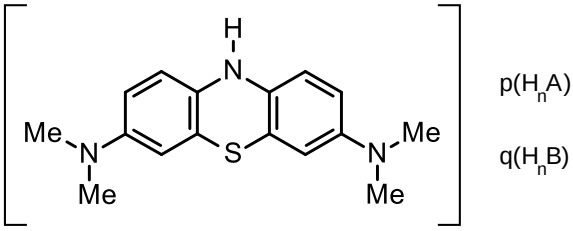
Claims

1 Non-therapeutic use of a methylthioninium (MT) containing compound to stimulate cognitive function in a healthy subject,

wherein said use comprises administering between 2 and 100 mg of MT to the subject per day, optionally split into 2 or more doses,

wherein the MT compound is an LMTX compound of the following formula:



wherein each of H_nA and H_nB (where present) are protic acids which may be the same or different,

and wherein p = 1 or 2; q = 0 or 1; n = 1 or 2; (p + q) × n = 2

or a hydrate or solvate thereof.

2 The non-therapeutic use of claim 1 wherein the LMTX compound stimulate basal choline levels and synaptophysin in the subject.

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3 The non-therapeutic use as claimed in claim 1 or claim 2 wherein the stimulation of cognitive function is for the purpose of stimulating alertness, attention, reasoning, concentration, learning, or language processing in the subject.

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4 The non-therapeutic use as claimed in any one of claims 1 to 3 wherein the subject has an MMSE of 30.

5 The non-therapeutic use as claimed in any one of claims 1 to 4 wherein the subject is has not previously received, treatment with an acetylcholinesterase inhibitor or an N-methyl-D-aspartate receptor antagonist, or has discontinued such treatment prior to administration of the LMTX compound.

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6 The non-therapeutic use as claimed in any one of claims 1 to 5 wherein the total daily dose of MT is from 10 - 60 mg.

7 The non-therapeutic use as claimed in any one of claims 1 to 6 wherein the total daily dose of MT is from 20 - 60 mg.

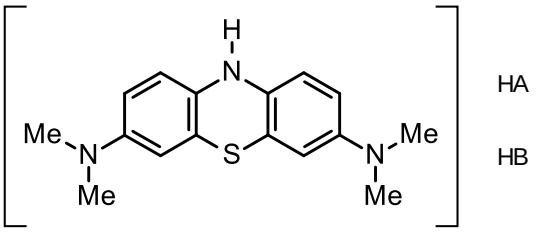
8 The non-therapeutic use as claimed in any one of claims 1 to 6 wherein the total daily dose of MT is from 10 - 40 mg.

9 The non-therapeutic use as claimed in any one of claims 1 to 8 wherein the total daily dose of MT is from 20 - 40 mg.

10 The non-therapeutic use as claimed in any one of claims 1 to 5 wherein the total daily dose of MT is from around any of 2, 2.5, 3, 3.5, or 4 mg to around any of 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 50 or 60 mg.

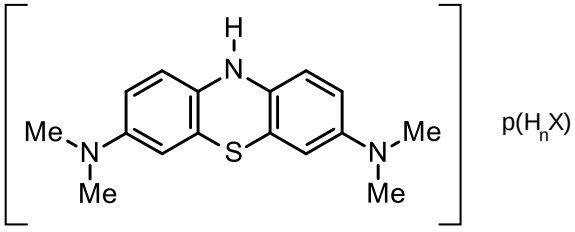
11 The non-therapeutic use as claimed in any one of claims 1 to 10 wherein the total daily dose of the compound is administered as a split dose twice a day or three times a day.

