(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 May 2006 (26.05.2006)

PCT

(10) International Publication Number
WO 2006/055640 A2

(51) International Patent Classification:
C06D 7/00 (2006.01)

(21) International Application Number:
PCT/US2005/041542

(22) International Filing Date:
10 November 2005 (10.11.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/629,364 19 November 2004 (19.11.2004) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2006/055640 A2

(54) Title: GEL COMPOSITIONS

(57) Abstract: Pepper gel compositions according to the present invention include 0.1 - 5 parts by weight capsaicinoid compounds, 0.25 - 2 parts by weight of a thickening agent; and 30 - 90 parts by weight water. The thickening agent is typically a vegetable gum, especially xanthan gum. The capsaicinoid compounds may be derived from a water-dispersible oleoresin capsicum containing at least 3.25% capsaicinoids, preferably at least 14% capsaicinoids. In some embodiments, the compositions may additionally include 20 60 parts by weight of at least one water-miscible solvent, such as monohydric alcohols, polyhydric alcohols and mixtures thereof. The water--miscible solvent may be methyl alcohol, ethyl alcohol, isopropyl alcohol, n-propyl alcohol, isobutyl alcohol, sec-butyl alcohol, n-butyl alcohol, ethylene glycol, propylene glycol or a mixture thereof, and preferably a mixture of isopropyl alcohol and propylene glycol.

GEL COMPOSITIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a PCT application, and claims priority from, U.S. Provisional Application No. 60/629,364, filed November 19, 2004, the entire disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] Personal defense sprays incorporating chloroacetophenone (CN) or *o*-chloro-benzalmalononitrile (CS) teargas are used by police and military personnel to subdue unruly or disruptive persons, and by private citizens to ward off attackers and/or to repel animals such as dogs and bears without inflicting long-term or permanent damage. Sprays based on natural capsaicins or oleoresin capsicum (OC) have several advantages over teargas sprays: With pain-sensitive subjects, they have about the same speed as CN teargas combined with the effectiveness of CS teargas. But they are also effective on pain-resistant subjects within a few seconds of inhalation. This effectiveness on both pain-sensitive and pain-resistant subjects makes it particularly appropriate for use in law enforcement and pepper sprays have thoroughly captured the attention, interest, and approval of the law enforcement community.

[0003] Capsaicin-based products are inflammatory agents, and work on pain-resistant subjects by inflaming the mucous membranes of the trachea when inhaled. Upon application, the subject is overcome by eye, nose and mouth irritation and rendered harmless, being temporarily disabled with intense burning eye pain, blepharospasm, acute bronchitis and respiratory irritation. The products do not work by affecting the central nervous system, and thus causing pain, as do the irritants used in teargas. This is important because inflammation of tissues is a very low level physiological response, and is unaffected by factors such as training, stress, drugs, alcohol, psychosis, goal-orientation, or any other form of pain resistance. Capsaicin-based products produce dermal discomfort, and additionally dilate the capillaries of the subject's eyelids, causing the eyes to close temporarily. The subject's eyes and vision are not actually affected. It is merely that the eyelids are clamped shut for a brief period of time. Since, for sighted people, the greater portion of our contact with the world is visual, this can give a victim a significant advantage in getting away. When a mist of atomized spray is inhaled it temporarily inflames the mucous membranes of the throat. This induces a bout of uncontrollable coughing which typically

causes the subject to double over at the waist, and produces a temporary loss of muscular strength and coordination. The uncontrollable coughing (combined with the closed eyes) drastically reduces the attacker's desire and ability to continue fighting, and affects even the most hardened cases.

[0004] While current pepper sprays are very effective, and are widely accepted by users, there are several problems with available formulations. Most pepper sprays include a flammable solvent to dissolve the active ingredient, and can be ignited by weapons such as stun guns and TASER® electronic weapons. Because the sprays are aerosols, they have a limited range, usually less than fifteen feet, and can't be used under windy conditions or indoors because of the danger of cross-contamination. Therefore, there is a need for a pepper spray having an increased spray distance with less potential for cross-contamination, that is, where the active ingredient remains in the stream and can be sprayed under windy conditions.

