

**AMMONIUM FERRIC CITRATE-ORGANIC ACID
COMPLEX, AND PREPARATION METHOD THEREFOR
AND USE THEREOF**

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Technical Field

[0001] The present invention relates to an ammonium ferric citrate-organic acid complex or a salt thereof and a preparation method therefor, further relates to a composition comprising the ammonium ferric citrate-organic acid complex or the salt thereof and the use of the complex as an animal feed additive and a food additive, and further relates to the use of the ammonium ferric citrate-organic acid complex or the salt thereof in the preparation of a drug for preventing and treating diarrhea in a farmed animal.

15 **Background Art**

[0002] Ammonium ferric citrate, also known as ferric ammonium citrate and 2-hydroxy-1,2,3-propanetricarboxylic acid ferric ammonium salt, is a double salt of ferric citrate and ammonium citrate, is an organic non-hemoglobin iron complex or iron salt composed of naturally occurring substances (iron with citric acid and ammonia), and plays an important role in the fields of food and animal farming.

[0003] In foods or drugs, ammonium ferric citrate is used as an iron source in the treatment of elemental iron deficiency, is used as a food additive in the fortification of bread nutrition or is used as a dietary iron supplement, and is used as an anti-caking agent in the production of products containing a compounded sweetener and in the production of table salt.

[0004] In the field of animal farming, ammonium ferric citrate is used to alleviate the generation of H₂S in rumen, is used as a nutritional ingredient in a health care product to promote the growth of dogs and cats, supplement various trace elements and vitamins required for their growth, beautify their hair, enhance the immune function of the body, balance nutrition, regulate estrus, increase the number of fetuses, promote the health of reproductive system, etc., and is further used as a complex mineral in a poultry feed additive to supplement the needs of poultry for mineral elements and promote the growth and development of poultry.

[0005] However, as described in CN 113234107 A, the ammonium ferric citrate is easily deliquescent, easily deteriorates in the presence of light, and needs to be protected from light and stored at a low temperature, and the direct use of the ammonium ferric citrate in products such as foods, feeds or drugs may result in problems such as unstable quality, easy moisture absorption, or easy deterioration of the products, thereby failing to satisfy the practical use in the field of animal farming.

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Summary of the Invention

- 5 [0006] In order to solve the technical problems that ammonium ferric citrate is easily deliquescent, easily deteriorates in the presence of light, and needs to be protected from light and stored at a low temperature, etc., the present invention provides an ammonium ferric citrate-organic acid complex or a salt thereof which is not easy to absorb moisture and deteriorate, and has improved stability.
- [0007] The present invention further provides a method for preparing an ammonium ferric citrate-organic acid complex or a salt thereof.
- 10 [0008] The present invention further provides a composition acceptable in feeds, food composition and pharmaceutical composition comprising an ammonium ferric citrate-organic acid complex or a salt thereof.
- [0009] The present invention further provides the use of an ammonium ferric citrate-organic acid complex or a salt thereof as an animal feed additive or a food additive or in the preparation of an animal feed additive or a food additive.
- 15 [0010] The present invention further provides the use of an ammonium ferric citrate-organic acid complex or a salt thereof in the preparation of a drug for preventing and treating diarrhea in an animal.
- [0011] In order to achieve the above objects of the present invention, the following technical solutions are particularly used:
- 20 [0012] the present invention provides an ammonium ferric citrate-organic acid complex comprising ammonium ferric citrate and an organic acid and a salt thereof.
- [0013] In some technical solutions, the ammonium ferric citrate-organic acid complex or the salt thereof further comprises at least one solvent capable of solvating ammonium ferric citrate and the organic acid.
- 25 [0014] In another aspect, the present invention further provides a method for preparing the above-mentioned ammonium ferric citrate-organic acid complex or the salt thereof, comprising the following steps:
- [0015] (1) dissolving an organic acid or a salt thereof in a solvent to obtain a solution of the organic acid or the salt thereof;
- 30 [0016] (2) dissolving ammonium ferric citrate in a solvent to obtain a solution of ammonium ferric citrate;
- [0017] (3) adding the solution of ammonium ferric citrate to the solution of the organic acid or the salt thereof to obtain a reaction solution, and stirring the reaction solution for 1-4 h at a reaction or heating temperature of 25°C-60°C;
- 35 [0018] (4) stirring the reaction solution obtained in step (3) at room temperature for 4-15 h; and
- [0019] (5) filtering the reaction solution obtained in step (4), and concentrating and drying the resulting filtrate to obtain the ammonium ferric citrate-organic acid complex comprising ammonium ferric citrate and the organic acid or the salt thereof.
- 40 [0020] The present invention further provides a composition, comprising the above-mentioned ammonium ferric citrate-organic acid complex or the salt thereof; and

preferably, the composition is used as a drug, a feed, or a food.

