CLAIMS

1. A composition comprising a recombinant human acid sphingomyelinase, wherein the composition is a lyophilized composition comprising:

4-7% w/w olipudase alfa set forth in SEQ ID NO:2,

3-7% w/w sodium phosphate,

15-25% w/w L-methionine, and

65-75% w/w sucrose,

wherein the composition contains no detectable amount of mannitol or chelating agents.

2. The composition of claim 1, consisting essentially of:

5.5% w/w olipudase alfa,

2.3% w/w sodium phosphate dibasic heptahydrate,

2.6% w/w sodium phosphate monobasic monohydrate,

20.5% w/w L-methionine, and

68.6% w/w sucrose.

3. A composition comprising a recombinant human acid sphingomyelinase, wherein the composition is an aqueous liquid composition comprising:

1-10 mg/mL olipudase alfa,

10-50 mM sodium phosphate,

70-150 mM L-methionine, and

1-10% w/v sucrose,

wherein the composition has a pH of 5-8, and contains no detectable amount of mannitol or chelating agents.

4. The composition of claim 3, wherein the composition is an aqueous liquid composition comprising:

3-5 mg/mL olipudase alfa,

10-30 mM sodium phosphate,

80-120 mM L-methionine, and

4-6% w/v sucrose,

wherein the composition has a pH of 6-7.

5. The composition of claim 3, consisting essentially of:

4 mg/mL olipudase alfa,

20 mM sodium phosphate,

100 mM L-methionine, and

5% w/v sucrose,

wherein the composition has a pH of 6.5.

6. The composition of any one of claims 3-5, further comprising 0.005% w/v polysorbate 80.

7. A composition obtained by lyophilizing the aqueous liquid composition of any one of claims 3-6.

8. A process for manufacturing a lyophilized composition, comprising:
obtaining the aqueous liquid composition of any one of claims 3-6, and
lyophilizing the aqueous liquid composition.

9. A vial containing a lyophilized composition consisting essentially of:
21.2 mg olipudase alfa,
9.0 mg sodium phosphate dibasic heptahydrate,
10.0 mg sodium phosphate monobasic monohydrate,
79 mg L-methionine, and
265 mg sucrose.

10. An aqueous liquid composition obtained by reconstituting a lyophilized composition consisting essentially of:
21.2 mg olipudase alfa,
9.0 mg sodium phosphate dibasic heptahydrate,
10.0 mg sodium phosphate monobasic monohydrate,
79 mg L-methionine, and
265 mg sucrose,
in 5.1 mL of sterile water.

11. A vial containing a lyophilized composition consisting essentially of:

4.8 mg olipudase alfa,

2.0 mg sodium phosphate dibasic heptahydrate,

2.3 mg sodium phosphate monobasic monohydrate,

17.9 mg L-methionine, and

60 mg sucrose.

12. An aqueous liquid composition obtained by reconstituting a lyophilized composition consisting essentially of:

4.8 mg olipudase alfa,

2.0 mg sodium phosphate dibasic heptahydrate,

2.3 mg sodium phosphate monobasic monohydrate,

17.9 mg L-methionine, and

60 mg sucrose

in 1.1 mL of sterile water.

13. The composition of claim 1, 2 or 7, or the vial of claim 9 or 11, wherein the lyophilized composition comprises 0.1%, 0.2%, 0.3%, 0.4%, or 0.5% moisture.

14. An article of manufacture comprising the vial of claim 9 or 11 and a vial containing sterile water, 0.9% sodium chloride, or phosphate-buffered saline for reconstituting the lyophilized composition.

15. A composition of any one of claims 1-7, 10, 12 and 13 for use in treating ASMD in a human patient.

16. Use of a composition of any one of claims 1-7, 10, 12 and 13 for the manufacture of a medicament for treating ASMD in a human patient.

17. The composition for use of claim 15, or the use of claim 16, wherein the ASMD is Niemann-Pick Disease type A/B or type B.

18. The composition for use or use of any one of claims 15-17, wherein the treatment is for non-neurological manifestations of ASMD.