of steam to the headspace specifically allows for rapid heating of extremities such as inlet ports, sterile filters and tank tops and hence reduces the total heat load on the bulk material. Utilising headspace steam heating offers the following advantages:

Property	Advantage
Rapid, even heating through latent heat transfer	Improved heating of system extremities with ensuing lowering of the heat load inflicted on the bulk material, decreased degradation and improved product quality and productivity
Pressure control temperature	Target temperature can be quickly and precisely established
High heat transfer coefficient	Smaller required heat transfer surface area, enabling reduced initial equipment outlay.

Summary

The present disclosure provides a method of sterilisation of a phospholipid suspension, which comprises:

(i) mixing said phospholipid together with propyleneglycol in an aqueous biocompatible carrier in a jacketed vessel to give an aqueous phospholipid suspension; and

(ii) autoclaving the aqueous phospholipid suspension from step (i), wherein said autoclaving enables reaching F_0 values > 15 in all parts of the sterilization system, and wherein heating, in addition to sensible heat from heating the jacket of said vessel, comprises the addition of steam to:

(a) the headspace of the vessel of step (i); or

(b) the aqueous phospholipid suspension of step (i); or

(c) a combination of (a) and (b);

(iii) cooling the hot suspension from step (ii) to 15 to 30 °C to give the sterile phospholipid suspension;

wherein said phospholipid is hydrogenated egg phosphatidylserine (H-EPS).

In an aspect, there is provided a method of sterilisation of a phospholipid suspension, which comprises:

(iv) mixing said phospholipid together with propyleneglycol in an aqueous biocompatible carrier in a jacketed vessel to give an aqueous phospholipid suspension; and

(v) autoclaving the aqueous phospholipid suspension from step (i), wherein said autoclaving enables reaching F_0 values > 15 in all parts of the jacketed vessel, and wherein heating, in addition to sensible heat from heating the jacket of said vessel, comprises the addition of steam to:

(c) the headspace of the vessel of step (i); or

(d) the aqueous phospholipid suspension of step (i); or

(c) a combination of (a) and (b);

(vi) cooling the hot suspension from step (ii) to 15 to 30 °C to give the sterile phospholipid suspension;

wherein said phospholipid is hydrogenated egg phosphatidylserine (H-EPS).

CLAIMS.

1. A method of sterilisation of a phospholipid suspension, which comprises:
   (i) mixing said phospholipid together with propyleneglycol in an aqueous biocompatible carrier in a jacketed vessel to give an aqueous phospholipid suspension; and
   (ii) autoclaving the aqueous phospholipid suspension from step (i), wherein said autoclaving enables reaching F_0 values > 15 in all parts of the jacketed vessel, and wherein heating, in addition to sensible heat from heating the jacket of said vessel, comprises the addition of steam to:
      (a) the headspace of the vessel of step (i); or
      (b) the aqueous phospholipid suspension of step (i); or
      (c) a combination of (a) and (b);
   (iii) cooling the hot suspension from step (ii) to 15 to 30 °C to give the sterile phospholipid suspension;

   wherein said phospholipid is hydrogenated egg phosphatidylserine.

2. The method of claim 1, where the addition of steam is to the headspace of the vessel of step (i).

3. The method of claim 2, where the addition of steam to the headspace is performed multiple times during the autoclave cycle.

4. The method of any one of claims 1 to 3, which further comprises the application of vacuum to the headspace of the vessel of step (i), before the addition of steam to said headspace.

5. The method of any one of claims 1 to 4, where the F_0 values reacted are between 15 and 25.

6. The method of any one of claims 1 to 5, where the content of phosphatidylserine (PS), relative to the sum of PS and related substances, in the sterile phospholipid suspension of step (iii) is at least 68%.