[0005] U.S. Patent No. 6,399,073 discloses a personal defense spray containing about 0.1 to about 0.8 percent by weight capsicum, propylene glycol and water. Use of a thickener is not disclosed. The advantage of such a spray over solvent-based sprays is its non-flammability. However, it retains the same spray distance, and the potential for cross-contamination from overspray, of previous pepper spray compositions.

[0006] U.S. Patent No. 5,178,879 describes a capsaicin gel for use as a topical analgesic. Use of the gel for personal defense is not contemplated. The gel contains 0.025 to 0.075% of a synthetic capsaicin, *trans*-8-methyl-N-vanillyl-6-nonenamide. The formulation also includes a carboxypolymethylene thickener, a polysorbate, ethyl alcohol and water. However, there remains a need for a personal defense spray containing greater amounts of the capsaicinoid active ingredient.

SUMMARY OF THE INVENTION

[0007] It has been unexpectedly discovered that a personal defense spray composed of a pepper gel composition containing 0.1-1.5% capsaicinoid compounds, and preferably at least 1.4% capsaicinoids clings to surfaces, and has an extended spray distance and significantly reduced potential for overspray, compared to conventional solvent-based pepper sprays.

[0008] Accordingly, in one aspect, the present invention relates to pepper gel compositions according to the present invention include at least 1.4 parts by weight

capsaicinoid compounds, 0.25 – 2 parts by weight of a thickening agent; and 30 – 90 parts by weight water. The thickening agent is typically a vegetable gum, especially xanthan gum. The capsaicinoid compounds may be derived from a water-dispersible oleoresin capsicum containing at least 3.25% capsaicinoids, preferably at least 14% capsaicinoids. In some embodiments, the compositions may additionally include 20-60 parts by weight of at least one water-miscible solvent, such as monohydric alcohols, polyhydric alcohols and mixtures thereof. The water--miscible solvent may be methyl alcohol, ethyl alcohol, isopropyl alcohol, n-propyl alcohol, isobutyl alcohol, sec-butyl alcohol, n-butyl alcohol, ethylene glycol, propylene glycol or a mixture thereof, and preferably a mixture of isopropyl alcohol and propylene glycol.

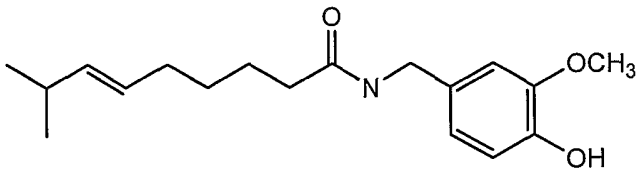
[0009] In another aspect, the present invention relates to a method of crowd control and/or personal defense. The method includes spraying toward a threatening person or animal a pepper gel composition according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0010] The present invention relates to water based pepper gel compositions containing at least 1.4 parts by weight capsainoid compounds, 0.25-2 parts by weight thickening agent and 30-90 parts by weights water. The pepper gel compositions may be sprayed at a target up to 25 feet away, a significant increase over conventional solvent-based sprays that travel only about 15 feet. The formulation is ideal for indoor use as cross-contamination is minimized, since the active ingredient is contained in the gel which sticks to the affected area. Conventional pepper sprays can contaminate a home, hospital, business, prison cell or police car with an uncomfortable pepper scent that can take hours to dissipate. The composition sticks to the target. Where the target is the face of an assailant, he may be temporarily blinded, allowing for safe detention by law enforcement or military officials and/or safe escape by potential victims. Because the composition is non-flammable, it may be used together with a stun gun, TASER® electronic weapons, and/or similar weapons without the danger of the electric or electronic weapons igniting a fire. Water miscibility allows for quick and easy decontamination of an assailant using just soap and water.

[0011] Capsaicinoids are a group of chemical compounds that have no flavor or odor, but act directly on the pain receptors in the mouth and throat, producing a burning sensation in mucous membranes. In addition, the compounds are lachrymators and cause the eyes to water and the nose to run. The group includes five naturally occurring members and one

synthetic member: capsaicin (8-methyl-N-vanillyl-*trans*-6-nonenamide), dihydrocapsaicin, nordihydrocapsaicin, homocapsaicin, and homodihydrocapsaicin.



