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Kuntawala et al.(10) **Pub. No.: US 2016/0198759 A1**(43) **Pub. Date: Jul. 14, 2016**(54) **E-CIGARETTE OR VAPING FLUID****Publication Classification**(71) Applicant: **ZIP LLC**, Manhattan Beach, CA (US)(51) **Int. Cl.***A24B 15/16* (2006.01)(72) Inventors: **Shyam Kuntawala**, Grapevine, TX
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(2013.01); *A24B 15/308* (2013.01)(73) Assignee: **ZIP LLC**, Manhattan Beach, CA (US)

(57)

ABSTRACT(21) Appl. No.: **14/984,774**(22) Filed: **Dec. 30, 2015****Related U.S. Application Data**(60) Provisional application No. 62/102,894, filed on Jan.
13, 2015.

Improved vaping fluids for energy boos, relaxation, appetite and other functions contain active ingredients combined with cyclodextrin to enhance absorption and avoid irritation. Active ingredients include caffeine, theophylline, yerba mate and valerian as well as taurine, carnitine and L-tryptophan. The active ingredients are combined with an aqueous solution of hydrophilic solvents (such as glycerin or propylene glycol) as well as traces of scents or flavors.

E-CIGARETTE OR VAPING FLUID**CROSS-REFERENCE TO PRIOR APPLICATIONS**

[0001] This application is based on and claims the priority and benefit of U.S. Provisional Patent Application No. 62/102,894 which was filed on 13 Jan. 2015.

[0002] U.S. GOVERNMENT SUPPORT

[0003] Not applicable.

BACKGROUND OF THE INVENTION

[0004] 1. Area of the Art

[0005] The current invention is in the area of e-cigarettes and “vaping” and concerns an improved non-nicotine fluid for e-cigarette devices.

[0006] 2. Description of the Invention

[0007] Smoking has a long history in human cultures. When plant materials are burned various organic chemicals that are constituents of the plant vaporize and attach themselves to the smoke particles. At the same time heat and combustion break down constituent organic chemicals and produce new chemicals all of which are present in the vapor state and/or attach themselves to the smoke particles. When the smoke is inhaled, the particles come into contact with the surface of lung cells and the chemicals absorbed to the particles transfer to the lung cells and eventually are transferred into the circulatory system. Because of the extremely large surface area of the lung, smoking is an extremely effective route for administering active compounds. Because plants contain a wide variety of secondary products inhaling the smoke delivers these products to the human body. The physiological results can be stimulation, depression or even hallucination depending on what type of plant is burned to produce the smoke.

[0008] Of course, the active molecules delivered by the smoke can be highly addictive as in the case of nicotine in tobacco smoke. Probably because of its addictive nature tobacco has become the primary plant material that is smoke worldwide—to the point that “smoking” has become essentially synonymous with “tobacco smoking.” Whereas tobacco smoking was once considered to be a benign or even healthful pastime, it is now considered to be a health hazard. Over the last fifty years it has been shown that tobacco smoking is major cause of lung as well as other cancers in smokers as well as those exposed to “second hand” smoke. In addition, there is a correlation between smoking tobacco and heart as well as vascular disease.

[0009] It is true that because of the wide range of natural chemicals (“natural products”) in plants, smoke from burning many different plants shows at least some carcinogenic properties. However, for whatever reason it appears as if tobacco smoke may be more carcinogenic than other types of smoke. In addition, it also appears as if exposure to tobacco smoke results in more vascular damage than other smoke exposure. This may be because there are insufficient data on long term exposure to other types of smoke. Or perhaps chronic exposure to constituents of tobacco smoke results in vascular damage. In any case, there is a worldwide effort to reduce or eliminate tobacco smoking. Today smoking is prohibited on airlines, in most restaurants and buildings as well as a variety of other locales. Because nicotine is addictive, there is a major industry that attempts to help smokers stop smoking.

[0010] “Electronic cigarettes” (e-cigarettes) have been developed as a safer alternative to smoking tobacco. In an

e-cigarette a mechanism reduces a liquid (“e-cigarette fluid,” “e-fluid” or “vaping fluid”) into a smoke-like mixture of air and tiny droplets (an aerosol) which material is then inhaled. Any active constituents in the vaping fluid are then absorbed by the lungs like real smoke. Because e-cigarettes do not produce smoke, other terms have been developed to describe using the devices. One such term that is gaining popularity is “vaping.” Thus, one does not smoke an e-cigarette—one “vapes” it. E-cigarettes are thought to be safer than smoking tobacco because nothing is actually burned in an e-cigarette. The most common type of e-cigarette has a heating element which vaporizes the e-fluid to create an aerosol. Less commonly there is mechanical production of the aerosol. For example, some devices use a piezoelectric diaphragm which vibrates at ultrasonic speeds to directly form an aerosol from the e-fluid rather like a cool-mist humidifier.

