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(54) EMU-BASED FORMULATIONS FOR WOUND TREATMENT RELATED APPLICATION INFORMATION

FORMULIERUNGEN AUF EMU-BASIS ZUR WUNDBEHANDLUNG BETREFFENDE ANWENDUNGSINFORMATIONEN

PREPARATIONS A BASE D'EMEU POUR LE TRAITEMENT DE BLESSURES

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Description

[0001] The present application claims priority to U.S. Patent Application Serial No. 09/939,335, filed in the United States Patent and Trademark Office on August 8,2001.

BACKGROUND OF THE INVENTION

[0002] Found in the wild only in Australia, Emus (dromiceius novae-hollandiae) are the second largest members of the ratite group of flightless birds in the world. The Emu have wings but they are very tiny. They can run up to 35-40 miles an hour, as they have very large and strong legs. Although a very docile creature, the Emu's legs are so strong; one kick can break a man's leg. Now Emus are being farmed in many parts of the world. They are raised for their valuable products, which include very low fat meat, supple leather hides, decorative and nutritional eggs, and very rich oil, which are obtained from the Emu. Emus are by nature, very healthy and immune to many diseases. Emus are referred to a "living dinosaurs," as their skeletal structure closely resembles some dinosaurs. Emus living today closely resemble their ancestors of millions of years ago. Emu oil, a food by product, is obtained from the fat of the Emu. It is an all-natural substance. When processed, the fat is taken through a series of steps to refine, sterilize and deodorize the oil. Not all Emu oil on the market is refined. Some Emu oil is simply rendered, which means the oil is simply filtered, and may contain contaminants. Emu oil contains high amounts of EFA's (essential fatty acids). EFA's produce energy in the process of oxidation. In humans EFA's govern growth, vitality and mental state of mind. Oxidation is the central and most important living process in our body.

[0003] Emu oil by nature is not regarded as a sterile ingredient. Due to lack of regulatory controls and procedures, Emu oil is processed in many different ways, i.e., some forms of rendering, which is simply a filtration process, which leaves the Emu oil with its natural yellow color, and a slight odor. The present invention uses a refinement process, which yields a clearly pure Emu oil product, creamy white and odor free. The present invention utilizes a sterilization technique to render the Emu oil in the present invention free of contaminants to be used as a preparation and treatment for cutaneous wounds and burn ulcers.

[0004] Various patents discuss the use of Emu oil, for example, U.S. Patent No. 5,662,921 discusses how Emu oil can be use to prevent scarring when applied to a newly received cut or bum. It has been known for a long time that Emu oil also diminishes old scars, even stretch marks. Also U.S. Patent No. 5,662,921 discusses how Emu oil increases high-density lipoproteins, preventing and treating scarring. U.S. Patent No. 5,958,384 teaches that topical or parenteral administration of Emu oil to a mammal stimulates the proliferation of skin, as well as rejuvenating photo-damaged skin. This same patent teaches that Emu oil also stimulates melanogenesis in the skin and it can be used to treat disorders such as hypo-pigmentation.

[0005] WO 01/13956 discloses various pharmaceutical compositions comprising Emu oil, lactic acid producing bacteria and an anti-microbial agent. Further it is disclosed that Emu oil has various properties such as being bacteriostatic, antioxidizing and having a high degree of emollient properties.

[0006] US-5472713 discloses that Emu oil may be used to treat a number of conditions and notes that Emu oil may be refined by gas chromatography.

[0007] Zemstova et al (Australiasian Journal of Dermatology, 1996) discloses a study to compare the moisturising and cosmetic properties of Emu oil with mineral oil. The study showed that Emu oil is capable of penetrating the stratum corneum barrier and therefore may find use in combination with antifugals to aid transfer across the skin.

[0008] US-5431924 discloses that a yellow component of Emu oil may be sterilized by filtration through a membrane filter and that the filtrate may be used in intra muscular injections.

[0009] Even so, a need has long existed for a formula, using Emu oil which can be used in hospitals, as a sterile formula for treating of wounds, burns, and other dermatological problems, while remaining stable and usable over time without degradation.

SUMMARY OF THE INVENTION

[0010] The present invention provides an analgesic, anesthetic and anti-pruritic formulation comprising from 0.01 to 13 wt.% alkyl esters; from 20 to 70 wt.% Emu oil; from 10 to 33 wt.% benzyl alcohol; from 10 to 33 wt.% benzoin; from 0.2 to 2 wt.% allantoin; from 0.25 to 1.25 wt.% methylparaben and from 0.01 to 0.30 wt.% propylparaben.

