CLAIMS

1. A reconstituted high density lipoprotein (rHDL) formulation comprising an apolipoprotein or fragment thereof; a lipid; and a detergent at a level which is about 5-50% of that present in an rHDL formulation that displays liver toxicity upon administration to a human.

2. The rHDL formulation of Claim 1 wherein the level of detergent is about 5-10 % of that which displays liver toxicity.

3. The rHDL formulation Claim 1 or Claim 2 wherein the level of detergent is about 0.5 -1.5 g/L.

4. The rHDL formulation of any one of Claims 1-3, wherein the level of detergent is about 0.015-0.030 g/g apolipoprotein.

5. The rHDL formulation of any preceding claim, wherein the detergent is a bile salt or bile acid.

6. The rHDL formulation of Claim 6, wherein the detergent is sodium cholate.

7. The rHDL formulation of any preceding claim wherein the apolipoprotein is Apo-A1 or a fragment thereof.

8. The rHDL formulation of any preceding claim wherein the lipid is a phospholipid.

9. The rHDL formulation of Claim 8, wherein the phospholipid is phosphatidylcholine.

10. The rHDL formulation of any preceding claim wherein the lipid is at a level 20-70% of that which displays liver toxicity.

11. The rHDL formulation of any preceding claim, wherein the formulation further comprises a stabilizer.

12. A method of producing a rHDL formulation comprising an apolipoprotein; a lipid; and a detergent, said method including the step of providing said detergent at a level which is about 5-50% of that present in an rHDL formulation that displays liver toxicity upon administration to a human.

13. The method of Claim 12, wherein the level of detergent is about 5-10 % of that which displays liver toxicity.

14. The method of Claim 12 or Claim 13 wherein the level of detergent is about 0.5 -1.5 g/L.

15. The method of any one of Claims 12-14, wherein the level of detergent is about 0.015-0.030 g/g apolipoprotein.

16. The method of any preceding claim, wherein the detergent is a bile salt or bile acid.

17. The method of Claim 16, wherein the detergent is sodium cholate.

18. The method of any preceding claim wherein the apolipoprotein is Apo-A1 or a fragment thereof.

19. The method of any preceding claim wherein the lipid is a phospholipid.

20. The method of Claim 19, wherein the phospholipid is phosphatidylcholine.

21. The method of any preceding claim wherein the lipid is at a level 20-70% of that which displays liver toxicity.

22. The method of any preceding claim, including the steps of:

(A) adding phosphatidylcholine without organic solvent and a cholate detergent to an Apo-A1 solution;

(B) reducing the level of cholate detergent in the solution produced at step (I) to about 0.03g/g Apo-A1;

(C) adding a stabilizer to the solution at step (B).

23. A rHDL formulation obtainable according to the method of any one of Claims 12-22.

24. A method of treating a disease, disorder or condition in a human including the step of administering to the human a rHDL formulation according to any one of Claims 1-11 or Claim 23, to thereby treat said disease, disorder or condition in the human.

25. The method of Claim 24, wherein the disease, disorder or condition includes cardiovascular disease, hypercholesterolaemia or hypocholesterolaemia.

26. The method of Claim 25, wherein the disease, disorder or condition includes acute coronary syndrome (ACS), atherosclerosis and myocardial infarction.

27. A rHDL formulation according to any one of Claims 1-11 or Claim 23, for use in treating a disease, disorder or condition in a human.

28. A rHDL formulation for use according to Claim 27, wherein the disease, disorder or condition includes cardiovascular disease, hypercholesterolaemia or hypocholesterolaemia.

29. A rHDL formulation for use according to Claim 28, wherein the disease, disorder or condition includes acute coronary syndrome (ACS), atherosclerosis and myocardial infarction.

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CLAIMS

1. A reconstituted high density lipoprotein (rHDL) formulation comprising an apolipoprotein or fragment thereof; a lipid; and a detergent at a level which is about 5-50% of that present in an rHDL formulation that displays liver toxicity upon administration to a human.

2. The rHDL formulation of Claim 1 wherein the level of detergent is about 5-10 % of that which displays liver toxicity.

3. The rHDL formulation Claim 1 or Claim 2 wherein the level of detergent is about 0.5 -1.5 g/L.

4. The rHDL formulation of any one of Claims 1-3, wherein the level of detergent is about 0.015-0.030 g/g apolipoprotein.

5. The rHDL formulation of any preceding claim, wherein the detergent is a bile salt or bile acid.

6. The rHDL formulation of Claim 6, wherein the detergent is sodium cholate.

7. The rHDL formulation of any preceding claim wherein the apolipoprotein is Apo-A1 or a fragment thereof.

8. The rHDL formulation of any preceding claim wherein the lipid is a phospholipid.

9. The rHDL formulation of Claim 8, wherein the phospholipid is phosphatidylcholine.

10. The rHDL formulation of any preceding claim wherein the lipid is at a level 20-70% of that which displays liver toxicity.

11. The rHDL formulation of any preceding claim, wherein the formulation further comprises a stabilizer.

12. A method of producing a rHDL formulation comprising an apolipoprotein; a lipid; and a detergent, said method including the step of providing said detergent at a level which is about 5-50% of that present in an rHDL formulation that displays liver toxicity upon administration to a human.

13. The method of Claim 12, wherein the level of detergent is about 5-10 % of that which displays liver toxicity.

14. The method of Claim 12 or Claim 13 wherein the level of detergent is about 0.5 -1.5 g/L.

15. The method of any one of Claims 12-14, wherein the level of detergent is about 0.015-0.030 g/g apolipoprotein.

16. The method of any one of Claims 12-15, wherein the detergent is a bile salt or bile acid.

17. The method of Claim 16, wherein the detergent is sodium cholate.

18. The method of any one of Claims 12-17 wherein the apolipoprotein is Apo-A1 or a fragment thereof.

19. The method of any one of_Claims 12-18 wherein the lipid is a phospholipid.

20. The method of Claim 19, wherein the phospholipid is phosphatidylcholine.

21. The method of any one of Claims 12-20 wherein the lipid is at a level 20-70% of that which displays liver toxicity.

22. The method of any one of Claims 12-21, including the steps of:

(A) adding phosphatidylcholine without organic solvent and a cholate detergent to an Apo-A1 solution;

(B) reducing the level of cholate detergent in the solution produced at step (I) to about 0.03g/g Apo-A1;

(C) adding a stabilizer to the solution at step (B).

23. A rHDL formulation obtainable according to the method of any one of Claims 12-22.

24. A rHDL formulation according to any one of Claims 1-11 or Claim 23, for use in treating a disease, disorder or condition in a human.

25. A rHDL formulation for use according to Claim 24, wherein the disease, disorder or condition includes cardiovascular disease, hypercholesterolaemia or hypocholesterolaemia.

26. A rHDL formulation for use according to Claim 25, wherein the disease, disorder or condition includes acute coronary syndrome (ACS), atherosclerosis and myocardial infarction.

27. Use of an apolipoprotein or fragment thereof; a lipid; and a detergent at a level which is about 5-50% of that present in an rHDL formulation that displays liver toxicity upon administration to a human; in the manufacture of a reconstituted rHDL formulation for treating a disease, disorder or condition in a human.

28. The use of Claim 27, wherein the disorder or condition includes cardiovascular disease, hypercholesterolaemia or hypocholesterolaemia.

29. The use of Claim 28, wherein the disease, disorder or condition includes acute coronary syndrome (ACS), atherosclerosis and myocardial infarction.