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Edible pet chew and method of making the same

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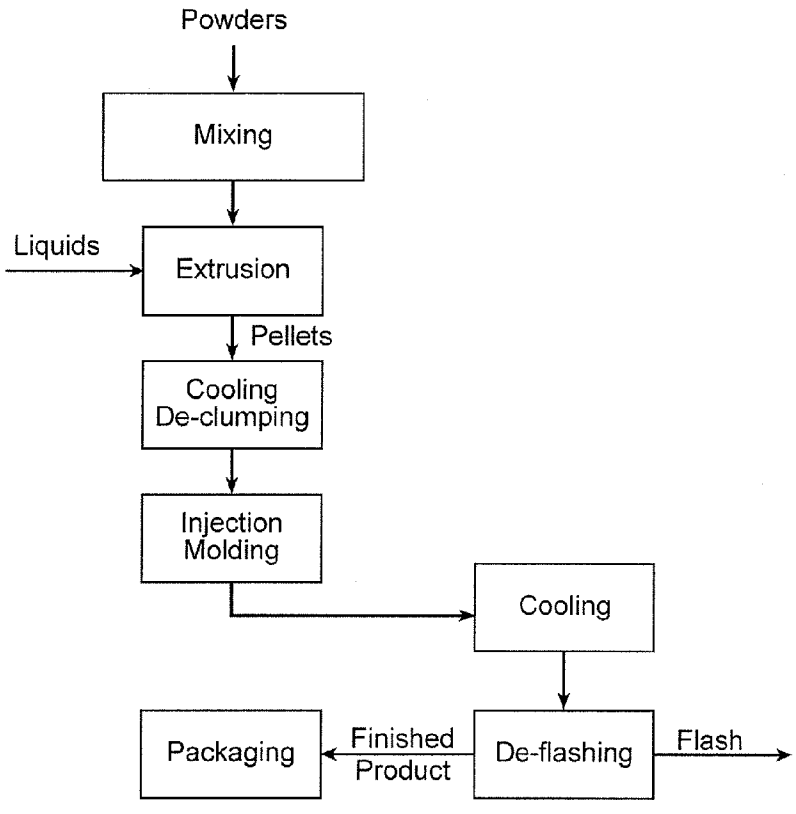

(57) Abstract: An edible pet chew is disclosed that is comprised of fibrous protein, water absorbing polymer, plasticizer and water. The pet chew provides excellent textural properties and improved solubility in the stomach and intestinal environment for improved pet safety.

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TITLE

EDIBLE PET CHEW AND METHOD OF MAKING THE SAME

This application claims the benefit of U.S. provisional patent application No. 60/815,682, filed June 21, 2006, the disclosure of which is incorporated by reference herein.

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates to edible pet chews, the compositions from which they are made and methods for making pet chew products. In particular, the pet chew of the present invention is formed from a thermoplastic material comprising fibrous protein, water absorbing polymer, plasticizer, and water.

Related Background Art

[0002] Current pet chew products can be loosely grouped into two categories. One type is relatively hard and friable, which crumbles or breaks down relatively quickly and is more easily digested, but has relatively short lasting times in consumption. The second group is comprised of highly dense or compacted products with more elastic or rubbery properties, that are more difficult to chew, harder to digest, and have more extended lasting times in consumption.

[0003] There has been a proliferation of pet dental chews in the market, specially designed to address oral care problems. The majority of these products are based on hard textures that require repeated chewing for efficacy. There is ample published literature to support the assertion that dogs chew of various textures can reduce build up of tartar (Gorrel and Rawlings, 1996; Rawlings et al., 1998; Gorrel and Bierer; 1999; Gorrel et al., 1999 and Lage at al., 1990).

[0004] While such products may offer teeth cleaning functions, in many cases they pose risks to dogs either from physical injury such as gum injury, teeth fracture, and blockage of the digestive system. This situation is further exacerbated by the wide difference in skull (Jaslow, 1987) and breed sizes with in the domestic dog (Canis familiaris). A chew that may seem perfectly safe for some breeds or skull types may raise safety concerns when offered to different breeds or skull types. There is also the risk of nutrient inadequacy as most of these products are not nutritionally "complete and balanced".

[0005] Other dental chews are made with non-food materials such as thermoplastic polymers that offer no nutritional benefits to dogs. The associate safety risks include blockage of the digestive system since they are not digestible, and in extreme situations may require surgical intervention to correct.

[0006] There remains a need for a product that is completely edible, long lasting and safe, that is designed to effectively clean teeth without risk of health damage such as choking, tooth damage, intestinal obstruction or other injury.

SUMMARY OF THE INVENTION

[0007] This invention is directed to an edible pet chew comprising:

a) fibrous protein in an amount of about 30 to about 50% by weight of the chew, wherein said fibrous protein includes a quantity of wheat protein isolate;

b) water absorbing polymer in an amount of about 15 to about 35% by weight of the chew, wherein the water absorbing polymer is gelatin;

c) plasticizer in an amount of about 5 to about 40% by weight of the chew; and

d) water in an amount of about 1 to about 20% by weight of the chew.

[0007a] The pet chew product is a thermoplasticized molded product that has the texture necessary to function as an oral care device, but reduces the potential that large pieces of the chew will be broken off during chewing and is a highly soluble chew composition in the stomach and intestinal environment of the pet. In preferred embodiments, the water absorbing polymer of the pet chew is gelatin. Most preferably the pet chew is a dog chew that provides oral care benefits.

[0008] The invention is also directed to the composition used to make the pet chew and the method to prepare the thermoplasticized molded pet chew product.

[0008a] Accordingly disclosed herein is an edible pet chew composition for preparing a thermoplasticized molded pet chew, said composition comprising:

a) fibrous protein in an amount of about 30 to about 50% by weight of the composition, wherein said fibrous protein includes an amount of wheat protein isolate;

b) water absorbing polymer in an amount of about 15 to about 35% by weight of the chew, wherein the water absorbing polymer is gelatin;

c) plasticizer in an amount of about 5 to about 40% by weight of the composition; and

d) water in an amount of about 1 to about 20% by weight of the composition.

[0008b] Also disclosed is a method of preparing an edible pet chew, the method comprising the steps of:

a) forming a pet chew composition by admixing (i) fibrous protein in an amount of about 30 to about 50% by weight of the composition, wherein said fibrous protein includes a quantity of wheat protein isolate, (ii) water absorbing polymer in an amount of about 15 to about 35% by weight of the chew, wherein the water absorbing polymer is gelatin, iii) plasticizer in an amount of about 5 to about 40% by weight of the composition, and (iv) water in an amount of about 1 to about 20% by weight of the composition;

b) thermoplasticizing the pet chew composition; and

c) molding the thermoplastic pet chew composition to form the pet chew.