5 [0021] The present invention further provides a composition acceptable in feeds, comprising the above-mentioned ammonium ferric citrate-organic acid complex or the salt thereof, and one or more of a carrier, an excipient, a diluent, or a vehicle acceptable in feeds.

[0022] The present invention further provides a food composition, comprising the above-mentioned ammonium ferric citrate-organic acid complex or the salt thereof, and a nutriologically acceptable adjuvant.

10 [0023] The present invention further provides a pharmaceutical composition, comprising the above-mentioned ammonium ferric citrate-organic acid complex or the salt thereof, and a pharmaceutically acceptable adjuvant.

[0024] The present invention further provides the use of the above-mentioned ammonium ferric citrate-organic acid complex or the salt thereof as an animal feed additive or in the preparation of an animal feed additive.

15 [0025] The present invention further provides the use of the above-mentioned ammonium ferric citrate-organic acid complex or the salt thereof as a food additive or in the preparation of a food additive.

20 [0026] The present invention further provides the use of the above-mentioned ammonium ferric citrate-organic acid complex in the preparation of a drug for preventing and treating diarrhea in an animal.

[0027] The present invention further provides the use of the above-mentioned ammonium ferric citrate-organic acid complex as a drug for preventing and treating diarrhea in an animal.

25 [0028] The present invention further provides a method for preventing and treating diarrhea in an animal, comprising applying to the animal the above-mentioned ammonium ferric citrate-organic acid complex.

30 [0029] Compared with ammonium ferric citrate, the ammonium ferric citrate-organic acid complex or the salt thereof provided in the present invention has beneficial technical effects of stable appearance, significantly improved or enhanced moisture absorption, and significantly enhanced stability under illumination. Animal farming experiments further show that the ammonium ferric citrate-organic acid complex or the salt thereof has farming effects comparable to or even more excellent than ammonium ferric citrate, and can be used as an upgrade product to replace ammonium ferric citrate.

35 [0030] Any embodiment according to any aspect of the present invention can be combined with other embodiments, unless they are contradictory to each other. In addition, in any embodiment according to any aspect of the present invention, any technical feature can be applied to the technical feature in other embodiments, unless they are contradictory to each other.

40 **Brief Description of the Drawings**

[0031] FIG. 1 is an FTIR spectrogram of ammonium ferric citrate-organic acid complex A.

[0032] FIG. 2 is a diagram of comparison among the FTIR spectra of ammonium ferric citrate-organic acid complex B, ammonium ferric citrate raw material, and fumaric acid raw material.

5 [0033] FIG. 3 is an FTIR spectrogram of ammonium ferric citrate-organic acid complex C.

[0034] FIG. 4 is an XRD pattern of ammonium ferric citrate-organic acid complex A.

[0035] FIG. 5 is an XRD pattern of ammonium ferric citrate-organic acid complex B.

10 [0036] FIG. 6 is an XRD pattern of ammonium ferric citrate raw material.

[0037] FIG. 7 is an XRD pattern of fumaric acid raw material.

[0038] FIG. 8 is an XRD pattern of ammonium ferric citrate-organic acid complex C.

15 [0039] FIG. 9 is an FTIR spectrogram of a mixture of ammonium ferric citrate raw material and fumaric acid raw material at a molar ratio of 2 : 1.

[0040] FIG. 10 is an XRD pattern of a mixture of ammonium ferric citrate raw material and fumaric acid raw material at a molar ratio of 2 : 1.

[0041] FIG. 11 is a DSC curve diagram of ammonium ferric citrate raw material.

20 [0042] FIG. 12 is a DSC curve diagram of ammonium ferric citrate-organic acid complex B.