CAPSAICIN

Natural abundance of the compounds in hot peppers is about 69% capsaicin, 22% dihydrocapsaicin, 7% nordihydrocapsaicin, 1% homocapsaicin, and 1% homodihydrocapsaicin. The synthetic capsaicinoid is the vanillylamide of n-nonanoic acid (VNA). Synthetic capsaicin or compositions containing synthetic capsaicin may also be used. Use of the synthetic material may result in improved batch-to-batch reproducibility because its composition may vary less than that of capsaicinoid compositions obtained from natural sources. For example, grades of synthetic capsaicin marketed by Fontarome Chemical, St. Francis, Wisconsin, contain either 94% capsaicin or 99% capsaicin. The term "capsaicin compounds", as used herein, includes one or more of capsaicin, dihydrocapsaicin, nordihydrocapsaicin, homocapsaicin, homodihydrocapsaicin and VNA, in any combination, in any proportion, and from any source.

[0012] The amount of capsaicin compounds contained in the pepper gel compositions ranges from about 0.1 to about 25 parts by weight, preferably about .1 to about 5 parts by weight and more preferably about 0.1 to about 1.5 parts by weight. In a preferred embodiment, the composition contains at least 1.4% capsaicinoids.

[0013] One measure of the amount of active ingredient in a pepper composition is the Scoville heat unit (SHU). The SHU rating relates to the hotness of the material as determined by a human taster, and is commonly used in the food industry. A more quantitative method used in the personal defense industry is to measure the amount of the three most abundant capsaicinoids, capsaicin, dihydrocapsaicin, and nordihydrocapsaicin, by high performance liquid chromatography (HPLC). The SHU scale corresponds to the amount of capsaicinoids in the material; 15 SHU is roughly equivalent to 1 ppm. An oleoresin capsicum composition containing about 3.25% (about 32,500 ppm) capsaicinoid compounds has a rating of about 500,000 SHU.

[0014] The capsaicinoid compounds are preferably used in the form of a water-soluble or dispersible oleoresin capsicum (OC), although oil-soluble or solvent-based grades may be used if desired. Oleoresin capsicum is obtained from natural sources, usually as an extract of hot peppers, and is typically available as a solution of capsaicins as an oil or as a water-soluble or dispersible composition. The water-soluble or dispersible versions usually contain a surfactant to facilitate mixing with water. Where solution grades are used, additional surfactants may be included in the formulation, either mixed with the OC and water to form a dispersion that may be mixed with the remaining ingredients, or added to the formulation before the OC is added. Water-soluble or dispersible grades may also benefit from additional surfactant in the formulation. In a preferred embodiment, a water-dispersible grade of OC is used in conjunction with 0.025 – 2% polysorbate emulsifier. The surfactant functions to increase long-term stability or shelf life of the dispersion. Grades of OC varying in Scoville pungency and solubility/ dispersability are commercially available from several suppliers, including Kalsec Inc, Kalamazoo, MI. Grades containing at least 3.25% (about 500,00 SHU) capsaicinoids are preferred, and those containing at least 14% capsaicinoids (about 2,000,000 SHU) are particularly preferred.

[0015] Thickeners for the composition are those that yield a sprayable, stable gel when used in the amount of 5% or less, preferably 2% or less, based on the total weight of the composition. One or more cationic, nonionic, and/or anionic thickeners may be used; suitable materials are listed in the Glossary and Chapters 3, 4, 12 and 13 of the Handbook of Water-Soluble Gums and Resins, Robert L. Davidson, McGraw-Hill Book Co., New York, N.Y., 1980, incorporated by reference herein.

[0016] Natural thickeners are preferred, especially those that are suitable as food additives, such as vegetable gums and celluloses, such as carboxymethylcellulose, methylethyl-cellulose sodium carboxymethylcellulose, and hydroxyethylcarboxymethylcellulose. Other natural and synthetic gums and gum-like materials may be used if desired, including natural and synthetic inorganic clays, such as bentonite; silicas; and polymeric thickeners, such as acrylates, polyvinylacetate, and acrylamide. The thickeners are typically hydrated or gelled with water or alkanols, especially with polyhydric alcohols such as glycerol and sorbitol. Vegetable gum thickeners are particularly preferred. These include alginic acid, sodium alginate, potassium alginate, ammonium alginate, calcium alginate, propylene glycol alginate, agar agar, isinglass, carrageenan, processed eucheuma seaweed, arabinogalactan, locust bean gum, guar gum,

tragacanth, acacia, karaya gum, and gellan gum. Xanthan gum is a microbial gum that is particularly preferred.

