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(54) ORAL ARTICLES AND METHODS OF USE

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See application file for complete search history.

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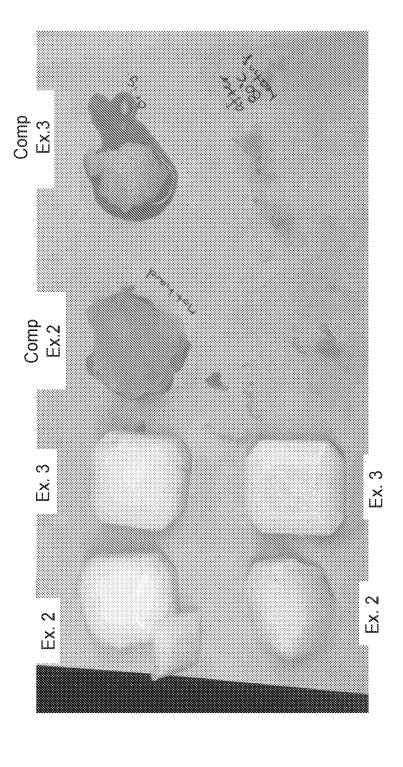
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(57) ABSTRACT

Articles that include from 70 wt-% to 99 wt-% of one or more plant based oil that is solid at 25° C., the weight percent based on the total weight of the article; and from 0.5 wt-% to 10 wt-% of fumed silica, the weight percent based on the total weight of the article. Methods of use of the articles are also included.

19 Claims, 1 Drawing Sheet

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ORAL ARTICLES AND METHODS OF USE

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a national stage filing under 35 U.S.C. 371 of PCT/IB2019/061406, filed 27 Dec. 2019, which claims the benefit of U.S. Provisional Application No. 62/786,359, filed 29 Dec. 2018, the disclosures of each of which are incorporated by reference herein in their entire-

SUMMARY

Disclosed herein are articles that include from 70 wt-% to 15 99 wt-% of one or more plant based oil that is solid at room temperature (25° C.), the weight percent based on the total weight of the article; and from 0.5 wt-% to 10 wt-% of fumed silica, the weight percent based on the total weight of the article, wherein the article is solid set and homogeneous. 20

Also disclosed are methods of preventing, inhibiting, disrupting, or any combination thereof the formation or maintenance of a biofilm in an oral tissue, the methods including contacting an oral tissue with disclosed articles.

Also disclosed are methods of affecting hydration loss in ²⁵ an oral tissue, the methods including contacting an oral tissue with disclosed articles.

Also disclosed are methods of affecting lubricity or lubriciousness in an oral tissue, the methods including contacting an oral tissue with disclosed articles.

Also disclosed are methods of affecting the effects of xerostomia, dry mouth, or both, the methods including contacting an oral tissue with disclosed articles.

The above summary is not intended to describe each embodiment of the present disclosure. The details of one or more embodiments of the present disclosure are also set forth in the description below. Other features, objects, and advantages of the present disclosure will be apparent from the description and from the claims.

BRIEF DESCRIPTION OF DRAWINGS

The disclosure may be more completely understood in consideration of the following detailed description of various illustrative embodiments in connection with the accompanying drawings, in which:

FIG. 1 shows photographs of the lozenges prepared above. The top row shows Example 3 and Comparative Examples 1 and 2. The bottom row shows Examples 2 and 3 that were poured after re-heating the mixed solution to 80° 50 C.

DETAILED DESCRIPTION

Xerostomia or dry mouth is a common condition that 55 results from insufficient saliva volume. It is increasingly prevalent in the aging population and is a side-effect of many medications, as well as cancer treatment. Severe cases of xerostomia are often related to salivary gland dysfunction, known as Sjögren's Syndrome.

The lack of moisture and lubrication typically provided by saliva has a range of negative effects on oral tissue (soft tissue) ranging from mild discomfort to extremely painful and infected mouth sores. The persistent discomfort and dryness can also contribute to larger health issues by causing 65 disruption of sleep, and impairing one's ability to talk (socialize, may impact psychological health) and eat (may

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impact nutrition). Dry buccal tissue is a less effective barrier and more susceptible to penetration by physical irritants such as toxins and carcinogens in foods, beverages and tobacco.

