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(54) NONCARIOGENIC COMESTIBLE

(71) We, INDIANA UNIVERSITY FOUNDATION, Indiana Memorial Union, P.O. Box 500, Bloomington, Indiana, 47401 U.S.A., a corporation organised under the laws of the State of Indiana, U.S.A. do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:

This invention relates to a noncariogenic nutritive sweetner and to a comestible such as a candy product which contains it.

The invention also relates to a process for rendering a comestible sweet but noncariogenic.

A means to compensate for the cariogenic potential of comestibles, particularly foods containing high preponderances of nutritive sweetners such as sucrose and other sugars and acids which erode tooth enamel and dentin has long been sought. It has been theorized that when sugars are placed in the mouth, they combine with acid-producing bacteria to form lactic, fumaric, and other acids which promote dental caries.

A contributing cause of dental caries in children is the adherence of highly refined sugars and their decomposition products to the dental plaque after ingestion, coupled with the slow rate of oral clearance, or the ability to produce high amounts of acid, or combinations of such factors.

A number of anticariogenic agents have been evaluated in the past in systems wherein the agent is applied or consumed topically (i.e. directly on the teeth) in the form of a dentifrice (e.g. a toothpaste or a toothpowder). However, knowledge gained on the anticariogenic effectiveness of agents used in such topical applications has not permitted prediction of efficacy for these anticariogenic agents in other applications, such as in foods, and particularly in foods containing a substantial portion of sugars.

Unfortunately, known anticariogenic agents have in general not provided any substantial degree of protection when used in food stuffs. Thus, known anticariogenic agents such as fluorides, phosphates, vitamin K, nitrofurans, ammonium compounds and iodoacetic acid when added separately to a foodstuff containing a high percentage of sugar, have little direct topical effect in a foodstuff environment.

We have sought to provide means for overcoming the disadvantages of the prior art approaches to reducing the dental caries potential of sugar containing foodstuffs.

Accordingly the present invention provides a noncariogenic nutritive sweetner comprising a mixture of at least one first sweetening agent selected from sorbitol, mannitol, inositol and xylitol and at least one second sweetening agent selected from dextrose, sucrose, fructose and lactose, the mixture containing at least 75% by weight of the first-agent based on the weight of the mixture, provided that when the mixture contains sorbitol and sucrose only, then sucrose is present in an amount of 5% by weight, or less, based on the weight of the mixture.

This nutritive sweetner may be employed in comestibles such as candies. Advantageously, such a noncariogenic nutritive sweetner may be combined in a candy with up to 6% by weight of the product of adipic acid, ascorbic acid, or a mixture thereof as flavouring agent.

By employing the sweetening and flavouring systems in candy products, products are obtained which, when introduced into the mouth, exhibit little or no harmful lowering of the dental plaque pH (indicating that the formation of decay causing oral acids has been minimized), no significant harmful decalcification of the dental enamel (decalcification

being a precursor of dental caries formation) and rapid oral clearance.

By this invention, comestibles such as candies which have heretofore used dental caries promoting nutritive sweeteners such as simple sugars, may be rendered noncariogenic by employing a nutritive sweetening system in accordance with the present invention.

As used herein, the term "comestible" means any food product suitable for ingestion by humans including without limitation candies, bakery products, chewing gum, prepared beverages, beverage mixes and fruit preparations.

Such a nutritive sweetening system is advantageously provided in cooked or uncooked hard candies in which up to 6% by weight of an adipic acid, ascorbic acid or a mixture thereof is provided as a flavouring adjuvant. The nutritive sweetening system of this invention may be used in other types of candies such as toffees and caramels, chocolates and chocolate coatings and in other candy products in which large amounts of nutritive sweeteners are employed. Where candy products are produced from a variety of individual constituents (as in candies in which a cooked sugar based centre may be coated with chocolate), the nutritive sweetening system of this invention may be employed in one or more of the constituents (e.g. as a replacement for the sugar in the cooked centre or in the chocolate coating), or in all of them.

In the sweeteners of the present invention sorbitol is the preferred first agent, with dextrose being the preferred second agent. Where sorbitol-dextrose mixtures are employed, a 75% sorbitol - 25% dextrose mixture is preferred. Where sucrose, fructose and lactose are employed, somewhat greater amounts of the first sweetening agent are preferably employed. Thus, 10% fructose is preferred in the case of sorbitol-fructose mixtures.