[0008c] Further disclosed is an edible pet chew comprising:

a) fibrous protein in an amount of about 30 to about 50% by weight of the chew, wherein said fibrous protein comprises soy protein isolate, wheat protein isolate, and sodium caseinate;

b) water absorbing polymer in an amount of about 5 to about 35% by weight of the chew, wherein the water absorbing polymer is gelatin;

c) plasticizer in an amount of about 5 to about 40% by weight of the chew; and

d) water in an amount of about 1 to about 20% by weight of the chew.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Figure 1 is a diagram of an exemplary method of producing the pet chew product according to the invention.

[0010] Figure 2 is another diagram of an exemplary method of producing the pet chew product according to the invention.

[0011] Figure 3 is yet another diagram of an exemplary method of producing the pet chew product according to the invention.

[0012] Figure 4 is a schematic drawing of the injection molding process that may be used to make the pet chew product according to the invention.

[0013] Figure 5 is an illustration of a particularly preferred pet chew of this invention.

DETAILED DESCRIPTION OF THE INVENTION

[0014] The present invention is directed to an edible pet chew and methods for manufacturing a nutritious product that is designed to remove plaque and tartar through mechanical abrasion while providing safe occupation and enjoyment. The pet chew of the invention provides rapid breakdown of the product once ingested by the animal and demonstrates significant reduction in plaque and tartar as compared to a standard test diet. The composition of the pet chew creates a nutritious and functional treat, which will promote a healthy life style for the animal. A particularly preferred pet chew is designed for dogs, and most preferably a class of dogs, such as described in U.S. provisional patent No. 60/815,686, filed June 21, 2006, the entire disclosure of which is incorporated by reference herein.

[0015] The edible pet chew composition of the invention is formed from a thermoplastic material comprising a fibrous protein, a water absorbing polymer, a plasticizer, and water. The pet chew of the invention is preferably a mono-component/mono-texture product, although it is also possible that it may form

part of a dual component product. As used herein, mono-component/mono-texture product means that the chew product is a substantially homogeneous molded mass that be formed into any shape desired for the a pet chew.

[0016] The pet chew exhibits ductile properties so that when chewed, the animal's teeth sink into the product causing the product to break down in a controlled manner under repetitive stress. The edible thermoplastic material can be molded into a variety of shapes to provide good strength and stiffness and other desired physical properties to enhance functionality and chewing enjoyment.

[0017] Unlike similar products in the marketplace, the present pet chew product is designed to be 100% nutritionally complete and balanced for animal nutrition. The softer, chewier texture of the present pet chew improves animal enjoyment and demonstrates enhanced oral care efficacy. The pet chew composition of the invention provides a balanced blend of highly digestible proteins in a matrix of water-soluble materials to improve nutritional performance and animal safety.

[0018] The fibrous protein for the pet chew may be derived from animals, but does not include muscle protein, or plants. One skilled in the art would recognize that insubstantial amounts of muscle protein could be present. Fibrous proteins are generally strong and relatively insoluble. Due to such properties, fibrous proteins are important in providing the structural backbone of the pet chew product. Exemplary fibrous proteins include, but are not limited to, wheat protein, wheat gluten, corn zein, corn gluten, soy protein, peanut protein, casein, keratin and mixtures thereof. Particularly preferred fibrous proteins include, without limitation, wheat protein isolate, soy protein isolate, sodium caseinate and mixtures thereof. A highly preferred fibrous protein is a mixture of wheat protein isolate, soy protein isolate and sodium caseinate.

[0019] The water absorbing polymer in the pet chew may be a gelling protein, a hydrocolloid, an edible hydrogel, or mixtures thereof. Gelling protein, sometimes known as globular protein, generally comprises globelike proteins that are relatively soluble in aqueous solutions where they form colloidal solutions or gels. Exemplary gelling proteins include, but are not limited to gelatin, albumin,

plasma, pea protein, lactoglobulins, surimi (fish) proteins, whey protein and mixtures thereof. A highly preferred gelling protein is gelatin.

[0020] A hydrocolloid may be used in the pet chew composition as the water absorbing polymer. A hydrocolloid is generally defined as a macromolecule (*e.g.*, a carbohydrate polymer or a protein) that is water soluble and forms a gel when combined with water. Exemplary hydrocolloids include, but are not limited to pectins, alginates, agars, carrageenan, xanthan gum, and guar gum.

[0021] An edible hydrogel may be used in the pet chew as the water absorbing polymer. The edible hydrogel may be a naturally occurring or synthetic material which swells in water or some liquid, retaining a large amount of the liquid without dissolving. Exemplary hydrogels include, but are not limited to maltodextrins, cetyl alcohol, chitosan, lecithins, polypeptides, waxes, and edible polymers.

[0022] In a preferred embodiment, the water absorbing polymer is a gelling protein. In a more preferred embodiment, the gelling protein is gelatin, having preferably a bloom strength in a range of about 100 to about 400. Most preferably, the gelatin will have a bloom strength in a range of about 100 to about 200.

[0023] Plasticizers dissolve in the polymer, separating polymer chains and thus facilitating molecular movement. Plasticizers are commonly used to increase workability, flexibility and extensibility of polymers (Ferry, 1980). Plasticizers also reduce water activity of food systems by binding water that is otherwise available for biological reactions such as microbial growth. Exemplary plasticizers generally used in food applications include, but not limited to water, polyalcohols (*e.g.* sorbitol, mannitol, maltitol, glycerol and polyethylene glycol), gum arabic, hydrogenated starch hydrolysate and protein hydrolysate. In a preferred embodiment, the plasticizer is glycerol. In yet another preferred embodiment, the plasticizer is hydrogenated starch hydrolysate.

[0024] Yet another embodiment of the invention is directed to a pet chew composition that is a mixture comprising fibrous protein in an amount of about 15 to about 90%, preferably about 20 to about 80%, more preferably about 30 to about 50% by weight of the composition, water absorbing polymer in an amount

of about 5 to about 35%, preferably about 10 to about 30%, more preferably about 15 to about 25% by weight of the composition, plasticizer in an amount of about 5 to about 40%, preferably about 10 to about 35%, more preferably about 15 to about 30% by weight of the composition, and water in an amount of about 1 to about 20%, preferably about 2 to about 18%, more preferably about 5 to about 15% by weight of the composition. In a preferred embodiment the pet chew composition will contain starch in an amount less than about 5%, preferably less than about 4% and more preferably less than about 3% by weight of the composition. This composition is thermoplasticized, preferably by extrusion, and molded to form the pet chew product. The pet chew product is preferably formed by injection molding. One skilled in the art will readily recognize that the pet chew of this invention could also be prepared by compression molding, extrusion without molding or tabletting techniques.

[0025] The properties of the proteinaceous materials used in the pet chew are subject to chemical and physical interactions (e.g., protein/protein and with other materials including water absorbing polymers) to improve their solubility and textural properties to enhance oral care benefits and animal safety. Animal safety is achieved through product design to minimize risk in all areas. Control of texture minimizes risks of dental fractures; controlled product size reduction through chewing reduces risk of choking; and superior solubility/digestibility eliminates risk of intestinal blockage.