The amount of thickener to be used depends on the amount and type of the other materials included in the formulation, especially the amount of water, and on the desired viscosity/rheology of the final product. Typically, it is desired that the product have a viscosity/rheology profile such that the product remains on vertical surfaces on which it is sprayed for at least a few seconds, and seeks its own level inside the container during spraying so that the container does not retain an appreciable amount of residue upon emptying. Typically, the amount of thickener used ranges from about 0.25 – 2 percent by weight. For compositions thickened with xanthan gum, amounts of thickener are typically 0.3% to 1%, preferably 0.5%-0.75%. For pH dependent thickeners, the amount and type is based upon the pH of the composition. Modifiers such as urea, sodium chloride, sodium sulfate, magnesium sulfate, ammonium chloride and magnesium chloride and combinations thereof may be present in the compositions in addition to the thickener(s) if non-pseudoplastic compositions are desired or if pseudoplastic compositions are to be modified in their viscosity behavior

[0017] Pepper gel compositions according to the present invention may additionally include a water-miscible solvent in the amount of 20 – 60 parts by weight or 20%-60%, to prevent freezing. Food-grade solvents and/or those that are 'generally regarded as safe" by the U.S. Federal Department of Agriculture are preferred. Water-miscible solvents are capable of being mixed with water in any concentration without separation of phases; e.g., water and ethyl alcohol are miscible. Water-miscible solvents that may be used in the compositions of the present invention include alcohols, such as methanol, ethanol, isopropanol, n-propanol, 2-butanol, isobutanol, n-butanol, t-butyl alcohol, amyl alcohol, methyl amyl alcohol, cyclohexanol, 2-ethylhexanol; glycols, such as propylene glycol, ethylene glycol, hexylene glycol, dipropylene glycol, diethylene glycol, tripropylene glycol, triethylene glycol; glycol ethers such as glyme, diglyme; glycol ether PM, glycol ether EP, glycol ether PP, glycol ether PTB, glycol ether EB, glycol ether PB, glycol ether DPM, glycol ether DM, glycol ether DE, glycol ether DP, glycol ether DPP, glycol ether DB, glycol ether DPB, glycol ether TPM, and glycol ether TPB; esters, such as methyl acetate, ethyl acetate, isopropyl acetate, t-butyl acetate, n-propyl acetate, ethyl propionate, isobutyl acetate, n-butyl acetate, glycol ether PM acetate, amyl acetate, isobutyl isobutyrate, n-butyl propionate, ester solvent EEP, n-pentyl propionate, glycol ether EB acetate, 2-ethylhexyl acetate, glycol ether DPM acetate, dibasic ester, glycol ether DE acetate, and glycol ether DB acetate; ketones, such as acetone, methyl ethyl ketone, methyl propyl ketone, methyl isobutyl ketone, methyl

isoamyl ketone, diacetone alcohol, methyl amyl ketone, cyclohexanone, diisobutyl ketone and isophorone; chlorinated solvents, such as methylene chloride, chloroform, 1,1,1-trichloroethane, carbon tetrachloride, ethylene dichloride, trichloroethylene, propylene dichloride, perchlorethylene, monochlorobenzene and ortho-dichlorobenzene; and other solvents such as acetic acid, acetonitrile, dimethyl formamide, dimethyl sulfoxide, dioxane, glycerin, and tetrahydrofuran. Preferred water-miscible solvents include monohydric alcohols, such as methyl alcohol, ethyl alcohol, isopropyl alcohol, n-propyl alcohol, isobutyl alcohol, sec-butyl alcohol, n-butyl alcohol, or mixtures thereof; polyhydric alcohols, such as ethylene glycol, propylene glycol or mixtures thereof; and mixtures of monohydric and polyhydric alcohols. Preferably the solvent is a mixture of isopropyl alcohol and propylene glycol.

[0018] Minor amounts of additional components such as a ultra-violet marking dye may be added to the compositions. The marking dyes are used so that a person sprayed with the pepper gel composition may be identified under UV light.

[0019] In another aspect, the present invention relates to methods for crowd control and/or personal defense. The method may be used with people or animals that the operator or user of the pepper gel wishes to control or escape from. For best results, the composition is usually sprayed toward the subject's eyes; shortly thereafter, the subject may be subdued without harm and/or the potential victim may escape without permanent physical injury.