12 The non-therapeutic use as claimed in any one of claims 1 to 11 wherein the compound has the following formula, where HA and HB are different mono-protic acids:



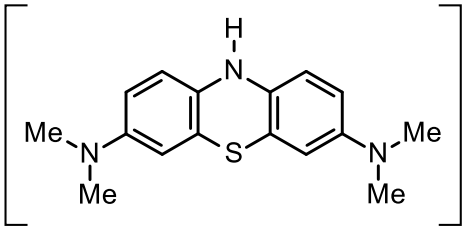
wherein HA and HB are different mono-protic acids:

13 The non-therapeutic use as claimed in any one of claims 1 to 11 wherein the compound has the following formula:



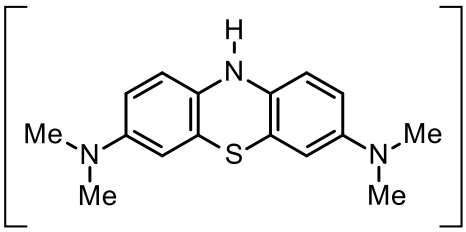
wherein each of H_nX is a protic acid.

14 The non-therapeutic use as claimed in any one of claims 1 to 11 wherein the compound has the following formula and H_2A is a di-protic acid:



H_2A

15 The non-therapeutic use as claimed in claim 13 wherein the compound has the following formula and is a bis-monoprotic acid:



2(HA)

16 The non-therapeutic use as claimed in any one of claims 1 to 15 wherein the or each protic acid is an inorganic acid.

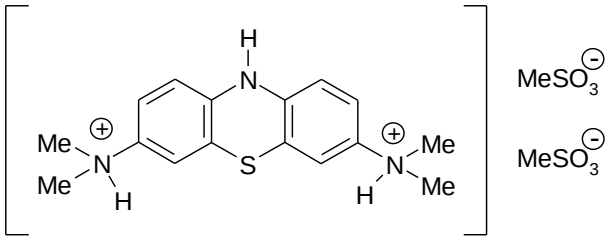
17 The non-therapeutic use as claimed in claim 16 wherein each protic acid is a hydrohalide acid.

18 The non-therapeutic use as claimed in claim 16 wherein the or each protic acid is selected from HCl; HBr; HNO_3; H_2SO_4.

19 The non-therapeutic use as claimed in any one of claims 1 to 15 wherein the or each protic acid is an organic acid.

20 The non-therapeutic use as claimed in claim 19 wherein the or each protic acid is selected from H_2CO_3; CH_3COOH; methanesulfonic acid, 1,2-ethanedisulfonic acid, ethanesulfonic acid, naphthalenedisulfonic acid, p-toluenesulfonic acid.

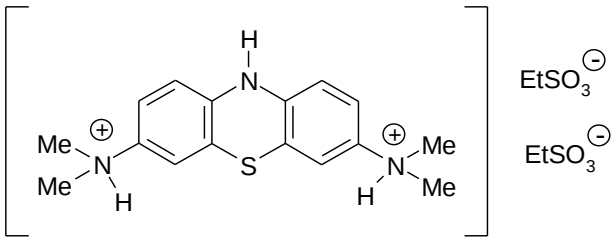
21 The non-therapeutic use as claimed in claim 20 wherein the compound is LMTM:

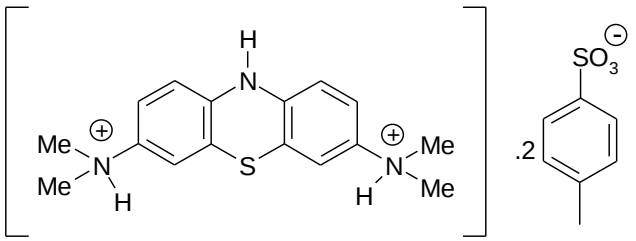


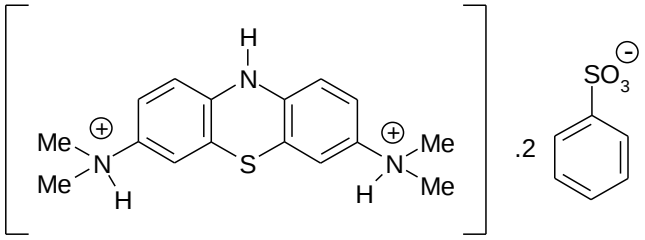
22 The non-therapeutic use as claimed in claim 21 wherein the total daily dose of LMTM is around 3.4 to 100mg/day, more preferably 34 to 100 mg/day of LMTM total.

