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(54) Title: A SOLID, EDIBLE, CHEWABLE LAXATIVE COMPOSITION

(57) Abstract: The invention is directed to an edible solid composition having laxative properties. The composition has a smooth mouth feel, in non-gritty and has a pleasant taste. It is prepared by melt-combining together the ingredients including a bulking agent and laxative as well as an optional flavor agent and electrolyte. The melt is a dispersion containing a substantially homogeneous combination of ingredients. The melt is cooled to form an amorphous solid dispersion or solution of the ingredients. The ingredients are mutually compatible so that upon cooling they do not separately crystallize to form a gritty mouth feel product.



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A SOLID, EDIBLE, CHEWABLE LAXATIVE COMPOSITIONClaim of Priority

5 This application claims the benefit of priority of U.S. Provisional Application No. 61/538,488, filed September 23, 2011, entitled "SOLID, EDIBLE, CHEWABLE LAXATIVE COMPOSITION," and claims the benefit of priority of U.S. Provisional Application No. 61/620,688, filed April 5, 2012, entitled "A SOLID, EDIBLE, CHEWABLE LAXATIVE COMPOSITION," which applications are herein incorporated by reference in
10 their entirety.

Background

 Polyethylene glycol (PEG), particularly PEG 3350 is a known osmotic laxative. PEG 3350 is sold in US in laxative compositions which typically are to be combined with an aqueous medium. For example 17 g of PEG powder is dissolved in about 8 ounces of
15 aqueous beverage and consumed to provide a laxative dosage. Examples of such products include Miralax® (MSD consumer care) and Gavilax® (Gavis Pharmaceuticals, NJ).

 Formulation of PEG as a beverage or in an aqueous medium is inconvenient, unsatisfying and uncomfortable to the consumer. The aqueous formulation has an undesirable mouth-feel and can create a bloated, overwhelmed feeling in the consumer's
20 stomach. The aqueous formulation is also not a drink that can be discretely consumed so that consumers typically use restrooms in which to mix and drink the formulation. This practice is uncomfortable, disagreeable and ill tasting. The discomfort and inconvenience leads to reduction of dose compliance of the product as directed. Thus, there is a need for more conveniently dosed polyethylene glycol.

25 While there are certain products, for example Movicol® (Norgine Ltd, Midx UB9 6NS, UK) that are sachets for combination with aqueous media, they contain in addition to polyethylene glycol, electrolytes such as sodium chloride, sodium bicarbonate and potassium chloride. These salts do not impart good taste and suffer from the same discomfort and inconvenience as an aqueous formulation containing only PEG.

30 Other laxatives formulated for oral consumption suffer from the same problems. All have disagreeable tastes, cause a bloated feeling in the stomach and require inconvenient mixing as aqueous formulations. Chief among these are the laxative preparations with water insoluble substances such as psyllium, bran husk, microcrystalline cellulose and the like. These all form gritty distasteful aqueous
35 formulations that leave thick residue in the glass when drunk.

Therefore, there is a need to provide a laxative dosage form that has a good taste and would enhance patient compliance.

Summary of Invention

The present invention is directed to a laxative based edible, solid composition. An aspect of the invention provides that the composition preferably is formed as a bar or candy. According to another aspect of the invention, the composition of such ingredients as a laxative, a bulking agent and an optional sweetening agent.

An embodiment of the invention provides that the solid composition is formed as an edible solid bar or candy by heating the ingredients to form a fluid dispersion and cooling the fluid dispersion, preferably in a mold to form a solid bar. In particular, and preferably, another aspect of the invention provides that the laxative is first melted or otherwise converted into a flowable viscous to fluid state. The additional ingredients are then combined with the fluid bulking agent and mixed to form the hot fluid dispersion. The fluid dispersion is added to molds preferably sized to produce mouth-sized pieces, and allowed to cool to ambient temperature.

According to yet another aspect of the invention, the dispersion constituting the chewable, edible composition is solid at ambient temperature.

The edible solid composition formed in this manner has a smooth, non-crystalline, non-gritty mouth feel. Its physical consistency is that of a substantially homogeneous dispersion or preferably a solid solution. The laxative, bulking agent and sweetening agent are physically compatible so that they will form smooth intimate mixtures and will not separate or individually crystallize out of the mixture or solution after formation. Additional components of the composition are also mutually compatible so that separation and/or crystallization do not occur.

Additional aspects of the invention provide that the composition may optionally include electrolytes such as sodium chloride, sodium bicarbonate and potassium chloride. Other optional aspects include sweeteners and flavoring agents that can also be added to the composition as appropriate. Specialized flavors that target saltiness can be also advantageously utilized to reduce the salty taste according to further aspects of the invention. Optionally soluble fibers such as wheat dextrin (for example, Nutriose®, Roquette, France), Inulin, partially hydrolyzed guar gum can be included in the bar.

A further aspect of the invention is the benefit provided by the process employed to produce the solid composition. The melt process provides a better taste and mouth-feel for the solid composition compared with processes for formation such as compression,

mixing with adherent substances, mixing with liquids that are evaporated upon standing and the like.

Detailed Description

According to the foregoing aspects of the invention, the solid, edible composition
5 may contain such laxatives as polyethylene glycol, castor oil, senna, bisacodyl, sodium
pico sulfate, magnesium citrate, magnesium hydroxide (milk of magnesia), magnesium
carbonate magnesium sulfate (Epsom salt), sodium sulfate, potassium sulfate, aloes,
cascara sacra, psyllium husk (Metamucil), guar gum, maltodextrins, inulin, docusate
sodium, methyl cellulose, monobasic sodium phosphate, dibasic sodium phosphate,
10 glycerin, sorbitol, mannitol, sodium potassium tartrate, mineral oil (liquid paraffin),
lactulose, rhubarb, agar agar, figs (Syrup of Figs), L-glucose and any combination
thereof. The preferred laxatives are PEG, magnesium citrate, lactulose or bisacodyl and
especially preferred laxatives include PEG's of number designations 400, 3350, 4000,
6000, 18000 and 20000. Of particular preference is PEG 3350.

15 The bulking agent forming an ingredient aspect of the composition includes
carbohydrates and carbohydrate derivatives such as hydrogenated carbohydrates and
compounds mimicking carbohydrates either in taste or bulk or pharmaceutical acceptability
or any combination thereof. The carbohydrates and carbohydrate derivative and mimics are
selected to provide digestive and substance bulk, diluent properties as well as
20 pharmaceutical, nutritional and consumable acceptability. Such bulking agents preferably
will have physical properties that will enable melt or fluid processing and will produce firm
solids at ambient temperature either as the bulking agents alone or in combination with the
sweetening agent and the laxative. The bulking agents include all forms of carbohydrates
having the foregoing properties. The bulking agents include but are not limited to such
25 carbohydrates as such as corn syrup, sorbitol, sucrose, dextrose, invert sugar, ludiflash,
chocolate, maltitol, high fructose syrup, golden syrup, rice syrup, barley malt syrup, sugar
syrup, glycerin, maltodextrins, starch hydrolysate, honey, molasses, lecithin, condensed
milk, sweetened condensed milk and any combination thereof. Many of the bulking agents
also provide sweetness to the solid composition which minimizes or eliminates the
30 inclusion of separate sweetening agents.

Corn Syrup, Maltitol Syrup and/or maltodextrin are preferred. Sweetening agents
that give pleasant mouth feel such as sorbitol can also be utilized. Alternatively other
sugar alcohols or carbohydrates can be used such as sugar syrup, mannitol, sorbitol,
xylitol, lactitol, isomalt, maltitol, or hydrogenated starch hydrolysates.

Sweetening agents include all manner and configuration of natural and artificial agents that provide a mouth-feel and taste like that of sugar. Included are sugar, lactose, sorbitol, saccharine, aspartame, acesulfame potassium, sucralose, isomalt, mannitol, stevia, cyclamate, dextrose, glucose, fructose, honey, high fructose syrup and any
5 combination thereof. The natural sweetening agents such as sorbitol, dextrose, glucose, sucrose can also be employed in part to provide bulk and diluent properties to the composition.