Where manitol, inositol and/or xylitol are employed in addition to or in place of sorbitol, such sweetening mixtures may contain at least 75%, preferably as much as 90%, first sweetening agent by weight of the mixture.

Generally, the sweetening mixtures of this invention are employed at the same levels that the sugar or other cariogenic sweetening systems have been employed. Thus, the noncariogenic nutritive sweetening systems of this invention are employed in a candy product, preferably at a level of from 40 to 100% by weight of the candy product.

Where it is desired that a carboxylic acid be employed in the candy product for its tart taste and in order to enhance fruit flavours, it is preferred that adipic acid, ascorbic acid or a mixture thereof be used in order that the desired objective of a noncariogenic candy product may be maintained. An important feature of this invention is the discovery that, in comparison with other conventionally used carboxylic acids such as citric acid and malic acid, ascorbic acid adipic acids are relatively safe and do not decalcify the teeth when present in the mouth during the rapid oral clearance period achieved with the candies of this invention. Such an acid constituent of a candy is provided at a level of up to 6% by weight of the candy, preferably from 2 to 4% by weight of the candy.

Candy products produced in accordance with this invention are essentially the same as prior art candy products with the exception that, by virtue of the substitution of the noncariogenic nutritive sweetening system of this invention, the candy products hereof may be safely consumed without causing or promoting dental caries.

Thus, noncariogenic candy products produced in accordance with this invention may contain the usual and customary complementary ingredients conventionally found in candy products such as colourings, flavourings, dairy and vegetable fats, foaming agents and texturing agents such as crisped rice and nuts. However, in addition to the sugar sweeteners usually employed, certain conventional candy ingredients are undesirable from a dental standpoint. For example, significant amounts of fats and texturing agents such as crisped rice may adversely affect the oral clearance of the candy. Nonetheless, by employing the sweetening agents of this invention in place of the cariogenic sweeteners heretofore employed, the candies may be rendered less harmful to the teeth.

Candies produced in accordance with this invention may be prepared using the noncariogenic nutritive sweetening system of this invention in place of the simple sugar or other cariogenic sweetening system heretofore employed. Manufacturing techniques are generally the same although certain modifications must be made by reason of the use of sorbitol as the principal constituent of the sweetening system.

Thus, in the case of tableted candies, the same techniques of mixing the ingredients and forming them into tablets are used, but somewhat greater humidity control must be exerted because sorbitol is a desiccant. An agent such as magnesium stearate may also be added at low levels in order to facilitate removal of the tablets from the mould. However, in the case of cooked, hard candies, which are normally mixed, cooked and cooled in the desired shape, it is necessary to mould them and let them harden for several hours because sorbitol containing candies do not fully harden immediately upon cooling.

With the knowledge of these properties of the sorbitol containing sweetening agents of

this invention, one skilled in the art can readily adapt existing candy processing techniques to the preparation of other candy products.

The following Examples illustrate compositions of noncariogenic candies produced in accordance with this invention.

Example I - Tableted Candy

Constituent	Parts by Weight
Sorbitol	72.4
Dextrose	24.1
Flavouring and Colour	0.5
Adipic Acid	3.0

Example II-Tableted Candy

Constituent	Parts by Weight
Sorbitol	82.0
Dextrose	14.5
Ascorbic Acid	3.0
Flavouring and Colour	0.5

Example III - Tableted Candy

Constituent	Parts by Weight
Sorbitol	90.5
Sucrose	4.8
Adipic Acid	3.0
Flavouring and Colour	0.7
Magnesium Stearate	1.0

Example IV - Tableted Candy

Constituent	Parts by Weight
Sorbitol	71.4
Fructose	23.4
Adipic Acid	3.0
Flavouring and Colour	0.7
Magnesium Stearate	1.0

Example V - Tableted Candy

Constituent	Parts by Weight
Sorbitol	85.8
Fructose	9.5
Adipic Acid	3.0
Flavouring and Colour	0.7
Magnesium Stearate	1.0

Example VI - Tableted Candy

Constituent	Parts by Weight
Sorbitol	71.3
Dextrose	15.8
Fructose	7.9
Adipic Acid	1.5
Ascorbic Acid	1.5
Flavouring and Colour	1.0
Magnesium Stearate	1.0