[0011] Most e-fluids contain nicotine (approximately 0.04M-0.12M) so that vaping an e-cigarette can act as a substitute for smoking tobacco by delivering nicotine to the user. There is considerable use of such nicotine e-cigarettes as smoking cessation devices. The idea is that the users transition to the e-cigarettes and then use e-fluids with diminishing levels of nicotine until the user’s nicotine addiction is overcome. However, many users alternate between “real” cigarettes and e-cigarettes so the usefulness of vaping e-cigarettes as an aid to smoking cessation is somewhat questionable. Certainly, the e-cigarette avoids the dangers of secondhand tobacco smoke.

[0012] There has been considerable development of e-fluid formulations with various flavors and scent ingredients being added to enhance the user’s enjoyment. In addition, e-fluids without any nicotine have been marketed. The idea being that the user will sufficiently enjoy vaping so that nicotine becomes unnecessary. However, if the goal is to replace addictive nicotine, it is probably necessary to provide some other active component so that the user gets some sort of physiological result from the vaping process.

[0013] There is a very long history of humans ingesting various plant products for their physiological effects. Some plant products are intoxicating or even hallucinogenic. Generally, such materials are subject to strict legal controls. Other plant products are stimulants many of which are legal and widely used such as the methylxanthines: caffeine (coffee), theobromine (chocolate) and theophylline (tea). These agents improve energy and feeling of well-being. These stimulants are considered safe and many people enjoy their effects. The present inventor has considered substituting them for nicotine in e-fluid. It is believed that secondhand “smoke” from e-cigarettes containing methylxanthine derivatives would be free of the health concerns that attend secondhand e-cigarette nicotine “smoke.” There is a long history of inhaling strong preparations of theophylline and other methylxanthine derivatives as a bronchial dilator for the treatment of asthma and other obstructive lung conditions. Inhalation of these agents has not been associated with significant health problems. Therefore, use of much lower concentrations of methylxanthine derivatives in e-fluids is unlikely to have any negative health consequences. However, when inhaled, these agents will be systemically absorbed with general stimulant effects similar to consuming methylxanthine containing beverages. This will impart the physiological result to enhance the desirability of vaping.

SUMMARY OF THE INVENTION

[0014] The inventors have discovered that improved vaping fluids can be obtained by combining a variety of active ingredients with the hydrophilic solvents typical of such fluids. The active ingredients are chosen depending on the desired effects of using the fluid. For example, methylxanthines such as caffeine can be used to provide an energy boost product. Energy boost formulae can also contain taurine, cyanocobalamin, carnitine, guarana, and ginseng. Relaxation/sleep formulae can include chamomile, valerian, kava and other active ingredients. Appetite suppressant formulae can contain hoodia, yerba mate, caralluma and lecithin. Besides active ingredients a variety of scents/flavors and colors can also be included. It is preferred to use natural plant extracts to impart colors. Cyclodextrin is included to enhance absorption of the active ingredients as well as to limit any tendency of the inhaled aerosol to cause irritation. Detailed Description of the Invention

The following description is provided to enable any person skilled in the art to make and use the invention and sets forth the best modes contemplated by the inventor of carrying out his invention. Various modifications, however, will remain readily apparent to those skilled in the art, since the general principles of the present invention have been defined herein specifically to provide improved non-nicotine fluids for vaping.

[0015] Generally, e-fluids contain water and one or more hydrophilic solvent such as glycerol, propylene glycol and/or polyethylene glycol. The hydrophilic solvent is important for the production of aerosols by a heat source. When a water solution of these solvents contacts a heat source, the water rapidly vaporizes leaving behind an aerosol of hydrophilic solvent particles which contain the other ingredients that were dissolved in the original e-fluid and/or the other ingredients are present as tiny particles. The “other ingredients” (besides “active” ingredients such as nicotine, in traditional e-fluid, or methylxanthine or other active ingredients in the alternative e-fluid disclosed here) include flavors, scents and additives intended to enhance the efficacy of the other ingredients. To be effective the ingredients must be carried into the user’s lungs. This generally occurs because the ingredients are bound to or dissolved in the aerosol particles. However, the aerosol particles may not always be of optimum size so that they are filtered out by lung structures before there is a chance for the active ingredients to be properly absorbed. In other cases the aerosol particles are somewhat irritating to the user’s throat and other tissues.