[0026] The pet chew composition may also contain at least one fat, flavor enhancers, preservatives, nutrients, and/or colorants. As used herein fat includes edible oils and preferably will be liquid fat at room temperature. Exemplary fats include corn oil, soybean oil, peanut oil, cottonseed oil, grapeseed oil, sunflower oil, flaxseed oil (and other sources of omega-3 and omega-6 fatty acids), vegetable oil, palm kernel oil, olive oil, tallow, lard, shortening, butter and combinations thereof. In a preferred embodiment, the fat is vegetable oil. If the fat is present, it will generally be in a range of about 1 to about 20%, preferably about 1.5 to about 10% and more preferably about 2 to about 5% by weight of the pet chew composition. Flavors are well known. For example, the use of flavor oils such as rosemary oil, eucalyptus oil and clove oil may be employed.

Nutrients include, but not limited to vitamins, minerals, and functional ingredients. Other ingredients may also be included in the composition, for example, release agents, stabilizers, and emulsifiers.

[0027] In a preferred embodiment, the thermoplastic composition may also contain active ingredients for removal of plaque and tartar, and materials for breath freshening and general oral health.

[0028] The pet chew of the present invention demonstrates high flexibility and elastic properties to improve chewing enjoyment and lasting time. The product is designed to break down in a controlled fashion under repetitive chewing. The texture of the pet chew ensures proper balance between animal safety, oral care efficacy, enjoyment and lasting time. Further, the breakdown or fracture of the pet chew of the invention under mechanical stress is controlled to avoid release of large pieces that can be swallowed intact and increase risk of choking and digestive obstruction.

Example 1

[0029] A preferred pet chew composition of the invention:

Ingredients	**Liquid/Powder**	**Weight percent**
Fibrous protein	Powder	30-50 %
Gelling protein (Gelatin 100-200 bloom)	Powder	15-25 %
Glycerine	Liquid	15-25 %
Water	Liquid	5-15 %
Hydrogenated Starch Hydrolysate	Liquid	0-15%
Flavor enhancer	Powder	1-10 %
Fat	Liquid	1-10%
Nutrients	Powder	3-7 %
Preservative	Powder	0.05-0.55%
Colorant	Powder	0.005-0.045%

[0030] The water activity of the final products ranges from 0.2-0.85. In addition, individual ingredient levels and ratios of liquid to powder may be modified to obtain various final product textures. Further, replacing ingredients with alternatives may also result in different final product textures. For example, the use of 200-bloom gelatin instead of 100-bloom gelatin would result in a firmer product.

Example 2

[0031] A particularly preferred pet chew composition:

Ingredients	**Weight percent**
Wheat Protein Isolate	17 %
Soy Protein Isolate	14 %
Sodium Caseinate	8 %
Glycerin	17 %
Hydrogenated Starch Hydrolysate	9 %
Gelatin (100 Bloom)	17 %
Water	7 %
Vegetable Oil	3 %
Flavor/Nutrients/Preservatives/Colorant	8%

Example 3

Yet another preferred pet chew composition:

Ingredients	**Weight percent**
Wheat Protein Isolate	18%
Soy Protein Isolate	15%
Sodium Caseinate	8.5%
Glycerin	17.5%
Hydrogenated Starch Hydrolysate	2.8%
Gelatin (100 Bloom)	18.5%
Water	9.2%
Corn Oil	1.5%
Flavor/Nutrients/Preservatives/Colorant	9%

Example 4

Another preferred pet chew composition:

Ingredients	**Weight Percent**
Wheat Protein Isolate	18.8%
Soy Protein Isolate	15.6%
Sodium Caseinate	8.9%
Glycerin	15.8%
Hydrogenated Starch Hydrolysate	2.5%
Gelatin (100 Bloom)	19.3%
Water	8.3%
Corn Oil	1.4%
Flavor/Nutrients/Preservatives/Colorant	9.4%

[0032] Product performance of the pet chew is measured against a number of criteria including plaque and tartar reduction, breath freshening, lasting time, palatability as measured by paired preference, solubility, textural attributes

including hardness, density, elasticity, friability, water absorption capacity, and speed of solubilization.

[0033] Texture measurements were performed with a TA.HDi Texture Analyzer (Texture Technologies Corp., Scarsdale, New York) equipped with a 250-500 kg load cells. A 5mm diameter cylindrical probe was used for uniaxial compression or puncture tests, and the tests were conducted at a room temperature of 25°C. Data was collected using the Texture Expert software (version 2.12) from Texture Technologies Corp. Two different uniaxial compression or puncture tests were run. These tests were selected because they best resemble the biting and chewing of the test samples by dogs.

[0034] The compression analysis parameters are as follows. Work (W) is defined as an estimate of work; and therefore shows the toughness of the product. A tough product will have a higher work value than a less tough product. The area shows the "force" or load that must be applied to the product to cause it to break. The area under the curve represents toughness. The expressed "Area" units come from the multiplication of y-axis per x-axis as N*mm. To convert "Area" to Work –W- (F/d) multiply by 0.1020408 $m^2/mm/s^2$.

[0035] The Max Force (N) is defined as the maximum amount of force needed to overcome the product's hardness. Usually a hard product will be associated with high ordinate (y –axis) values. The expressed "Force" unit derives from a direct association with mass weight in kg. To convert "Force" to "Max Force" –N- multiply by 9.81 m/s^2 (the acceleration of gravity).

[0036] Travel (mm) is represented as the point (distance) at which the peak force is reached. Thus it emulates the resistance of the product as a combination between toughness and hardness, in addition to elasticity, attributed to a measurement of how far the probe has traveled to reach the maximum force. Larger travel numbers are indicative of more elastic products. Resistance to breaking is directly proportional to travel values.

[0037] Linear Distance (mm) is calculated by measuring the length of an imaginary line pulled taunt joining all the trajectory points. This measure describes crumbly verses cohesive product attributes. It is a direct assessment of

brittleness where a brittle product will produce more sharp peaks, resulting in a higher linear distance.

[0038] The values of hardness, toughness, elasticity, toughness were determined using whole product samples. A base platform, as observed with the TA.HDi, provided by Texture Technologies, was used to measure force/distance. An exemplary product sample that was made and tested is shown in Figure 5.

[0039] The sample was centered on the platform such that the knife will contact one location along the sample bone length at a time. Chosen locations included the brush head, the joint of the shaft to the brush head and the knuckle at the end of the shaft of the pet chew. Each location is contacted with the knife at a 90° angle while the sample is laying on its side placed on a flat platform surface. This is repeated at the three chosen locations along the length of the bone. The brush head, the joint of the shaft to the brush head and the knuckle at the end of the shaft of a pet chew are clearly visible in Figure 5. A minimum of 5 bones is generally measured per evaluated variable, with each of the following conditions.