Saliva is also the mouth's primary defense against tooth decay. Healthy saliva flow helps prevent cavities by physically removing bacteria from the oral cavity before they can become attached to tooth and tissue surfaces and form a protected biofilm. The flow of saliva also helps dilute sugars and acids introduced by intake of food and beverages. The buffering capacity neutralizes acids and aids in the digestive process. The presence of calcium and phosphate salts provides continuous opportunity for re-mineralization of tooth enamel, serving to reverse the tooth decay process.

Many who suffer with xerostomia use separate products to address hard tissue health and soft tissue comfort. For soft tissue comfort, saliva substitute products are typically designed to provide lubrication and moisture. The format of these products is varied, and includes viscous gels/pastes, sprays, rinses, mints, and slow-release tablets. These are applied multiple-times per day or as needed for comfort. For hard-tissue health, different treatments are used to directly address cavity prevention (antiseptic rinses, fluoride products, calcium/phosphate treatments). Often "dry mouth-friendly" versions of products, such as toothpastes and mouth rinses are recommended. Dry mouth friendly products typically have a neutral pH and do not contain alcohol or other irritating components (e.g. anionic surfactants or emulsifiers).

There is a desire to design a single product that effectively and easily addresses the need for dry mouth symptom relief (soft tissue comfort) and oral health preventative benefits (tooth enamel and cavity protection). A fully ingestible, lozenge type product is well suited for this purpose. It addresses both the health of hard-tissue and soft tissue.

Disclosed herein are articles that can be utilized as oral articles, for example. Disclosed articles can be in the form of a lozenge, for example. Disclosed articles are not gums. A gum does not dissolve in the mouth of a user, whereas a lozenge does dissolve in the mouth of a user.

Disclosed articles, one or more components in an article, or both can be characterized as edible. Referring to a component, composition or article as edible can mean that the particular ingredient, composition or article is safe for daily, long-term ingestion at recommended use levels. In some embodiments, the GRAS (generally regarded as safe) list from the United States Food and Drug Administration (FDA) can be utilized to determine if a component is edible at the levels utilized in a composition.

Disclosed articles include one or more useful oil, and fumed silica.

Disclosed articles include one or more oil that is a solid at room temperature (25° C.). In some embodiments, useful oils do not include silicone based oils (e.g., simethicone or dimethicone). Useful oils can include any oils, but in some embodiments can include plant based oils. Many plant based oils can be made to exist as a solid at room temperature by hydrogenating them. The articles can include a single edible oil, or as many as two, three, four, five or more edible oils. Examples of suitable edible oils that are solid at room temperature can include, but are not limited to hydrogenated plant based oils and the like, and mixtures or fractions thereof. A specific and non-limiting example includes cocoa butter.

Disclosed articles can include not less than 70 percent of one or more oils that are solid at room temperature based on the total weight of the article, not less than 75 percent of one 22,230,1002

or more oils that are solid at room temperature based on the total weight of the article, not less than 76 percent of one or more oils that are solid at room temperature based on the total weight of the article, not less than 80 percent of one or more oils that are solid at room temperature based on the total weight of the article, or not less than 85 percent of one or more oils that are solid at room temperature based on the total weight of the article. Disclosed articles can include not greater than 99 percent of one or more oils that are solid at room temperature based on the total weight of the article, not 10 greater than 97 percent of one or more oils that are solid at room temperature based on the total weight of the article, or not greater than 95 percent of one or more oils that are solid at room temperature based on the total weight of the article.

Disclosed articles also include fumed silica. In some 15 embodiments, disclosed articles can include not less than 0.5 percent of fumed silica based on the total weight of the article, not less than 1 percent of fumed silica based on the total weight of the article, not less than 2 percent fumed silica based on the total weight of the article, or not less than 2 percent fumed silica based on the total weight of the article. In some embodiments, disclosed article can include not greater than 10 percent fumed silica based on the total weight of the article, not greater than 9 percent fumed silica based on the total weight of the article, or not greater than 25 percent of fumed silica based on the total weight of the article, or not greater than 25 percent of fumed silica based on the total weight of the article.