[0011] The clinical benefits of this formula include reduced wound sepsis rates, improved hempdynamic status, and decreased requirement for donor site harvest. Since engraftment rates are high with good standard care, it is important to evaluate healing outcomes such as durability, functionality, and cosmetic appearance, including scarring. The formula also provides improved quality of healing and products that reduce scarring may also improve function, for example, range of motion, the counter and feel of healed skin, or normalization of skin pigmentation or markings. The present invention enables tissue to regenerate, restore, and rebuild in the underlying wound itself and surrounding tissue, therefore

fortifying, increasing energy to the existing cells that are not necrotic, and fortifying cells that are necrotic. The invention is able to improve wound closure time, and facilitation of surgical closures.

DETAILED DESCRIPTION

[0012] The present invention is an Emu oil based formula that is capable of improved transdermal properties, thus creating healthier cells that proliferate at an accelerated rate. Increasing the feeding of the skin cells causes proliferation and thus the theory of Emu oil being biologically active to human skin.

[0013] The invention has a preferred formula which comprises from about 20 to about 70 wt.% Emu oil; from about 10 to about 33 wt.% benzyl alcohol; from about 10 to about 33 wt.% benzoin; from about 0.2 to about 2.0 wt.% allantoin; from about 0.025 to about 1.25 wt.% methylparaben; from about 0.01 to about 13 wt.% alkyl esters; and from about 0.01 to about 0.30 wt.% propylparaben.

[0014] The invention based on Emu oil accelerates wound closure, reduces wound debribement, reduces scar tissue and enhances the smoothness and appearance to the skin while maintaining and feeding skin cells with linoleic acid. The invention increases cell proliferation, therefore increasing the ability to heal.

[0015] In an alternative embodiment, the present invention can be in the form of a spray comprising about 63.45% Emu oil; about 20.0% benzyl alcohol; about 10.0% benzoic acid; about 1.25% methylparaben; about 0.3% propylparaben; about 2.0% allantoin and about 3.0% alkyl esters.

[0016] The Emu oil, which is most preferred in this invention, has the following chemical analysis:

Free Fatty Acid	0.33 - 0.02%
Acid Value	0.66%
Calculated Iodine value	69.7 - 72.8 mEq/100g
OSI	11.95 Hours @ 110.0°C.

wherein the fatty acid composition of the Emu oil can be compared to human skin as follows:

Fatty Acid		Emu Oil	Human Skin Oil
Myristic	C:14:0	0.3%	2.1%
Palmitic	C:16:0	20.3%	20.2%
Palmitoleic	C:16:1	3.2%	3.8%
Margaric	C:17:0	0.2%	
Margaric oleic	C:17:1	0.1%%	
Stearic	C:18:0	10.1%	11.2%
Oleic	C:18:1	51.6%	30.8%
Linoleic	C:18:2	13.1 %	15.1%
Linolenic	C:18:3	0.5%	0.3%
Arachidic	C:20:0	0.1%	
Eicosinoac	C:20:1	0.5%	

Other fatty acids, which may be in Emu oil include elaidic and vaccenic fatty acids.

[0017] Analysis of the Emu oil shows calculated iodine content of 72.8%. The present invention embodies the natural iodine properties of the Emu oil. Iodine has long been known for its antiseptic and germicide properties, in turn helping to accelerate wound closure by minimizing infection. Normally, iodine does not occur naturally in nature. In combination as iodides, it is found in the ashes of certain marine algaes and weeds. Until recently, the most important source of iodine was crude Chile saltpeter, and now is been found in the brine of oil wells. Elementary iodine is toxic. The iodine content in the Emu oil is a naturally occurring property, and no reports of toxicity have been noted. The present invention embodies the use of the iodine in the Emu oil as an enhancement to the germicide, fungicide and all around antiseptic properties of the invention. Topical skin dosages of iodine can be used full strength or diluted to 0.1 % for applications to wounds. Typically, the therapeutic index for iodine is among the highest of the antiseptics. Unfortunately, iodine bums are common and largely the result of the use of tinctures and solutions with concentrations higher than tolerated by certain skin types. It is the object of the present invention to embody the features, values and benefits of the high iodine content of the Emu oil, in its natural state, and in combination with the Emu oil fatty acid composition, creating a buffer against the harmful side effects of typical iodine.