[0043] FIG. 13 is a DSC curve diagram of fumaric acid raw material.

[0044] FIG. 14 is a DSC curve diagram of a mixture of ammonium ferric citrate raw material and fumaric acid raw material at a molar ratio of 2 : 1.

25 [0045] The foregoing content is merely a summary of certain aspects of the present invention, but is not limited to these aspects. The content involved above and in other aspects will be described more specifically and completely below.

Detailed Description of the Invention

30 [0046] The following detailed description is intended to enable those skilled in the art to implement different embodiments. Specific devices, techniques or applications are described by way of example only. The present invention intends to cover all alternative, modified and equivalent technical solutions, which are all included within the scope of the present invention as defined by the claims. Additionally, for clarity, some technical features of the present invention are described in multiple independent embodiments, respectively, but they may also be provided in combination or in the form of any suitable sub-combination in a single embodiment.

Ammonium ferric citrate-organic acid complex involved in the present invention

[0047] The present invention provides an ammonium ferric citrate-organic acid

complex and a salt thereof,

5 [0048] wherein the organic acid is an organic acid or acidic amino acid acceptable in pharmacy, foods and feeds, the organic acid is selected from fumaric acid, maleic acid, succinic acid, malonic acid, oxalic acid, benzoic acid or sorbic acid, and the acidic amino acid is selected from glutamic acid or aspartic acid; and preferably, the organic acid is fumaric acid or maleic acid.

10 [0049] In some particular embodiments, at least one solvent capable of solvating ammonium ferric citrate and the organic acid are further comprised; and preferably, the solvent is selected from water, methanol, ethanol, an aqueous methanol solution, or an aqueous ethanol solution.

[0050] In some particular embodiments, the salt of the ammonium ferric citrate-organic acid complex is selected from a sodium salt, a potassium salt or an ammonium salt; and preferably, the salt of the ammonium ferric citrate-organic acid complex is a sodium salt of the ammonium ferric citrate-organic acid complex.

15 [0051] In some particular embodiments, the ammonium ferric citrate-organic acid complex or the salt thereof is used as a drug, a feed, or a food; and preferably, the ammonium ferric citrate-organic acid complex or the salt thereof is used as a drug for preventing and treating diarrhea in an animal.

20 [0052] The term “acidic amino acid” refers to an amino acid that comprises 1 amino group and 2 carboxyl groups and has an isoelectric point between about 2.8 and 3.2.

[0053] The term “acceptable in pharmacy, foods and feeds” means that a substance or composition must be suitable in terms of chemistry or toxicology, and related to the drugs, foods and feeds.

25 [0054] In the present invention, the term “comprise” is an open-ended expression that encompasses both the content explicitly indicated in the present invention and the content from other aspects.

[0055] Provided is a method for preparing the ammonium ferric citrate-organic acid complex, comprising the following steps:

30 [0056] (1) dissolving an organic acid in a solvent to obtain a solution of the organic acid;

[0057] (2) dissolving ammonium ferric citrate in a solvent to obtain a solution of ammonium ferric citrate;

35 [0058] (3) adding the solution of ammonium ferric citrate to the solution of the organic acid to obtain a reaction solution, and stirring the reaction solution at 25°C-60°C for 1-4 h;

[0059] (4) stirring the reaction solution obtained in step (3) at room temperature for 4-15 h; and

40 [0060] (5) filtering the reaction solution obtained in step (4), and concentrating and drying the resulting filtrate to obtain the ammonium ferric citrate-organic acid complex comprising ammonium ferric citrate and the organic acid,

[0061] wherein the organic acid is an organic acid or acidic amino acid acceptable in pharmacy, foods and feeds, the organic acid is selected from fumaric acid, maleic acid,

5 succinic acid, malonic acid, oxalic acid, benzoic acid or sorbic acid, and the acidic amino acid is selected from glutamic acid or aspartic acid; and the solvents in step (1) and step (2) are solvents capable of solvating ammonium ferric citrate and the organic acid, and are selected from water, methanol, ethanol, an aqueous methanol solution, or an aqueous ethanol solution.