In some embodiments, disclosed articles can also optionally include water. The water can be used to contain water soluble materials within the final article. In some embodiments, water can be added to a composition to make a disclosed article in combination with a number of different components, for example as a buffer solution. Illustrative materials can include minerals (e.g., calcium), sweeteners, etc. In some embodiments, disclosed articles can include not 35 less than 0.5 percent water based on the total weight of the article, not less than 1 percent water based on the total weight of the article, or not less than 2 percent water based on the total weight of the article. In some embodiments, disclosed articles can include not greater than 10 percent 40 water based on the total weight of the article, not greater than 8 percent water based on the total weight of the article, or not greater than 5 percent water based on the total weight of the

Disclosed articles can also optionally include additional 45 components other than those discussed above. Illustrative optional components can include, for example, sweeteners (e.g., non-carcinogenic sweeteners), mineral salts, buffering components, flavorants, preservative agents, humectants, or combinations thereof. Other optional beneficial ingredients 50 can also be included at appropriate levels such as, aloe vera (multi-benefit), folic acid (related to B12), hyaluronic acid (lubricating, moisturizing), ceramides, amino acids (e.g., glycine, arginine), betaines or oxygenated glycerol triesters, vitamin E (antioxidant), vitamin B12 EDTA, cetyl pyridinium chloride, chlorhexidine, other antiseptics, etc., or combinations thereof.

In some embodiments, disclosed articles can include flavorants including for example, spearmint, peppermint, strawberry, butter, vanilla, coconut, almond, bubble gum, 60 berry, fruit punch, butterscotch, caramel, or combinations thereof. In some embodiments, some flavorants, e.g., mint, citrus, etc. can also be advantageous because they stimulate salivary production when utilized in articles. Artificial sweeteners may also be used (stevia, aspartame, sucralose, 65 neotame, acesulfame potassium (Ace-K), saccharin, and advantame, for example). In some embodiments, disclosed

articles can include one or more sweeteners including for example, non-cariogenic polyols, or sugar substitutes (e.g., sucralose). In some embodiments, disclosed articles can include non-cariogenic polyol sweeteners such as xylitol, sorbitol, maltitol, erythritol, isomalt, or combinations thereof. In some embodiments, disclosed articles can include non-cariogenic polvol sweeteners such as xylitol, sorbitol, or combinations thereof. In articles that include optional sweeteners, the sweetener can be present in an amount that is not less than 2.5 percent based on the total weight of the article or not less than 1 percent based on the total weight of the article. In some embodiments, an optional sweetener can be present in an amount that is not greater than 30 percent based on the total weight of the article, not greater than 20 percent based on the total weight of the article, not greater than 15 percent based on the total weight of the article, not greater than 10 percent based on the total weight of the article, or not greater than 8 percent based on the total weight of the article.

In some embodiments, disclosed articles can optionally include one or more minerals that may be useful or beneficial for ingestion or oral health. Illustrative optional minerals that can be included in disclosed articles can include calcium (Ca), phosphorus (P), magnesium (Mg), fluorine (F), iron (Fe), strontium (Sr), zinc (Zn), potassium (K), or combinations thereof. In some embodiments, some minerals can be provided by including magnesium chloride (MgCl₂), calcium chloride (CaCl₂), strontium chloride, zinc chloride, zinc gluconate, potassium nitrate, potassium phosphate dibasic (KH₂PO₄), or combinations thereof. In some embodiments, where fluorine is included, it can be included as the fluoride ion (F—) in salt form (MgF₂, CaF₂, etc.), at a concentration that is not greater than 4 milligrams per liter (mg/L).

In some embodiments, disclosed articles can include one or more preservatives to render the article microbiologically stable, to increase the microbiological stability thereof, or some combination thereof. In some embodiments, useful preservatives include those that work at a neutral pH, do not detrimentally affect taste, are edible, are effective against a broad spectrum of pathogens, or combinations thereof. Specific illustrative useful preservatives can include GEOGARD® preservatives, which are commercially available from Lonza (Basel, Switzerland) and include salicyclic acid, benzyl alcohol, sodium benzoate, potassium sorbate, parabens, natural preservatives, polyglyceryl esters, monolaurin,1,2 octanediol, caprylic/capric triglycerides, DHA, aloe vera, potassium sorbate, cetyl pyridinium chloride (CPP), polyhexamethylene biguanide (PHMB), methylparaben, and chlorhexidine gluconate (CHG) for example.