[0016] The problem with the aerosol particles not being efficiently absorbed can be dealt with by increasing the concentration of the active ingredients. However, this may also increase the ability of the particles to cause irritation. Where the active ingredient is nicotine, it can be dangerous to increase the nicotine concentration too much since nicotine is extremely toxic. What is needed is a method to enhance the effectiveness of active ingredients while at the same time reducing any propensity for irritation. The present inventor has found that certain polysaccharides can serve this function. Addition of cyclodextrin to e-fluid enhances the absorbability of active ingredients while suppressing any irritating tendency of the aerosol. Cyclodextrin is a cyclic polysaccharide made of a 1, 4 linked glucose units. There are three common types: a cyclodextrin (6 glucose units), cyclodextrin (7 glucose units) and γ cyclodextrin (8 glucose units). It is known that cyclodextrins are useful for sequestering hydrophobic

molecules and for forming droplets in a nebulizer. Until now it was not appreciated that cyclodextrins also promote aerosol formation with the heating elements of common e-cigarettes (as well as with the spray jets of nebulizers). More importantly, the addition of sufficient cyclodextrin to e-fluid enhances the absorption and bioavailability of any active ingredients while at the same time reducing any tendency towards irritation caused by the aerosol.

[0017] In solution the cyclodextrin molecules form a somewhat conical structure—that is, a hollow cylinder having a smaller opening at one end than the other. The cyclodextrin molecule in solution has an interior that is more hydrophobic than its exterior (i.e., the exterior is relatively hydrophilic). For the cyclodextrin to operate in the current invention, the molecule to be sequestered must be at least partially hydrophobic and of dimensions to fit within the cyclodextrin ring. Active ingredients such as methylxanthines and nicotine are of the right size for sequestration and are essentially hydrophobic at physiological and acid pHs. The choice of cyclodextrin is affected by the active ingredient as well as the other ingredients in the e-fluid formula. Both α and γ cyclodextrin have a water solubility that is approximately an order of magnitude higher than that of β cyclodextrin. Therefore, if it is desired to use a relatively high level of active ingredient, α and γ cyclodextrin are preferred. Otherwise, β cyclodextrin operates adequately.

[0018] Active Ingredients

[0019] For an “Energy Boost” formulation a methylxanthine alkaloid such as caffeine is combined with taurine which has beneficial biological as well as surfactant properties. As already explained methylxanthine alkaloids improve energy and provide a feeling of well-being. Taurine is a natural amino acid derivative that has an anti-anxiety effect as well as many health benefits. In addition, taurine has surfactant properties and aids in the dispersion of insoluble ingredients. Caffeine is effective in e-fluids of 0.01M to 0.15M. Much below this concentration range, there is little discernible effect whereas at much higher concentrations, the caffeine effect can be excessive. Currently, a concentration of 0.05M is preferred. Taurine has a wide effective range of at least 0.01M to 0.1M; currently 0.015M is preferred. To these active ingredients can be added cyanocobalamin (vitamin B12). This water soluble vitamin is important for many cellular functions and seems to potentiate the effects of caffeine and taurine. The cyanocobalamin has a red-magenta color and can be used as the sole coloring agent or other colors may be added as desired. This has been tested at concentrations between 0.01% and 0.1%; currently 0.083% (weight by volume) is preferred. Other common methylxanthines such as theophylline or theobromine can be substituted or used in conjunction with caffeine.

[0020] Other “Energy Boost” ingredients can be used either alone or in conjunction with the methylxanthines. For example, green tea extracts can be employed not only as a source of caffeine and theophylline but also for beneficial antioxidants (and to impart a flavor). Extracts of guarana (*Paullinia cupana*) can be used to supply caffeine as well as other beneficial natural ingredients. Extracts of *Ginkgo biloba* can be used to supply antioxidants. Extracts of ginseng (*Panax* species) are also effective when combined with cyclodextrins. Finally, carnitine is effective in energy formulae. These ingredients are generally used at concentration of about 0.5% by weight or less.

[0021] Caffeine, other methylxanthines and taurine can be stabilized as metal complexes (zinc, magnesium and/or sodium) and/or cyclodextrin complexes. Metal complexes are formed by adding a molar excess of a water soluble salt of the desired metal. Cyclodextrin complexes form best with a molar excess of cyclodextrin. It has been found that a 2-3 fold molar excess works well although cyclodextrin is effective in the range of 0.5 to 5.0 molar ratio of cyclodextrin to active ingredient. Cyclodextrin is used preferable but can be used with the metal complex as well. That is, the required concentration of both metal and cyclodextrin can be used.