Artificial sweetening agents such as sucralose, acesulfame, isomalt, mannitol, stevia, Cyclamates, aspartame, saccharine, sugar and flavoring agents are preferred for some
10 purposes especially when dietary constraints are important. Several types of chocolates are available such as dark chocolate, milk chocolate, semi-sweet chocolate, sweet chocolate, hard chocolate, soft chocolate, bitter chocolate, Cocoa mass, cocoa butter mix, hard boiled toffees, and the like. The chocolate can be added as a coat to the bar or included in the bar.

In certain embodiments, less or no corn syrup can be utilized to reduce the calorific
15 value of the bar. Similarly, in certain other embodiments, less or no sorbitol or other sugar alcohols were utilized to reduce the calorific value of the bar. Other embodiments include bars made without bodying or sweetening agents with only chocolate included in the bar. Another embodiment include bars using Soy lecithin and condensed milk in the bar.

Flavoring agents such as bubble gum, cherry, mixed berry, fruit punch, pine
20 apple, caramel, mixed fruit, chocolate, spearmint, peppermint, menthol, licorice, orange, lemon, Watermelon, melagawine, cranberry, tutti frutti, mix of cardamom and orange, vanilla, ice cream soda, salt masking flavor and any combination thereof may be included as optional ingredients.

Electrolytes such as sodium chloride, potassium chloride, potassium bicarbonate,
25 magnesium chloride may also be optionally included.

The compositions of the invention may contain a reasonable portion of the bulking agent, typically at least about 10% by weight, preferably at least about 20% by weight and especially preferably at least about 30 to 40% by weight. The combination of the bulking agent and the natural sweetening agents may be formulated as a combination portion of
30 the composition such as from about 10% to about 80% by weight. The flavoring agents, electrolytes and other optional ingredients may be omitted but when formulated into the composition, may constitute from about 1% up to about 20% by weight of the composition. The laxative can be formulated into the composition according to the FDA guidelines. Up to about 70% of the composition may be a PEG laxative. More potent

laxatives such as magnesium citrate, docusate sodium, sodium pico sulfate may be present in lesser weight percents according to the FDA monograph on laxatives.

If caloric intake is to be considered, the carbohydrate quantity provided by the bulking and optional sweetening agents may be kept at a minimum or non-caloric semisynthetic food grade carbohydrate substitutes may be employed. Such non-caloric bulking and sweetening agents include xylitol, mannitol, sorbitol, sucralose, stevia, aspartame, neotame, cyclamate, saccharine, and other non or minimal caloric bulking agents and/or sweeteners such as hydroxyethyl starch, inulin and the like.

According to the inventive aspects described above, the solid, edible compositions of the invention are prepared by melt forming. The bulking agent, PEG or combination thereof are heated either to melt it or to convert it into a flowable fluid. The additional ingredients are added while stirring and maintaining the mixture in a melted or flowable fluid condition. After all ingredients are combined, the hot mixture is agitated until a substantially homogeneous suspension or preferably a solution of the ingredients is achieved. The suspension or solution is then placed or poured into receptacles such as molds and allowed to cool to ambient temperature. The molds are shaped to provide appropriately sized pieces of the solid composition suitable for entry into the mouth. The weight percents of ingredients are calculated so as to provide the desired concentration and amount of laxative, sweetening agent, flavoring agent and bulking agent in each piece of chewable, edible, solid composition. The ratios of ingredients can be adjusted to provide pieces of composition that are and remain solid at ambient temperature. The ratios of ingredients per piece of composition are also calculated to deliver the appropriate amount of laxative for the purpose intended. For example, use of the composition to foster natural bowel movements will employ a lesser amount of laxative than will use of the composition for colonic purposes or for complete flushing of the colon in preparation for a full colonoscopy.

It has been found that the foregoing process provides an unexpected benefit to the solid composition of the invention in that its taste and mouth-feel are better than those characteristics of products of the same ingredients prepared by other processes such as compression forming, inclusion of adhering (adhesive) ingredients, molding and covering with edible coating, and mixing while warming but not melting. The compositions of the invention prepared by the foregoing process have little or no waxy taste, little or no gritty mouth-feel and are pleasing to the consumer. In contrast, products produced by alternative methods are waxy in taste and mouth-feel and are

non-homogeneous in taste. Chocolate has been found to be a preferred bulking/sweetening agent with low caloric contribution and significant benefit for taste and mouth feel. The chocolate may be dark chocolate or milk chocolate and the milk ingredient may be dairy, coconut, soybean, almond or other milk-like substance. In
 5 another embodiment lecithin, condensed milk, sweetened condensed milk, evaporated milk, fat free sweetened condensed milk or the combination thereof can be also used as bulking agent to obtain low caloric, non-chocolate product that is homogeneous with pleasant taste.

10 All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

Examples

15 The following experiments exemplify the invention. The process for formation is provided in each example after the tabular description of the ingredients and their amounts. The amounts are given in weight percents relative to the total weight of the composition.

Example 1

Ingredients	Amount
PEG 3350	17
Corn Syrup (Karo)	8
Sorbitol 70%	1
Sucralose	0.07
Strawberry flavor	0.2
Total	26.07

- 1) Mix Sorbitol 70% and corn syrup together.
 - 20 2) Heat them in a water bath up to 70 C.
 - 3) Add PEG 3350 and mix them together. Dissolve Sucralose in approximately 2 ml of water and add to the mixture.
 - 4) Cool the mixture to 50-55 C and add strawberry flavor.
- Pour the mixture into a mold and cool it. Once the mold is set, cut the bars into appropriate
 25 size.

Example 2

Ingredients	Amount
PEG 3350	17
Corn Syrup (Karo-light)	7
Sorbitol 70%	5.57
Sucralose	0.08
Citric acid	0.15
Red #40	0.05
Strawberry flavor	0.15
Total	29.9

- 1) Melt PEG 3350 on a water bath. When the temperature reads 70 C, add corn syrup and sorbitol 70% and mix
- 5 2) Add sucralose and mix
- 3) Add citric acid and dissolve
- 4) Continue heating at about 70 C for 15 minutes
- 5) Cool the mixture under stirring
- 6) At or below 50 C, add color and flavor
- 10 7) Pour into a mold
- 8) Cut into pieces when the mold is set

Example 3

Ingredients	Amount
PEG 3350	17
Corn Syrup (Karo-light)	7
Sorbitol 70%	4.875
Sucralose	0.05
Condensed milk	5
Pineapple flavor	0.05

Tropical fruit flavor	0.025
Total	34

- 1) Melt PEG 3350 on a water bath and heat on a hot plate. When the temperature reads 70 C, add corn syrup and sorbitol 70% and mix.
- 2) Add condensed milk, sucralose and mix.
- 5 3) Continue heating at about 70 C for 15 minutes
- 4) Cool the mixture under stirring
- 5) Between 50-55 C, add color and flavor.
- 6) Pour into a mold.
- 7) Cut into pieces when the mold is set.
- 10 Observation: The product did not set. Very soft.

Example 4

Ingredients	Amount
PEG 3350	17
Corn Syrup	7
Sorbitol 70%	8
Sucralose	0.05
Mixed Berry flavor	0.1
Total	32

- 1) Mix corn syrup and sorbitol 70% and heat on water bath to 60 C
- 2) Add PEG 3350 and mix well.
- 15 3) Add sucralose and mix.
- 4) Continue heating for 30 minutes.
- 5) Cool the mixture under stirring.
- 6) Between 50-55 C, add color and flavor.
- 7) Pour into a mold.
- 20 8) Cut into pieces when the mold is et. Observation: Taste is very good.

Example 5

Ingredients	Amount
PEG 3350	17

Corn Syrup	8
Sorbitol 70%	8
Sucralose	0.05
Strawberry flavor	0.1
Total	33

- 5 1) Mix corn syrup and sorbitol 70% and heat on water bath to 70 C
- 2) Add PEG 3350 and mix well.
- 3) Add sucralose and mix.
- 4) Continue heating for 30 minutes.
- 5) Cool the mixture under stirring.
- 10 6) At 50-55 C, add color and flavor.
- 7) Pour into a mold.
- 8) Cut into pieces when the mold is set.