[0062] In some particular embodiments, the molar ratio of the ammonium ferric citrate to the organic acid in the preparation method is 1 : 1-3 : 1; preferably, the molar ratio of the ammonium ferric citrate to the organic acid is 2 : 1; more preferably, the organic acid is fumaric acid or maleic acid.

10 [0063] In some particular embodiments, in order to obtain an ammonium ferric citrate-organic acid complex or a salt thereof having a higher chemical purity and a lower impurity content, the preparation for the ammonium ferric citrate-organic acid complex or the salt thereof provided in the present invention further comprises: concentrating and drying the filtrate obtained in step (5) in the above-mentioned preparation method to
15 obtain an ammonium ferric citrate-organic acid complex comprising ammonium ferric citrate and the organic acid, and subjecting the complex to slurring treatment in methanol, ethanol, an aqueous methanol solution or an aqueous ethanol solution to further remove impurities.

20 [0064] In some embodiments, in order to improve the solubility or effective utilization in an organism, the ammonium ferric citrate-organic acid complex can be prepared into a salt by a chemical synthesis method. Provided is a method for preparing a salt of the ammonium ferric citrate-organic acid complex, comprising the following steps:

25 [0065] (1) dissolving an organic acid salt in a solvent to obtain a solution of the organic acid salt;

[0066] (2) dissolving ammonium ferric citrate in a solvent to obtain a solution of ammonium ferric citrate;

30 [0067] (3) adding the solution of ammonium ferric citrate to the solution of the organic acid salt to obtain a reaction solution, and stirring the reaction solution for 1-4 h while heating;

[0068] (4) stirring the reaction solution obtained in step (3) at room temperature for 4-15 h; and

35 [0069] (5) filtering the reaction solution obtained in step (4), and concentrating and drying the resulting filtrate to obtain the salt of the ammonium ferric citrate-organic acid complex comprising ammonium ferric citrate and the organic acid salt,

40 [0070] wherein the organic acid salt is an organic acid salt or an acidic amino acid salt acceptable in pharmacy, foods and feeds, the organic acid is selected from fumaric acid, maleic acid, succinic acid, malonic acid, oxalic acid, benzoic acid or sorbic acid, and the acidic amino acid is selected from glutamic acid, aspartic acid or γ -aminobutyric acid; and the solvents in step (1) and step (2) are solvents capable of solvating ammonium ferric citrate and the organic acid salt, and are independently selected from water, methanol, ethanol, an aqueous methanol solution, or an aqueous ethanol solution. Preferably, the heating is performed at 25°C-60°C.

[0071] In some particular embodiments, the organic acid salt is a sodium salt of the organic acid, the product obtained by the above-mentioned method for preparing a salt of an ammonium ferric citrate-organic acid complex is a sodium salt of the ammonium ferric citrate-organic acid complex, and the molar ratio of the sodium ions to the organic acid in the sodium salt of the organic acid is 1 : 1-1 : 2. For example, taking fumaric acid as an example, the sodium salt of fumaric acid may include monosodium fumarate and disodium fumarate.

[0072] In some embodiments, the ammonium ferric citrate-organic acid complex and the salt thereof obtained by the above-mentioned preparation method further comprise at least one solvent capable of solvating ammonium ferric citrate, the organic acid and a salt thereof, wherein the solvent is selected from water, methanol, ethanol, or a combination thereof.

[0073] In some embodiments, the present invention provides an ammonium ferric citrate-organic acid complex, wherein the organic acid is selected from fumaric acid or maleic acid.

[0074] Fumaric acid is trans-butenedioic acid. Maleic acid is cis-butenedioic acid, which has the same molecular formula, same molecular weight, and same number of carboxyl groups as fumaric acid, and can be used as a substitute for fumaric acid in the preparation of an ammonium ferric citrate-organic acid complex.

[0075] In some embodiments, the solvent capable of solvating ammonium ferric citrate and the organic acid is selected from water.