Disclosed articles can generally be formed by heating the one or more oil that is a solid at room temperature (25° C.) to melting and then adding the fumed silica. Optional ingredients can be dissolved in water, e.g., with heating. The water-based composition can then be added to the oil-based composition and the mixture can then be further mixed.

Disclosed articles can have varied properties. In some embodiments, disclosed articles can be described by the pH thereof, the viscosity thereof, the stability thereof, various other properties, or combinations thereof.

In some embodiments, disclosed articles can have a pH that is acceptable for use in the mouth of a person, for example. In some embodiments, disclosed articles can have a pH from 4.5 to 9.5, for example. In some embodiments, the article can have a pH in a more neutral range from 5.0-8.5 or 5.5-8.5 for example, as dry mouth sufferers can have a

higher sensitivity to pH. The article can naturally have such a pH or can be buffered to have a pH in a useful, e.g., a "neutral" range.

In some embodiments, disclosed articles can be described as solid set (e.g., the article does not flow at room temperature (25° C.)) and homogenous (e.g., the article has no visible separation). In some embodiments, disclosed articles can be described as solid set and homogenous even after speed mixing, re-heating, cooling, or any combinations thereof. Articles that are solid set and homogeneous even 10 after any of re-heating, cooling, or any combination thereof may be advantageous due to extreme environmental conditions that they may be subjected to by a user (e.g., storage of the articles in automobiles, which could subject them to extreme temperatures).

Disclosed articles can be packaged in any of a number of commonly utilized fashions, including for example blister packages, bags, etc. The articles themselves can also be molded into virtually any size or shapes.

In some embodiments, disclosed articles can have desired 20 effects when utilized. Such effects can include, for example the article's effect on biofilms, the article's effect on plaque buildup, the article's effect on water loss, the article's ability to maintain or provide lubricating properties, resist dilution or wash-off by saliva or water, or drinking and eating in 25 general or combinations thereof.

In some embodiments, disclosed articles can prevent, inhibit, disrupt the formation or maintenance of a biofilm in an area contacted with the article. The area contacted can be in vivo or in vitro. In some embodiments, an article can 30 prevent, inhibit, disrupt the formation or maintenance of a biofilm in a mouth of a user where the article was applied to the mouth, for example via placing the article into the mouth when compared to a mouth without the article applied thereto. In some embodiments, an article can prevent, 35 inhibit, disrupt the formation or maintenance of a biofilm in a container in which a biofilm exists and the article was applied to the container via contact when compared to a container without the article contacted thereto. Preventing, inhibiting, disrupting, or some combination thereof the 40 formation or maintenance of biofilms can be measured using a modified version of the MBEC assay (described in ASTM E2799), which measures disruption of strep mutans biofilms grown on special pegs in a microtiter plate. The biofilms growing on the pegs are treated by periodic submersion into 45 test materials, followed by washing in saliva and water. The biofilm remaining on each peg following treatment is quantified by measuring the amount of fluorescently labeled bacteria that eluted from the pegs at the end of the treatment cycles (see example). In some embodiments, disclosed 50 articles can affect the buildup of plaque in an area contacted by the article. The area contacted can be in vivo or in vitro. In some embodiments, an article can decrease plaque buildup on at least one tooth in a mouth of a user where the article was applied to the mouth, for example via contacting 55 the article into the mouth when compared to a mouth without the article applied thereto. In some embodiments, an article can decrease plaque buildup in a container in which plaque can develop and the article was applied to the container via pouring, spraying, etc. when compared to a container with- 60 out the article contacted thereto. Decreasing plaque buildup can be measured by a variety of methods in vivo including for example plaque scoring, dyeing of plaque, etc.

In some embodiments, disclosed articles can affect hydration loss in an area contacted by the articles. The area 65 contacted can be in vivo or in vitro. In some embodiments, an article can decrease hydration loss in a mouth of a user

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where the article was applied to the mouth, for example via contacting the article into the mouth when compared to a mouth without the article applied thereto. In some embodiments, an article can decrease hydration loss from a tissue in which hydration can be lost and the article was applied to the tissue via contact when compared to a tissue without the article applied thereto.