Example 6

Ingredients	Amount
PEG 3350	17
Corn Syrup	10
Sorbitol 70%	7
Sucralose	0.041
Mint flavor	0.12
Total	35
Chocolate coat	~5

- 15 1) Mix corn syrup and sorbitol 70% and heat on water bath to 70 C
- 2) Add PEG 3350 and mix well.
- 3) Add sucralose and mix.
- 4) Continue heating for 30 minutes.
- 5) Cool the mixture under stirring.
- 20 6) At 50-55 C, add flavor.
- 7) Pour into a mold.
- 8) Cut into pieces when the mold is set.

- 9) Coat with melted chocolate.

Example 7

Ingredients	Amount
PEG 3350	17
Corn Syrup	10
Sorbitol 70%	4
Sucralose	0.041
Strawberry flavor	0.1
Red color	0.0005
Total	31
Chocolate coat	~5

- 1) Mix corn syrup and sorbitol 70% and heat on water bath to 70 C
- 5 2) Add PEG 3350 and mix well.
- 3) Add sucralose and mix.
- 4) Continue heating for 30 minutes.
- 5) Cool the mixture under stirring.
- 6) At 50-55 C, add color and flavor.
- 10 7) Pour into a mold.
- 8) Cut into pieces when the mold is set.
- 9) Coat with melted chocolate.

Example 8

Ingredients	Amount
PEG 3350	17
Ludiflash®*	13
Sucralose	0.041
Orange flavor	0.1
Mg Stearate	0.015
Total	30

*BASF

- 15 1) Mix PEG 3350, Ludiflash, Sucralose and Orange flavor
- 2) Add Mg stearate and mix

- 3) Compress using a tablet machine

Observation: Not as good as the bar.

Example 9

Ingredients	Amount
PEG 3350	17
Corn Syrup	5
Sorbitol 70%	3
Sucralose	0.041
Mint flavor	0.1
Total	25

- 5 1) Mix corn syrup and sorbitol 70% and heat on water bath to 70 C
- 2) Add PEG 3350 and mix well.
- 3) Add sucralose and mix.
- 4) Continue heating for 30 minutes.
- 5) Cool the mixture under stirring.
- 10 6) At 50-55 C, add color and flavor.
- 7) Pour into a mold.
- 8) Cut into pieces when the mold is set.

Observation: The bar did not set well. Sticky bar. Taste is good.

Example 10

Ingredients	Amount
PEG 3350	17
Corn Syrup	10
Sucralose	0.041
Mint flavor	0.1
Total	25

- 15 1) Mix corn syrup and PEG 3350 and heat on water bath to 70 C
- 2) Add sucralose and mix.
- 3) Continue heating for 30 minutes.
- 4) Cool the mixture under stirring.
- 20 5) At 50-55 C, add color and flavor.
- 6) Pour into a mold.

- 7) Cut into pieces when the mold is set.

Example 11

Ingredients	Amount
PEG 3350	17
Corn Syrup	10
Sorbitol 70%	4
Sucralose	0.041
Sodium Chloride	0.351
Sodium bicarbonate	0.17
Pot Chloride	0.047
Mint flavor	0.1
Total	31

- 1) Mix corn syrup and sorbitol and heat on water bath to 70 C.
- 2) Add PEG 3350 and mix.
- 5 3) Add sucralose and mix.
- 4) Dissolve sodium chloride, sodium bicarbonate and Potassium chloride in small quantity of water and add.
- 5) Continue heating for 30 minutes.
- 6) Cool the mixture under stirring.
- 10 7) At 50-55 C add flavor.
- 8) Pour into a mold.

Observation: Did not set well. Became pasty. Salts seem to inhibit proper setting. Salty taste.

Example 12

Ingredients	Amount
PEG 3350	17
Corn Syrup	7
Sorbitol 70%	3
Sucralose	0.041
Mint flavor	0.1
Total	27

- 15 1) Mix corn syrup and sorbitol 70% and heat on water bath to 70 C.

- 2) Add PEG 3350 and mix well.
- 3) Add sucralose and mix.
- 4) Continue heating for 30 minutes.
- 5) Cool the mixture under stirring.
- 5 6) At 50-55 C, add color and flavor.
- 7) Pour into a mold.
- 8) Cut into pieces when the mold is set.

Observation: Sticky

Example 13

Ingredients	Amount
PEG 3350	17
Corn Syrup	10
Sorbitol 70%	2
Sucralose	0.041
Mint flavor	0.1
Total	29

10

- 1) Mix corn syrup and sorbitol 70% and heat on water bath to 70 C
- 2) Add PEG 3350 and mix well.
- 3) Add sucralose and mix.
- 4) Continue heating for 30 minutes.

15

- 5) Cool the mixture under stirring.
- 6) At 50-55 C, add color and flavor.
- 7) Pour into a mold.
- 8) Cut into pieces when the mold is set.

Example 14

Ingredients	Amount
PEG 3350	17
Corn Syrup	15
Sucralose	0.041
Sodium Chloride	0.351
Sodium bicarbonate	0.179

Pot Chloride	0.047
Mint flavor	0.1
Total	32

- 1) Mix corn syrup and sorbitol and heat on water bath to 70 C
 - 2) Add PEG 3350 and mix
 - 3) Add sucralose and mix.
 - 5 4) Dissolve sodium chloride, sodium bicarbonate and Potassium chloride in small quantity of water and add
 - 5) Continue heating for 30 minutes.
 - 6) Cool the mixture under stirring.
 - 7) At 50-55 C, add flavor.
 - 10 8) Pour into a mold
- Sticky . Little rubbery.

Example 15

Ingredients	Amount
PEG 3350	17
Corn Syrup	10
Chocolate – semisweet*	8
Sucralose	0.041
Mint flavor	0.1
Total	35

*Nestle™ semi-sweet chocolate (0-28000-21580-4). Ingredients: semisweet chocolate, sugar, chocolate, cocoa butter, milk fat, soy lecithin, natural flavors

- 15 1) Mix corn syrup and sorbitol and heat on water bath to 70 C
- 2) Add PEG 3350 and mix
- 3) Add chocolate and mix
- 4) Add sucralose and mix.
- 5) Continue heating for 30 minutes.
- 20 6) Cool the mixture under stirring.
- 7) At 50-55 C, add flavor.
- 8) Pour into a mold.

Observation: Sets well. Good taste & texture.

Example 16

Ingredients	Amount
PEG 3350	17
Corn Syrup	15
Chocolate – semisweet*	8
Sucralose	0.041
Sodium Chloride	0.351
Sodium bicarbonate	0.179
Pot Chloride	0.047
Mint flavor	0.1
Total	40

*Nestle™ semi-sweet chocolate (0-28000-21580-4). Ingredients: semisweet chocolate, sugar, chocolate, cocoa butter, milk fat, soy lecithin, natural flavors

- 1) Mix corn syrup and sorbitol and heat on water bath to 70 C.
- 5 2) Add PEG 3350 and mix.
- 3) Add chocolate and mix.
- 4) Add sucralose and mix.
- 5) Cool to 50-55 C or less and add the water solution of salts.
- 6) Continue heating for 30 minutes.
- 10 7) Cool the mixture under stirring.
- 8) At 50-55 C, add flavor.
- 9) Pour into a mold

Little rubbery. Taste is good.

Example 17

Ingredients	Amount
PEG 3350	17
Corn Syrup	15

Chocolate -- Dark Ghirardelli chocolate*	8
Sucralose	0.041
Sodium Chloride	0.351
Sodium bicarbonate	0.179
Pot Chloride	0.047
Mint flavor	0.1
Total	40

*Ghirardelli unsweetened chocolate (7-47599-60106-4); Ingredients: Unsweetened chocolate.