[0076] In a particular embodiment, the ammonium ferric citrate-organic acid complex provided in the present invention comprises ammonium ferric citrate and fumaric acid, and a method for preparing the ammonium ferric citrate-organic acid complex comprises the following steps:

[0077] (1) dissolving fumaric acid in water to obtain a solution of fumaric acid;

[0078] (2) dissolving ammonium ferric citrate in water to obtain a solution of ammonium ferric citrate;

[0079] (3) adding the solution of ammonium ferric citrate to the solution of fumaric acid to obtain a reaction solution, and stirring the reaction solution at 50°C for 1-4 h;

[0080] (4) stirring the reaction solution obtained in step (3) at room temperature for 4-15 h; and

[0081] (5) filtering the reaction solution obtained in step (4), and concentrating and drying the resulting filtrate to obtain an ammonium ferric citrate-fumaric acid complex comprising ammonium ferric citrate and fumaric acid.

[0082] In some embodiments, in the above-mentioned method for preparing an ammonium ferric citrate-fumaric acid complex, the molar ratio of the ammonium ferric citrate to the fumaric acid is from 1 : 1 to 3 : 1, and the content of elements in the provided ammonium ferric citrate-fumaric acid complex is: C 23.8%-25.82%, H 4.09%-4.29%, N 5.74%-6.19%, O 45.12%-48.84%, and Fe 16.13%-18.8%.

[0083] Further, the ammonium ferric citrate-fumaric acid complex provided in the present invention further comprises a certain amount of water.

[0084] In a particular embodiment, in the above-mentioned method for preparing an ammonium ferric citrate-fumaric acid complex, the molar ratio of the ammonium ferric citrate to the fumaric acid is 2 : 1, and the content of elements in the provided ammonium ferric citrate-fumaric acid complex is: C 25.82%, H 4.09%, N 6.19%, and Fe 18.8%.

- 5 [0085] In some preparation schemes, the ammonium ferric citrate-sodium fumarate provided in the present invention is prepared by the above-mentioned method, wherein step (1) of the preparation method involves dissolving sodium fumarate in water to obtain a sodium fumarate solution.

- 10 [0086] In some particular preparation schemes, the sodium fumarate is monosodium fumarate, and a salt of the ammonium ferric citrate-fumaric acid complex is ammonium ferric citrate-monosodium fumarate.

[0087] In some particular preparation schemes, the sodium fumarate is disodium fumarate, and a salt of the ammonium ferric citrate-fumaric acid complex is ammonium ferric citrate-disodium fumarate.

- 15 [0088] The present invention provides a method for characterizing the ammonium ferric citrate-organic acid complex and the salt thereof, including, but not limited to elemental analysis, Fourier transform infrared spectroscopy (FTIR), X-ray diffraction (XRD), and differential scanning calorimetry (DSC).

- 20 [0089] Elemental analysis: The elemental analysis results are collected in an Elementar Vario EL Cube elemental analyzer at a combustion furnace temperature of 950°C and a reduction furnace temperature of 600°C. The data are analyzed with reference to JY/T 0580-2020 (General rules of analytical methods for elemental analyzer).

- 25 [0090] Fourier transform infrared spectroscopy (FTIR): The FTIR spectrum is collected in a Fourier transform infrared spectrometer (FT-IR NICOLET 6700) at an absorption wavelength of 400-4000 cm⁻¹. The test method involves potassium bromide pellet, and the detection is performed based on GB/T 6040-2019 (General rules for infrared analysis).

- 30 [0091] X-ray powder diffraction (XRD): The XRD pattern is collected in an X-ray diffractometer (Empyrean). Detection conditions involve Cu target K α radiation, X-ray light pipe with a voltage of 40 kV and a current of 40 mA, divergence slit of 1/8°, measurement of anti-scattering slit at a step size of 1/4°, anti-scattering slit of 7.5 mm, step size of 0.02° 2 θ , measurement angle ranging from 0° 2 θ to 90° 2 θ , and dwell time per step of 40 s. The detection is performed based on Pharmacopoeia of the People's Republic of China (Edition 2020), volume IV, section 0451 X-ray diffraction method.

- 35 [0092] Differential Scanning Calorimetry (DSC): DSC data is collected on a DSC214 differential scanning calorimeter from NETZSCH. 0.5-5 mg of samples are placed into an aluminum tray having pinholes, purged with dry nitrogen at 40 mL/min, and heated from room temperature to 180°C at a rate of 10°C/min. The test is performed based on JY/T 0589.3-2020 (General rules of analytical methods for thermal analysis-Part 3: Differential scanning calorimetry).
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[0093] The experiments for studying the stability of physicochemical properties of the ammonium ferric citrate-organic acid complex provided in the present invention include a stability experiment under high humidity and a stability experiment under illumination.