[0018] An analysis of fatty acids in Emu oil reveals that the oil contains approximately 70% unsaturated fatty acids.

The major fatty acid found in Emu oil is oleic acid, which is monosaturated and which comprises over 40% of the total fatty acid contents. This fatty acid is a known enhancer for penetration and transportation of compounds through the pores of the epidermis, the membrane of the skin, and, thus, delivering the active ingredients into the lipid layer at the cellular level. Emu oil also contains both of the two EFA's, which are important to human health and include: 20% linoleic and 1-2% linolenic acid. Essential fatty acid are by definition those fatty acids which we must obtain from our diet since the body cannot manufacture them, hence, making them essential as transdermal supplements to nourish and proliferate new skin cells for chronic cutaneous ulcers and burn wounds. As one can see in the analysis of Emu oil to human skin oil, Emu oil so closely resembles human skin oil; it is a natural food for skin cells.

[0019] Emu oil is unique, as most land animals have a higher concentration of saturated fats. Typical fat contains both saturated and unsaturated fatty acids. The fats found in land animals have a higher percentage of side chains than do the fats in sea animals. Although unsaturated fats are less efficient storage sites for food energy because they have fewer CH bonds than do saturated fats, they have a distinct advantage for animals that live in cold water. Saturated fats melt at higher temperatures than do unsaturated fats. In cold waters, sea animals with solid fats would have the reduced ability to move. This theory also is subject to analysis and it may be proven that it is easier to transport unsaturated fats through the skin structure and membrane into the lipid layer, rather than a saturated fat.

[0020] The monosaturated fatty acid, oleic acid, is the major fatty acid in Emu oil. This fatty acid is a known enhancer for penetration and transportation of compounds through the pores and the membrane of the skin, thus, delivering the active ingredients into the lipid layer at the cellular level.

[0021] Essential fatty acids (EFA's) play two important roles in human physiology. Both derive from their incorporation into the phospholipids of cell membranes. By virtue of their high degree of unsaturation, and, hence low melting points, they decrease membrane viscosity and affect several aspects of membrane function. Nearly all cells contain basic fat and oil substances. Fats are called energy storehouses, as on a weight-by-weight basis; they contain twice as much energy as a carbohydrate or protein. Fats are also a heterogeneous group of compounds, which are characterized by their solubility in solvents such as ether and therefore insoluble in water. Emu oil is rendered primarily from the fat pads of the bird or from what is referred to as the storage lipids. Emu fat is storage fat, as in most animals and organisms, which mean it is the principal form of stored energy. As an energy source, it is completely combustible to carbon dioxide and water. This releases a quantity of energy similar to the combustion of fossil fuel.

[0022] The fats, which are not reactive to sodium or potassium are referred to as unsaponofiable fats. The major portion of unsaponificable fraction is the sterols. These are cholesterol and cholesterol like substances, which have a characteristic chemical composition, which may simply be described as closed ring in contrast to the chain or open ring appearance of the triglycerides and fatty acids. The cholesterol molecule is the classic steroid molecule. This molecule is common to a number of chemicals important to humans, for example, the anti inflammatory steroidal hormones such as hydrocortisone, and androgens such as testosterone, the progestogens, the bile acids, the vitamin D, and estrogen. The restoration of hormonal balance has been attributed to the restoration of many normal functions of the body, as well as general health care and maintenance.

[0023] Inflammation is the normal response to healing chronic ulcers and burn wounds. Inflammation also causes scar tissue to form. A product that could decrease wound sensitivity and inflammation, but increase moisture content would be desirable. Adequate lubrication aids the healing process by providing moisture in areas where sebaceous glands are depleted or currently dysfunctional, increasing pliability of the wound area, thus improving pigmentation and vascularity.

[0024] The present invention, when topically applied is seen to increase the synthesis ofDNA in the epidermis, which is a measure of increase in the proliferative activity of the dermis. It is contemplated that the presence of Oleic acid, a simple triglyceride which contains only one type of fatty acid (oleic acid) enables the present invention to work effectively. A triglyceride is comprised of a glycerin backbone to which the fatty acids are attached. Naturally occurring triglycerides usually are mixed triglycerides; i.e., they contain more than one fatty acid. An example of a mixed triglyceride is palm-mitodiolein, the fatty acid composition of which is, as the name indicates, one molecule of palmitic acid and two molecules of oleic acid. This triglyceride may have structural arrangements other than the one shown, *i.e.*, the fatty acid molecules may be arranged with palmitic acid occupying any of the two possible different positions. Oleic acid is also a monosaturated fat.