[0020] Pepper gel compositions according to the present invention may be prepared by mixing the capsaicinoid compounds, preferably in the form of a water-dispersible oleoresin capsicum, thickening agent(s) and solvent(s), if solvents are to be used. Water is gradually added to form a gel. Any other emulsifiers are added before the water, usually with the OC. In an alternate process, the thickening agent is mixed with water initially and then the capsaicinoid compounds and solvent(s) are added.

[0021] Any numerical values recited herein include all values from the lower value to the upper value in increments of one unit provided that there is a separation of at least 2 units between any lower value and any higher value. As an example, if it is stated that the amount of a component or a value of a process variable such as, for example, temperature, pressure, time and the like is, for example, from 1 to 90, preferably from 20 to 80, more preferably from 30 to 70, it is intended that values such as 15 to 85, 22 to 68, 43 to 51, 30 to 32 etc. are expressly enumerated in this specification. For values which are less than one, one unit is considered to be 0.0001, 0.001, 0.01 or 0.1 as appropriate. These are only

examples of what is specifically intended and all possible combinations of numerical values between the lowest value and the highest value enumerated are to be considered to be expressly stated in this application in a similar manner.

EXAMPLES

MATERIALS

Oleoresin Capsicum (1,000,000 SHU) was obtained from Citrus and Allied Essences Ltd., Belcamp, Maryland, and contained 4.055% capsaicin, 2.401% dihydrocapsaicin, and 0.224% nordihydrocapsaicin, dispersed in water with polysorbate 80.

PROCEDURE

1. Weigh and record the weight of an empty drum.
2. Add to the empty drum propylene glycol, anhydrous isopropanol (IPA), water-soluble oleoresin capsicum, Tween 80, Pyaklor LX-10747 UV dye and Kelzan RD.
3. Premix the above for 30 minutes.
4. Slowly add triple-filtered water while maintaining constant, moderate agitation using a high-shear, variable speed mixer. Once all of the water has been added the final product must be agitated for approximately one hour.
5. Mix the drum for one hour before use.

EXAMPLE 1: 10% OLEORESIN CAPSICUM (1,000,000 SHU)

41.43 lbs.	Triple-filtered water
23.35 lbs.	Propylene glycol
23.35 lbs.	Anhydrous (99%) isopropanol (IPA)
10.00 lbs.	Water soluble oleoresin capsicum (1,000,000 SHU)
1.00 lbs.	Tween 80
0.20 lbs.	Pyaklor LX-I0747 Ultraviolet Dye
0.67 lbs.	Kelzan RD (xanthan gum)
100.0 lbs.	Total Net Weight

EXAMPLE 2: 10% OLEORESIN CAPSICUM (2,000,000 SHU)

41.43 lbs.	Triple-filtered water
23.35 lbs.	Propylene glycol
23.35 lbs.	Anhydrous (99%) isopropanol (IPA)
10.00 lbs.	Water soluble oleoresin capsicum (2,000,000 SHU)
1.00 lbs.	Tween 80
0.20 lbs.	Pyaklor LX-I0747 Ultraviolet Dye
0.67 lbs.	Kelzan RD (xanthan gum)
100.0 lbs.	Total Net Weight

EXAMPLE 3: 10% OLEORESIN CAPSICUM (500,000 SHU)

41.43 lbs.	Triple-filtered water
23.35 lbs.	Propylene glycol
23.35 lbs.	Anhydrous (99%) isopropanol (IPA)
10.00 lbs.	Water soluble oleoresin capsicum (500,000 SHU)
1.00 lbs.	Tween 80
0.20 lbs.	Pyaklor LX-I0747 Ultraviolet Dye
0.67 lbs.	Kelzan RD (xanthan gum)
100.0 lbs.	Total Net Weight

EXAMPLE 4: 1% OLEORESIN CAPSICUM (1,000,000 SHU)

50.43 lbs.	Triple-filtered water
23.35 lbs.	Propylene glycol
23.35 lbs.	Anhydrous (99%) isopropanol (IPA)
1.00 lbs.	Water soluble oleoresin capsicum (1,000,000 SHU)
1.00 lbs.	Tween 80
0.20 lbs.	Pyaklor LX-I0747 Ultraviolet Dye
0.67 lbs.	Kelzan RD (xanthan gum)
100.0 lbs.	Total Net Weight

CLAIMS

1. A pepper gel composition comprising
   at least 1.4 parts by weight capsaicinoid compounds;
   0.25 – 2 parts by weight thickening agent; and
   30 – 90 parts by weight water.

