablet using powdered milk and freeze dried starter medium. This is also a binding medium but it may include gelatine or sodium caseinate or other suitable binder to develop a more stable chewy bolus.

Another suitable sealant formula consists of calcium hydroxide or carbonate compressed at around one tone pressure into a chewy relatively insoluble tablet to ensure a range of particle sizes to fit inside and seal pits and fissures.

calcium hydroxide or calcium carbonate 80%

5 gelatine or sodium caseonate 17%

Sweetner selected from Xylitol or sodium cyclamate, Saccharine, Aspartame (Nutrasweet™), Sucralose (Splenda™) 3%
peppermint flavour 0.2%

10 **Example 2** - an antibacterial tablet for use prior to eating.

Any powdered antibacterial agent like chlorhexidine can be bulked with a suitable salt like calcium carbonate, sweetener like saccharine, and a binding agent to improve the chewy bolus, then compressed in a tableting machine at one to two tonne.

15 Chewing this tablet before eating forces the antibacterial agent into pits and fissures, between teeth and around gum margins to inactivate most bacteria that cause acid attack or gum disease.

A suitable formula is:

Formula 2A

20 calcium hydroxide or calcium carbonate 80%

gelatine or sodium caseinate 17%

Sweetner selected from Xylitol or sodium cyclamate, Saccharine, Aspartame (Nutrasweet™), Sucralose (Splenda™) 3%
peppermint flavour 0.2%

25 chlorhexidine gluconate 0.1%

Formula 2 B

Sodium Bicarbonate 80%

gelatine or sodium caseinate 18%

30 Thymol 0.08%,

Eucalyptol 0.1%,

Methyl Salicylate 0.07%,

Menthol 0.05%.

Formula 2C

Sodium bicarbonate 80%

Gelatine 18%

Flavour and sweetener 1.18%

5 chlorhexidine gluconate 0.12%

Example 3 - after eating cleaning tablet

The purpose of the after eating tablets is to remove food from teeth particularly from inside pits and fissures.

- 10
1. Prepare tooth surfaces for mineralization or
 2. Provide a matrix of nuclei inside pits and fissures for mineralization or
 3. Deliver agents like fluoride or Recaldent™ to aid saliva mineralisation.

- 15
- The cleaning agent may be any solid fine soluble powder in a tablet form that breaks into various size particles and mix with saliva under chewing pressure. Particles the same size or smaller than the fissure are forced inside pits and fissures to displace trapped food. Soluble particles like sodium bicarbonate dissolve in saliva after displacing food and are easy to remove compared to insoluble particles. An abrasive agent such as dental grade silica, feldspar or
- 20
- calcium carbonate may be used or an anticariogenic such as a mixture of acid neutralising compounds or an anti bacterial agent.

A suitable dental cleaning composition includes powders compressed into a tablet:

Formulation 3A

- 25
- | | |
|---|-----|
| sodium bicarbonate or instant coffee | 89% |
| Binder powder like solid sodium caseinate | 8% |
| PureSweet (sugarless powdered sweetener) or saccharin | 2% |
| Peppermint crystal powder | 1% |

30 Formula 3 B

- | | |
|---------------------------|-----|
| Sodium bicarbonate powder | 65% |
| Instant Coffee | 20% |
| sodium caseinate | 15% |

Formula 3 C

	Sodium bicarbonate powder	80%
	peppermint	2%
5	Pure Sweet tm (non sugar sweetener)	2%
	Soluble Binder sodium caseinate	16%

Formula 3 D

	calcium hydroxide	40%
10	sodium bicarbonate	40%
	Flavour	2%
	PureSweet	2%
	gelatine	16%

15 Formula 3 E

	Sodium bicarbonate	77%
	Sodium caseinate	20%
	Flavour (spearmint) and sweetner (PureSweet)	3%

20 Formula 3 F

Any toothpaste preferably without foaming agents can be mixed with binding agents such as sodium caseinate or gelatine to tabletise or confectionise the toothpaste into a chewy format that is easy to use and can effectively penetrate pits and fissures to clean teeth after eating.

25	Tooth paste formula	50%
	gelatine	50%

Formula 3 G

	Tooth paste	50%
30	sodium bicarbonate	10%
	sodium caseonate	40%

Example 4 –

a tablet that prepares the tooth surface for mineralisation.

The purpose of these after eating tablets is to:

1. Prepare tooth surfaces for mineralization or
- 5 2. Provide a matrix of nuclei inside pits and fissures for mineralization or
3. Deliver agents like fluoride or Recaldent to aid saliva mineralisation

Acid is usually used by dentists to prepare tooth surfaces for mineralisation.

- Powdered citric acid crystals can be combined with a powdered filler like calcium carbonate, which can also be a sealant before eating however it is used here to
- 10 form a matrix framework of nuclei for the mineralising process that may build a permanent seal inside a fissure or even fully remineralise a small cavity.

A suitable formulation is:

Formula 4A

	Powdered Citric acid crystals	1g
15	Powdered ascorbic acid	50mg
	Powdered sodium bicarbonate	0.5g
	Powdered sodium caseinate	0.45g

Formula 4 B

20	Citric acid	70%
	Sodium bicarbonate	30%

Formula 4C

	Citric acid	60%
25	Sodium bicarbonate	20%
	Calcium hydroxide	20%

Formula 4D

	Citric acid	60%
30	Sodium bicarbonate	20%
	Calcium Phosphate	20%

After eating the saliva flow decreases and calcium salts are deposited on teeth more so when food and bacteria are present on teeth to act as nuclei for deposits

which form the calculus or tater that dentists scrape off teeth. However fluoride or Recaldent™ (caseinate) tablets improve mineralisation of tooth surfaces. Tablets contain up to 1 mg of fluoride for adults and 0.1mg of fluoride for children combined with a filler like calcium carbonate and a binder like sodium caseinate. It is possible achieve optimal dietary and topical fluoride delivery for any particular community.