[0025] Linoleic acid is an essential polyunsaturated fatty acid. Linoleic acid deficiency symptoms include scaly skin and slow to heal wounds. Linoleic acid supplementation may be essential and crucial to fortify slow to heal wounds and strengthen and rebuild the skin by increasing linoleic acid content through the membrane and into the lipid layer, thus allowing and enhancing new skin cell and membrane proliferation, as well as minimizing scar tissue. Linoleic acid is required for the formation and maintenance of the epidermal barrier. The present invention requires linoleic acid. Stearic acid is also called octadecanoic acid, one of the most common long chain fatty acids, found in combined form in natural animal and vegetable fats. Commercial stearic acid is a mixture of approximately equal amounts of stearic and palmitic acids and small amounts of oleic acid. In nature stearic acid occurs primarily as a mixed triglyceride, or fat, with other long-chain acids and as an ester of fatty alcohol. It is much more abundant in animal fat than in vegetable fat; lard and

tallow often contain up to 30 percent stearic acid. Stearic acid is a natural component of the present invention.

[0026] The composition and structure of the fatty acids of the naturally occurring lipids have an even number of carbon atoms because they are synthesized from acetyl groups, each of which contains two carbon atoms. Fatty acids with 16 (palmitic acid) and 18 (stearic acid) carbon atoms are most commonly found in nature, but the reason for their abundance have not yet been established. Fatty acids constitute important components of lipids in plants, animals and microorganisms. In most cases, they are not found in free form, but instead are bound to other compounds to form fatty acid containing lipid, e.g., neutral lipids (triglycerides) steals, phosphoglycerides such as lecithin, and sphingolipids such as sphingomyelin. Two typical fatty acids are oleic and palmitic. Although palmitic acid and stearic acid are the major saturated fatty acids found in animal and plant tissues, significant amounts of other saturated fatty acids such as myristic acid and lauric acid, occur in certain tissues, and lignoceric acid and behenic acid are found in high concentrations in brain sphingolipids. Small amounts of fatty acids with an odd number of carbon atoms are also known, *e.g.*, pentadecanoic acid and heptadeconoic acid.

[0027] Linoleic acid which when transferred to the lipid layer may be crucial to "feeding" the skin cells, creating more energy to burn, thus enhancing skin and membrane cell proliferation and fortification, thus reducing scar tissue as well.

[0028] Linoleic acid is require for the formation and maintenance of the epidermal barrier. Emu oil has been used in many preparations over the years for all types of skin complaints and maintenance. It has been noted that Emu oil has a positive effect on chronic cutaneous ulcers and burn wounds. Because a wound represents a breach in the body's natural barrier to microbial invasion, the final formulation of topical products used for the treatment of chronic cutaneous ulcers and burn wounds should be sterile to avoid introducing exogenus microorganisms. With this in mind, a product that could be sterilized for chronic cutaneous ulcers and burn wounds that could contain a high amount of Emu oil would be favorable to avoid touching sensitive areas associated with chronic cutaneous ulcers and burn wounds.

[0029] The formulation may be used to treat chronic cutaneous ulcers, which also includes and addresses venous stasis ulcers, diabetic foot ulcers, pressure ulcers, graft sites, donor sites and burn wounds. The present invention is contemplated as a sterile formulation. The guidance on validation of the manufacture of sterile products can be found in the FDA's submission Documentation for Sterilization Process Validation for Human and Veterinary Drug Products (November 1994).

[0030] The present formulation is usable to reduce debridement on tissue. It is generally accepted that necrotic tissue inhibits wound healing by interfering with tissue repair and promoting microbial growth. Thorough debridement of wounds is therefore considered standard care essential to healing. Thus, the unique formulation of the present invention can be used in wound pain control.

[0031] The invention also can be in the form of a spray-on product, which is sterilized by the addition of a germicide, a bactericide, an antiseptic, an antifungal, a bacteriostatic agent and combinations thereof. A spray-on formulation-, plus any additional environmentally friendly propellants, can be the preferred embodiment.