[0094] Stability experiment under high humidity: Samples are placed in petri dishes, and spread into a thin layer of ≤ 5 mm. The petri dishes are placed in a high humidity environment (25°C , $75\% \pm 5\%$ RH). Sampling is performed on day 5 and day 10 for detection, wherein each sample is sampled twice in parallel.

- 5 [0095] Stability experiment under illumination: Samples are placed in petri dishes, and spread into a thin layer of ≤ 5 mm. The petri dishes are placed in an illumination environment ($4500 \text{ Lx} \pm 500 \text{ Lx}$). Sampling is performed on day 0, day 5 and day 10 for detection, wherein each sample is sampled twice in parallel.

- 10 [0096] Compared with ammonium ferric citrate, the ammonium ferric citrate-organic acid complex or the salt thereof provided in the present invention has beneficial technical effects of significantly enhanced appearance stability and significantly improved or enhanced moisture absorption at room temperature and high humidity conditions, and significantly enhanced stability of chemical properties under illumination conditions.

- 15 [0097] Experiments for studying the bioavailability of the ammonium ferric citrate-organic acid complex provided in the present invention include an experiment for studying the effect of the complex and the salt thereof on the growth performance and diarrhea of piglets, an experiment for studying the effect of the complex and the salt thereof on the growth performance of broilers, and an experiment for studying the application effect of the complex and the salt thereof in feeds for meat ducks. The study results fully show that, when used in the farming of pigs, chickens and ducks, the ammonium ferric citrate-organic acid complex and the salt thereof can have farming effects comparable to or even more excellent than ammonium ferric citrate in terms of improving the growth performance of pigs, chickens and ducks, can effectively improve the growth performance or production performance of the animals, and can be used as an upgrade product to replace ammonium ferric citrate.

Use of ammonium ferric citrate-organic acid complex involved in the present invention

- 30 [0098] In foods, ammonium ferric citrate can be used as: (1) an iron source in the treatment of elemental iron deficiency; (2) a food additive in the fortification of bread nutrition; (3) a dietary iron supplement; and (4) an anti-caking agent in the production of products containing a compounded sweetener and in the production of table salt. Ammonium ferric citrate can further be used in the prevention or treatment of intestinal microbial dysregulation caused by elemental iron in a human body, including controlling the growth of pathogenic bacteria such as *Escherichia coli*, *Enterobacter* bacteria, and *Streptococcus pneumoniae*, or in the prevention or treatment of intestinal dysfunction, including diarrhea, enteritis, or intestinal infection.

- 40 [0099] In the field of animal farming, ammonium ferric citrate can be used to alleviate the generation of H_2S in rumen; and ammonium ferric citrate, as a nutritional ingredient, can be further used in a health care product to promote the growth of dogs and cats, supplement various trace elements and vitamins required for their growth, beautify their hair, enhance the immune function of the body, balance nutrition, regulate estrus, increase the number of fetuses, and promote the health of reproductive system, and can further be used as a complex mineral in a poultry feed additive to supplement the needs of poultry for mineral elements and promote the growth and development of
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poultry.

[0100] The results of the experiments for studying the bioavailability of the ammonium ferric citrate-organic acid complex and the salt thereof provided in the present invention show that the ammonium ferric citrate-organic acid complex and the salt thereof have farming effects comparable to or even more excellent than ammonium ferric citrate in animal experiments. Due to the alleviation of the moisture absorption, the stability of the ammonium ferric citrate-organic acid complex and the salt thereof in feeds, foods and drugs is improved, and the reaction with other ingredients is reduced, thereby avoiding the reduction of the content of other nutritional ingredients or formula active ingredients coexisting therewith; and due to the effectiveness in animals, the ammonium ferric citrate-organic acid complex and the salt thereof can replace ammonium ferric citrate for use in feeds, foods, and drugs. Therefore, the uses of ammonium ferric citrate mentioned above and not mentioned above are all within the scope of protection of the claims of the present invention.