- 1) Mix corn syrup and sorbitol and heat on water bath to 70 C.
 - 2) Add PEG 3350 and mix.
 - 5 3) Add chocolate and mix.
 - 4) Add sucralose and mix.
 - 5) Cool to 50 C or less and add the salts.
 - 6) Continue heating for 30 minutes.
 - 7) Cool the mixture under stirring.
 - 10 8) At 50-55 C add flavor.
 - 9) Pour into a mold.
- Good taste and texture.

Example 18

Ingredients	Amount
PEG 3350	13.125
Dark Chocolate*	6.18
Sucralose	0.041
Sodium Chloride	0.351

Sodium bicarbonate	0.179
Pot Chloride	0.047
Mint flavor	0.1
Total	20

*ADM cocoa: DC-1015 value BS Choc. Ingredients: Sugar, chocolate liquor, cocoa butter, chocolate liquor processed with alkali, soy lecithin, vanilla, salt and artificial flavor. May contain milk.

- 5 1) Melt PEG to 65 C on a water bath.
- 2) Add chocolate and mix.
- 3) Add sucralose and mix.
- 4) Cool to below 60 C and add salts and mix.
- 5) Cool the mixture under stirring.
- 10 6) At 50- 55 C add flavor.
- 7) Pour into a mold.

Example 19

Ingredients	Amount
PEG 3350	13.125
Milk	6.18
Chocolate*	
Sucralose	0.041
Sodium Chloride	0.351
Sodium bicarbonate	0.179
Pot Chloride	0.047
Mint flavor	0.1
Total	20

*ADM MC-050 Marquis MC. Ingredients: Sugar, milk, cocoa butter, chocolate liquor, soy lecithin, and vanilla.

- 15 The processing procedure used is the same as described for experiment 18.

Example 20

Ingredients	Amount
PEG 3350	13.125
Corn Syrup	11.7
Dark Chocolate (ADM DC-1015)	6.18
Sucralose	0.041
Sodium Chloride	0.351
Sodium bicarbonate	0.179
Pot Chloride	0.047
Mint flavor	0.1
Total	31

- 1) Melt PEG to 65 C on a water bath. Add corn syrup and mix.
- 2) Add chocolate and mix.
- 3) Add sucralose and mix.
- 4) Cool to below 60 C and add salts and mix.
- 5) Cool the mixture under stirring.
- 6) At 50- 55 C add flavor.
- 7) Pour into a mold.

Example 21

Ingredients	Amount
PEG 3350	13.125
Corn Syrup	11.7
Milk Chocolate (MC-050)	6.18
Sucralose	0.041

Sodium Chloride	0.351
Sodium bicarbonate	0.179
Pot Chloride	0.047
Mint flavor	0.1
Total	31

The processing procedure used is the same as described for experiment 20.

Example 22

Ingredients	Amount
PEG 3350	13.125
Dark Chocolate (ADM DC-1015)	8.333
Sucralose	0.041
Sodium Chloride	0.351
Sodium bicarbonate	0.179
Pot Chloride	0.047
Mint flavor	0.1
Total	22

- 5 The processing procedure used is conducted as describe for experiment 20.

Example 23

Ingredients	Amount
PEG 3350	17
Corn Syrup	12
Sucralose	0.041
Mint flavor	0.1
Total	29.14

- 1) Melt PEG to 70 C on a water bath. Add corn syrup and mix.
- 2) Add sucralose and mix.

- 3) At about 65 C add flavor.
- 4) Pour into a mold.

Example 24

Ingredients	Amount
PEG 3350	17
Corn Syrup	12
Sucralose	0.041
Strawberry flavor	0.1
Red #40	0.05
Total	29.14

- 5 The processing procedure used is similar to that of experiment 23.

Example 25

Ingredients	Amount
PEG 3350	17
Dark chocolate (ADM DC 1015)	12
Sucralose	0.041
Mint flavor	0.1
Total	29.14

The processing procedure used is similar to that of experiment 23.

Example 26

Ingredients	Amount
PEG 3350	17
Dark chocolate (ADM DC 1015)	12
Sucralose	0.041
Strawberry flavor	0.1
Total	29.14

10

The processing procedure used is similar to that of experiment 23.

Example 27

Ingredients	Amount
PEG 3350	13.125

Dark Chocolate (ADM DC-1015)	9.0
Sucralose	0.041
Sodium Chloride	0.351
Sodium bicarbonate	0.179
Pot Chloride	0.047
Mint flavor	0.1
Total	22

The processing procedure used is similar to that of experiment 20.

Example 28

Ingredients	Amount
PEG 3350	13.125
Dark Chocolate (ADM DC-1015)	9.0
Sucralose	0.041
Sodium Chloride	0.351
Sodium bicarbonate	0.179
Pot Chloride	0.047
Strawberry flavor	0.1
Total	22

The processing procedure used is similar to that of experiment 20.

5

Example 29

Ingredients	Amount
PEG 3350	13.125
Corn Syrup	15
Sucralose	0.041
Sodium Chloride	0.351
Sodium bicarbonate	0.179
Pot Chloride	0.047
Strawberry flavor	0.1
Total	28

The processing procedure used is similar to that of experiment 20.

Example 30

Ingredients	Amount
PEG 3350	13.125
Corn Syrup	15
Sucralose	0.041
Sodium Chloride	0.351
Sodium bicarbonate	0.179
Pot Chloride	0.047
Strawberry flavor	0.1
Red #40	0.05
Total	28

The processing procedure used is similar that of experiment 20.

Example 31

Ingredients	Amount
PEG 3350	17
Bisacodyl	0.005
Dark Chocolate ADM DC-1015	12
Sucralose	0.041
Mint flavor	0.1
Total	29

5

The processing procedure used is similar as that of experiment 20.

Example 32

Ingredients	Amount
PEG 3350	17
Sod Pico Sulfate	0.005
Dark Chocolate ADM DC-1015	12
Sucralose	0.041
Mint flavor	0.1
Total	29

The processing procedure used is similar as that of experiment 20.

Example 33

Ingredients	Amount
PEG 3350	17
Dark Chocolate ADM DC- 1015	12
Sucralose	0.041
Mint flavor	0.1
Total	29

The processing procedure used is similar as that of experiment 20.

Example 34

Ingredients	Amount
PEG 3350	17
Docusate Sodium	0.1
Dark Chocolate ADM DC- 1015	12
Sucralose	0.041
Mint flavor	0.1
Total	29

5

The processing procedure used is similar as that of experiment 20.

Example 35

Ingredients	Amount
PEG 3350	17
White Chocolate	12
Sucralose	0.041
Mint flavor	0.1
Total	29

10

The processing procedure used is similar as that of experiment 20.

Formulation Summary (Per bar in grams)

Item	Ingredients	R B 1	RB 115 002	RB 115 003	RB 1150 04	RB 1150 05	RB 115 006	RB 115007
1	PEG 3350	17.0	17.0	17.0	17.0	17.0	17.0	17.0
2	Corn Syrup	8 .	7.0	7.0	7.0	8.0	10.0	10.0

3	Sorbitol 70%	1 .	5.5	4.88	8.0	8.0	7.0	4.0
4	Sucralose	0.07	0.08	0.05	0.05	0.05	0.04	0.04
5	Chocolate						5.0 coat	5.0 coat
6	Mint flavor						0.12	
7	Strawberry Flavor	0 . 2	0.15					
8	Pine app. Fla			0.05				
9	Mixed berry				0.1			
10	Trop. fla			0.03				
11	Orange fla							
12	Citric acid		0.15					
13	Ludiflash							
14	Mag. Stear							
15	Red # 40		0.05 mg					0.01
16	Condensed milk			5.0				
Total Wt		26.27	29.9	34.0	32.1	33.1	40.0	37.0
Commen ts		Explor- atory Waxy taste More sweet	Waxy	Very soft	Very soft Taste ok	Good	Good	Good Choco- late coat

Formulation Summary (per tablet equivalent) - Tablet dosage form

Item #	Ingredients	RB 115 008	RB 115 009	RB 115 010
1	PEG 3350	17.0	17.0	17.00
2	Sucralose		0.05	0.041
3	Orange flavor	0.13	0.13	0.100
4	Ludiflash		5.00	13.000
5	Mag. Stear			0.0150
Total Wt		17.13	22.18	30.156

