

Claims

1. Isolated Methyl 3-[(2-acetylaminoethylthio)carbonyl]propionate (Compound 1) in solid form.
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2. The isolated Compound 1 according to claim 1, which is in the form of the free form or a salt, hydrate, solvate or complex thereof.
3. The isolated Compound 1 according to claim 1 having a melting point or a melting
10 range in a range of from 35 to 55 °C.
4. The isolated Compound 1 according to any of the preceding claims, which is a crystalline product or an amorphous product, or a mixture thereof.
- 15 5. The isolated Compound 1 according to any of the preceding claims, having a purity of at least 20 %w/w, at least 30 %w/w, at least 40 %w/w, at least 50 %w/w, at least 60 %w/w, at least 70 %w/w, at least 75 %w/w, at least 80 %w/w, at least 90 %w/w, at least 95 %w/w, at least 97 %w/w, at least 98 %w/w or at least 99 %w/w.
- 20 6. The isolated Compound 1 according to any of the preceding claims having an aqueous solubility at room temperature of at least 300 mg/mL.
7. The isolated Compound 1 according to claim 6, wherein the aqueous solubility at room temperature is in a range of from 300 mg/mL to 900 mg/mL.
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8. The isolated Compound 1 according to any of the preceding claims having a crystallinity in a range of from 0 to 100% such as from 50 to 100%.
9. The isolated Compound 1 according to any of the preceding claims having a kinetic
30 aqueous solubility corresponding to a rate constant in a range of from 0.005 to 0.2 s⁻¹.
10. The isolated Compound 1 according to any of the preceding claims having an X-ray powder diffraction pattern with one or more signals at 21.4, 22.2, 22.8, 23.1 and 23.3 (± 0.2 degrees, 2-theta values).

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11. The isolated Compound 1 according to any of the preceding claims having an X-ray power diffraction pattern with one or more signals at 10.9, 13.1, 14.9, 16.2, 20.1, 24.0, 24.8, 26.1, (± 0.2 degrees, 2-theta values).
- 5 12. The isolated Compound 1 according to any of the preceding claims, for use in medicine.
13. The isolated Compound 1 according to any of the preceding claims, for use as the active pharmaceutical ingredient in a pharmaceutical product.
- 10 14. The isolated Compound 1 according to any of the preceding claims, for use in the treatment or prevention of a metabolic disease, a disease of mitochondrial dysfunction, a disease related to mitochondrial dysfunction, a mitochondrial disorder, mitochondrial energy deficiency, drug-induced mitochondrial side effects, cancer, diabetes, traumatic
- 15 brain injury, acute liver injury and atrial fibrillation.
15. The isolated Compound 1 according to any of the preceding claims, for use in the treatment or prevention of metabolic dysfunction.
- 20 16. The isolated Compound 1 according to any of the preceding claims for use in the treatment or prevention of Leigh Syndrome, LHON, MELAS, MERRF (myoclonic epilepsy with ragged red fibers).and other diseases/conditions relating to mitochondrial Complex I defects
- 25 17. The isolated Compound 1 according to any of claims 1-11, for non-pharmaceutical use in humans or animals.
18. The isolated Compound 1 according to claim 17, for use as a cosmeceutical or nutraceuticals.
- 30 19. Cosmeceutical comprising the isolated Compound 1 according to any of claims 1-11.
20. Nutricosmetics comprising the isolated Compound 1 according to any of claims 1-
- 35 11.

21. Energy drink comprising the isolated Compound 1 according to any of claims 1-11.

22. Pharmaceutical composition comprising isolated Compound 1 according to any of claims 1-16.

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23. A process for preparing isolated Compound 1 according to any of claims 1-16, said process comprising the steps of :

a) reacting N-acetyl cysteamine and monomethyl succinate, in the presence of a coupling reagent, in organic solvent, between 0°C and 100°C

10 b) isolating Compound 1,

so as to provide isolated Compound 1.

24. The compound according to any of claims 1-16 in the form of its Form I crystalline polymorph having an X-ray powder diffraction pattern with signals at 11.2, 16.9 ($\pm$ 0.2
15 degrees, 2-theta values).

25. A process for the preparation of Compound 1 in the form of its Form I crystalline polymorph according to claim 24 comprising the step of crystallising a compound of formula (I).

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