A matrix of nuclei tablet. A relatively insoluble powder such as calcium salts in a tablet that forms a matrix of nuclei inside pits and fissures to aid mineralisation.

10 **Formula 4E**

Calcium hydroxide or calcium carbonate	90%
Sodium caseinate or gelatine	7%
Xylitol or sodium cyclamate, Saccharine, Aspartame (Nutrasweet™),	
15 Sucralose (Splenda™)	3%
Peppermint	0.2%
chlorhexidine gluconate	0.1%

Formula 4F

20 Calcium hydroxide, calcium phosphate or calcium carbonate	70%
Sodium caseinate or gelatine	27%
Xylitol or sodium cyclamate, Saccharine, Aspartame (Nutrasweet™),	
Sucralose (Splenda™)	3%
25 Peppermint	0.2%
sodium fluoride	0.1% up to 1mg for adults

Formula 4G

Calcium carbonate	40-50%
30 sodium caseinate	40-50%),
peppermint	1-4%
a mineralising fluoride agent	0.1-0.8%
or sodium fluoride	0.15%,

This contains about 1100 parts per million of fluoride, approximately 1.1mg of fluoride per gram.

Formula 4H

- 5 Calcium hydroxide, calcium phosphate or calcium carbonate 70%
 Sodium caseinate or gelatine 27%
 Pure Sweet-8 powder 2%
 An outer coating of Polyisobutylene and sodium bicarbonate 1.9%
 sodium fluoride 0.1% to 1mg
- 10 This formulation may also include a flavour that fades with chewing as a signal to stop chewing so fluoride is not washed out of fissures after being forced in

Example 5

- A diagnostic formulation to be used in conjunction with dental x rays to highlight potential cavities in pits and fissures consists of :

Formula 5A

- Sodium caseinate 50%
 Barium Sulphate 50%
 20 peppermint 1-4%

From the above it can be seen that the present invention provides a composition which enable teeth to be cleaned or protected simply by chewing without the need for water and foaming compositions to obtain dispersal of the cleaning agents.

- 25 Those skilled in the art will realize that this invention can be practiced in a range of embodiments without departing from the essential teaching of the invention.

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CLAIMS

1. A convenient method of cleaning teeth, which consists of a chewable compressed non-cariogenic composition of fine solid particles in tablet, block, stick or bar form that readily disintegrate under chewing pressure and are compacted, trapped or penetrate between teeth and into deep cracks and fissures in teeth, displacing previously trapped food.
2. A method as claimed in 1 in which the composition also includes a
5 barrier material, which seals the deep cracks and fissures.
3. A method as in claim 1 in which the composition also includes one or more of a neutralizing agent, an abrasive agent, an antibacterial agent, or a remineralisation agent.
10
4. A method as in claim 1 where the fine solid particles are derived from toothpaste formulae preferably without foaming agents.
5. A method as in claim 1 where the fine solid particles are derived from
15 relatively insoluble salts that are difficult to displace.
6. A method as in claim 1 where the fine solid particles are derived from soluble salts that displace trapped food before dissolving.
- 20 7. A method as in claim 1 where the fine solid particles are derived from a food.
8. A method as in claim 1 of displacing previously trapped food from
25 between teeth and inside pits and fissures in grooves on chewing surfaces with a chewable dental product of fine non cariogenic solid particles that are compacted under chewing pressure and that are hard to remove, sealing teeth or blocking food from being trapped while eating.

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- 5
9. A method as in claim 1 of displacing previously trapped food, neutralizing acid and remineralising any demineralised tooth after eating.
10. A method as in claim 1 and one or more of other previous claims that is a convenient form to chew on each side of the mouth before eating to prevent food being trapped and changed to acid.
- 10
11. A method as in claim 1 and one or more of other previous claims that is a convenient form to chew on each side of the mouth before eating to inactivate bacteria and prevent carbohydrate being changed to acid while eating.
- 15
12. A method as in claim 1 and one or more of other previous claims that is a convenient form to chew on each side of the mouth after eating to displace trapped food and reduce acid demineralization.
- 20
13. A method as in claim 1 and one or more of other previous claims that is a convenient form to chew on each side of the mouth and prepare tooth surfaces for mineralisation.
- 25
14. A method as in claim 1 and one or more of other previous claims that is a convenient form to chew on each side of the mouth to provide a matrix of fine mineral particles to aid mineralisation.
- 30
15. A method as in claim 1 that is convenient to chew before x-rays to show where food is trapped while eating and diagnose potential sites of dental cavities.
16. A chewable dental care composition as in claims 1, 10, 11, 12, 13, 14 and 15 which is **not a gum or a foam** and includes one or more of

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- a) a chewable carrier material which is not readily soluble or dispersible in the mouth
- b) a cleaning agent which is not foaming
- c) optionally a barrier material
- d) optionally an anticariogenic agent, a mineralising agent or an antibacterial agent.
- e) a binder like gelatine, a caseinate, methyl cellulose, or milk powder
- f) a cleaning agent selected from fine particles of dental grade silica, felspar, calcium carbonate, calcium phosphate (hydroxyapatite), sodium bicarbonate or powdered foods like instant coffee, cheese, cocoa or soy
- g) flavouring agents and non-sugar sweeteners.
- h) a mineralising agent like a fluoride, a caseinate, cheese or milk powder
- i) a barrier agent like powdered cocoa, soy, calcium carbonate and cheese
- j) flavouring agents and non sugar sweeteners.
- k) colouring agents.

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