2. A pepper gel composition comprising
   0.1 - 5 parts by weight capsaicinoid compounds;
   0.25 – 2 parts by weight thickening agent; and
   30 – 90 parts by weight water.

3. A pepper gel composition according to claim 2, comprising 0.2 – 1.5 parts by weight capsaicinoid compounds.

4. A pepper gel composition according to claim 2, comprising 0.5 – 1.5 parts by weight capsaicinoid compounds.

5. A pepper gel composition according to any of the above claims, wherein the thickening agent is a vegetable gum

6. A pepper gel composition according to any of the above claims, wherein the gum is xanthan gum.

7. A pepper gel composition according to any of the above claims, additionally comprising 20-60 parts by weight of at least one water-miscible solvent.

8. A pepper gel composition according to claim 7, wherein the at least one water-miscible solvent is selected from monohydric alcohols, polyhydric alcohols and mixtures thereof.

9. A pepper gel composition according to claim 7, wherein the at least one water-miscible solvent is selected from methyl alcohol, ethyl alcohol, isopropyl alcohol, n-propyl alcohol, isobutyl alcohol, sec-butyl alcohol, n-butyl alcohol, ethylene glycol, propylene glycol and mixtures thereof.

10. A pepper gel composition according to claim 7, wherein the at least one water-miscible solvent is a mixture of isopropyl alcohol and propylene glycol.

11. A pepper gel composition consisting essentially of
at least 1.4% capsaicinoid compounds;
0.25 – 2% xanthan gum;
20 – 60% mixture of isopropyl alcohol and propylene glycol;
0.025 - 2% polysorbate emulsifier; and
30-77.6% water.

12. A pepper gel composition comprising
at least 10 parts by weight water-dispersible oleoresin capsicum comprising at least 14% capsaicinoid compounds;
0.25 – 2 parts by weight thickening agent; and
30 – 90 parts by weight water.

13. A pepper gel composition comprising
0.1 - 25 parts by weight water-dispersible oleoresin capsicum comprising at least 3.25% capsaicinoid compounds;
0.25 – 2 parts by weight thickening agent; and
30 – 90 parts by weight water.

14. A pepper gel composition according to claim 13, comprising 0.2 – 25 parts by weight capsaicinoid compounds.

15. A pepper gel composition according to claim 13, comprising 0.5 – 10 parts by weight capsaicinoid compounds.

16. A pepper gel composition according to any of claims 12-15, wherein the thickening agent is a vegetable gum

17. A pepper gel composition according to any of claims 12-15, wherein the gum is xanthan gum.

18. A pepper gel composition according to any of claims 12-15, additionally comprising 20 – 60 parts by weight of at least one water-miscible solvent.

19. A pepper gel composition according to claim 18, wherein the at least one water-miscible solvent is selected from monohydric alcohols, polyhydric alcohols and mixtures thereof.

20. A pepper gel composition according to claim 18, wherein the at least one water-miscible solvent is selected from methyl alcohol, ethyl alcohol, isopropyl alcohol, n-propyl alcohol, iso-butyl alcohol, sec-butyl alcohol, n-butyl alcohol, ethylene glycol, propylene glycol and mixtures thereof.

21. A pepper gel composition according to claim 18, wherein the at least one water-miscible solvent is a mixture of isopropyl alcohol and propylene glycol.

22. A pepper gel composition according to any of the above claims, additionally comprising an ultraviolet dye.

23. A method of crowd control and/or personal defense, said method comprising spraying toward a threatening person or animal a pepper gel composition according to any of the above claims.

24. A method for manufacturing a pepper gel composition, said method comprising mixing at least 1.4 parts by weight capsaicinoid compounds, 0.25 – 2 parts by weight thickening agent and 20 – 60 parts by weight of a solvent; and gradually adding water to form a gel.

25. A method for manufacturing a pepper gel composition, said method comprising mixing 0.25 – 2 parts by weight thickening agent and 30 – 90 parts by weight water; and adding at least 1.4 parts by weight capsaicinoid compounds and 20 – 60 parts by weight of a solvent to form a pepper gel composition.