In some embodiments, disclosed articles can affect lubricity or lubriciousness of an area contacted by the article. The area contacted can be in vivo or in vitro. In some embodiments, an article can maintain or increase lubricity in a mouth of a user where the article was applied to the mouth, for example via contacting the article into the mouth when compared to a mouth without the article applied thereto.

Also disclosed herein are methods of using disclosed articles. Disclosed methods can include contacting an oral cavity or oral tissue with a disclosed article. The step of contacting the oral cavity or oral tissue can be accomplished by applying the article in any way, for example by simply placing the article in the mouth. Disclosed methods can be useful for preventing, inhibiting, disrupting, or any combination thereof the formation or maintenance of a biofilm in an area contacted with the article; for affecting hydration loss in an area contacted by the article; for affecting lubricity or lubriciousness of an area contacted by the article; for affecting or alleviating the effects of xerostomia, dry mouth, or both.

All scientific and technical terms used herein have meanings commonly used in the art unless otherwise specified. The definitions provided herein are to facilitate understanding of certain terms used frequently herein and are not meant to limit the scope of the present disclosure.

As used in this specification and the appended claims, the singular forms "a", "an", and "the" encompass embodiments having plural referents, unless the content clearly dictates otherwise.

As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise. The term "and/or" means one or all of the listed elements or a combination of any two or more of the listed elements.

As used herein, "have", "having", "include", "including", "comprise", "comprising" or the like are used in their open ended sense, and generally mean "including, but not limited to". It will be understood that "consisting essentially of", "consisting of", and the like are subsumed in "comprising" and the like. For example, a composition that "comprises" silver may be a composition that "consists of" silver or that "consists essentially of" silver.

As used herein, "consisting essentially of," as it relates to a composition, apparatus, system, method or the like, means that the components of the composition, apparatus, system, method or the like are limited to the enumerated components and any other components that do not materially affect the basic and novel characteristic(s) of the composition, apparatus, system, method or the like.

The words "preferred" and "preferably" refer to embodiments that may afford certain benefits, under certain circumstances. However, other embodiments may also be preferred, under the same or other circumstances. Furthermore, the recitation of one or more preferred embodiments does not imply that other embodiments are not useful, and is not intended to exclude other embodiments from the scope of the disclosure, including the claims.

Also herein, the recitations of numerical ranges by endpoints include all numbers subsumed within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, 5, etc. or 10 or less

includes 10, 9.4, 7.6, 5, 4.3, 2.9, 1.62, 0.3, etc.). Where a range of values is "up to" a particular value, that value is included within the range.

Use of "first," "second," etc. in the description above and the claims that follow is not intended to necessarily indicate 5 that the enumerated number of objects is present. For example, a "second" substrate is merely intended to differentiate from another substrate (such as a "first" substrate). Use of "first," "second," etc. in the description above and the claims that follow is also not necessarily intended to indicate 10 that one comes earlier in time than the other.

Example articles and techniques according to the disclosure provide will be illustrated by the following non-limiting examples.

EXAMPLES

TABLE 1

Materials							
Chemical/Material Name	Abbreviation CAS	Manufacturer					
Dulbecco's phosphate buffered saline (contains 100 mg/L CaCl ₂ , 100 mg/L MgCl ₂ —6H ₂ O, 200 mg/L KCl, 200 mg/L KH ₂ PO ₄ , 8 g/L	DPBS	Gibco (Life Technologies Limited), Paisley,					
NaCl, 200 ling/L RH ₂ FO ₄ , 8 g/L NaCl, 2.16 g/L Na ₂ HPO ₄ —7H ₂ O (DPBS)		UK					
KNOX Original Unflavored Gelatine	Gelatin	E.D. Smith Foods, Ltd, Ontario, Canada					
WECOBEE M (solid at 25° C., room temperature)		Stepan Lipid Nutrition, Maywood, NJ					
NEOBEE 1053 (liquid at		Stepan Lipid					

8 TABLE 1-continued

Materials						
Chemical/Material Name	Abbreviation	CAS	Manufacturer			
25° C., room temperature)			Nutrition,			
A200 Fumed Silica			Maywood, NJ Evonik Industry,			
Xylitol			Parsippany, NJ Now Foods, Bloomingdale, IL			