Two sets of tests were conducted with the following parameters:

[0040] A. The circular probe or knife is run at a (1) pre test speed of 5 mm/s (speed of probe before contacting sampling); (2) a test speed of 2 mm/s (speed of probe while travelling within the sample); (3) a post test speed of 5 mm/s (speed that the probe is withdrawn from the sample); and a distance of 50% compression (distance that probe travels within the sample until it is withdrawn).

[0041] B. The circular probe or knife is run at a (1) pre test speed of 5 mm/s (speed of probe before contacting sampling); (2) a test speed of 10 mm/s (speed of probe while travelling within the sample); (3) a post test speed of 5 mm/s (speed that the probe is withdrawn from the sample); and a distance of 50% compression (distance that probe travels within the sample until it is withdrawn).

[0042] The force in kg (y axis) is plotted against distance in mm (x axis) in which the starting force of 0 may be set as point 1 on the graph and the Max Force may be set as point 2 on the graph. The following parameters were measured: the Max Force 2, which is the maximum force value of the curve, is a measurement of hardness; the Linear Distance (mm), is calculated by measuring the length of an imaginary line pulled taunt joining all the trajectory points. It is

a direct assessment of brittleness where a brittle product will produce more sharp peaks, resulting in a higher linear distance. For each of these parameters, the measurement was the average of the values of at least 5 samples of the product tested.

[0043] Hardness is measured as Max Force in N. As measured in the uniaxial compression or puncture test, the hardness or max force value of the inventive product, in certain embodiments, for the inventive pet chew is about 100 to about 700 Newtons, preferably about 150 to about 600 Newtons, more preferably about 200 to about 500 Newtons and most preferably about 250 to about 400 Newtons when the pet chew is designed for a dog that weighs less than 11.4 kg (25lbs) or about 200 to about 800 Newtons for a pet chew designed for a dog that weighs 11.4 kg (25lbs) or more measured as described above using a probe speed of 2.0 mm/sec. In a preferred embodiment, the pet chew designed for a dog that weighs 11.4kg or more has a hardness measurement of about 250 to about 650 Newtons, preferably about 275 to about 600 Newtons, and more preferably about 350 to about 550 Newtons measured using a probe speed of 2.0 mm/sec.

[0044] The toughness measured as Newtons x mm (Nmm) of the inventive product has a range of about 500 to about 12,000 Nmm, a preferred range of about 700 to about 10,000 Nmm, and a more preferred range of about 800 to about 5000 Nmm.

[0045] In yet another embodiment of this invention, it may be desirable to formulate the hardness of the pet chew based on both dog skull type and weight. In this embodiment, the hardness range for each category of dog type is set forth in the table below.

	Dog Size		
Skull type	**Small < 10 kg**	**Medium 10-20 kg**	**Large > 20 kg**
dolichocephalic			
hardness range (N)	33-1270	300-2125	445-2295
preferred range	50-1220	350-2040	540-2210
most preferred range	65-1125	410-1875	665-2030
mesaticephalic			
hardness range (N)	140-1850	215-2700	485-3630
preferred range	170-1785	235-2600	560-2500
most preferred range	210-1050	260-2380	700-3200
brachycephalic			
hardness range (N)	125-1535	150-3100	710-4780
preferred range	145-1480	145-3010	875-4590
most preferred range	180-1375	140-2760	1100-4200

[0046] The brittleness or linear distance of the inventive product was measured. The brittleness value of the inventive product has a range of about 100 to about 1500 mm, a preferred range of about 150 to about 1300 mm, and a most preferred range of about 200 to about 1000 mm.

Solubility

[0047] The in vitro measurement of solubility/digestibility of a pet chew may be used to indicate the amount of the pet chew that would solubilize or be digested in the gastrointestinal tract of a pet, and particularly a dog. The test performed is based on a portion or whole piece of a pet chew product. A particular size portion or piece, e.g., a 32-gram pet chew portion, may be used so that different formulations can be accurately compared. The outcome is expressed as percent (%) *in vitro* disappearance (IVD). The solubility measurement is performed by subjecting a specific amount of product to a number of solutions which represent the stomach and intestinal environments of a pet. Generally, the stomach

environment is relatively acidic and the intestinal environment is relatively more alkaline compared to the stomach. After subjecting the product to these environments, any product left is filtered and dried. This leftover product is weighed and compared with the weight of the initial product. Percent IVD is the percentage of the weight of the dissolved product in comparison to the weight of the initial product. The solubility test is further described below.

Solutions Utilized:

[0048] Phosphate Buffer, 0.1M, pH 6.0 Solution: 2.1 grams of sodium phosphate dibasic, anhydrous, and 11.76 grams of sodium phosphate monobasic, monohydrate were dissolved in a 1 liter volumetric flask and brought up to volume with distilled/deionized (dd) water.

[0049] HCl Solution: 17.0 ml concentrated HCl was added to a 1 liter volumetric flask containing 500 ml dd water and brought up to volume with dd water. When 100 ml of HCl:pepsin is added to 250 ml of phosphate buffer, the pH should be close to 2.0. One way to achieve this is to use 850 ml of 0.1 N HCl + 150 ml of 1 N HCl to make 1000 ml of HCl stock solution. When 100 ml of HCl:pepsin is added to 250 ml phosphate buffer, the pH of the solution is about 1.9-2.0.

[0050] HCl:Pepsin Solution: The appropriate amount of pepsin (Sigma P-7000, pepsin amount is dependent on sample size being tested. 0.01 gram pepsin per 1 gram sample must be obtained in the final mixture at Step 6 of the procedure. For example 0.3 gram pepsin would be used for 30 grams sample) was placed in a 1 liter volumetric flask and brought up to volume with the HCl solution made above.

[0051] Chloramphenicol Solution: 0.5 gram chloramphenicol (Sigma C-0378) was brought up to volume in a 100 ml volumetric flask with 95% ethanol.

[0052] Sodium Hydroxide Solution, 0.5N: 20 grams NaOH was brought up to volume in a 1 liter volumetric flask with dd water.

[0053] Phosphate Buffer, 0.2M, pH 6.8 Solution: 16.5 grams of sodium phosphate dibasic, anhydrous, and 11.56 grams of sodium phosphate monobasic, monohydrate were dissolved in a 1 liter volumetric flask and brought to volume with distilled water.

[0054] Pancreatin:Phosphate Buffer Solution: The appropriate amount of porcine pancreatin (Sigma P-1750, enzyme amount is dependent on sample size being tested. 0.05 gram porcine pancreatin per 1 gram sample must be obtained in the final mixture of Step 8. For example, 1.5 grams of pancreatin would be used for 30 grams samples) was dissolved in a 500 ml volumetric flask and brought up to volume with 0.2M, pH 6.8 phosphate buffer solution made above.