Example VII - Tableted Candy

Constituent	Parts by Weight
Mannitol	71.4
Dextrose	23.8
Adipic Acid	3.0
Flavouring and Colour	0.7
Magnesium Stearate	1.0

Example VIII - Tableted Candy

Constituent	Parts by Weight
Xylitol	71.4
Dextrose	23.8
Adipic Acid	3.0
Flavouring and Colour	0.7
Magnesium Stearate	1.0

Example IX - Tableted Candy

Constituent	Parts by Weight
Inositol	71.4
Dextrose	23.8
Adipic Acid	3.0
Flavouring and Colour	0.7
Magnesium Stearate	1.0

Example X - Tableted Candy

Constituent	Parts by Weight
Sorbitol	50.0
Mannitol	23.3
Dextrose	15.0
Sucrose	7.2
Adipic Acid	3.0
Flavouring and Colour	0.5
Magnesium Stearate	1.0

Example XI - Cooked Hard Candy

Constituent	Parts by Weight
Sorbitol (70% solution)	81.8
Dextrose	17.3
Adipic Acid	0.8
Flavouring and Colour	0.2

Example XII - Cooked Hard Candy

Constituent	Parts by Weight
Sorbitol (70% solution)	89.0
Fructose	9.9
Ascorbic Acid	0.8
Flavouring and Colour	0.2

Example XIII - Cooked Hard Candy

Constituent	Parts by Weight
Sorbitol	89.0
Lactose	5.0
Ascorbic Acid	2.5
Adipic Acid	2.5
Flavouring and Colour	1.0

Example XIV - Toffee

Constituent	Parts by Weight
Sorbitol (70% solution)	70.1
Dextrose	16.3
Egg Albumin (45.27% solution)	2.4
92 degree coconut oil	8.9
Adipic Acid	1.7
Sodium Alginate	0.3
Calcium Acetate	0.1
Emulsifier	0.1
Flavouring and Colour	0.2

Example XV - Chocolate Candy Coating

Constituent	Parts by Weight
Sorbitol	42.0
Dextrose	14.0
Kaomel (hard butter)	30.9
Cocoa Powder	7.8
Non Fat Dry Milk	4.2
Lecithin	0.3
Salt	0.1
Vanilla Powder	0.9

Example XVI - Peanut Brittle

Constituent	Parts by Weight
Sorbitol	50.1
Dextrose	16.7
Mannitol	0.5
Spanish Peanuts	30.0
Butter	2.0
Antioxidant Salt	0.7

The noncariogenic attributes of the products produced in accordance with this invention have been verified by the following experimental studies.

The prime criteria employed in evaluating the noncariogenicity of the candy products of this invention are (1) the effect of such candy on the pH of the dental plaque, (2) the degree to which such candies cause decalcification of the dental enamel; and (3) the time taken for the product to clear the oral cavity following ingestion.

The pH of dental plaque is determined intraorally by use of a standard pH meter in conjunction with specially developed antimony micro-electrodes and a salt bridge similar to the assembly described in Kleinberg, "The Construction and Evaluation of Modified Types of Antimony Micro-Electrodes for Intra-Oral Use", *British Dental Journal*, Vol. 104, pages 197 to 204 (1958). The micro-electrodes are placed on the mesial surface of the maxillary left first molar, all subsequent measurements being made from this same area. Each test subject is not allowed to brush his teeth for two days (in order to develop sufficient plaque for testing) or eat anything one hour before testing. Initially a Stephan curve is obtained for each child by challenging the subject for 1 minute with a 25% glucose solution. The plaque pH is measured initially before challenging and then afterwards over two-minute intervals until the resting plaque pH is restored. The subject is then allowed to brush his teeth and

develop a new growth of two day old plaque. Subsequent testing is then conducted by having each subject eat the appropriate candy product and again determining the plaque pH versus time. The plaque pH lowerings produced by the candy or candy ingredients are then compared with the standard glucose plaque pH drop of each subject and are expressed on a percentage basis, the glucose pH decrease being taken as 100%. Thus, the smaller the percentage decrease or the greater percentage increase, the less cariogenic the candy product.