[0032] The formulation of the present invention can be adapted such that it can be prepared in the form of a gel, a cream, a lotion, a spray, a patch, or an enhanced oil. The present formulation additionally inhibits the adverse affects and allergic reactions to benzoin derivatives.

[0033] Emu oil may be used as a transdermal facilitator with other components that act to provide effective transport across the dermis or mucous membranes. This component reduces necrotic tissue, to reduce infection, fight the infection that is in the tissue, and keep tissue from growing fungus, or going into sepsis. The Emu oil and components also act as an anti-inflammatory agent.

[0034] The present invention can include analgesic, anesthetic, and anti-puritic ingredients.

[0035] The present invention can additionally contain antimicrobial agents for wound infection control, a topical anti-infective, and elimination of microbial growth and necrotic tissue, which interferes with tissue repair. In addition, the formula can include a topical analgesic/anesthetic at active levels (as set by FDA) and act as a topical pain control product.

[0036] The active ingredients of the product may consist of any of the following, within the established concentration for each ingredient: from about 20 to about 70 wt.% Emu oil, preferably from about 60 to about 65 wt.% Emu oil and more preferably from about 60 to 65 wt.% Emu oil which has been referred and sterilized.

[0037] Benzyl alcohol can be added in weight percents ranging from about 10 to about 33 wt.% and preferably from about 10 to about 20 wt.%. The most preferred formulation utilizes about 20.0 wt.% benzyl alcohol. Benzyl alcohol is listed in a summary of ingredient categories and testing as a category 1 analgesic, anesthetic, and anti-puritic active ingredient. Suitable examples of benzyl alcohol include NF-Benzenemethanol; Phenylcarbinol CH_2OH, and benzyl alcohol C_7H_8. The benzyl alcohol, which can be used within the scope of the invention, involves using esters of benzoic and cinnamic acids in storax, Peruvian balsam, and tolu balsam. A product currently on the market can be used which is made synthetically from benzyl chloride by distilling it from an aqueous solution of potassium carbonate with thorough agitation.

[0038] The formula may be used as a local anesthetic by injection and by application to mucous membranes. Externally the formula can be applied as an ointment or as a lotion in topical preparations and used as a bacteriostatic agent in various parenteral preparations. Externally the formula can also be applied to nasal passages and gum tissues.

[0039] The formulation may further include an aromatic alcohol, in amounts from about 0.5 to about 1.2 wt.% which can be used in a concentration of 0.9% as a bacteriostatic preservative in multiple dose vials of solution or drugs for parenteral therapy. An aromatic alcohol such as benzyl alcohol also can be used.

[0040] Various antimicrobial drugs can be added to the Emu oil, including but not limited to: methylparaben or benzoic acid, or an alkyl ester such as 4-hydroxy-, methyl ester; or possibly Solbrol made by Charkit Chemical Corporation, P.O. Box 1725, Darien, CT 07407; Methyl Parasept made by Charkit Chemical Corporation, P.O. Box 1725, Darien, CT 07407; Nipagin or even a Methyl p-hydroxybenzoic acid (99-76-3) $C_8H_8O_3$. An antimicrobial additive can be formed by esterifying para-hydrozybenzoic acid with methanol using known techniques. The parahydroxybenzoic acid is obtained by passing carbon dioxide under pressure into dry potassium pheolate heated to about 200 degrees. The resulting potassium salt is decomposed with HCl yielding the free parabic acid. These components can be added in amounts ranging from about 0.25 to about 1.25 wt.% and most prefereably about 2.5 wt.%.

[0041] Additional preservatives can be added to the inventive formula such as Imidazolidinyl Urea in concentrations ranging from about 0.05 to about 1.0%.

[0042] Methylparabens and other related esters ofpara-hydroxybenzoic acid which are odorless and harmless to the skin can be employed in the formula. A combination of two or more esters of parahydroxybenzoic acid has a "synergistic" antiseptic value, i.e. the antiseptic effect of the combination is greater than the total effect as calculated from the values of the individual components; thus a preparation containing about 0.15% of the propyl ester (propylparaben) and about 0.05%of the benzyl ester has a stronger antiseptic value than about 0.2% of either ester alone. The benzyl ester has a high antiseptic value and is suitable for the preparation of antiseptic creams. The preferred amount of alkyl ester for use in the invention is between about 1 to about 13 wt.% and most preferably about 3.0 wt.%.

