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(54) Title: SENSITIZATION COMPOSITION AND METHOD OF USE

(57) Abstract: The present invention relates to a topical composition and method of use, specifically an oil-in-water emulsion, comprised of sweet almond oil, lavender oil, rose oil, cinnamon bark oil, and coriander seed oil in a physiologically acceptable topical carrier. The composition is applied to a circumcised penis to enhance sensitivity, preferably twice daily for a time period of at least about two weeks. Thereafter a maintenance dose can be applied once a day to maintain a desired level of sensitivity.

SENSITIZATION COMPOSITION AND METHOD OF USE

Cross-Reference to Related Application

5 This application claims the benefit of U.S. Provisional Application No. 61/638,106, filed on April 25, 2012, which is incorporated herein by reference in its entirety.

Field of the Invention

10 This invention relates generally to a non-irritating topical composition for increasing the sensitivity of the penis during sexual activity. More specifically, the invention relates to an oil-in-water emulsion for application to a circumcised penis for enhanced sensitivity.

Background of the Invention

15 An intact human penis is covered by a single continuous sheath or skin system which is partly folded at different times. The folded portion of the skin system is called the foreskin or prepuce. Historically, the foreskin has been delineated as a separate anatomical structure; however, this is not correct. The foreskin is not a separate anatomical structure from the rest of the skin of the penis
20 but rather it is the portion of the continuous skin system which happens to be folded over the glans at any given time.

Circumcision is the surgical procedure by which the foreskin is removed. Many cultures perform circumcision on infant males soon after birth; however, the procedure is also sometimes performed on adult males. Male
25 circumcision is performed for a variety of reasons; religious, health, aesthetic, tradition, etc. Recent studies have brought into question some of the justifications for circumcision inasmuch as circumcision removes a complex, pentilaminar functional structure that contains nearly all fine touch neuroceptors of the penis and can reduce sensitivity of the glans penis to fine touch and vibration. Van Howe,
30 Nat. Clin. Pract. Urol. 6(2):74-75 (2009).

Summary of the Invention

A composition for topical application to a circumcised penis to enhance sensitivity comprises an admixture of sweet almond oil, lavender oil, cinnamon bark oil, coriander seed oil and rose oil in a physiologically acceptable topical cream, i.e, an oil-in-water emulsion having the consistency of a viscous liquid or semi-solid.

Detailed Description of Preferred Embodiments

The composition of the present invention is an oil-in-water emulsion comprising sweet almond oil, lavender oil, cinnamon bark oil, coriander seed oil and rose oil, preferably in a respective weight proportion of about 200:33:25:17:1. The oil-in-water emulsion is a viscous liquid or semi-solid having a cream-like consistency. The preferred dosage amount is approximately 150-300 mg of the composition per dose.

Table 1 lists the components of the composition in recommended weight percent ranges, as well as the preferred weight percent.

- 3 -

Table 1

	Component	wt %	pdf wt %
	sweet almond oil ¹	2 - 10	6
	lavender oil ²	0.01-2	1
5	rose oil ³	0.005-1	0.03
	cinnamon bark oil ⁴	0.01-2	0.75
	coriander seed oil ⁵	0.01-1	0.5
	sorbitol	0.7-7	3.5
	isopropyl alcohol	0-7	2.8
10	propylene glycol	5-25	20
	butylated hydroxytoluene	0.01-2	1
	triethanolamine	0.05-3	1
	benzyl alcohol	0.01-3	1
	benzyl benzoate	0.01-5	1
15	PEG 40-hydrogenated castor oil ⁶	1-5	3.5
	acrylate/C10-30 alkyl acrylate crosspolymer ⁷	0.25-4	1.3
	disodium EDTA	0.01-0.2	0.1
	water	q.s. to 100%	q.s. to 100%

20 ¹ Prunus Amygdalus Dulcis oil

² Lavandula Angustifolia oil

³ Rosa Damascena oil

⁴ Cinnamomun Zeylanicum bark oil

⁵ Coriandrum Sativum seed oil

25 ⁶ Cremophor RH40

⁷ Pemulen TR1

- 4 -

The present compositions can be prepared in a batch process as described below.

An aqueous dispersion is prepared using about 90 weight percent of required water, to which are added the acrylate crosspolymer and disodium
5 ethylene diamine tetraacetic acid (EDTA). The resulting admixture is stirred until a substantially complete dispersion is achieved usually for about two hours. A 70 weight percent solution of sorbitol in water is then added with stirring, and the stirring is continued until a substantially homogeneous composition is obtained.

A separate homogenous dispersion is prepared by admixing PEG
10 40-hydrogenated castor oil, benzyl alcohol, benzyl benzoate butylated hydroxytoluene, isopropanol and propylene glycol.

The prepared dispersions are then quantitatively combined in a single vessel with stirring and the mixture of sweet almond oil, lavender oil, cinnamon bark oil, coriander seed oil and rose oil is added to the combined
15 dispersions with stirring until a homogenous dispersion is produced. The stirring is continued for at least about one hour.

A solution of triethanolamine in the remaining ten weight percent of water is then slowly added to the produced homogenous dispersion with stirring which is continued for at least 30 minutes to produce a smooth, cream-like
20 composition.

EXAMPLE

A cream prepared in the foregoing manner and containing the preferred amount of constituents shown in Table 1 was administered to eight
25 circumcised male patients (age: 28 to 65 years). A dose of about 150 milligrams was applied to the glans penis twice a day for a two week period.