[0055] Procedure Example:

1. Place numbered pieces of dacron fabric in a 57°C oven overnight and weigh the next day.
2. Weigh samples into Erlenmeyer flasks. (Weigh additional sample to dry as a control along with residue to account for moisture loss during %IVD calculation). Add 250 ml 0.1M pH6.8 Phosphate Buffer Solution to each flask.
3. Add 100 ml HCl:Pepsin Solution to each flask. Check that the pH of the mixture is about 2. Adjust with HCl if needed.
4. Add 5 ml Chloramphenicol Solution to each flask.
5. Stopper the flasks. Mix gently. Incubate at 39°C for 6 hours. Mix on a regular basis using a shaking water bath, set at a speed that causes the samples to constantly move in the flask while keeping the products submerged in the solution.
6. After incubation, add enough 0.5N Sodium Hydroxide Solution to each flask to reach a final pH of 6.8 for the mixture.
7. Add 100 ml Pancreatin: Phosphate Buffer Solution to each flask. Mix gently.
8. Stopper the flasks. Incubate at 39°C for 18 hours. Mix on a regular basis using a shaking water bath, set at a speed that causes the samples to constantly move in the flask while keeping the products submerged in the solution.
9. Filter the sample through tared pieces of dacron fabric from Step 1. Rinse with three times with dd water. Maintain at 57°C until constant weight is reached.
10. Record pH at the following stages:

a. At step 4.
b. After 6 hours of digestion.
c. After addition of NaOH solution at step 7.
d. After addition of pancreatin:phosphate buffer solution.
e. After 24 hours.

[0056] Calculations:

[0057] Residue Weight = (Filter + Sample weight after incubation) - Dry filter weight

[0058] % IVD = 1 - (Sample residue weight) - (Blank residue weight) x 100
Dry matter weight

[0059] In certain embodiments, the pet chew composition possesses a solubility of at least 60% IVD, preferably at least 70 % IVD and more preferably at 75% IVD based on a maximum 32-gram piece (if the pet chew is less than 32 grams then typically a single chew product of a given gram weight will be used. It is not recommended to use a piece larger than 32 gram for a realistic reading. Of course one of ordinary skill will recognize that the mass of the pieces analyzed need to be substantially equivalent to make a comparison of the solubility numbers). While the solubility of the pet chew of this invention may be close to 100%, it generally will be in the range of about 60 to about 95% IVD. The solubility of a pet chew made from the formulation of Example 2 by extrusion and injection molding as described herein was about 85% IVD.

Extrusion

[0060] In a preferred embodiment, extrusion may be used to manufacture the products according to the present invention, preferably twin-screw extrusion for production of pellets. The pellets are subsequently melted and formed into particular shapes by post-extrusion forming, preferably by injection molding. Subsequent to injection molding, individual pieces of the products are trimmed for flash removal followed by cooling prior to packaging.

[0061] Figure 1 shows a diagram of an exemplary method of producing the pet chew product according to the invention. As shown in Figure 1, the manufacturing process from mixing of ingredients to finished product packaging occurs on a continuous basis. Powder ingredients are mixed in the mixer for

about 5-30 minutes. Uniform mixture of powder ingredients is subsequently fed into an extruder, preferably a twin-screw extruder. Downstream from the powder inlet, liquid ingredients are added to transform the mixture of powder and liquid ingredients into a uniformly plasticized, moldable mass in the presence of heat and shear. During this process, the moldable mass is also cooked by the increased temperature in the extruder barrels. The temperature profile of the extruder barrels are determined by, among others, the composition, pressure, residence time in the extruder barrels, screw profile, screw speed and shear rate.

[0062] The temperature and shear in the extruder zones will be set to provide sufficient thermoplastification. This may be achieved with temperatures in a range of about 88°C to about 141°C in the middle zones and lower temperatures at either end of the barrel. Of course, greater temperatures may be employed in the middle zones.

[0063] Thus the temperature can be controlled across the barrel to enable optional venting of energy and moisture along the extruder. Forced venting may also be achieved by using vent/vacuum stuffers at the end of process section where most cooking is achieved on the moldable mass inside the extruder barrel.

[0064] At the extruder exit, extrudate is forced through a die with small orifices. Immediately behind the die, the extrudate is exposed to increasing pressure and temperature due to the restriction imposed by the small die openings thus use of extra cooling becomes increasingly important to ensure pellet quality.

[0065] Subsequent to exiting the extruder die, the plasticized extrudate is cut at the die surface by a surface cutter equipped with at least one blade in to small pellets. Rotational speed of the cutter may be adjusted depending on the size requirements of the pellets in addition to flow properties of the extrudate. Product temperature at the die exit may range from about 82°C to about 95°C, and is most preferably about 85°C.

[0066] After cutting, pellets are placed on moving conveyors to carry the pellets away from the extruder exit. This process also facilitates cooling of the pellets to prevent caking which reduces the need for a subsequent de-clumping step in the process sequence. Conveyors may be kept at ambient temperatures, however, in

order to reduce cooling time, forced air circulation with chiller air may be applied to induce rapid cooling.

[0067] Depending on the formulation, speed and extent of cooling, pellets may stick together forming clumps of variable sizes. These clumps must be reduced in size, achieved by de-clumping, to ensure a steady and stable injection molding process.

[0068] Subsequent to cooling and de-clumping, pellets are conveyed to injection molding, where the final product shape is achieved.

[0069] An alternative manufacturing process can be seen in Figure 2. Figure 2 shows a diagram of another exemplary method of producing the pet chew product according to the invention, in which pellets are manufactured well prior to being used in injection molding.

[0070] While the mixing, extrusion, cooling and de-clumping steps may be similar to that described above (see Figure 1), in the alternative manufacturing process illustrated in Figure 2, pellets are packed into suitable containers upon cooling or de-clumping. For packaging, totes, sacks, super-sacks, barrels, cartons, etc. may be used for storage and transfer. The selection of packaging depends on, among others, packing characteristics of pellets, environmental and safety regulations, handling/transportation requirements, usage frequencies and sizes.

[0071] Pellet containers must be appropriate for target use and inert enough to protect their contents from external elements such as insects, birds, dust, temperature and humidity fluctuations, sun exposure, aroma and flavor transfer/leach from the containers.

[0072] Prior to injection molding, an additional de-clumping process may be required to break up clumps into individual pellets again if packing or clumping of pellets is observed in the containers during storage or transport. Upon de-clumping, pellets are molded into final product shape by injection molding as described below.

[0073] Figure 3 shows yet another diagram of an exemplary method of producing the pet chew product according to the invention. The process, shown in Figure 3, combines powder and liquid ingredients together in a high shear

mixer to form a uniform mass. According to the process shown in Figure 3, pellet production step is also eliminated by feeding the uniform mass directly into the injection molder's barrel.