[0043] Parahydroxybenzoic acid esters and mixtures of methylparaben and propylparaben can be used in the invention with excellent and unexpected results. They are commonly used as antimicrobial preservatives; and the amount of their use is contemplated to be in following ranges: methylparaben: from about 0.025 to about 0.2 wt.% , preferably from about 0.1 to about 1.25 %; propylparaben: from about 0.01 to about 0.4 wt.%, preferably from about 0.3% to about 0.04 wt.%.

[0044] Specific benzoic acids having between 12 and 15 carbon atoms, and alkyl esters can be added to an embodiment for the formula. For example, flowers of Benzoin; flowers of Benjamin; Phenylformic Acid, and Benzoic Acid, which is $C_7H_6O_2$, can be used. Benzoic Acid is the simplest acid of the aromatic series. Although the acid is of minor significance as a medicinal agent, it derivatives and salts constitute an important group of valuable medical agents. The addition of this component to the formula, enable the invention to act as an antifungal agent chiefly in combination with salicylic acid as well as being an anesthetic. When the Emu oil contains enough benzoic acid it can then be used in the treatment of athletes' feet and to a lesser extent in the management of ringworm, for humans and animals. Benzoin is preferably used in amounts between 10-33 wt.% and most preferably about 10 wt.%.

[0045] Still another ingredient, Allantoin can be used, specifically, Allantoin-5-Ureidohydantoin $C_4H_6N_4O_3$ can be added to the formula. Allantoin is used topically as a vulnerary to stimulate tissue repair in suppurating wounds, resistant ulcers, acne seborrhea, and basic dermatological infections. It is also included in some topical preparations for oral and dental use. It is frequently combined with antiseptics and antifungal drugs. The silver salt is used in the topical treatment of extensive bums. Typically, from about 0.2 to about 2.0% of this ingredient can be used in the formula, particularly when the invention is used as creams, lotions or shampoo.

[0046] The formula of this invention uniquely can be sterilized. Traditionally, sterilization has broken down the components of oils, which contain these types of fatty acids. The objective of a sterilization process is to remove or destroy all microorganisms in or on a preparation and to assure in this way the preparation is free of infectious hazards when used with a patient. Since the variety and amounts of the variety and amounts of sterile materials required for health care have increased in significant proportions, sterilization technology has become increasingly important. Alternatively, if sterilization of the oil is not preferred, then a disinfectant can be added to the formula to render the skin noninfectious. A usable disinfectant may be an antiseptic or a germicide.

[0047] A most preferred formulation for the present invention has the following components, each component being listed in weight percent:

Component	wt.%
Emu oil	63.5
Benzyl alcohol	20.0
Benzoin	10.0
Allantoin	2.0
Methylparaben	1.25
Alkyl esters	3.0

(continued)

Component	wt.%
Propylparaben	0.04

[0048] The present invention also contemplates a spray on transdermal formula having the additional transdermal effect of promoting the transdermal delivery of additional antiseptic, antifungal, and pain relieving medicine by proliferating new skin cell growth and development, comprising from about 0.01 to about 13 wt.% alkyl esters; from about 20 to about 70 wt.% Emu oil; from about 10 to about 33 wt.% benzyl alcohol; from about 10 to about 33 wt.% benzoin; from about 0.2 to about 2 wt.% allantoin; from about 0.25 to about 1.25 wt.% methylparaben and from about 0.01 to about 0.30 wt. % propylparaben; and sufficient and effective amounts of environmentally safe propellants.

[0049] In addition to being used as a topical treatment for the epidermis of humans, the formulation of the present invention also can be used for topical treatment on horses and other animals.

[0050] The present embodiment are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description. All changes, which come within the meaning and range of equivalency of the claims, are therefore intended to be embraced therein.

Claims

1. Analgesic, anesthetic and anti-pruritic formulation comprising:

from 0.01 to 13 wt.% alkyl esters;
from 20 to 70 wt.% Emu oil;
from 10 to 33 wt.% benzyl alcohol;
from 10 to 33 wt.% benzoin;
from 0.2 to 2 wt.% allantoin;
from 0.25 to 1.25 wt.% methylparaben;
and from 0.01 to 0.30 wt.% propylparaben.