Methods

Method of Making Lozenges: The oil was heated to 80° C., mixed with fumed silica, and placed into a container 15 compatible with the speed mixer. Sugar alcohol (e.g., xylitol) and other optional ingredients were dissolved in the DPBS by heating (80° C.) and stirred and then added to the container. The wt % in the tables for the CaCl₂, MgCl₂-6H₂O, KCl, KH₂PO₄, NaCl, Na₂HPO₄-7H₂O, and H₂O are 20 presented calculated based on the known amount of DPBS buffer added and the amounts of the components therein. The solution was cooled to about 40° C. and placed in the speed mixer (FlackTek, Inc. DAC150.1 FVZ; Landrum, S.C.) for 30 seconds to 1 minute at 3500 rpm. The mixed solution was then transferred to a silicone mold or observed in its original speed mixer container and set at room temperature. The mixed solution was then re-heated to 45° C. for 5-10 minutes and then returned to room temperature to observe if separation occurred. No significant weight loss was observed with these lozenge samples due to low initial 30 water weight.

Examples 1-3 and Comparative Examples C1 and C2

Example lozenges 1, 2 and 3 as well as comparative Examples C1 and C2 were made according to Table 2 below.

TABLE 2

	(all amounts are shown in wt-%)						
	Ex. 1	Ex. 2	Ex. 3	Comp. Ex. 1	Comp. Ex. 2		
Water Phase							
CaCl ₂	0.00085	0.0003	0.0003	0.0003	0.0003		
MgCl ₂ —6H ₂ O	0.00085	0.0003	0.0003	0.0003	0.0003		
KCl	0.0017	0.0006	0.0006	0.0006	0.0006		
KH_2PO_4	0.0017	0.0006	0.0006	0.0006	0.0006		
NaCl	0.068	0.024	0.024	0.024	0.024		
Na ₂ HPO ₄ —7H ₂ O	0.018	0.0064	0.0064	0.0064	0.0064		
H ₂ O	8.4	3.0	3.0	3.0	3.0		
Xylitol	6.9	12	12	12	12		
Gelatin	1.4	0	0	0	0		
Oil Phase							
WECOBEE M	75.8	77.35	85.0	0	0		
NEOBEE 1053	0	0	0	77.4	85.0		
Fumed Silica	7.5	7.7	0	7.7	0		
Homogenous after speed mixing?	Yes	Yes	Yes	Yes	No		
Solid set upon cooling to room temperature?	Yes	Yes	Yes	No	No		
Homogenous after re-heating to 80° C.?	Yes	Yes	No	Yes	No		

FIG. 1 shows photographs of the lozenges prepared above. The top row shows Example 3 and Comparative Examples 1 and 2. The bottom row shows Examples 2 and 3 that were poured after re-heating the mixed solution to 80° C. The lozenge of Example 2 remained homogeneous but 5 Comparative Example 1 had visible separation of xylitol in the middle of the lozenge even after re-heating and pouring.

Examples 4-8 and Comparative Examples 3-7

Example lozenges 4-8 as well as Comparative Examples 3-7 were made according to Table 3 and Table 4 below.

Illustrative embodiments include but are not limited to the following:

Articles comprising: from 70 wt-% to 99 wt-% of one or more plant based oil that is solid at 25° C. (room temperature), the weight percent based on the total weight of the article; and from 0.5 wt-% to 10 wt-% of fumed silica, the weight percent based on the total weight of the article, wherein the article is solid set and homogeneous.

Articles according to any of the above embodiments, wherein the one or more oil that is solid at room temperature is selected from hydrogenated vegetable oil.

TABLE 3

(all amounts presented in wt-% based on the total weight of the article)							
	Ex. 4	Ex. 5	Ex. 6	Ex. 7	Ex. 8		
Water Phase							
CaCl ₂	0.00070	0.00047	0.00023	0.00012	0.00047		
KCl	0.0014	0.00094	0.00046	0.00024	0.00094		
KH_2PO_4	0.0014	0.00094	0.00046	0.00024	0.00094		
NaCl	0.056	0.38	0.018	0.0096	0.038		
Na ₂ HPO ₄ —7H ₂ O	0.015	0.010	0.0050	0.0026	0.010		
H ₂ O	6.9	4.6	2.3	1.2	4.6		
Xylitol	8.0	5.3	2.7	1.3	5.3		
Oil Phase	•						
WECOBEE M	80	85	90	92	87		
Fumed Silica	5.0	5.0	5.0	5.0	2.7		
Homogenous after speed mixing?	Yes	Yes	Yes	Yes	Yes		
Homogenous after re-heating to 45° C. and then cooling?	Yes	Yes	Yes	Yes	Yes		