[0074] Subsequent to injection molding, the product is cooled and subjected to a de-flashing process where excess material on the product is removed. De-flashing may be achieved by vibration of product inside vibrating hoppers, vibrating tables and/or tumblers.

Injection Molding

[0075] Figure 4 shows a schematic drawing of the injection molding process that may be used to prepare the pet chew product according to the invention. Material for the injection molding process may be delivered in containers 1 in the form of pellets. Occasionally, due to transport, load pressure and the nature of the recipe, the pellets have a tendency to pack together and form large adhesive blocks. Thus, if necessary, each container is transferred to a de-clumper 2 to break up and separate the individual pellets to allow feeding into the injection molders 4. The individual pellets are collected in a container 3 and then vacuum fed to a feeder 5 leading to the injection molders for forming.

[0076] As the pellets are conveyed across the injection molder screw 6, the high temperatures, shear and pressure generated by the screw transforms the solid pellets into a melted product that can be injected into the mold 7 and take form. The melted product travels through the sprue and/or manifolds, runners and/or nozzles and then the cavities to form the final product shape. Once the shot is complete, the injection screw will retract and refill with melted product for the next shot.

[0077] As the injection molder is being filled, the formed products in the cavities are either cooled or heated as required to cool and/or set the products. Once the desired cooling or set time is achieved, the mold opens and the products are released from the cavities through ejector pins on the backside of the product. The molded products fall on to a mechanical conveyor, which are subsequently collected for cooling. If runners are present, they are removed and the molded products are laid out on a cooling table to allow the temperature of the bones to

reach ambient temperature prior to packaging. An exemplary molded pet chew is shown in Figure 5.

[0078] Exemplary injection molding process parameters for the formation of the molded products are shown in Table 2.

Parameters	**Units**	**Range**
Feed Rate	Kilogram/hour (kg/hr)	20-250
Barrel Temperatures	Degrees Fahrenheit (F)	60-350 (16-178°C)
Injection Speeds	Inches/second (in/s)	1-10 (2.54-25.4 cm/s)
Injection Pressures	Pound per square inch (psi)	5000-25000 (34.5 – 172.4 Mpa)
Injection Times	Second (s)	3-40
Stroke	Inches/second (in/s)	0.5-8.0 (1.27 – 20.32 cm/s)
Screw Speed	Revolutions per minute	50-300
Mould Temperatures	Degrees Fahrenheit (F)	140-350 (60-178°C)
Cooling/Set Times	Second (s)	10-175

Table 2. Exemplary injection molding process parameters.

[0079] Once enough molded products are collected, they are transferred to the de-flasher to remove excess flash. At the exit of the de-flasher, the product is screened where the de-flashed products are sent for packaging and flash is collected for regrind. Flash that is removed throughout the system and products that do not meet product specifications are also collected and used for regrind.

[0080] It is also possible to simply admix the ingredients for the formulation and go directly to the injection molder so long as the parameters are controlled to achieve thermoplasticization of the formulation.

[0081] Comprises/comprising and grammatical variations thereof when used in this specification are to be taken to specify the presence of stated features, integers, steps or components or groups thereof, but do not preclude the presence or addition of one or more other features, integers, steps, components or groups thereof.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An edible pet chew comprising:

a) fibrous protein in an amount of about 30 to about 50% by weight of the chew, wherein said fibrous protein includes a quantity of wheat protein isolate;

b) water absorbing polymer in an amount of about 15 to about 35% by weight of the chew, wherein the water absorbing polymer is gelatin;

c) plasticizer in an amount of about 5 to about 40% by weight of the chew; and

d) water in an amount of about 1 to about 20% by weight of the chew.

2. The edible pet chew of claim 1, wherein the hardness of the pet chew is in a range of:

- about 100 to about 700 Newtons when the chew is for a dog that weighs less than 11.4 kg; and
- about 200 to about 800 Newtons when the chew is for a dog that weighs 11.4 kg or more.

3. The edible pet chew of claim 1, wherein the solubility of the pet chew is at least about 85% in vitro disappearance (IVD).

4. The edible pet chew of claim 1, further comprising at least one component selected from the group consisting of fat, a flavor enhancer, a preservative, a humectant, a nutrient, and a colorant.

5. The edible pet chew of claim 4, wherein the fat is vegetable oil.

6. The edible pet chew of claim 1, wherein the pet chew is comprised of a homogeneous mass.

7. An edible pet chew composition for preparing a thermoplasticized molded pet chew, said composition comprising:

a) fibrous protein in an amount of about 30 to about 50% by weight of the composition, wherein said fibrous protein includes an amount of wheat protein isolate;

b) water absorbing polymer in an amount of about 15 to about 35% by weight of the chew, wherein the water absorbing polymer is gelatin;

c) plasticizer in an amount of about 5 to about 40% by weight of the composition; and

d) water in an amount of about 1 to about 20% by weight of the composition.

8. The pet edible pet chew composition of claim 7, wherein the composition further comprises at least one component selected from the group consisting of fat, a flavor enhancer, a humectant, a preservative, a nutrient, and a colourant.

9. A method of preparing an edible pet chew, the method comprising the steps of:

a) forming a pet chew composition by admixing (i) fibrous protein in an amount of about 30 to about 50% by weight of the composition, wherein said fibrous protein includes a quantity of wheat protein isolate, (ii) water absorbing polymer in an amount of about 15 to about 35% by weight of the chew, wherein the water absorbing polymer is gelatin, iii) plasticizer in an amount of about 5 to about 40% by weight of the composition, and (iv) water in an amount of about 1 to about 20% by weight of the composition;

b) thermoplasticizing the pet chew composition; and

c) molding the thermoplastic pet chew composition to form the pet chew.

10. The method of claim 9, wherein the step of thermoplasticizing is by extrusion.

11. The method of claim 9, wherein the step of molding is injection molding.

12. The method of claim 10, wherein the pet chew composition is passed through an extruder barrel that reaches a temperature in a range of about 88 to about 150°C.

13. The edible pet chew of claim 1, wherein the pet chew is for a dog having a dolichocephalic skull type and the hardness of the chew is in a range of:

- about 33 to 1270 Newtons for a dog that weighs less than 10 kg,
- about 300 to about 2125 Newtons for a dog that weighs 10 to 20 kg; and
- about 445 to about 2295 Newtons for a dog that weighs greater than 20 kg.

14. The edible pet chew of claim 1, wherein the pet chew is for a dog having a mesaticephalic skull type and the hardness of the chew is in a range of:

- about 140 to about 1850 Newtons for a dog that weighs less than 10 kg;
- about 215 to about 2700 for a dog that weighs between 10 to 20 kg; and
- about 485 to about 3630 Newtons for a dog that weighs greater than 20kg.

15. The edible pet chew of claim 1, wherein the pet chew is for a dog having a brachycephalic skull type and the hardness of the chew is in a range of:

- about 125 to about 1535 Newtons for a dog that weighs less than 10 kg;
- about 150 to 3100 Newtons for a dog that weighs 10 to 20 kg; and
- about 710 to 4780 Newtons for a dog that weighs greater than 20 kg.