Six of the eight patients reported that they experienced a lasting increased sensitivity of the glans penis after the two-week treatment period.

A preferred method of use comprises application of the composition
30 to the glans penis twice daily for at least about two weeks, preferably in an amount in the range of about 150 to about 300 milligrams per application. Thereafter a

- 5 -

maintenance dose can be applied once a day to maintain a desired level of sensitivity.

5 The foregoing description and the example are intended as illustrative and are not to be taken as limiting. Still other variants within the spirit and scope of the present invention are possible and will readily present themselves to those skilled in the art.

WE CLAIM:

1. A topical composition which comprises an admixture of sweet almond oil, lavender oil, cinnamon bark oil, coriander seed oil and rose oil in a physiologically acceptable oil-in-water emulsion.
- 5 2. The topical composition in accordance with claim 1 wherein the oil-in-water emulsion is a topical cream.
3. The topical composition in accordance with claim 1 wherein said oils are present in said admixture in a respective weight proportion of about 200:33:25:17:1.
- 10 4. A topical composition comprising, based on the weight of the composition:
about 2 to about 10 weight percent sweet almond oil, about 0.01 to about 2 weight percent lavender oil, about 0.005 to about 1 weight percent of rose oil, about 0.01 to about 2 weight percent cinnamon bark oil, about 0.01 to about 1
15 weight percent of coriander seed oil, about 0.7 to about 7 weight percent sorbitol, zero to about 7 weight percent isopropyl alcohol, about 5 to about 25 weight percent of propylene glycol, about 0.01 to about 2 weight percent butylated hydroxytoluene, about 0.05 to about 3 weight percent triethanolamine, about 0.01 to about 3 weight percent benzyl alcohol, about 0.01 to about 5 weight percent
20 benzyl benzoate, about 1 to about 5 weight percent of polyethylene glycol (40)-hydrogenated castor oil, about 0.25 to about 4 weight percent acrylate/C10-30 alkyl acrylate crosspolymer, about 0.01 to about 0.2 weight percent disodium ethylene diamine tetraacetic acid, and the remainder water.
- 25 5. The topical composition of claim 4 and consisting essentially of, based on the weight of the composition:
about 6 weight percent sweet almond oil, about 1 weight percent lavender oil, about 0.03 weight percent of rose oil, about 0.75 weight percent cinnamon bark oil, about 0.5 weight percent coriander seed oil, about 3.5 weight percent sorbitol, about 2.8 weight percent isopropyl alcohol, about 20 weight
30 percent propylene glycol, about 1 weight percent butylated hydroxytoluene, about 1 weight percent triethanolamine, about 1 weight percent benzyl alcohol, about 1

- 7 -

weight percent benzyl benzoate, about 3.5 weight percent polyethylene glycol (40)-hydrogenated castor oil, about 1.3 weight percent acrylate/C10-30 alkyl acrylate crosspolymer, about 0.1 weight percent disodium ethylene diamine tetraacetic acid, and the remainder water.

5 6. A method of enhancing sensitivity of a circumcised penis which comprises applying to the glans penis the topical composition of claim 1.

7. A method of enhancing sensitivity of a circumcised penis which comprises applying to the glans penis the topical composition of claim 4.

10 8. A method of enhancing sensitivity of a circumcised penis which comprises applying to the glans penis the topical composition of claim 5.

9. The method of claim 6 wherein about 150 to about 300 milligrams of the topical composition is applied twice daily for a time period of at least about two weeks.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/032371

<p>A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61K 8/97 (2013.01) USPC - 424/725 According to International Patent Classification (IPC) or to both national classification and IPC</p>														
<p>B. FIELDS SEARCHED</p> <p>Minimum documentation searched (classification system followed by classification symbols) IPC(8) - A61K 8/92, 8/97, 9/107, 36/23, 36/53, 36/54, 36/736, 36/738; A61P 15/00, 15/10, 15/12 (2013.01) USPC - 424/725, 735, 739, 765</p> <p>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched CPC - A61K 8/92, 8/97, 9/0034 (2013.01)</p> <p>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Orbit, GOOGLE Patent, GOOGLE Scholar</p>														
<p>C. DOCUMENTS CONSIDERED TO BE RELEVANT</p> <table border="1"> <thead> <tr> <th>Category*</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>A</td> <td>US 2009/0068128 A1 (WADDINGTON) 12 March 2009 (12.03.2009) entire document</td> <td>1-9</td> </tr> <tr> <td>A</td> <td>US 2010/0215775 A1 (SCHMAUS et al) 26 August 2010 (26.08.2010) entire document</td> <td>1-9</td> </tr> <tr> <td>A</td> <td>US 2011/0086116 A1 (FLORENCE et al) 14 April 2011 (14.04.2011) entire document</td> <td>1-9</td> </tr> </tbody> </table>			Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	A	US 2009/0068128 A1 (WADDINGTON) 12 March 2009 (12.03.2009) entire document	1-9	A	US 2010/0215775 A1 (SCHMAUS et al) 26 August 2010 (26.08.2010) entire document	1-9	A	US 2011/0086116 A1 (FLORENCE et al) 14 April 2011 (14.04.2011) entire document	1-9
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<p>Name and mailing address of the ISA/US</p> <p>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201</p>		<p>Authorized officer:</p> <p>Blaine R. Copenheaver</p> <p>PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774</p>												