TABLE 4

(all amounts presented in wt-% based on the total weight of the article)					
	Comp. Ex. 3	Comp. Ex. 4	Comp. Ex. 5	Comp. Ex. 6	Comp. Ex. 7
Water Phase					
$\begin{array}{c} {\rm CaCl_2} \\ {\rm KCl} \\ {\rm KH_2PO_4} \\ {\rm NaCl} \\ {\rm Na_2HPO_4} \\ {\rm H_2O} \\ {\rm Xylitol} \\ {\rm Oil\ Phase} \end{array}$	0.0011 0.0022 0.0022 0.089 0.024 11 39	0.00033 0.00066 0.00066 0.026 0.0071 3.3	0.00011 0.00022 0.00022 0.0089 0.0024 1.1 3.9	0.00070 0.0014 0.0014 0.056 0.015 6.9 8.0	0.00023 0.00046 0.00046 0.018 0.0050 2.3 2.7
WECOBEE M Fumed Silica Homogenous after speed mixing? Homogenous after re-heating to 45° C. and then cooling?	50 0 No No	85 0 Yes No	95 0 Yes No	80 0 Yes No	95 0 Yes No

Upon flipping over the containers that had undergone a re-heating (45° C.) and cooling (room temperature) cycle after speed mixing, it was discovered that the samples without fumed silica (Comparative examples 3-7) had undergone separation and the water phase was trapped in the bottom of the container. When the samples were removed from the containers, there was visible water phase in Comparative examples 3-7, but not in Examples 4-8.

Articles according to any of the above embodiments, wherein the one or more oil that is solid at room temperature is present in an amount from 75 wt-% to 99 wt-% based on the total weight of the article.

Articles according to any of the above embodiments, wherein the one or more plant based oils are present in an amount from 80 wt-% to 85 wt-% based on the total weight of the article.

Articles according to any of the above embodiments, wherein the fumed silica is present in an amount from 1 wt-% to 9 wt-% based on the total weight of the article.

Articles according to any of the above embodiments, wherein the fumed silica is present in an amount from 2 5 wt-% to 8.5 wt-% based on the total weight of the article.

Articles according to any of the above embodiments, wherein the fumed silica is present in an amount from 4 wt-% to 8.5 wt-% based on the total weight of the article.

Articles according to any of the above embodiments further comprising water in an amount from 0.5 wt-% to 10 wt-% based on the total weight of the article.

Articles according to any of the above embodiments further comprising water in an amount from 1 wt-% to 8 wt-% based on the total weight of the article.

Articles according to any of the above embodiments further comprising water in an amount from 2 wt-% to 5 wt-% based on the total weight of the article.

Articles according to any of the above embodiments further comprising sweeteners, mineral salts, buffering com- 20 ponents, flavorants, preservative agents, humectants, or combinations thereof.

Articles according to any of the above embodiments further comprising aloe vera, folic acid, hyaluronic acid, ceramides, glycine, arginine, betaines or oxygenated glyc- 25 erol triesters, vitamin E, vitamin B12, EDTA, cetyl pyridinium chloride, chlorhexidine, other antiseptics, or combinations thereof.

Articles according to any of the above embodiments, wherein the article comprises from 1 wt-% to 20 wt-% 30 sweeteners based on the total weight of the article.

Articles according to any of the above embodiments, wherein the article is solid set.

Articles according to any of the above embodiments, wherein the article is homogeneous.

Articles according to any of the above embodiments, wherein the article is solid set and homogenous after being subjected to heating to 45° C., then speed mixing at 3500 RPM, and then cooling to 25° C.

Articles according to any of the above embodiments, 40 wherein the article is solid set and homogenous after being subjected to heating to 80° C.