[0101] The present invention provides the use of the ammonium ferric citrate-organic acid complex and/or the salt thereof as a feed additive or in the preparation of a feed additive, wherein the feed additive is suitable for animals at various growth stages.

[0102] The animals may be selected from livestock, poultry, aquaculture animals or pets at various growth stages.

[0103] Further, the livestock include, but are not limited to pigs, cattle, sheep, horses, rabbits, minks, or donkeys; the poultry include, but are not limited to chickens, turkeys, ducks, geese, quails, or pigeons; the aquaculture animals include, but are not limited to fishes, shrimps, tortoises, crabs, soft-shelled turtles, bullfrogs, eels, or loaches; and the pets include, but are not limited to dogs or cats of various subspecies.

[0104] In one embodiment, the ammonium ferric citrate-organic acid complex and/or the salt thereof are/is used as an iron supplement or in the preparation of an iron supplement, and preferably, the ammonium ferric citrate-organic acid complex and/or the salt thereof are/is: an ammonium ferric citrate-fumaric acid complex and/or a sodium salt thereof.

[0105] In one embodiment, the ammonium ferric citrate-organic acid complex and/or the salt thereof are/is used to alleviate the generation of H₂S in rumen.

[0106] In one embodiment, the ammonium ferric citrate-organic acid complex and/or the salt thereof are/is used as an animal feed additive or in the preparation of an animal feed additive, and further, the animal feed additive is used in animal farming to promote the growth of animals; and the feed additive is selected from an animal iron supplement and/or an animal growth promoter.

[0107] In one embodiment, the ammonium ferric citrate-organic acid complex and/or the salt thereof are/is used as a health care product for dogs and cats or in the preparation of a health care product for dogs and cats, wherein the health care product for dogs and cats promotes the growth of dogs and cats. Preferably, the ammonium ferric citrate-organic acid complex and/or the salt thereof are/is used as a nutritional ingredient.

[0108] In one embodiment, the ammonium ferric citrate-organic acid complex and/or the salt thereof are/is used as a nursery feed or in the preparation of a nursery feed. Further, the nursery feed can reduce the diarrhea rate of weaned pigs, increase the feed

intake of weaned pigs, and reduce the feed conversion rate, thereby increasing the growth speed of weaned pigs, increasing the feed reward, and promoting the growth of weaned pigs.

5 [0109] In another embodiment, the ammonium ferric citrate-organic acid complex and/or the salt thereof are/is used as a feed for broilers or in the preparation of a feed for broilers. Further, the feed for broilers can increase the feed intake and reduce the feed conversion ratio of broilers, that is, increase the feed conversion rate, thereby effectively promoting the growth of broilers.

10 [0110] In another embodiment, the ammonium ferric citrate-organic acid complex and the salt thereof are used as a feed for meat ducks or in the preparation of a feed for meat ducks. Further, the feed for meat ducks can increase the feed intake and reduce the feed conversion ratio of meat ducks, that is, increase the feed conversion rate, thereby promoting the growth of meat ducks by increasing the feed intake and feed conversion thereof.

15 [0111] The present invention provides the use of the ammonium ferric citrate-organic acid complex and/or the salt thereof as a food additive or in the preparation of a food additive; and preferably, the food additive is a food iron fortifier.

20 [0112] In one embodiment, the ammonium ferric citrate-organic acid complex and/or the salt thereof are/is used as an iron source or in the preparation of an iron source for use in a drug for treating a disease of elemental iron deficiency.

[0113] In one embodiment, the ammonium ferric citrate-organic acid complex and/or the salt thereof are/is used as an iron source in the treatment of a disease of elemental iron deficiency.

25 [0114] In one embodiment, provided is a method for treating a disease of elemental iron deficiency, comprising applying to an animal an ammonium ferric citrate-organic acid complex and/or a salt thereof.

30 [0115] In one embodiment, the ammonium ferric citrate-organic acid complex and/or the salt thereof are/is used in the preparation of bread. Further, the ammonium ferric citrate-organic acid complex and/or the salt thereof are/is used in the fortification of bread nutrition.

[0116] In one embodiment, the ammonium ferric citrate-organic acid complex and/or the salt thereof are/is used in the preparation of a dietary iron supplement.

