#### SPECIFICATION

To All Whom It May Concern:

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Be it known that We, Donald W. Miller and Jonathan L. Vennerstrom, being a citizens of the United States, and residing in the City of Omaha, and State of Nebraska, and whose full post office addresses are 2573 South 138<sup>th</sup> Street, Omaha, Nebraska, 68144, and 3209 South 73<sup>rd</sup> Street, Omaha, Nebraska, 68124, have invented new and useful improvements in

## CREATINE ORAL SUPPLEMENTATION USING CREATINE HYDROCHLORIDE SALT

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#### **BACKGROUND OF THE INVENTION**

Dietary supplementation with creatine is an approved and accepted means for increasing muscle performance, and increasing muscle mass. Most current commercial applications involving creatine supplementation use

- 5 the creatine monohydrate form as the primary embodiment. A limitation of creatine supplements using the creatine monohydrate form is that the products have low aqueous solubility and requires relatively large doses of creatine be consumed with large amounts of fluid. The physiochemical properties of creatine monohydrate are such that oral absorption is limited.
- 10 There are other salt forms including creatine citrate (creatine effervescent) and creatine pyruvate that have been patented and marketed as improvements over creatine monohydrate. Despite the various salt forms currently marketed, there is an unmet need for an improved form of creatine that could be taken in a more convenient dosage form and have better oral
- 15 absorption characteristics.

#### SUMMARY OF THE INVENTION

This invention relates principally to the use of creatine hydrochloride salt for application to aqueous solutions for use as a beverage in the sports environment, liquid meal replacement, nutritional energy bars, and other fortified foods.

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In essence, this invention relates to the usage of a granular precipitate consisting of creatine hydrochloride salt in a high purity and yield. More specifically, the creatine hydrochloride salt, when added to a solution, and used as a beverage or other form of drink, functions as a nutritional

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supplement for enhancing muscle performance and developing muscle mass
in both humans and livestock.

It is, therefore, the principle object of this invention to utilize creatine hydrochloride salt, apart from other forms of creatine, but in this instance, having high aqueous solubility so as to readily mix with any liquid, or

10 beverage, and having application in the field of athletics to enhance developed and generated strength.

Another object of this invention is the application of hydrochloride salts, of creatine form, that may be added as a feed additive when fed to livestock, or other animals.

15 These and other objects may become more apparent to those skilled in the art upon review of the summary of the invention as provided herein and upon undertaking a study of the description of its preferred embodiment.

#### DESCRIPTION OF THE PREFERRED EMBODIMENT

20 The present invention involves a process for the production of the hydrochloride salt form of creatine. The process uses creatine monohydrate and acetyl chloride as the reactants and ethanol as the preferred solvent. The product of this reaction is a granular precipitate consisting of the creatine

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hydrochloride salt in high purity and yield. The invention also involves an application/use of the creatine hydrochloride salt as a nutritional supplement for enhancing muscle performance and muscle mass in both humans and livestock. What sets the creatine hydrochloride salt apart from the other

5 forms of creatine is its high aqueous solubility. Studies in our laboratory indicate that the aqueous solubility of the creatine hydrochloride is 150 mg/ml or greater, while that of creatine monohydrate and creatine citrate salt is at least an order of magnitude lower (approximately 10-15 mg/ml). As the low oral absorption of creatine supplements are believed to be attributable in part 10 to reduced solubility, the creatine hydrochloride would be expected to have

better oral absorption properties.

Various other applications for use with this type of a salt, other than in the sports beverage area, may include its application as a feed additive in livestock. Certainly, based upon what is now known about the product, it

15 would have immediate applications in the solid oral dosage supplementation area, as an additive or a feed supplement in livestock feed. Or, it may be added into a liquid, or any water, that is fed to the livestock, during there consumption of liquids and solids.

This is contemplated within the essence of this invention that the formulation for the oral supplementation of this invention could be provided in a solid oral dosage form, such as in a capsule form, or tablets, for treatment requirements when taken by the human, animal, and the like. This is known in the art. The formulation for the creatine oral supplementation, using the

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Creatine Hydrochloride Salt, is CrHCI. The formulation could be added into a beverage in addition the CrHCI may be provided as an ingredient to a sports drink, liquid meal replacement, or the like, and as can be understood. Furthermore, the concept of this invention for use of this formulation within a

- 5 supplementation can be used and applied for nutritional and energy purposes. Furthermore, the composition could be added as a fortification to other foods. Finally, it is likely that this composition could be added as a feed supplement, to further enhance the energy requirements of the horses, and other animals, as may be desired and required.
- 10 Variations or modifications to the subject matter may occur to those skilled in the art upon review of the invention as described herein. Such variations, if within the spirit of this development, are intended to be encompassed within the scope of the invention as defined herein. The description of the preferred embodiment, as provided, is set forth for

15 illustrative purposes only.

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