CLAIMS

WHAT IS CLAIMED IS:

1. A recombinant lipase comprising a polypeptide sequence having at least 95%, sequence identity to SEQ ID NO: 868.

2. The recombinant lipase of Claim 1, wherein said polypeptide sequence comprises at least one substitution or substitution set at one or more positions selected from 24, 38, 49, 70, 149, 161, 174, 175, 189, 193, 225, 231, 243, 252, 271, 287, 292, 293, 296, 303, 334, 344, 373, and 385, wherein the amino acid positions of the polypeptide sequence are numbered with reference to SEQ ID NO: 868.

3. The recombinant lipase of any of Claims 1-2, wherein said recombinant lipase is more thermostable than the lipase of SEQ ID NO: 2.

4. The recombinant lipase of any of Claims 1-3, wherein said recombinant lipase is more stable at acidic pH levels, than the lipase of SEQ ID NO: 2.

5. The recombinant lipase of any of Claims 1-4, wherein said recombinant lipase is more resistant to proteolysis than the lipase of SEQ ID NO: 2.

6. The recombinant lipase of any of Claims 1-5, wherein said recombinant lipase is more active in the presence of at least one bile salt than the lipase of SEQ ID NO: 2.

7. The recombinant lipase of any of Claims 1-6, wherein said recombinant lipase is purified.

8. The recombinant lipase of any of Claims 1-7, wherein said recombinant lipase exhibits at least one improved property selected from: i) enhanced catalytic activity; ii) increased tolerance to acid pH; iii) increased tolerance to pH 3.5; iv) increased tolerance to pH 3; v) increased tolerance to at least one protease; vi) increased tolerance to at least one bile salt; vii) increased thermotolerance; or a combination of any of i), ii), iii), iv), v), vi), and vii) as compared to SEQ ID NO: 2.

9. A composition comprising at least one recombinant lipase of any of Claims 1-8.

10. A recombinant polynucleotide sequence encoding at least one recombinant lipase set forth in any of Claims 1-8.

11. The recombinant polynucleotide sequence of Claim 10, wherein said polynucleotide sequence is codon-optimized.

12. An expression vector comprising at least one recombinant polynucleotide sequence of Claim 10 and/or 11.

13. The expression vector of Claim 12, wherein said recombinant polynucleotide sequence is operably linked to a control sequence.

14. The expression vector of Claim 12 or 13, wherein said control sequence is a promoter.

15. The expression vector of Claim 14, wherein said promoter is a heterologous promoter.

16. A host cell comprising the expression vector of any of Claims 12-15.

17. The host cell of Claim 16, wherein said host cell is eukaryotic or prokaryotic.

18. A method of producing a recombinant lipase, comprising culturing said host cell of Claim 16 or 17, under conditions that said recombinant lipase encoded by said recombinant polynucleotide is produced.

19. The method of Claim 18, further comprising the step of recovering said lipase.

20. The method of Claim 19, further comprising the step of purifying said lipase.

21. A pharmaceutical composition for use in the treatment of pancreatic insufficiency, comprising the composition of Claim 9.

22. The pharmaceutical composition for use of Claim 21, further comprising a pharmaceutically acceptable carrier and/or excipient.

23. The pharmaceutical composition for use of Claim 21 and/or 22, further comprising at least one additional enzyme selected from at least one protease and at least one amylase.

24. The pharmaceutical composition for use of Claim 21 and/or 22, further comprising a pancreatic extract, containing lipase, protease, and amylase activity.

25. The pharmaceutical composition for use of any of Claims 21 to 24, wherein said composition is suitable for parenteral injection or infusion, subcutaneous injection, inhalation, or dermal application to a human.

26. The pharmaceutical composition for use of any of Claims 21 to 24, wherein said composition is suitable for oral administration to a human.

27. The pharmaceutical composition for use of Claim 26, wherein said composition further comprises an enteric coating.

28. Use of a composition of any one of claims 9 or 21 to 27, or a recombinant lipase according to any of Claims 1 to 8, in the manufacture of a medicament for the treatment and/or prevention of the symptoms of pancreatic insufficiency in a subject.

29. Use of the composition or the recombinant lipase according to Claim 28, wherein said symptoms of pancreatic insufficiency are ameliorated.

30. Use of the composition or the recombinant lipase according to Claim 28 and/or 29, wherein said subject is able to eat a diet that is less restricted in its lipid content than diets required by subjects exhibiting the symptoms of pancreatic insufficiency.

31. Use of the composition or the recombinant lipase according to any of Claims 28-30, wherein said subject is an infant or child.

32. Use of the composition or the recombinant lipase according to any of Claims 28-30, wherein said subject is an adult or young adult; wherein the term "young adult" refers to a person less than 18 years of age, but who has reached sexual maturity.

33. A recombinant lipase according to any of Claims 1-8, or a composition according Claim 9, for use as a medicament.

34. A recombinant lipase according to any of Claims 1-8, or a composition according Claim 9, for use as a nutritional supplement.