Comments		Tablets compressed by manual operation	Tablets compressed by manual operation	Tablets compressed with Mini-press
		Hard	Hard	Not as good as bar

Formulation Summary with PEG + Electrolytes (Per bar in grams)

5

Item	Ingredient s	RB 115 011	RB 115 012	RB 11500 13	RB 115014	RB 11501 5	RB 115 016	R B 11 50 17	RB 115 018	RB 115 019
1	PEG 3350	17.0	17.0	17.0	17.0	17.0	17.0	17.0	17.0	17.0
2	Corn Syrup	5.0	10.0	10.0	7.0	10.0	15.0	10.0	15.0	15.0
3	Sorbitol 70%	3.0		4.0	3.0	2.0				
4	Sucralose	0.04	0.04	0.04	0.04	0.04	0.04	0.04	0.04	0.04
5	Chocolate							8.0	8.0 Semi Sweet	8.0 Dark Chire delli
6	Sodium Chloride			0.35			0.35		0.35	0.35
7	Sod. Bi carb			0.17			0.17		0.17	0.17
8	Pot. Chloride			0.04			0.04		0.04	0.04
9	Mint flavor	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Total Wt		25.1	27.1	31.1	27.1	29.1	32.7	35.1	40.7	40.7
Comm ents		Poor Set Taste ok	Good Set Taste ok	Do not Set Salt affects setting	Sticky Rubbery	Sticky	Less sticky Taste ok	Good Set Good taste	Good set Taste good	Good set Taste good

Formulation Summary with electrolytes (Per bar in grams)

Item	Ingredients	RB 115 020	RB 115 021	RB 115 0022	RB 115 023	RB 115 025
1	PEG 3350	13.125	13.125	13.125	13.125	13.125
2	Corn Syrup			11.700	11.700	
3	Sucralose	0.041	0.041	0.041	0.041	0.041
4	Chocolate	6.180 Dark	6.180 Milk	6.180 Dark	6.180 Milk	8.333 Dark
5	Sodium Chloride	0.351	0.351	0.351	0.351	0.351
6	Sod. Bi carb	0.179	0.179	0.179	0.179	0.179
7	Pot. Chloride	0.047	0.047	0.047	0.047	0.047
8	Mint flavor	0.100	0.100	0.100	0.100	0.100
Total Wt		20.0	20.0	31.72	31.72	22.4
Comments		V. Good Set Release from mold easily	Good Set A little sticky Release from mold is bad	Harder chocolate Release from mold easily Taste good	Sticky Taste ok	Taste good Easy release from mold A lead for future experiments

Formulation Summary (Per bar- in grams)

Item	Ingredients	RB 115 026	RB 115 027	RB 115 028	R B 1
1	PEG 3350	17.000	17.00	17.00	1
2	Corn Syrup	12.000	12.00		
3	Sucralose	0.041	0.041	0.041	0.
4	Chocolate			12.00	1
5	Mint flavor	0.100		0.100	
6	Strawberry flavor		0.100		0.
7	Red # 40		0.05 mg		
Total Wt		29.141	29.141	29.141	29.141

Comments		Difficulty in releasing from mold	Difficulty in releasing from mold	Good taste; release from mold easily	Good taste; release from mold easily
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Bar Formulation Summary with PEG + Electrolytes (Per bar- in grams)

Item	Ingredients	RB 115 030	RB 115 031	RB 115 032	RB 115 033
1	PEG 3350	13.125	13.125	13.125	13.125
2	Corn Syrup			15.000	15.000
3	Sucralose	0.041	0.041	0.041	0.041
4	Chocolate	9.000	9.000		
5	Sodium Chloride	0.351	0.351	0.351	0.351
6	Sod. Bi carb	0.179	0.179	0.179	0.179
7	Pot. Chloride	0.049	0.049	0.049	0.049
8	Mint flavor	0.100		0.100	
9	Strawberry Flavor		0.100		0.100
10	Red # 40				0.05mg
	Total Wt	22.845	22.845	28.845	28.845
	Comments	Good taste; Good release from mold	Good taste; Good release from mold	Difficult to release from mold	Difficult to release from mold

5

Formulation Summary (Per bar in grams)

Item	Ingredients	RB 115 034	RB 115 035	RB 115 036	RB 115 037	RB 115 038
1	PEG 3350	17	17	17	17	17
2	Bisacodyl	0.005				
3	Sod Pico Sulfate		0.005			
4	Docusate Sodium				0.1	
5	Dark Chocolate	12	12	12	12	
6	White Chocolate					12
7	Sucralose	0.041	0.041	0.041	0.041	0.041
8	Mint flavor	0.100	0.100	0.100	0.1	0.1
	Total Wt	29	29	29	29	29

Formulation Summary (Per bar in grams)

Item	Ingredients	RB-115 039	RB-115 040	RB-115 041
1	PEG 3350	-	4.000	4.000
2	Pectin	0.320	0.320	0.320
3	Corn Syrup	4.000	4.000	4.000
4	Sugar	3.200	3.280	3.280
5	Citric acid	0.128	0.128	0.128
6	Strawberry fla	0.010	0.010	0.020
7	Purified water	2.280	2.280	2.880
Comments		Good taste Soft	Good taste A little harder in texture	Good taste A little harder in texture

Chocolate Bars

Item	Ingredients	RB 115 053	RB115 056
1	PEG 3350	17.000	17.000
2	Bisacodyl	-	-
3	Sodium Pico Sulfate	-	-
4	Docusate Sod	-	-
5	Sucralose	0.041	0.041
6	Chocolate	12.000 (white)	17.000 (white)
7	Mint flavor		
8	Strawberry flavor	0.100	0.100
9	Red # 40	0.0004	0.005
	Total Wt	29.1414	34.100
	Comments	Good taste Hard texture	Not good in taste and

Chocolate Bars

Item	Ingredients	RB 115 068	RB115 069	RB115 072	RB115 073	RB115 075
1	PEG 3350	17.000	17.000	17.000	17.000	17.000
2	Sucralose	0.041	0.041	0.041	0.041	0.041
3	Dark Chocolate – ADM	13.000	-	13.000 (ADM)	-	13.000 (ADM)
4	White Chocolate		13.000 (ADM)		13.000 (Nestle)	-
5	Purified Water	-	-	-	-	0.416
6	Mint flavor					
7	Strawberry flavor	0.100	0.100	0.100	0.100	0.100
8	Red # 40		0.0005		0.0005	
	Total Wt	30.141	30.142	30.141	30.142	30.557
	Comments	Good Taste Appear- ance not good	Good Taste Appear- ance not good	Silicon pop mold Good taste Appear- ance not good	Appea- rance is good Good taste	Appear- ance is good Good taste Texture is good
Procedure 068: Melt PEG in a container on a water bath at 80°C. Add Sucralose and dissolve . Mix well. Add Chocolate and mix well to disperse uniformly. Start cooling , add flavor. Mix well. Pour into molds. Cool to set . 069: Melt PEG in a container on a water bath at 80°C. Add Sucralose and dissolve . Mix well. Add Chocolate and mix well to disperse uniformly. Add color and mix well. Start cooling , add flavor. Mix well. Pour into molds. Cool to set . 072: Same as 068 073:ame as 069 075: Melt PEG in a container on a water bath at 80°C. Dissolve Sucralose in a small quantity of water and add to the bulk. Mix well. Add Chocolate and mix well to disperse uniformly. Start cooling , add flavor. Mix well. Pour into molds. Cool to set .						

Chocolate Bars

Item	Ingredients	RB115 070	RB115 071
1	PEG 3350	17.000	17.000
2	Sucralose	0.041	0.041
3	Sod.Chloride	0.351	0.351
4	Pot.Chloride	0.049	0.049
5	Sod.bi carbonate	0.179	0.179
6	Dark Chocolate – ADM	16.155	-
7	White Chocolate (Nestle)	-	116.155
8	Mint flavor	0.100	0.100
	Total Wt	30.000	30.000
	Comments	Good Taste Appear- ance not good Texture is spotty	Good Taste Appear- ance is okay Texture is hard
	Procedure 070 & 071: Melt PEG in a container on a water bath at 80°C till it forms a clear solution. Add Sucralose and dissolve . Grind all the 3 salts with a mortar and pestle and add to the bulk and mix well to disperse uniformly. Add the chocolate and disperse uniformly maintaining the temperature at 80°C. Add the flavor , mix well .pour into molds and cool to set.		