16. An edible pet chew comprising:

a) fibrous protein in an amount of about 30 to about 50% by weight of the chew, wherein said fibrous protein comprises soy protein isolate, wheat protein isolate, and sodium caseinate;

b) water absorbing polymer in an amount of about 5 to about 35% by weight of the chew, wherein the water absorbing polymer is gelatin;

c) plasticizer in an amount of about 5 to about 40% by weight of the chew; and

d) water in an amount of about 1 to about 20% by weight of the chew.

17. The edible pet chew of claim 7, wherein said gelatin has a bloom strength of about 100-200 bloom.

18. The edible pet chew of claim 7, wherein said gelatin has a bloom strength of about 100-200 bloom.

19. The method of claim 9, wherein said gelatin has a bloom strength of about 100-200 bloom.

20. The edible pet chew of claim 16, wherein said gelatin has a bloom strength of about 100-200 bloom.

MARS, INCORPORATED

WATERMARK PATENT AND TRADE MARKS ATTORNEYS

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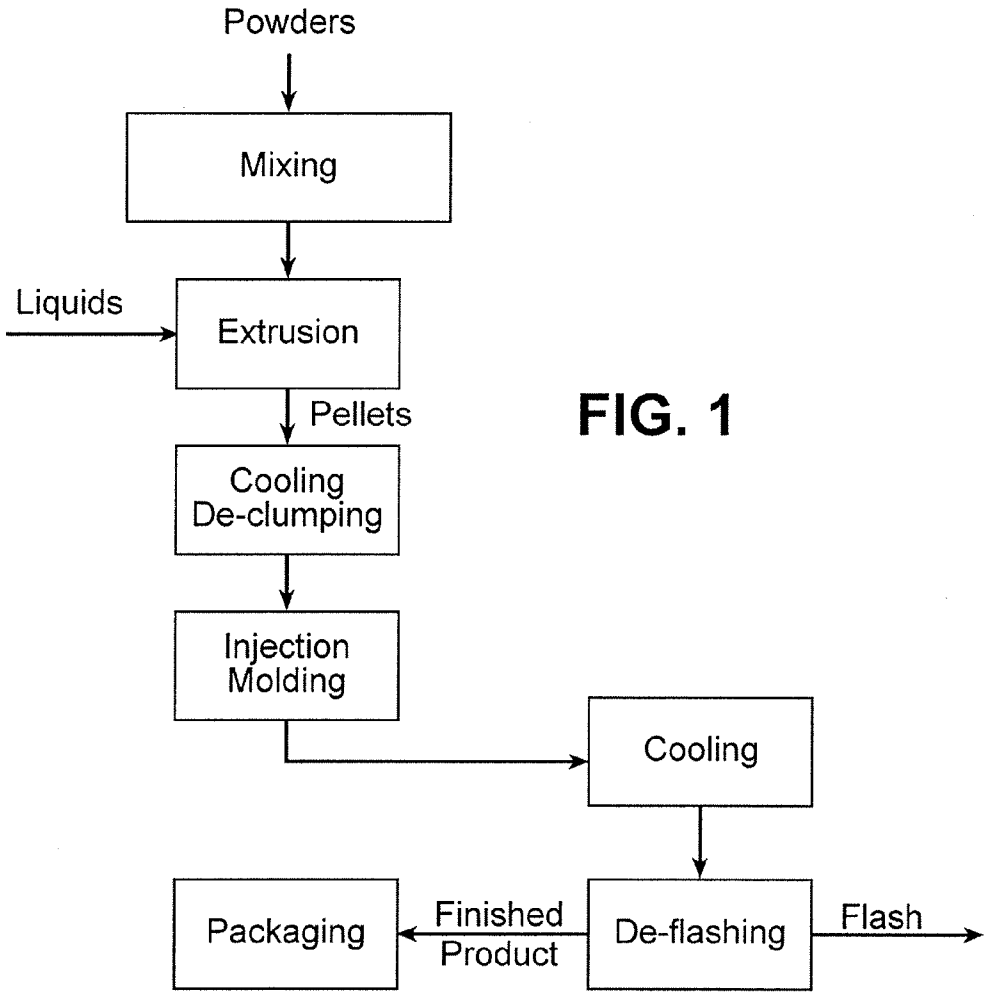
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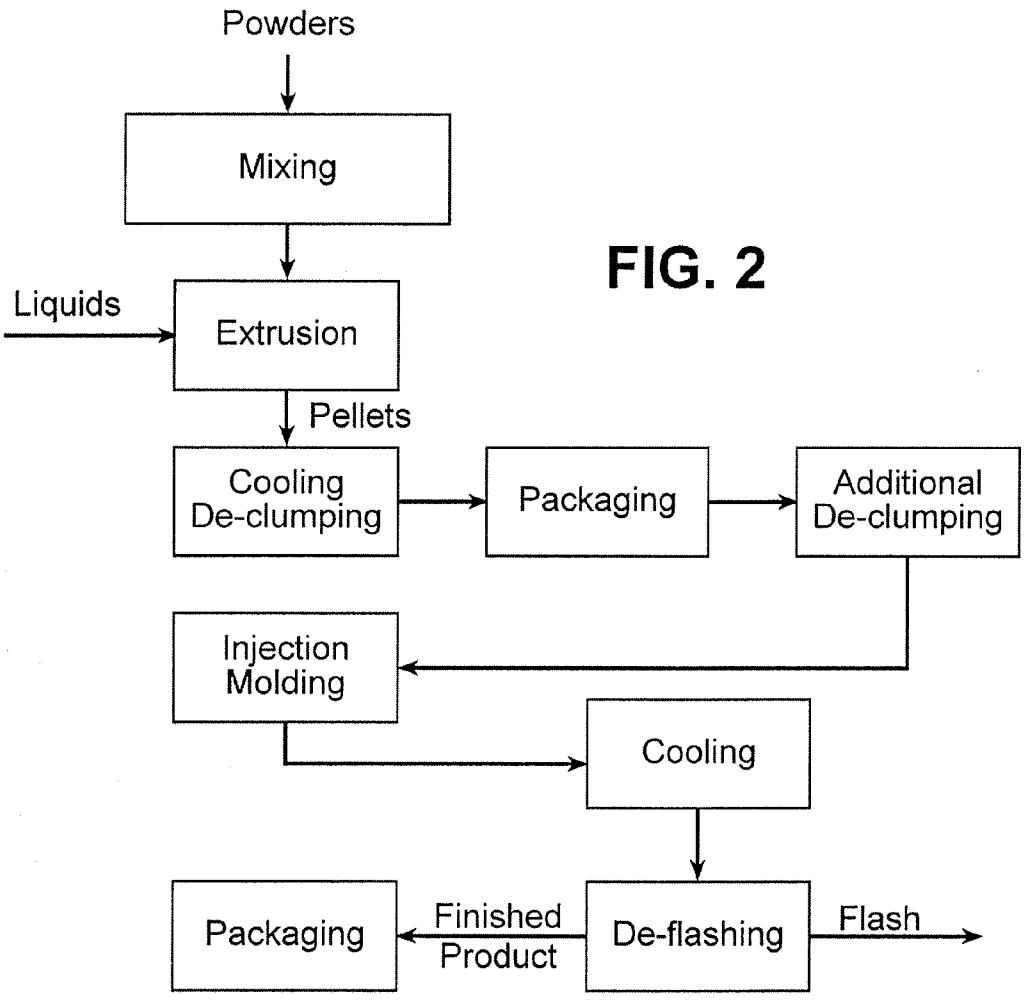
Liquids
Extrusion
Pellets
Cooling
De-clumping
Injection
Molding
Cooling
Packaging
Finished
Product
De-flashing
Flash