[0022] Besides Energy formulae, "Relaxation/sleep" formulae are also useful. In these formulae ingredients such as extracts of chamomile (*Matricaria chamomilla* and/or *Chamaemelum nobile*), extracts of kava (*Piper methysticum*), extracts of valerian (*Valeriana officinalis*), L-tryptophan and/or melatonin are used in place of the "energy" ingredients. Again these ingredients are used in the 0.5% by weight or lower concentration range.

[0023] Finally, it is also possible to use safe appetite suppressants in place of the energy ingredients to yield a "weight loss" formula. Various plant extracts are useful—in particular extracts of yerba mate (*Ilex paraguariensis*), extracts of *Hoodia gordonii* and extracts of *Carafiuma fimbriata*. In addition, certain compounds such as chromium chelate and lecithin are useful in these formulae. The chromium is used at a few parts per million (ppm) while the other ingredients are used up to 0.5% by weight.

[0024] Vehicle and Inactive Ingredients

[0025] The main vehicle is an approximately 50% aqueous solution of high boiling point hydrophilic solvent. It is not essential that the fluid be precisely 50% water. Typically either glycerol and/or propylene glycol are used as hydrophilic solvents. This translates to a 5.4M glycerol or a 6.6M propylene glycol solution. Tests suggest that a solution being at least about 2M of either of these solvents (or a combination thereof) is adequate. Using excess hydrophilic solvent increases both the cost and viscosity of the product. The hydrophilic solvents increase the solubility of the active ingredients and act as particle formers when the e-cigarette mechanism boils away much of the water. Without these solvents aerosol formation would be much less efficient.

[0026] Besides the vehicle, the inactive ingredients include a variety of flavors and/or scents. Actually, these additives are primarily scents because the human sense of taste is primarily limited to sweet, salty, sour, bitter and umami. What we perceive of as "orange" flavor or taste is actually orange scent combined with a taste of sweet and sour. The glycerol and propylene glycol components of the vehicle have an actual sweet taste that can be detected by most users. Depending on the pH of the vehicle there may also be a slight sour (low pH) taste. If active ingredients such as caffeine or nicotine are present at sufficiently high concentrations, there may also be an actual discernible bitter taste. Useful scents are practically unlimited. Traditionally, menthol and mint-related scents were used in tobacco cigarettes. Therefore, mint-related scents are useful in e-fluid. In addition, fruit flavors (i.e., orange and banana) are popular as are more floral or "perfumed" scents such as vanilla. Currently, the preferred "flavors" are green apple, vanilla cupcake, blueberry, and mango. However, various herbal, musky and other scents may also be appropriate. Generally, these are used at very low concentrations. Generally, under 0.1% by volume. Many of the plant extracts mentioned above also provide a unique flavor/scent.

[0027] Sample e-fluid formulae are given in the following tables.

[0028] Energy Boost (100 ml)

Ingredient	Concentration
Caffeine	0.05M
Taurine	0.015M
Magnesium Chloride	0.06M
Cyanocobalamin	0.083% (weight by volume)
Cyclodextrin	0.2M
Scent/Flavor	trace
Vehicle	To make 100 ml

[0029] The ingredients are mixed, the pH adjusted to 6.5 and heated to 60° C. to ensure that the scent/flavor is properly dispersed.

[0030] Focus Boost (100 ml)

Ingredient	Concentration
<i>Ginkgo biloba</i> extract	0.25% (volume by volume)
Caritine	0.1% (weight by volume)M
Magnesium Chloride	0.06M
Cyclodextrin	0.2M
Scent/Flavor	trace
Vehicle	To make 100 ml

[0031] The ingredients are mixed, the pH adjusted to 6.5 and heated to 60° C. to ensure that the scent/flavor is properly dispersed.

[0032] Focus Boost II (100 ml)

Ingredient	Concentration
Taurine	0.015M
Sodium Chloride	0.06M
Cyanocobalamin	0.083% (weight by volume)
Cyclodextrin	0.05M
Scent/Flavor	trace
Vehicle	To make 100 ml

[0033] The ingredients are mixed, the pH adjusted to 6.5 and heated to 60° C. to ensure that the scent/flavor is properly dispersed.

[0034] Sleep (100 ml)

Ingredient	Concentration
Valerian extract	0.5% (volume by volume)
Chamomile extract	0.25% (volume by volume)
Sodium Chloride	0.06M
Cyclodextrin	0.05M
Scent/Flavor	trace
Vehicle	To make 100 ml

[0035] The ingredients are mixed, the pH adjusted to 6.5 and heated to 60° C. to ensure that the scent/flavor is properly dispersed.