Articles according to any of the above embodiments, wherein the article can prevent, inhibit, disrupt, or any combination thereof the formation or maintenance of a 45 biofilm in an area contacted with the article.

Articles according to any of the above embodiments, wherein the article can affect hydration loss in an area contacted by the article.

Articles according to any of the above embodiments, 50 wherein the article can affect lubricity or lubriciousness of an area contacted by the article.

Methods of preventing, inhibiting, disrupting, or any combination thereof the formation or maintenance of a biofilm in an oral tissue, the method comprising: contacting 55 increases lubricity or lubriciousness of an area contacted by an oral tissue with any of the above embodied articles.

Methods of affecting hydration loss in an oral tissue, the method comprising: contacting an oral tissue with any of the above embodied articles.

Methods of affecting lubricity or lubriciousness in an oral 60 tissue, the method comprising:

contacting an oral tissue with any of the above embodied

Methods of affecting the effects of xerostomia, dry mouth, or both, the method comprising: contacting an oral tissue 65 with an article according to any of the above embodied articles.

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Thus embodiments of oral compositions and methods of use are disclosed. The implementations described above and other implementations are within the scope of the following claims. One skilled in the art will appreciate that the present disclosure can be practiced with embodiments other than those disclosed. The disclosed embodiments are presented for purposes of illustration and not limitation.

What is claimed is:

1. An article comprising:

an oil phase comprising:

one or more plant-based oil present in an amount from 75 wt-% to 99 wt-%;

fumed silica present in an amount from 0.5 wt-% to 10 wt-%; and

wherein the one or more plant-based oil is a solid at 25° C.,

wherein the article is solid set and homogenous at 25° C. without requiring emulsifiers,

wherein the article is characterized by a homogeneity that is stable upon heating to 45° C. and subsequently cooling to 25° C., and

wherein each wt-% is with respect to the weight of the article.

- 2. The article according to claim 1, wherein the one or more plant-based oil is a hydrogenated vegetable oil.
- 3. The article according to claim 1, wherein the one or more plant-based oil is present in an amount from 75 wt-% to 85 wt-% with respect to the weight of the article.
- 4. The article according to claim 1, wherein the fumed silica is present in an amount from 4 wt-% to 8.5 wt-% with respect to the weight of the article.
- 5. The article according to claim 1, wherein the water is present in an amount from 0.5 wt-% to 10 wt-% with respect to the weight of the article.
- 6. The article according to claim 1, further comprising sweeteners, mineral salts, buffering components, flavorants, preservative agents, humectants, or a combination thereof.
- 7. The article according to claim 1, further comprising aloe vera, folic acid, hyaluronic acid, ceramides, glycine, arginine, betaines, oxygenated glycerol triesters, vitamin E, vitamin B12, EDTA, cetyl pyridinium chloride, chlorhexidine, antiseptics, or a combination thereof.
- **8**. The article according to claim **1**, wherein the article is characterized by a homogeneity that is stable upon heating to 80° C. and subsequently cooling to 25° C.
- 9. The article according to claim 1, wherein the article prevents, inhibits, and/or disrupts the formation or maintenance of a biofilm in an area contacted with the article.
- 10. The article according to claim 1, wherein the article reduces hydration loss in an area contacted by the article.
- 11. The article according to claim 1, wherein the article the article.
- 12. A method of one or more of preventing, inhibiting, and disrupting the formation or maintenance of a biofilm in an oral tissue, the method comprising:

contacting an oral tissue with an article according to claim

13. A method of reducing hydration loss in an oral tissue, the method comprising:

contacting an oral tissue with an article according to claim

14. A method of increasing lubricity or lubriciousness in an oral tissue, the method comprising:

an aqueous phase comprising:

water,

contacting an oral tissue with an article according to claim

- **15**. A method of reducing the effects of xerostomia, dry mouth, or both, the method comprising:
 - contacting an oral tissue with an article according to claim 5
- 16. The article of claim 1, further comprising a sweetener and one or more mineral salt.
 - 17. The article of claim 1, further comprising xylitol.
- **18**. The article of claim **1**, further comprising a calcium 10 salt, a magnesium salt, a phosphate salt, or a combination thereof.
- 19. The article of claim 1, further comprising xylitol and one or more of a calcium salt, a magnesium salt, and a phosphate salt.

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