2. The formulation of claim 1, comprising 60 to 65 wt.% Emu oil, wherein said Emu oil is refined and sterilized.

3. The formulation of claim 1, wherein said formulation can be applied topically to humans, horses and other animals.

4. The formulation of claim 1, further comprising an aromatic alcohol.

5. The formulation of claim 4, wherein said aromatic alcohol is present in an amount from 0.5 to 1.2 wt.% and wherein said aromatic alcohol can be present in a concentration of 0.9% for use as a bacteriostatic preservative.

6. The formulation of claim 1, wherein said Emu oil is a refined and sterilized Emu oil comprising at least 70 wt.% linoleic acid and linolenic acid in combination.

7. The formulation of claim 1, further comprising at least one member selected from the group consisting of a germicide, a bactericide, an antiseptic, an antifungal, a bacteriostatic agent and combinations thereof.

8. The formulation of claim 1, which can be adapted for preparation in the form of a gel, a lotion, a spray, a patch or an enhanced oil.

9. An analgesic, anesthetic and antipruritic spray-on transdermal formula having the additional transdermal effect of promoting the transdermal delivery of additional antiseptic, anti-fungal, and pain relieving medicine by proliferating new skin cell growth and development, comprising:

from	0.01 to	13 wt.% alkyl esters;
from	20 to	70 wt.% refined and sterilized Emu oil;
from	10 to	33 wt.% benzyl alcobol;
from	10 to	33 wt.% benzoin;
from	0.2 to	2 wt.% allantoin;

(continued)

from	0.25 to	1.25 wt.% methylparaben;
from	0.01 to	0.30 wt.% propylparaben; and

sufficient and effective amounts of environmentally safe propellants.

10. A spray-on transdermal formulation comprising:

Emu oil	63.5wt.%
Benzyl alcobol	20.0wt.%
Benzoin	10.0wt.%
Allantoin	2.0wt.%
Methyl paraben	1.25wt.%
Alkyl esters	3.0wt.%
Propylparaben	0.04wt.%, and

a sufficient and effective amount of at least one environmentally safe propellant.

Patentansprüche

1. Schmerzstillende, anästhetische und juckreizstillende Formulierung, die folgendes umfaßt:

von 0,01 bis 13 Gew.-% Alkylester;
von 20 bis 70 Gew.-% Emu-Ö1;
von 10 bis 33 Gew.-% Benzylalkohol;
von 10 bis 33 Gew.-% Benzoin;
von 0,2 bis 2 Gew.-% Allantoin;
von 0,25 bis 1,25 Gew.-% Methylparaben;
und von 0,01 bis 0,30 Gew.-% Propylparaben.

2. Formulierung nach Anspruch 1, die 60 bis 65 Gew.-% Emu-Öl umfaßt, wobei das Emu-Öl raffiniert und sterilisiert ist.

3. Formulierung nach Anspruch 1, die topisch beim Menschen, beim Pferd und bei anderen Tieren angewandt werden kann.

4. Formulierung nach Anspruch 1, die weiterhin einen aromatischen Alkohol umfaßt.

5. Formulierung nach Anspruch 4, wobei der aromatische Alkohol in einer Menge von 0,5 bis 1,2 Gew.-% vorliegt und wobei der aromatische Alkohol in einer Konzentration von 0,9% als bakteriostatisches Konservierungsmittel vorliegen kann.

6. Formulierung nach Anspruch 1, wobei es sich bei dem Emu-Öl um ein raffiniertes und sterilisiertes Emu-Öl handelt, das mindestens 70 Gew.-% Linolsäure in Kombination mit Linolensäure umfaßt.

7. Formulierung nach Anspruch 1, die weiterhin mindestens einen Bestandteil ausgewählt aus der Gruppe bestehend aus einem keimtötenden Mittel, einem Bakterizid, einem Antiseptikum, einem Antimykotikum, einem bakteriostatischen Mittel und Kombinationen davon umfaßt.

8. Formulierung nach Anspruch 1, die zwecks Herstellung in Form eines Gels, einer Lotion, eines Sprays, eines Pflasters oder eines verbesserten Öls adaptiert werden kann.