The phenomena of dental enamel decalcification is measured in the following manner. Sound central incisors are mounted in self-curing acrylic resin, with only the labial surface exposed and are given a thorough prophylaxis with a flour of pumice. A "window" is then formed on the labial surface by clamping a 1.0 cm diameter inert silicon rubber circle to the surface and covering remaining exposed enamel with self-curing acrylic. When the acrylic has hardened, the silicon rubber circle is removed, thus exposing a 1.0 cm round area of enamel of reproducible size.

The candy to be evaluated is initially dissolved at a level of 1 part by weight with 3 parts of redistilled water to simulate dilution in the mouth. The windowed teeth are then placed into 25.0 mls of the candy solution for a specific period of time (5.0 minutes approximately the oral clearance time of the candy of this invention) at a constant stirring rate of 60 rpm. When the treatment is completed, the amount of demineralized calcium present in the candy solution is determined by means of standard atomic absorption spectrophotometry. An appropriate blank of the candy solution is also analyzed to determine the amount of calcium, if any, that is inherently present. This inherent calcium is then subtracted to give the true value for the amount of calcium decalcified from the tooth enamel.

Oral clearance of candy products is determined as follows. Each candy product is incorporated with a low level of non-toxic water insoluble blue dye, such as purified copper phthalocyanine. After the subject has eaten the candy containing the dye, a visual inspection using a pen flashlight and mouth mirror is made periodically until all traces of blue dye have dissipated. The time required for the dyed candy to be no longer visible on any tooth surface is taken as the oral clearance time. The foregoing method for determining oral clearance is preferred to the alternative of determining the presence of carcohydrates in the saliva because the latter methodology is not sensitive to the presence of candy fragments in interproximal areas or below the gingival margin, which fragments may significantly contribute to dental caries formation.

Plaque pH drop, enamel decalcification, and oral clearance data have been obtained for several candy products produced in accordance with this invention (e.g. the candies of Examples I, XI, XV and XVI). For comparative purposes, similar data have been obtained for a series of conventional candy products of the same type and differing from the candies of this invention only in that conventional nutritive sweeteners were employed. These data, which are given in Table I, dramatically demonstrate the difference in terms of pH effects and enamel decalcification encountered with the candy products of this invention as compared with the prior art sucrose containing candies, and they further show that rapid oral clearance is not sacrificed in achieving these objectives. In the case of "sticky" candies (e.g. peanut brittle, toffee, and chocolate candy coatings), the slow oral clearance rates of conventional sucrose containing products are greatly improved by using the sweetening system of this invention.

TABLE I

Product Description	% Change in Plaque pH	Oral Clearance (min).	Enamel Dissolved (μg Ca^{+2})
Example I - Tableted Candy	18.8	3.6	0.21
Corresponding dextrose candy	105.6	3.6	5.16
Example XIV - Toffee	33.3	4.2	--
Corresponding sucrose candy	82.4	9.0	--
Example XV - Chocolate candy coating	8.4	8.0	--
Corresponding sucrose candy	139.0	14.0	--
Example XVI - Peanut brittle	+9.3	5.5	--
Corresponding sucrose candy	92.5	10.8	--
Example XI - cooked hard candy	+7.6	4.4	--
Corresponding sucrose candy	132.1	4.6	--

The maximum levels of 25% dextrose in the sorbitol - dextrose mixtures and 5 % sucrose in the sorbitol-sucrose mixtures of this invention have been determined on the basis of the plaque pH data given in Table II. A plot of these data demonstrates that mixtures of sorbitol and dextrose containing more than 25% dextrose and mixtures of sorbitol and sucrose containing more than 5 % sucrose, by weight, have an undesirable effect on plaque pH, which drops below the desired minimum level of 5.5 to 5.6. The preferred mixtures of 75% sorbitol and 25% dextrose and 95% sorbitol and 5% sucrose are based on the foregoing dental criteria and considerations of taste and cost as well.

TABLE II

Composition Weight %			
Sorbitol	Dextrose	Sucrose	Plaque pH & Drop After Challenge
100	0	0	+24.6
75	25	0	13.5
50	50	0	73.1
25	75	0	74.1
0	100	0	105.6
95	0	5	+5.0
75	0	25	45.2
50	0	50	53.4
25	0	75	85.9
0	0	100	118.6

The safety of adipic and ascorbic acids is demonstrated by the data given in Table III, which reports the enamel decalcification levels caused by a variety of carboxylic acids. The candy base used in this study consisted of a tableted candy containing on a part by weight basis, 72.4 parts sorbitol, 24.1 parts dextrose, and 0.5 parts flavouring and colourings.