Chocolate Bar

			PEG 3350 alone		PEG 3350 + Electrolytes		
Item	Ingredients	RB115 - 081	RBMP-115- 88	RB115- 082	RB115- 080	RB115- 083	RB115-083A Chocolate coated
1	PEG 3350	17.000	17.000	17.000	13.125	13.125	13.125
2	Sucralose	0.042	0.040	0.042	0.042	0.042	0.042
3	P. Water	0.832	0.830	0.832	0.832	0.832	0.832
4	Sod. Benzoate	-	0.030	-	-	-	
5	Sodium Chloride	-	-	-	0.351	0.351	0.351
6	Pot. Chloride	-	-	-	0.049	0.049	0.049
7	Sod.bi carb	-	-	-	0.179	0.179	0.179
8	Dark Chocolate (ADM)	12.000	12.000		11.000		
9	White Chocolate			12.000 (Nestle)		11.000 (Nestle)	11.000 (Nestle)
10	Mint flavor	-	-	0.100	0.100	0.100	0.100
11	Strawberry Flavour	0.100	0.100	-	-	-	-
	Total Wt	29.975	30.000	29.975	25.261	25.261	25.261 + 5 gm. dark chocolate coat
	Comments	Brown	Brown Taste texture appearance -good	White	Brown	White	White core inside brown coat outside

Procedure

081: Melt PEG in a container on a water bath at 80°C till it forms a clear solution. Dissolve Sucralose in a small quantity of water and add to the bulk. Add the chocolate, mix well to distribute uniformly maintaining the temperature at 80°C. Discontinue heating, add the flavor and mix well. Pour into molds and cool to set.

082: Same as 081

088: Melt PEG in a container on a water bath at 80°C till it forms a clear solution. Dissolve Sodium benzoate and Sucralose in a small quantity of water and add to the bulk. Add the chocolate, mix well to distribute uniformly maintaining the temperature at 80°C. Discontinue heating, add the flavor and mix well. Pour into molds and cool to set.

080: Melt PEG in a container on a water bath at 80°C till it forms a clear solution. Add Sucralose and dissolve. Grind all the 3 salts with a mortar and pestle and add to the bulk and mix well to disperse uniformly. Add the chocolate and disperse uniformly maintaining the temperature at 80°C. Add the flavor, mix well. Pour into molds and cool to set.

083A: The core chocolates from the experiment 083 are coated with 5 gms of dark chocolate to form a uniform coat.

Non-Chocolate Bars (Grams per bar)

Item	Ingredients	RB115-091	RB115-092	RB115-093	RB115-094	RB115-095
1	PEG 3350	17.000	17.000	13.125	17.000	17.000
2	Sod.Chloride	-	-	0.351	-	-
3	Pot. Chloride	-	-	0.049	-	-
4	Sod.bicarb	-	-	0.179	-	-
5	Sucralose	0.042	0.042	0.042	0.042	0.042
6	Maltitol Syrup	5.000	-	-	-	-
7	Pectin	-	-	-	-	0.167
8	Citric acid	0.100	0.100	0.100	-	-
9	Orange shade color	0.002	0.002	0.002	-	-
10	Red # 40	0.100	-	-	-	0.002
11	Mint Flavor	-	-	-	0.100	-
12	Orange flavor	-	0.100	0.100	-	-
13	Strawberry Flavor	-	-	-	-	0.100
14	Purified water	0.100	2.000	1.66	2.000	2.00
Total		22.344	19.244	15.614	19.142	19.311

	Comments	PEG gets separated	Waxy taste	PEG gets separated	Waxy taste	Taste, Texture and appearance are not good at all
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Procedure:

RB-115-091: Melt PEG 3350 in a SS container kept on a water bath at 80°C till it forms a clear liquid. Dissolve Sucralose in it. Mix Maltitol syrup, orange color, orange flavor.

- 5 Dissolve citric acid in water and add to the maltitol syrup solution containing the flavor and color. Add this mixture to the melted PEG solution and mix well to form homogeneous mixture. Pour into Silicon molds. Cool to set.

- RB-115-092: Melt PEG 3350 in a SS container kept on a water bath at 80°C till it forms a clear liquid. Dissolve Sucralose in it. Dissolve flavor, color and citric acid in water and add to the melted PEG 3350. Mix well .It forms a clear solution. Pour into the molds. Cool to set.

RB-115-093: Melt PEG 3350 in a SS container kept on a water bath at 80°C till it forms a clear liquid. Dissolve Sucralose in it. Dissolve all the 3 salts, citric acid in water . It forms a hazy solution. Add this solution to the melted PEG solution. Pour in to molds. Cool to set.

- RB-115-094: Melt PEG 3350 in a SS container kept on a water bath at 80°C till it forms a clear liquid. Dissolve Sucralose in it. Add the mint flavor, add the water, mix well. Pour into the molds. Cool to set.

RB-115-095: Melt PEG 3350 in a SS container kept on a water bath at 80°C till it forms a clear liquid. Dissolve Sucralose in it. Suspend the Pectin in it. Dissolve the color, flavor in water and add the bulk. Pour in to the molds. Cool to set.

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Non-Chocolate Bars (Grams per bar)

Item	Ingredients	RB115-096	RB115-097	RB115-098	RB115-099	RB115-100
1	PEG 3350	17.000	17.000	17.000	17.000	17.000
2	Sucralose	--				0.042
3	Glycerin	1.666	1.666	2.083	3.666	3.000
4	Sugar	-	4.166	8.333	-	-
5	Isomalt	-	-	-	8.333	-
6	Red # 40	-	-	0.002	0.002	0.001
7	Vanilla Flavor	-	-	-	-	0.050

8	Strawberry Flavor	-	-	0.100	0.100	0.100
9	Purified water	-	-	-	-	-
	Total Wt	18.166	22.832	27.578	29.102	20.193
	Comments	Taste not good	Taste not good	Taste not good	Bad taste	Waxy taste

Procedure:

RB-115-096: Melt PEG 3350 in a container on a water bath at 80°C till it forms a clear solution. Add glycerin and mix well. Cool to 60°C and pour into molds. Cool to set.

- 5 RB-115-097: Melt PEG 3350 in a container on a water bath at 80°C till it forms a clear solution. Add glycerin and mix well. Suspend sugar and mix well. Pour into molds. Cool to set.

- RB-115-098: Melt PEG 3350 in a container on a water bath at 80°C till it forms a clear solution. Dissolve the color and flavor in glycerin and add to the bulk. Suspend the sugar and mix well. Pour into the molds and cool to set.

- 10 RB-115-099: Melt PEG 3350 in a container on a water bath at 80°C till it forms a clear solution. Dissolve the color and flavor in glycerin and add to the bulk. Suspend Isomalt and mix well. Pour into molds and cool to set.

- 15 RB-115-100: Melt PEG 3350 in a container on a water bath at 80°C till it forms a clear solution. Add sucralose and dissolve. Dissolve the color and flavor in glycerin and add to the bulk. Cool to 70°. Pour in to molds. Cool to set.

Non-Chocolate Bars (Grams per bar)

		PEG 3350 alone 17 gms		PEG 3350 + Electrolytes 13.125+0.351+0.049+0.179
Item	Ingredients	RB115-101	RB115-102	RB115-103
1	PEG 3350	17.000	17.000	13.125
2	Sucralose	0.021	0.042	0.042
3	Soy Lecithin	0.333	1.000	1.000
4	Sweetened Condensed milk	15.000	15.000	13.000
5	Sod.Chloride	-	-	0.351
6	Pot.Chloride	-	-	0.049
7	Sod.bi.carb	-	-	0.179
8	Red# 40	-	0.002	0.002
9	Vanilla Flavor	0.100	-	-

10	Strawberry Flavor		0.100	0.100
	Total Wt	32.450	33.144	27.848
	Comments	Taste, Texture and Appearance are good	Taste, Texture and Appearance are good	Taste, Texture and Appearance are good

Procedure:

RB115-101: Melt PEG in a container on a water bath at 80°C till it forms a clear solution.