9. Schmerzstillendes, anästhetisches und juckreizstillendes Transdermalspray-Produkt, das den zusätzlichen Transdermaleffekt aufweist, daß es die transdermale Abgabe eines zusätzlichen antiseptischen, antimykotischen und schmerzstillenden Mittels durch Proliferation des Wachstums und der Entwicklung von neuen Hautzellen fördert,

und das
von 0,01 bis 13 Gew.-% Alkylester;
von 20 bis 70 Gew.-% raffiniertes und sterilisiertes Emu-Ö1;
von 10 bis 33 Gew.-% Benzylalkohol;
von 10 bis 33 Gew.-% Benzoin;
von 0,2 bis 2 Gew.-% Allantoin;
von 0,25 bis 1,25 Gew.-% Methylparaben;
von 0,01 bis 0,30 Gew.-% Propylparaben; und
ausreichende und wirksame Mengen von umweltfreundlichen Treibmitteln umfaßt.

10. Transdermalspray-Produkt, das folgendes umfaßt:

Emu-Öl	63,5 Gew.-%
Benzylalkohol	20,0 Gew.-%
Benzoin	10,0 Gew.-%
Allantoin	2,0 Gew.-%
Methylparaben	1,25 Gew.-%
Alkylester	3,0 Gew.-%
Propylparaben	0,04 Gew.-%, und

eine ausreichende und wirksame Menge von umweltfreundlichen Treibmitteln.

Revendications

1. Formulation analgésique, anesthésique et antipruritique comprenant :

de 0,01 à 13 % en poids d'esters alkyliques ;
de 20 à 70 % en poids d'huile d'émeu ;
de 10 à 33 % en poids d'alcool benzylique ;
de 10 à 33 % en poids de benzoïne ;
de 0,2 à 2 % en poids d'allantoïne ;
de 0,25 à 1,25 % en poids de méthylparaben ;
et de 0,01 à 0,30 % en poids de propylparaben.

2. Formulation selon la revendication 1, comprenant de 60 à 65 % en poids d'huile d'émeu, **caractérisée en ce que** l'huile d'émeu est raffinée et stérilisée.

3. Formulation selon la revendication 1, **caractérisée en ce que** ladite formulation peut être appliquée par voie topique sur l'homme, le cheval et d'autres animaux.

4. Formulation selon la revendication 1, comprenant en outre un alcool aromatique.

5. Formulation selon la revendication 1, **caractérisée en ce que** ledit alcool aromatique est présent dans une quantité de 0,5 à 1,2 % en poids et **en ce que** ledit alcool aromatique peut être présent dans une concentration de 0,9 %, destinée à être utilisée comme conservateur bactériostatique.

6. Formulation selon la revendication 1, **caractérisée en ce que** ladite huile d'émeu est une huile d'émeu raffinée et stérilisée comprenant au moins 70 % en poids d'acide linoléique et d'acide linoléique en combinaison.

7. Formulation selon la revendication 1, comprenant en outre au moins un composant choisi dans le groupe constitué de germicide, de bactéricide, d'antiseptique, d'antifongique, d'agent bactériostatique et de combinaisons de ceux-ci.

8. Formulation selon la revendication 1, **caractérisée en ce qu'**elle est adaptée à une préparation sous forme de gel, de lotion, de spray, de timbre ou d'huile enrichie.

9. Formule transdermique analgésique, anesthésique et antipruritique à pulvériser ayant t l'effet transdermique supplémentaire de favoriser la délivrance transdermique de médicaments antiseptiques, antifongiques et analgésiques supplémentaires par la croissance et le développement de nouvelles cellules cutanées en prolifération, comprenant:

de 0,01 à 13 % en poids d'esters allyliques
de 20 à 70 % en poids d'huile d'émeu raffinée et stérilisée ;
de 10 à 33 % en poids d'alcool benzylique ;
de 10 à 33 % en poids de benzoïne ;
de 0,2 à 2 % en poids d'allantoïne ;
de 0,25 à 1,25 % en poids de méthylparaben ;
de 0,01 à 0,30 % en poids de propylparaben ; et
des quantités suffisantes et efficaces d'agents propulseurs respectueux de l'environnement.

10. Formulation transdermique à pulvériser, comprenant;

de l'huile d'émeu	63,5 % en poids
de l'alcool benzylique	20,0 % en poids
de la benzoïne	10,0 % en poids
de l'allantoïne	2,0 % en poids
du méthylparaben	1,25 % en poids
des esters alkyliques	3,0 % en poids
du propylparaben	0,04% en poids, et

une quantité suffisante et efficace d'au moins un agent propulseur respectueux de l'environnement.

REFERENCES CITED IN THE DESCRIPTION

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