[0004] Accordingly, there exists a need in the art for allergen compositions that can prevent and/or treat allergies, and methods for making allergen compositions to prevent and/or treat allergies.

SUMMARY

[0005] This disclosure is directed, at least in part, to a method of making a mixed allergen product substantially free of replication viable organisms. For example, in certain examples, the method comprises: providing bulk mixed allergen material comprising 2 to 20 individual complete food allergens; and sterilizing the bulk mixed allergen material by dry heat sterilization, thereby obtaining the mixed allergen product.

[0005a] In one aspect of the present disclosure, there is provided a method of making a mixed allergen product substantially free of replication viable organisms, comprising:

providing bulk mixed allergen material comprising 2 to 20 individual complete food allergens; and

sterilizing the bulk mixed allergen material by dry heat sterilization, thereby obtaining the mixed allergen product.

[0005b] In another aspect of the present disclosure, there is provided a method of making a mixed allergen product substantially free of replication viable organisms, comprising:

providing 2 to 20 individual complete food allergens;

sterilizing each of the 2 to 20 individual complete food allergens by dry heat sterilization, thereby obtaining 2 to 20 sterilized individual complete food allergens; and

blending the 2 to 20 sterilized individual complete food allergens together, thereby obtaining the mixed allergen product.

[0005c] In a further aspect of the present disclosure, there is provided a mixed allergen product substantially free of replication viable organisms prepared by the method disclosed herein.

[0006] In certain examples, a method further comprises providing 2 to 20 individual complete food allergens and blending the 2 to 20 individual complete food allergens together to obtain the bulk mixed allergen material.

[0007] In other examples, the disclosure provides a method, wherein the 2 to 20 individual complete food allergens are selected from the group consisting of almond, cashew, cod, egg, hazelnut, milk, oat, peanut, pecan, pistachio, salmon, sesame, shrimp, soy, walnut, and wheat.

[0008] In another example, the disclosure provides a method, wherein the blending further comprises blending the 2 to 20 individual complete food allergens with one or more than one bulking agent.

[0009] In certain examples of the present disclosure, blending comprises loading 2 to 20 individual complete food allergens into a ribbon blender set at about 10 Hz to about 50 Hz for about 10 minutes to about 50 minutes. In other examples, the bulk mixed allergen material is discharged into lined drums after blending.

[0010] In certain examples, a method of the present disclosure further comprises filtering the mixed allergen product. In some examples, filtering comprises passing the mixed allergen product through a screen ranging from a #5 mesh (US) screen to a #10 mesh (US) screen on a shaker for about 1 minute to about 10 minutes.

[0011] In some examples, a method of the present disclosure further comprises passing the mixed allergen product through a rare earth magnet, metal detector, and metal separator.

[0012] In certain examples, a described method of the present disclosure provides applying dry heat sterilization, wherein the dry heat sterilization is at a temperature of about 65 ºC to about 175 ºC for about 18 hours to about 72 hours. In some examples, the dry heat

sterilization comprises using a sterilization system having a furnace and a heating chamber, wherein the furnace provides about 250,000 BTUs to about 750,000 BTUs of heat to the heating chamber. In certain examples, the bulk mixed allergen material is first packaged into thermoresistant packaging before dry heat sterilization. In certain examples, temperature probes are placed with the bulk mixed allergen material during sterilizing to monitor the temperature of the dry heat sterilization.

[0013] In certain examples of the present disclosure, the mixed allergen product has at least about a 1 log reduction to at least about a 4 log reduction in aerobic bacterial organism plate counts as compared to corresponding bulk mixed allergen material that has not been sterilized. In some examples, the mixed allergen product has less than about 10,000 CFU/g of aerobic bacterial organisms. In other examples, the mixed allergen product has less than about 10 CFU/g of coliforms, *Escherichia coli*, *Enterobacteriaceae*, mold, *Staphylococcus aureus*, and yeast. In certain examples, the mixed allergen product has less than about 10 CFU/g of *Salmonella*. In certain examples, the mixed allergen product has less than about 10 CFU/g of *Cronobacter*. In further examples, the mixed allergen product is negative in PCR-based assays for *Listeria* species, *Cronobacter* species and *Salmonella* species per 25 g of mixed allergen product, 25 g of mixed allergen product, and 375 g of mixed allergen product, respectively.

[0014] In some examples of the present disclosure, the mixed allergen product has a fat content of about 10 % to about 20 % by weight.

[0015] In other examples, protein integrity of the mixed allergen product is substantially similar to protein integrity of corresponding bulk mixed allergen material that has not been sterilized. In some examples, the protein integrity of the mixed allergen product is determined by SDS-PAGE.

[0016] In certain examples, the mixed allergen product has a protein content of about 40 % to about 50 % by weight.

[0017] In certain examples, the mixed allergen product has about 1 % to about 10 % moisture by weight. In other examples, the mixed allergen product has a water activity of about 0.1 to about 0.6.

[0018] In certain examples of the present disclosure, the mixed allergen product comprises less than about 10 % by weight of particles having a diameter greater than 500 μm.

[0019] In some examples, the mixed allergen product is darker in color as compared to corresponding bulk mixed allergen material that has not been sterilized. In other examples, the mixed allergen product has a substantially similar taste profile as compared to corresponding bulk mixed allergen material that has not been sterilized.

[0020] In certain examples, a described method of the present disclosure comprises one or more than one further application of dry heat sterilization.

[0021] In an alternative example, the present disclosure describes a method of making a mixed allergen product substantially free of replication viable organisms, comprising: providing 2 to 20 individual complete food allergens; sterilizing each of the 2 to 20 individual complete food allergens by dry heat sterilization, thereby obtaining 2 to 20 sterilized individual complete food allergens; and blending the 2 to 20 sterilized individual complete food allergens together, thereby obtaining the mixed allergen product.

[0022] In another example, the present disclosure describes a method of making a mixed allergen product substantially free of replication viable organisms, wherein the method further comprises blending the mixed allergen product with one or more than one probiotic selected from the group consisting of *Lactobacillus rhamnosus, Anaerostipes caccae,* and *Bifidobactierium longum.*

[0023] In yet another example, the mixed allergen product is further blended with one or more than one prebiotic, for example, wherein the prebiotic is fructooligosaccharide.

[0024] Also disclosed is a mixed allergen product substantially free of replication viable organisms prepared by any one of the methods disclosed herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] FIG. 1 is a macroscopic image of non-sterilized bulk mixed allergen material sample and bulk mixed allergen material samples which have been heated in a laboratory oven for 5 minutes at 95 ºC, 105 ºC, 110 ºC, or 120 ºC.

[0026] FIG. 2A is a schematic showing the placement of pallets and sample boxes containing thermoresistant bags of bulk mixed allergen material in a dry heat sterilization chamber for validation trial 1. B3 of pallets 3, 4 and 12 have chamber probes placed inside the boxes for temperature monitoring. B4 of pallets 7 and 8 have chamber probes placed outside the boxes, and B4 of pallet 11 has a chamber probe placed inside the box. **FIG. 2B** is a schematic showing