

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: D. MILLER *et al.*

Attorney Docket No: 5415-002-US01CON1

Application No.: 12/477,413

Group Art Unit: 1614

Filed: June 3, 2009

Examiner: K. Weddington

For: CREATINE ORAL SUPPLEMENTATION
USING CREATINE HYDROCHLORIDE
SALT

RESPONSE TO OFFICE ACTION

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Sir:

In response to the Office Action mailed August 18, 2010, Applicants submit the following remarks for entry and consideration during the examination of the above-identified application.

IN THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1.-8. (canceled)

9. (Previously Presented) A granular precipitate consisting essentially of creatine hydrochloride salt formed from the reaction product of creatine monohydrate and acetyl chloride dissolved in a solution comprising a short chain alcohol, wherein the granular precipitate has an aqueous solubility of at least 150 mg/ml.

10. (Previously Presented) The granular precipitate of claim 9, wherein the creatine monohydrate is reacted with acetyl chloride in an amount of about 0.8 to about 1.2 mole equivalent.

11. (Previously Presented) The granular precipitate of claim 9, wherein the acetyl chloride is reacted with the creatine monohydrate in an amount of about 1.1 to about 1.4 mole equivalent.

12. (Previously Presented) The granular precipitate of claim 9, wherein the short chain alcohol is selected from the group consisting of methanol, ethanol, propanol, butanol, and isopropanol.

13. (Previously Presented) The granular precipitate of claim 9, wherein the short chain alcohol is ethanol.

14. (Previously Presented) The granular precipitate of claim 13, wherein the creatine monohydrate and the acetyl chloride are dissolved in about 6 to about 10 milliliters ethanol solution per gram of creatine hydrochloride salt at a temperature of about 25°C. to about 35°C.

15. (Previously Presented) The supplement of claim 9, wherein the yield of creatine hydrochloride salt is approximately 94 percent.

REMARKS

Claims 9-15 are pending in this application. In this Response, Applicants have not amended any claims. As no new matter has been added, Applicants respectfully request entry of these amendments at this time.

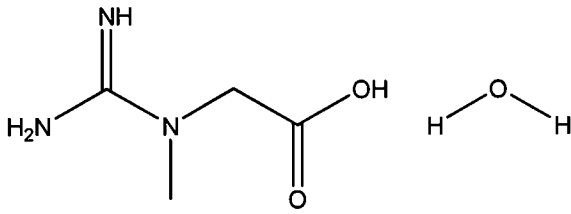
NON STATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 9-15 were rejected under the judicially created doctrine of obviousness-type double patenting as being obvious over claims 1-17 of U.S. Patent No. 6,897,334 to Vennerstrom (“Vennerstrom”). In addition, claims 9-15 were rejected under the judicially created doctrine of obviousness-type double patenting as being obvious over claims 1-17 of U.S. Patent No. 7,608,641 to Miller (“Miller”).

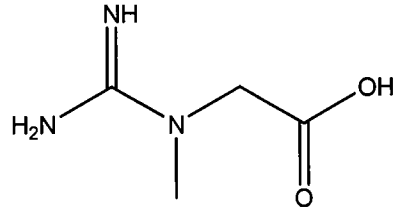
Regarding the rejection based on Vennerstrom, Applicants submit that the present invention is directed to a supplement formed from the reaction of creatine monohydrate and acetyl chloride in ethanol. In particular, the reactants are dissolved in ethanol to produce a granular precipitate consisting of creatine hydrochloride salt in high purity and yield. Page 3, lines 17-21. As further described in the Written Description, the high aqueous solubility of creatine HCl (150 mg/ml or greater) is, at least in part, what makes the reaction product novel over other forms of creatine, such as creatine monohydrate and creatine citrate salt. Page 3, line 24 to Page 4, line 1. In fact, the aqueous solubility of creatine monohydrate and creatine citrate salt is at least an order of magnitude lower than the reaction product of the present invention. *Id.*

Vennerstrom generally discloses a method of producing creatine esters using in situ acid production of an acid catalyst. *See e.g.*, Col. 2, lines 9-12. While the Examiner appears to equate the creatine ester reaction product of Vennerstrom and the presently recited supplement based on the similarity of the starting materials, the reaction products are very different.

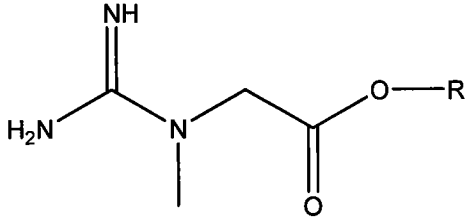
As a threshold matter, “creatine” may exist in many different forms that have distinct chemical compositions with different structures and properties. In fact, as shown below, creatine ester and creatine HCl are distinct chemical compositions with different structures and properties:



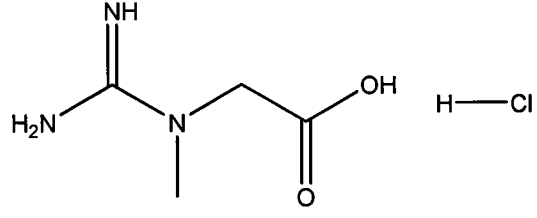
Creatine monohydrate



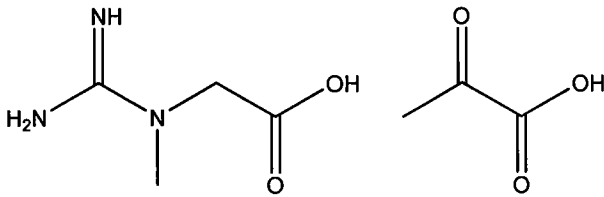
Creatine anhydrous



Creatine ester (where R is a hydrocarbonyl group)



Creatine hydrochloride



Creatine pyruvate

The goal of Vennerstrom is to produce creatine esters, not creatine HCl. Col. 4, lines 29-32. Accordingly, the discussion of creatine HCl is very limited in Vennerstrom. In fact, Vennerstrom specifically teaches that creatine HCl, the reaction product featured in the present application, is regarded as an unwanted impurity. Col. 4, lines 29-32 and 7, lines 12-14. Furthermore, even when Vennerstrom describes a reaction in which the acetyl chloride is used in an amount within the range disclosed in the present application such that some creatine HCl is produced, the product of the reaction purportedly consists of 99 percent creatine ester, as denoted by the 99 percent product purity. Col. 7, Table 2 (reproduced below).

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