Dissolve Sucralose in it. Add Lecithin and dissolve. Add Sweetened Condensed Milk and mix well maintaining the temperature at 80°C for 20 minutes. Cool to 70°C, add the flavor and

5 mix well. Pour into molds and cool to set.

RB115-102: Same as 101

RB115-103: Melt PEG in a container on a water bath at 80°C till it forms a clear solution.

Dissolve Sucralose in it. Add Lecithin and dissolve. Add Sweetened Condensed Milk and mix well maintaining the temperature at 80°C for 20 minutes. Add and mix well the salt blend

10 previously powdered and mixed. Cool to 70°C, add the flavor and mix well. Pour into molds and cool to set.

SUMMARY for Non-Chocolate bars for experiments 91-103: Maltitol syrup, Pectin and Glycerin were tried in the formulation and were unsuccessful. Subsequently, Sweetened Condensed Milk/Soy lecithin were tried and found to produce good soft tasty bars.

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Dark Chocolate bar with Fiber

Item	Ingredients	RB-115-106 Per bar (gms)
1	PEG 3350	17.000
2	Soluble fiber – (Wheat Dextrin); (Nutriose®)	6.000
3	Sucralose	0.042
4	Purified water	2.500
5	Sod. Benzoate	0.030
6	Dark Chocolate (ADM)	12.000
7	Strawberry Flavor	0.100
	Total wt	37.672
	Comments	Good taste, Good texture

Procedure: Melt PEG in a container on a water bath at 80°C till it forms a clear solution.

Dissolve Sucralose in it. Dissolve Sod. Benzoate in a small quantity of water and add to the bulk. Add Chocolate chips and disperse well by mixing and continuous heating at 80°C. Add

the Nutriose® and disperse well by mixing. Add the flavor. Pour in to molds and cool to set

Non-Chocolate bar with Fiber

Item	Ingredients	RB-115-107 Per bar (gms)
1	PEG 3350	17.000
2	Soluble fiber – Wheat Dextrin (Nutriose®)	6.000
3	Sucralose	0.042
4	Soy – Lecithin (WhC)	1.000
5	Sweetened Condensed Milk	15.000
6	Vanilla Flavor	0.100
7	Caramel Flavor	0.050
	Total Wt	39.192
	Comments	Good taste, Soft bar in texture

Procedure: Melt PEG in a container on a water bath at 80°C till it forms a clear solution.

- 5 Dissolve Sucralose in it followed by Lecithin. Mix well. Add Sweetened Condensed Milk and mix well. Stop heating. Add the flavors and mix well. Pour into molds and cool to set.

Aspects and Embodiments of the Invention

- Embodiment 1: An edible, solid composition, comprising: a laxative and a bulking agent wherein the composition is formed by heating the laxative and bulking agent together to form a fluid dispersion and cooling the fluid dispersion to form the edible solid composition, and wherein the edible solid composition has laxative properties.

- Embodiment 2: The edible, solid composition according to embodiment 1 or embodiment 22 wherein the bulking agent is selected from the group consisting of corn syrup, sorbitol, sucrose, dextrose, invert sugar, ludiflash, chocolate, maltitol, high fructose syrup, rice syrup, barley malt syrup, glycerin, maltodextrins, starch hydrolysate, honey, molasses, soy lecithin, condensed milk, fat free sweetened condensed milk, evaporated milk, sweetened condensed milk and any combination thereof.

Embodiment 3: The edible, solid composition according to embodiments 1 or 2 or embodiment 22 further comprising a sweetening agent.

- Embodiment 4: The edible, solid composition according to embodiment 3 or embodiment 22 wherein the sweetening agent is selected from the group consisting of sugar, sorbitol, saccharine, aspartame, acesulfame potassium, sucralose, isomalt, mannitol, stevia, cyclamate, dextrose, glucose, fructose, honey, high fructose syrup and any combination thereof.

Embodiment 5: The edible, solid composition according to any one of embodiments 1-4 or embodiment 22 wherein the laxative is selected from the group consisting of polyethylene glycol, castor oil, senna, bisacodyl, sodium pico sulfate, magnesium citrate, magnesium hydroxide (milk of magnesia), magnesium carbonate magnesium sulfate (Epsom salt), sodium sulfate, potassium sulfate, sodium chloride, potassium chloride, sodium bicarbonate, aloes, cascara sacra, psyllium husk (Metamucil), guar gum, maltodextrins, inulin, docusate sodium, methyl cellulose, monobasic sodium phosphate, dibasic sodium phosphate, glycerin, sorbitol, mannitol, sodium potassium tartrate, mineral oil (liquid paraffin), lactulose, rhubarb, agar agar, figs (Syrup of Figs), L-glucose and any combination thereof.

Embodiment 6: The edible, solid composition according to embodiment 5 or embodiment 22 wherein the laxative is polyethylene glycol, magnesium citrate, inulin, castor oil or lactulose.

Embodiment 7: The edible, solid composition according to any one of embodiments 1-6 or embodiment 22 wherein the laxative comprises at least 40 wt% relative to the total weight of the composition.

Embodiment 8: The edible, solid composition according to any of embodiments 1, 2, 3, 4 or 7 or embodiment 22 wherein the laxative is polyethylene glycol and the polyethylene glycol is melted or its physical form is converted to a flowable viscosity by application of heat.

Embodiment 9: The edible, solid composition according to any one of embodiments 1-8 or embodiment 22 wherein the bulking agent is mixed with the melted or flowably viscous polyethylene glycol to form a flowable dispersion of ingredients and the flowable dispersion is placed into one or more molds and cooled to form the solid composition.

Embodiment 10: The edible, solid composition according to any one of embodiments 1-9 or embodiment 22 in the form of a bar, a lozenge, a chewable candy, or a chewable solid confection.

Embodiment 11: The edible, solid composition according to any one of embodiments 1-10 or embodiment 22 wherein the form is substantially homogeneous.

Embodiment 12: The edible, solid composition according to any one of embodiments 1-11 or embodiment 22 which remains solid at ambient temperature.

Embodiment 13: The edible, solid composition according to any one of embodiments 1-12 or embodiment 22 wherein the bulking agent is selected from the group consisting of

soy lecithin, condensed milk, fat free sweetened condensed milk, evaporated milk, sweetened condensed milk and any combination thereof; and the laxative is selected from the group consisting of polyethylene glycol, magnesium citrate, lactulose and any combination thereof; and the composition is in the solid form of a bar or chewable candy.

5 Embodiment 14: The edible, solid composition according to embodiment 13 or embodiment 22 wherein the bulking agent is a combination of soy lecithin and a second bulking agent selected from the group consisting of condensed milk, fat free sweetened condensed milk, evaporated milk, sweetened condensed milk and any combination thereof; the laxative is polyethylene glycol; and the composition is in the solid form of a bar or
10 chewable candy.

 Embodiment 15: The edible, solid composition according to any one of embodiments 1-14 or embodiment 22 further comprising an electrolyte.

 Embodiment 16: The edible, solid composition according to any one of embodiments 1-15 or embodiment 22 further comprising a flavoring agent.

15 Embodiment 17: The edible, solid composition according to embodiment 15 or embodiment 22 wherein the electrolyte is selected from the group consisting of sodium chloride, potassium chloride, potassium bicarbonate, magnesium chloride and any combination thereof.

 Embodiment 18: The edible, solid composition according to embodiment 16 or
20 embodiment 22 wherein the flavoring agent is selected from the group consisting of bubble gum, cherry, mixed berry, fruit punch, pine apple, caramel, mixed fruit, chocolate, spearmint, peppermint, menthol, licorice, orange, lemon, Watermelon, melagawine, cranberry, tutti frutti, mix of cardamom and orange, vanilla, ice cream soda, salt masking flavor and any combination thereof.