TABLE III

Constituents	Enamel Decalcified ($\mu g\ Ca^{+2}$)	Statistical Difference
Candy Base	0.13±0.21	--
Candy base plus 3% adipic acid	0.21±0.26	none
Candy base plus 3% ascorbic acid	0.12±0.30	none
Candy base plus 3% citric acid	5.16±1.96	$p<.005$
Candy base plus 3% fumaric acid	2.25±1.56	$p<.025$
Candy case plus 3% glutaric acid	0.79±0.24	$p<.025$
Candy base plus 3% malic acid	2.66±0.88	$p<.025$
Candy base plus 3% succinic acid	0.62±0.30	$p<.05$
Candy base plus 3% tartaric acid	4.16±0.37	$p<.005$

While the foregoing invention has been described with respect to candy products in particular, these techniques can be used in other food products containing nutritive sweeteners in which the sweetener of the present invention may be employed.

WHAT WE CLAIM IS:

1. A noncariogenic nutritive sweetner comprising a mixture of at least one first sweetening agent selected from sorbitol, mannitol, inositol and xylitol and at least one second sweetening agent selected from dextrose, sucrose, fructose and lactose, the mixture containing at least 75% by weight of the first agent based on the weight of the mixture, provided that when the mixture contains sorbitol and sucrose only, then the sucrose is present in an amount of 5% by weight or less, based on the weight of the mixture.

2. A sweetened comestible containing as a sweetening agent the noncariogenic nutritive sweetener of claim 1.

3. A sweetened comestible, as claimed in claim 2 wherein the noncariogenic sweetener is present at a level of from 40 to 100% by weight of the comestible.

4. A sweetened comestible, as claimed in claim 2, and further containing adipic acid, ascorbic acid, or a mixture thereof.

5. A sweetened comestible, as claimed in claim 4, wherein adipic acid, ascorbic acid or mixture thereof is present at a level of up to 6% by weight.

6. A sweetened comestible, as claimed in any of claims 1 to 5, wherein the first agent is sorbitol and the second agent is dextrose.

7. A noncariogenic candy comprising as sweetening agent the noncariogenic nutritive sweetener of claim 1.

8. A noncariogenic candy, as claimed in claim 7, wherein the sweetening agent is a mixture of sorbitol and dextrose containing 25% by weight dextrose based on the weight of the mixture.

9. A noncariogenic candy, as claimed in claim 7 or 8, and further comprising adipic acid, ascorbic acid, or a mixture thereof.

10. A noncariogenic candy, as claimed in claim 9, wherein the nutritive sweetener is present at a level of from 40 to 100% by weight and adipic acid, ascorbic acid or mixture thereof is present at a level of up to 6%by weight.

11. A sweetened comestible as claimed in claim 2 substantially as described with reference to any of the Examples.

12. A process for rendering a nutritive sweetening agent-containing candy noncariogenic which comprises incorporating therein as a nutritive sweetening agent at least one first sweetening agent selected from sorbitol, mannitol, inositol, and xylitol and at least one second sweetening agent selected from dextrose, sucrose, fructose, and lactose, wherein the mixture contains at least 75% by weight of the first agent based on the weight of the mixture, provided that when the mixture contains sorbitol and sucrose only, then sucrose is present in an amount of 5% by weight or less, based on the weight of the mixture.

13. A process, as claimed in claim 12, wherein the nutritive sweetening agent is present at a level of from 40 to 100% by weight.

14. A process, as claimed in claim 12 or 13, and further comprising the step of incorporating in the candy adipic acid, ascorbic acid, or a mixture thereof as a flavouring agent.

15. A process, as claimed in claim 14, wherein the adipic acid, ascorbic acid or mixture thereof is incorporated at a level of up to 6% by weight.

16. A process, as claimed in claim 12, wherein the sweetener is a mixture of sorbitol and dextrose containing 25% by weight dextrose based on weight of the mixture.

17. A process as claimed in claim 12 substantially as described with reference to any one of the Examples.

18. A candy whenever prepared by a process as claimed in any one of claims 12 to 17.

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