FIG. 1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Extrusion
Pellets
Cooling
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Injection
Molding
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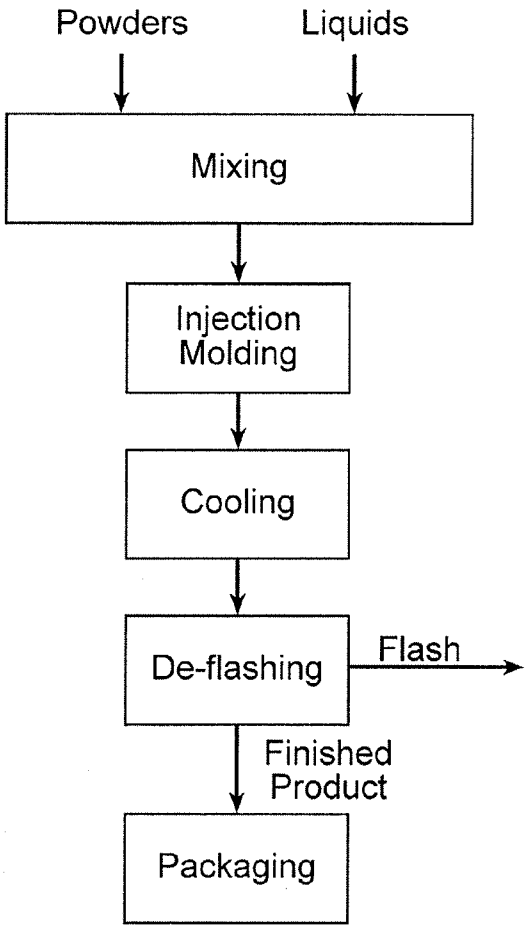
Finished
Product
De-flashing
Flash

FIG. 2

FIG. 3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Liquids
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Injection Molding
Cooling
De-flashing
Flash
Finished Product
Packaging

FIG. 4

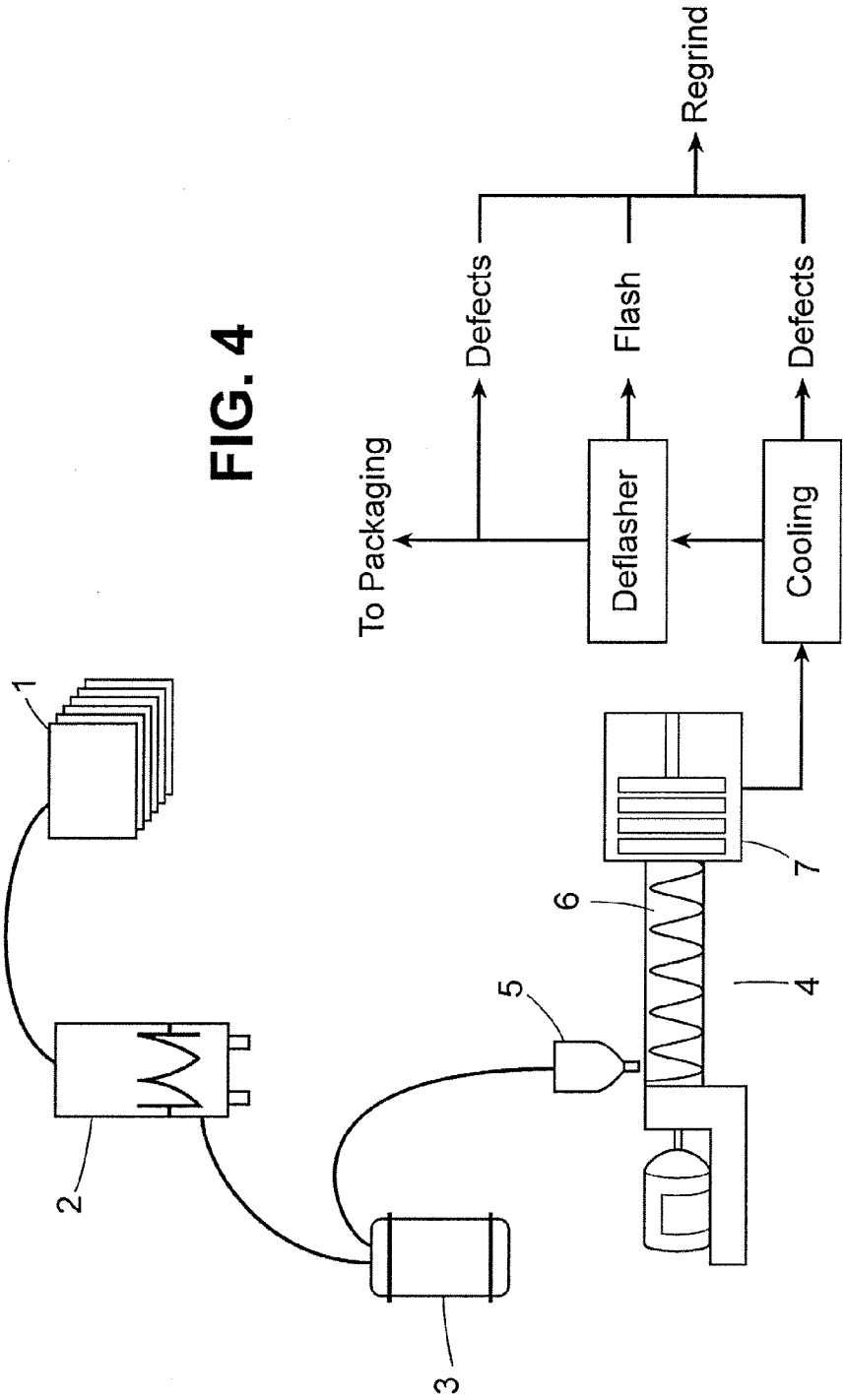
Regrind
Defects
Flash
Defects
To Packaging
Deflasher
Cooling
1
2
3
4
5
6
7

FIG. 5