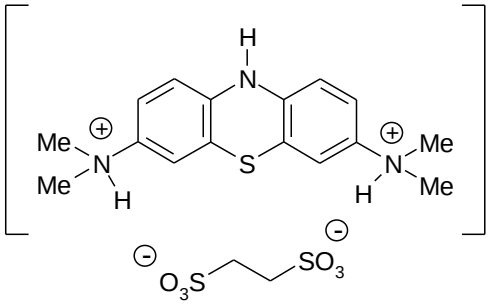
23 The non-therapeutic use as claimed in claim 22 wherein the dose of LMTM is around 34 mg/once per day; 15 mg b.i.d.; 8.7 mg t.i.d.

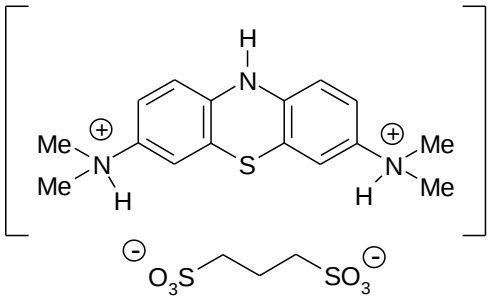
24 The non-therapeutic use as claimed in claim 20 wherein the compound is selected from the list consisting of:

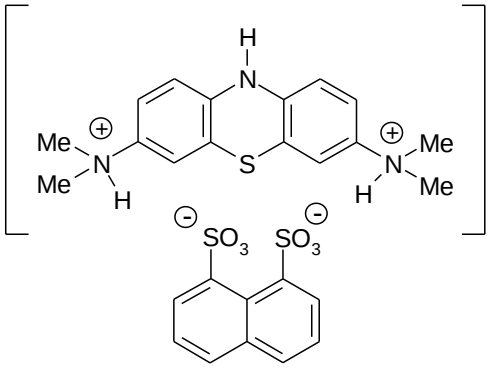












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25 The non-therapeutic use as claimed in any one of claims 1 to 24 wherein the MT compound is provided as a nootropic composition comprising the MT compound and a pharmaceutically acceptable carrier or diluent, optionally in the form of a dosage unit, which is optionally a tablet or capsule.

26 The non-therapeutic use as claimed in claim 25 wherein the amount of MT in the unit is about 4, 5, 6, 7, 8, 9, 10, 20, or 30 to about 40, 50 or 60 mg.

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27 The non-therapeutic use as claimed in any one of claims 1 to 26 wherein the MT compound is provided as a nootropic composition comprising the MT compound and a further nootropic agent, optionally in the form of a dosage unit.

~~28 The non-therapeutic use as claimed in claim 25 or claim 26 which is a tablet or capsule.~~

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~~29 A container comprising:~~
~~(i) a plurality of dosage units as defined in any of claims 25 to 28;~~
~~(ii) a label and\or instructions for their non-therapeutic use as defined in any one of claims 1 to 24.~~

~~30 A container as claimed in claim 29, wherein the dosage units are present in a blister pack which is substantially moisture-impervious.~~

~~31 A container as claimed in claim 29 or claim 30 wherein the label or instructions provide information regarding the stimulation of cognitive function for which the composition is intended.~~

~~32 A container as claimed in any one of claims 29 to 31 wherein the label or instructions provide information regarding the maximum permitted daily dosage of the dosage units.~~

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~~33~~28. A non-therapeutic method of treating a healthy human subject to stimulate their cognitive function,

the treatment comprising orally administering to the subject a nootropically effective amount of methylthioninium (MT) containing LTMX compound according to the use defined in any one of claims 1 to 2~~8~~7.

~~34 A methylthioninium (MT) containing LTMX compound as defined in any one of claims 1 to 28 for use in a non-therapeutic method of treating a healthy human subject to stimulate their cognitive function according to the use defined in any one of claims 1 to 28.~~

~~35 Use of a methylthioninium (MT) containing LTMX compound as defined in any one of claims 1 to 28 in the manufacture of a nootropic composition for stimulating cognitive function in a healthy human subject according to the use defined in any one of claims 1 to 28.~~