CLAIMS

Claim 1. A process for preparing an iron carbohydrate complex compound comprising the steps of

(i) providing an iron preparation comprising iron in a form selected from a water-soluble iron salt, an iron hydroxide or an iron oxide-hydroxide, wherein
- the amount of arsenic in the iron preparation does not exceed 4.5 µg per g of iron, and
- the amount of lead in the iron preparation does not exceed 1.5 µg per g of iron; and

(ii) contacting the iron preparation with a carbohydrate ligand in the presence of water so as to form the iron carbohydrate complex compound,
wherein the iron carbohydrate complex compound is an iron hydrogenated oligoisomaltose.

Claim 2. The process of claim 1, wherein
- the amount of cadmium in the iron preparation does not exceed 0.6 µg per g of iron, and
- the amount of mercury in the iron preparation does not exceed 0.9 µg per g of iron.

Claim 3. The process of claim 1 or claim 2, wherein
- the amount of chromium in the iron preparation does not exceed 330 µg per g of iron.

Claim 4. The process of any one of claims 1 to 3, wherein the amount of aluminum in the iron preparation does not exceed 200 µg per g of iron.

Claim 5. The process of any one of claims 1 to 4, wherein the iron preparation is obtained

(a) from iron pentacarbonyl; or
(b) by recrystallization of an iron salt from an aqueous solution thereof; or
(c) by extracting an aqueous iron salt solution with an organic solvent; or
(d) from iron precipitated at an anode during electrolysis of an aqueous iron salt solution; or

(e) by distillation of ferric chloride from a mixture comprising ferric chloride and non-volatile impurities.

Claim 6. The process of claim 5, wherein the iron preparation is obtained by extracting a ferric chloride solution with an alcohol having from 4 to 20 carbon atoms or an organic solution of an amine salt.

Claim 7. The process of claim 5, wherein the iron preparation is obtained from iron precipitated at an anode during electrolysis of an aqueous solution comprising iron chloride.

Claim 8. The process of any one of claims 1 to 7, wherein the iron preparation comprises a water soluble iron salt selected from ferric chloride, ferrous chloride or a mixture thereof.

Claim 9. The process of any one of claims 1 to 8, wherein the iron preparation of step (i) comprises a water-soluble iron salt and the step (ii) of the process comprises:

(ii-1) providing an aqueous solution comprising the iron preparation and a carbohydrate;

(ii-2) adding a base to the aqueous solution so as to form iron hydroxide, and

(ii-3) heating the aqueous solution so as to form the iron carbohydrate complex compound.

Claim 10. The process of claim 9, wherein the water-soluble iron salt is ferric chloride.

Claim 11. The process of any one of claims 1 to 4, wherein the iron preparation comprises an iron oxide-hydroxide in the form of β-FeO(OH).

Claim 12. An iron carbohydrate complex compound obtained by the process of any one of claims 1 to 11, wherein the iron carbohydrate complex compound is an iron hydrogenated oligoisomaltose.

Claim 13. An iron carbohydrate complex compound, wherein

- the amount of arsenic in the iron carbohydrate complex compound does not exceed 4.5 µg per g iron, and preferably does not exceed 1.5 µg per g of iron, and

- the amount of lead in the iron carbohydrate complex compound does not exceed 1.5 µg per g iron, and preferably does not exceed 0.5 µg per g of iron, and
- the iron carbohydrate complex compound is an iron hydrogenated oligoisomaltose.

Claim 14. The iron carbohydrate complex compound of claim 12 or claim 13, wherein

- the amount of cadmium in the iron carbohydrate complex compound does not exceed 0.6 µg per g of iron, and preferably does not exceed 0.4 µg per g of iron, and
- the amount of mercury in the iron carbohydrate complex compound does not exceed 0.9 µg per g of iron, and preferably does not exceed 0.3 µg per g of iron.

Claim 15. The iron carbohydrate complex compound of any one of claims 12 to 14, wherein

- the amount of chromium in the iron carbohydrate complex compound does not exceed 330 µg per g of iron, and preferably does not exceed 100 µg per g of iron.

Claim 16. An iron carbohydrate complex compound of any one of claims 12 to 15, wherein the amount of aluminum in the iron complex compound does not exceed 200 µg per g iron, and preferably does not exceed 25 µg per g of iron.