25 Embodiment 19: The edible, solid composition according to any of the foregoing embodiments or embodiment 22 wherein the laxative is polyethylene glycol is polyethylene glycol 3350.

 Embodiment 20: The edible composition according to any of the foregoing
embodiments or embodiment 22 wherein the bulking agents are less than 20% of the weight
30 of the bar.

 Embodiment 21: The edible, solid composition according to any of the foregoing
embodiments or embodiment 22 wherein the bulking agents are less than 10% of the weight
of the bar.

 Embodiment 22: An edible solid composition comprising a substantially

homogeneous, solid, amorphous dispersion of a laxative, a bulking agent and a sweetening agent, the dispersion having a smooth, non-crystalline, non-gritty mouth feel and a sweet taste.

Embodiment 23: The edible solid composition according to embodiment 22 wherein
5 the laxative is polyethylene glycol, magnesium citrate, inulin, castor oil or lactulose.

Embodiment 24: The edible solid composition according to embodiment 22 wherein the laxative is polyethylene glycol.

Embodiment 25: The edible solid composition according to embodiment 22
10 containing chocolate.

While preferred embodiments of the present invention have been shown and described herein, it will be apparent to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be
15 understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

CLAIMS

1. An edible, solid composition, comprising: a laxative and a bulking agent wherein the composition is formed by heating the laxative and bulking agent together to form a fluid dispersion and cooling the fluid dispersion to form the edible solid composition, and wherein the edible solid composition has laxative properties.
2. The edible, solid composition according to claim 1 wherein the bulking agent is selected from the group consisting of corn syrup, sorbitol, sucrose, dextrose, invert sugar, ludiflash, chocolate, maltitol, high fructose syrup, rice syrup, barley malt syrup, glycerin, maltodextrins, starch hydrolysate, honey, molasses, soy lecithin, condensed milk, fat free sweetened condensed milk, evaporated milk, sweetened condensed milk and any combination thereof.
3. The edible, solid composition according to claims 1 or 2 further comprising a sweetening agent.
4. The edible, solid composition according to claim 3 wherein the sweetening agent is selected from the group consisting of sugar, sorbitol, saccharine, aspartame, acesulfame potassium, sucralose, isomalt, mannitol, stevia, cyclamate, dextrose, glucose, fructose, honey, high fructose syrup and any combination thereof.
5. The edible, solid composition according to claims 1 or 2 wherein the laxative is selected from the group consisting of polyethylene glycol, castor oil, senna, bisacodyl, sodium pico sulfate, magnesium citrate, magnesium hydroxide (milk of magnesia), magnesium carbonate magnesium sulfate (Epsom salt), sodium sulfate, potassium sulfate, sodium chloride, potassium chloride, sodium bicarbonate, aloes, cascara sacra, psyllium husk (Metamucil), guar gum, maltodextrins, inulin, docusate sodium, methyl cellulose, monobasic sodium phosphate, dibasic sodium phosphate, glycerin, sorbitol, mannitol, sodium potassium tartrate, mineral oil (liquid paraffin),

lactulose, rhubarb, agar agar, figs (Syrup of Figs), L-glucose and any combination thereof.

6. The edible, solid composition according to claim 5 wherein the laxative is polyethylene glycol, magnesium citrate, inulin, castor oil or lactulose.

7. The edible, solid composition according to claim 1 wherein the laxative comprises at least 40 wt% relative to the total weight of the composition.

8. The edible, solid composition according to any of claims 1, 2, or 7 wherein the laxative is polyethylene glycol and the polyethylene glycol is melted or its physical form is converted to a flowable viscosity by application of heat.

9. The edible, solid composition according to claim 8 wherein the bulking agent is mixed with the melted or flowably viscous polyethylene glycol to form a flowable dispersion of ingredients and the flowable dispersion is placed into one or more molds and cooled to form the solid composition.

10. The edible, solid composition according to claim 1 in the form of a bar, a lozenge, a chewable candy, or a chewable solid confection.

11. The edible, solid composition according to claim 10 wherein the form is substantially homogeneous.

12. The edible, solid composition according to claim 11 which remains solid at ambient temperature.

13. The edible, solid composition according to claim 10 wherein the bulking agent is selected from the group consisting of soy lecithin, condensed milk, fat free sweetened condensed milk, evaporated milk, sweetened condensed milk and any combination thereof; and the laxative is selected from the group consisting of polyethylene glycol, magnesium citrate, lactulose and any combination thereof; and the composition is in the solid form of a bar or chewable candy.

14. The edible, solid composition according to claim 13 wherein the bulking agent is a combination of soy lecithin and a second bulking agent selected from the group consisting of condensed milk, fat free sweetened condensed milk, evaporated milk, sweetened condensed milk and any combination thereof; the laxative is polyethylene glycol; and the composition is in the solid form of a bar or chewable candy.
15. The edible, solid composition according to claim 1 further comprising an electrolyte.
16. The edible, solid composition according to claims 1, 14 or 15 further comprising a flavoring agent.
17. The edible, solid composition according to claim 15 wherein the electrolyte is selected from the group consisting of sodium chloride, potassium chloride, potassium bicarbonate, magnesium chloride and any combination thereof.
18. The edible, solid composition according to claim 16 wherein the flavoring agent is selected from the group consisting of bubble gum, cherry, mixed berry, fruit punch, pine apple, caramel, mixed fruit, chocolate, spearmint, peppermint, menthol, licorice, orange, lemon, Watermelon, melagawine, cranberry, tutti frutti, mix of cardamom and orange, vanilla, ice cream soda, salt masking flavor and any combination thereof.
19. The edible, solid composition according to claim 1, wherein the laxative is polyethylene glycol is polyethylene glycol 3350.
20. The edible composition according to claim 1, wherein the bulking agents are less than 20% of the weight of the bar.
21. The edible, solid composition according to claim 1, wherein the bulking agents are less than 10% of the weight of the bar.

22. An edible solid composition comprising a substantially homogeneous, solid, amorphous dispersion of a laxative, a bulking agent and a sweetening agent, the dispersion having a smooth, non-crystalline, non-gritty mouth feel and a sweet taste.
23. The edible solid composition according to claim 22 wherein the laxative is polyethylene glycol, magnesium citrate, inulin, castor oil or lactulose.
24. The edible solid composition according to claim 22 wherein the laxative is polyethylene glycol.
25. The edible solid composition according to claim 22 containing chocolate.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2012/056650

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61J 3/00 (2012.01)

USPC - 514/892

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A23G 4/00, 4/04; A61J 3/00; A61K 8/19; A23L 1/48 (2012.01)

USPC - 424/601; 426/61; 514/53; 514/892

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Orbit.com, Google Patents, Google

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 5,126,150 A (PIATT et al) 30 June 1992 (30.06.1992) entire document	1-7, 10-13, 15-18, 20-24 ----- 8, 9, 14, 19, 25
Y	US 2009/0053304 A1 (CHEN et al) 26 February 2009 (26.02.2009) entire document	8, 9
Y	US 6,576,253 B2 (MANNING et al) 10 June 2003 (10.06.2003) entire document	14
Y	US 5,710,183 A (HALOW) 20 January 1998 (20.01.1998) entire document	19
Y	EP 0 387 933 A1 (CAPPEL et al) 19 September 1990 (19.09.1990) entire document	25
A	Potassium Bicarbonate Material Safety Data Sheet. Document [online]. Teledyne Instruments Analytical Instruments. 2012 [retrieved on 2012-11-7]. Retrieved from the internet: <URL: http://www.teledyne-ai.com/pdf/msds_type_c_electrolyte.pdf > entire document	1-25
A	Sennosides natural, time-tested laxative. Article [online]. Metha Pharmaceuticals PVT LTD. 2012 [retrieved on 2012-11-6]. Retrieved from the internet: <URL: http://www.sennosides.com/constipation.htm > entire document	1-25

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

07 November 2012

Date of mailing of the international search report

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