[0036] Appetite suppressant (100 ml)

Ingredient	Concentration
<i>Yerba mate</i> extract	0.5% (volume by volume)
Lecithin	0.5% (weight by volume)

-continued

Ingredient	Concentration
Cyclodextrin	0.05M
Scent/Flavor	trace
Vehicle	To make 100 ml

[0037] The ingredients are mixed, the pH adjusted to 6.5 and heated to 60° C. to ensure that the scent/flavor is properly dispersed.

[0038] Flavor only (100 ml)

Ingredient	Concentration
Cyclodextrin	0.01M
Scent/Flavor	trace
Vehicle	To make 100 ml

[0039] The ingredients are mixed, the pH adjusted to 6.5 and heated to 60° C. to ensure that the scent/flavor is properly dispersed.

[0040] Enhanced Traditional (nicotine containing) (100 ml)

Ingredient	Concentration
Nicotine	0.08M
Taurine	0.015M
Sodium Chloride	0.015M
Cyanocobalamin	0.083% (weight by volume)
Cyclodextrin	0.2M
Scent/Flavor	trace
Vehicle	To make 100 ml

[0041] The ingredients are mixed, the pH adjusted to 6.5 and heated to 60° C. to ensure that the scent/flavor is properly dispersed.

[0042] Improved Traditional (nicotine containing) (100 ml)

Ingredient	Concentration
Nicotine	0.08M
Cyclodextrin	0.1M
Scent/Flavor	trace
Vehicle	To make 100 ml

[0043] The ingredients are mixed, the pH adjusted to 6.5 and heated to 60° C. to ensure that the scent/flavor is properly dispersed.

[0044] The following claims are thus to be understood to include what is specifically illustrated and described above, what is conceptually equivalent, what can be obviously substituted and also what essentially incorporates the essential idea of the invention. Those skilled in the art will appreciate that various adaptations and modifications of the just-described preferred embodiment can be configured without departing from the scope of the invention. The illustrated embodiment has been set forth only for the purposes of example and that should not be taken as limiting the inven-

tion. Therefore, it is to be understood that, within the scope of the appended claims, the invention may be practiced other than as specifically described herein.

What is claimed is:

1. An e-fluid for use in an e-cigarette or similar device comprising:

caffeine at a concentration of between about 0.01M to about 0.15M;

cyclodextrin at a concentration having a molar ratio with the caffeine concentration of 0.5 to 5.0; and
an aqueous solution of hydrophilic solvent being between about 2M and 10M hydrophilic solvent.

2. The e-fluid of claim 1 wherein the hydrophilic solvent is selected from the group consisting of glycerol and propylene glycol.

3. The e-fluid of claim 1 further comprising carnitine at a concentration of about 0.01% and about 0.5% volume by volume.

4. The e-fluid of claim 1 further comprising taurine at a concentration of between about 0.01M and about 0.1M.

5. The e-fluid of claim 1 further comprising cyanocobalamin at a concentration of between about 0.01% weight by volume and 0.1% weight by volume.

6. An e-fluid for use in an e-cigarette or similar device comprising:

valerian extract at a concentration of between about 0.01% and about 0.5% volume by volume;

cyclodextrin at a concentration having a molar ratio with the valerian extract concentration of 0.5 to 5.0; and
an aqueous solution of hydrophilic solvent being between about 2M and 10M hydrophilic solvent.

7. The e-fluid of claim 6 wherein the hydrophilic solvent is selected from the group consisting of glycerol and propylene glycol.

8. The e-fluid of claim 6 further comprising L-tryptophan at a concentration of about 0.01% and about 0.5% weight by volume.

9. The e-fluid of claim 6 further comprising extract of chamomile at a concentration of about 0.01% and about 0.5% volume by volume.

10. The e-fluid of claim 6 further comprising cyanocobalamin at a concentration of between about 0.01% weight by volume and 0.1% weight by volume.

11. An e-fluid for use in an e-cigarette or similar device comprising:

nicotine at a concentration of between about 0.01 M to about 0.2M;

cyclodextrin at a concentration having a molar ratio with the nicotine concentration of 0.5 to 5.0; and
an aqueous solution of hydrophilic solvent being between about 2M and 10M hydrophilic solvent.

12. The e-fluid of claim 11 wherein the hydrophilic solvent is selected from the group consisting of glycerol and propylene glycol.

13. The e-fluid of claim 11 further comprising taurine at a concentration of between about 0.01M to about 0.1M.

14. The e-fluid of claim 11 further comprising cyanocobalamin at a concentration of between about 0.01% weight by volume and 0.1% weight by volume.

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