Claim 17. The iron carbohydrate complex compound of any one of claims 12 to 16, wherein the iron hydrogenated oligoisomaltose comprises a colloidal complex of iron oxide-hydroxide in the form of β-FeO(OH) and hydrogenated oligoisomaltose.

Claim 18. The process of any one of claims 1 to 11 or the iron carbohydrate complex compound of any one of claims 12 to 17, wherein:

- the amount of arsenic in the iron carbohydrate complex compound does not exceed 1.5 µg per g iron; and
- the amount of lead in the iron carbohydrate complex compound does not exceed 0.5 µg per g iron; and
- the amount of cadmium in the iron carbohydrate complex compound does not exceed 0.4 µg per g iron; and

- the amount of mercury in the iron carbohydrate complex compound does not exceed 0.3 µg per g iron; and
- the amount of chromium in the iron carbohydrate complex compound does not exceed 100 µg per g iron; and
- the amount of aluminum in the iron carbohydrate complex compound does not exceed 15 µg per g iron.

Claim 19. The process of any one of claims 1 to 11 or 18 or the iron carbohydrate complex compound of any one of claims 12 to 18, wherein the hydrogenated oligoisomaltose has a weight average molecular weight of from 700 Da to 1,400 Da, and in particular of about 1,000 Da, and/or wherein the number average molecular weight (Mn) of the hydrogenated oligoisomaltose is in the range of from 400 Da to 1,400 Da, and 90 wt.% of the hydrogenated oligoisomaltose molecules have molecular weights of less than 3,500 Da, in particular, less than 2,700 Da, and the molecular weights of the remaining 10% of the hydrogenated oligoisomaltose molecules are below 4,500 Da, in particular below 3,200 Da.

Claim 20. The process of any one of claims 1 to11 or 18 or 19 or the iron carbohydrate complex compound of any one of claims 12 to 19, wherein at least 60% of the hydrogenated oligoisomaltose molecules have 3-10 monosaccharide units, preferably wherein at least 60% of the hydrogenated oligoisomaltose molecules have 3-6 monosaccharide units and/or wherein the apparent molecular weight (Mp) of the iron carbohydrate complex compound is in the range of from 90,000 Da to 200,000 Da, such as in the range of from 120,000 Da to 180,000 Da, preferably in the range of from 130,000 to 160,000 Da.

Claim 21. The process of any one of claims 1 to11 or 18 to 20 or the iron carbohydrate complex compound of any one of claims 12 to 20, wherein the iron carbohydrate complex compound is an iron(III) hydrogenated oligoisomaltose comprising a colloidal complex of ferric oxide-hydroxide in the form of β-FeO(OH) and hydrogenated oligoisomaltose, wherein at least 60% of the hydrogenated oligoisomaltose molecules have 3-6 monosaccharide units, and the hydrogenated oligoisomaltose has a weight average molecular weight of about 1,000 Da.

Claim 22. The process of any one of claims 1 to 11 or 18 to 21 or the iron carbohydrate complex compound of any one of claims 12 to 21, wherein the iron hydrogenated oligoisomaltose has the formula:

$\{FeO_{(1-3X)}(OH)_{(1+3X)}(C_6H_5O_7^{3-})_X\}$, $(H_2O)_T$, $(C_6H_{10}O_6)_R(-C_6H_{10}O_5-)_Z(C_6H_{13}O_5)_R$, $(NaCl)_Y$, wherein X is about 0.031, T is about 0.25, R is about 0.14, Z is about 0.49, and Y is about 0.14.

Claim 23. The process of any one of claims 1 to 11 or 18 to 21 or the iron carbohydrate complex compound of any one of claims 12 to 21, wherein the iron hydrogenated oligoisomaltose is ferric derisomaltose.

Claim 24. The iron carbohydrate complex compound of any one of claims 12 to 23, for use in therapy.

Claim 25. Use of the iron carbohydrate complex compound of any one of claims 12 to 23 in the manufacture of a medicament for use in the treatment or prophylaxis of iron-deficiency in a non-human animal or in a human subject, preferably a human subject suffering from lost or impaired kidney function, for example a human in need of dialysis.