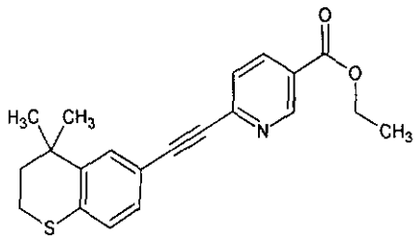
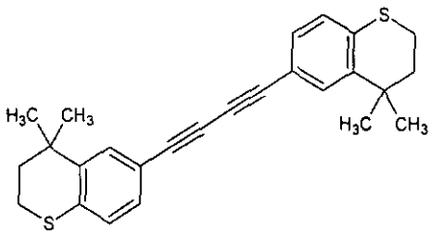
ABSTRACT

The present invention relates to a method of treating acne or psoriasis by topically administering Tazarotene, a compound of formula (I), substantially free of dimer impurity 4,4-dimethyl-6-[4-(4,4-dimethylthiochroman-6-yl)-buta-1,3-diynyl]-thiochroman, a compound of formula (II)



Formula I



Formula II

Dated 10 Dec 2013

(Signature)..... (Sunil Ajmera Company Secretary)

DILIP SHANTILAL SHANGHVI

MANAGING DIRECTOR

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Example 5: Composition for Tazarotene Gel (0.1% w/w)

Ingredients	Concentration (% w/w)
Disodium Edetate	0.05
Ascorbic acid	0.1
Carbomer homopolymer type B	1.25
Poloxamer 407	0.2
Tazarotene	0.1
Polyethylene Glycol 400	45
Hexylene Glycol	2
Butylated hydroxy toluene	0.05
Butylated hydroxy anisole	0.1
Polysorbate 40	0.2
Benzyl alcohol	1
Tromethamine	0.8
Purified water	q.s.

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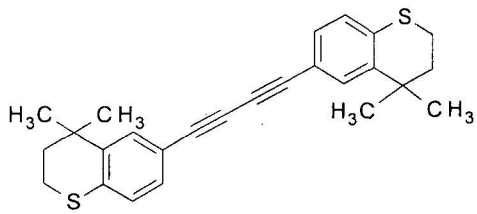
We Claim:

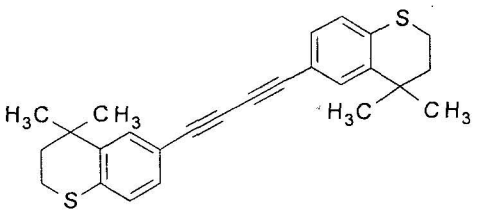
1. A method of treating acne or psoriasis by topically administering tazarotene substantially free of dimer impurity of Formula II.



Formula II

2. The method of claim 1 wherein, the tazarotene contains less than 100 ppm of dimer impurity of Formula II.
3. The method of claim 1 wherein, the tazarotene contains less than 30 ppm of dimer impurity of Formula II.
4. The method of claim 1 wherein, the tazarotene contains less than 10 ppm of dimer impurity of Formula II.

5. The method of claim 1 wherein, the dimer impurity of Formula II in tazarotene is not detectable in said tazarotene.
6. A process for preparation of Tazarotene substantially free of dimer impurity of Formula II



Formula II

comprising:

a. adding Tazarotene containing dimer impurity of Formula II to an organic solvent,
b. adding an acid and isolating the acid addition salt of tazarotene,
c. adding the tazarotene acid addition salt obtained in step b to an organic solvent and adding an aqueous solution of a base to obtain a biphasic mixture,
d. distilling the organic layer and treating the residue with a non-polar solvent,
e. optionally, repeating step a to d.

7. Tazarotene, obtained by the process of claim 6 containing less than 30 ppm of dimer impurity of Formula II.
8. Tazarotene, obtained by the process of claim 6 containing less than 10 ppm of dimer impurity of Formula II.
9. Tazarotene, obtained by the process of claim 6 wherein dimer impurity of Formula II is not detectable in said tazarotene.

Dated 12th Dec 2014

(Signature) .....

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