35 [0117] In one embodiment, the ammonium ferric citrate-organic acid complex and/or the salt thereof are/is used as an anti-caking agent in the production of a product containing a compounded sweetener and in the production of table salt.

40 [0118] The results of the experiments for studying the bioavailability of the ammonium ferric citrate-organic acid complex and/or the salt thereof provided in the present invention show that the ammonium ferric citrate-organic acid complex and/or the salt thereof have/has effects similar to ammonium ferric citrate on improving diarrhea in weaned pigs.

[0119] Therefore, in one embodiment, the ammonium ferric citrate-organic acid complex and/or the salt thereof are/is used in the prevention or treatment of intestinal microbial dysregulation caused by elemental iron in a human body, including controlling

the growth of pathogenic bacteria such as *Escherichia coli*, *Enterobacter* bacteria, and *Streptococcus pneumoniae*, or in the prevention or treatment of intestinal dysfunction, including diarrhea, enteritis, or intestinal infection, or as a pharmaceutical active ingredient in the preparation of a drug for preventing and treating diarrhea in humans or animals.

[0120] Provided is a method for feeding an animal, comprising applying to the animal the aforementioned ammonium ferric citrate-organic acid complex and/or the salt thereof, or the aforementioned composition comprising the ammonium ferric citrate-organic acid complex and/or the salt thereof.

10 Compositions involved in the present invention

[0121] Based on the use of the ammonium ferric citrate-organic acid complex and/or the salt thereof as a feed additive, a food additive, and a drug or in the preparation of a feed additive, a food additive, and a drug, the present invention provides a composition comprising the ammonium ferric citrate-organic acid complex and/or the salt thereof, wherein the composition includes a composition acceptable in feeds, a food composition, and a pharmaceutical composition.

[0122] The “composition” involved in the present invention refers to a collection or a set comprising one or more compounds provided in the present invention.

[0123] The present invention provides a composition, comprising the above-mentioned ammonium ferric citrate-organic acid complex or the salt thereof; and preferably, the composition is used as a drug, a feed, or a food.

[0124] The present invention provides a composition acceptable in feeds, comprising the above-mentioned ammonium ferric citrate-organic acid complex and/or the salt thereof, and one or more of a carrier, an excipient, a diluent, or a vehicle acceptable in feeds.

[0125] The “carrier” involved in the present invention refers to a substance that is acceptable in feeds, has the ability to carry active ingredients and improve their dispersibility, and exhibits good chemical stability and adsorbability. The carrier may be selected from an organic carrier and an inorganic carrier. The organic carrier is a material containing much crude fibers, including, but not limited to corn flour, corn cob powder, wheat bran, rice hull powder, defatted rice bran, rice mill by-product, corn stalk powder, peanut shell powder, etc. The inorganic carrier is selected from a mineral, preferably from calcium salts and oxides of silicon, and is used in the preparation of a trace element premix, including, but not limited to calcium carbonate, silicates, vermiculite, zeolite, sepiolite, etc.

[0126] The “diluent” involved in the present invention refers to a substance that enables additive raw materials to be uniformly distributed in a material and dilutes the high-concentration additive raw materials into a low-concentration premixed agent or premix, which can separate the trace ingredients from each other and reduce the interaction between active ingredients so as to increase the stability of the active ingredients without affecting the physicochemical properties of the material involved. The diluent is selected from an organic diluent and an inorganic diluent. The organic diluent includes, but is not limited to corn flour, degermed corn flour, dextrose (glucose), sucrose, semolina with bran, stir-fried soybean powder, wheat middling, corn gluten meal,

etc.; and the inorganic diluent includes, but is not limited to limestone, calcium dihydrogen phosphate, shell powder, kaolin (white clay), table salt and sodium sulfate.

5 **[0127]** The “excipient” involved in the present invention is a wetting agent that induces the inherent viscosity of a substance, an adhesive that binds substances together, a disintegrating agent that breaks the entire sheet of a substance into many fine particles, a retention aid that reduces the friction between particles, or an anti-sticking agent that prevents materials from adhesion. The excipient includes, but is not limited to magnesium stearate, talc powder, vegetable oil, magnesium lauryl sulphate, starch, starch slurry, water, inorganic salts, dextrin, powdered sugar, etc.

10 **[0128]** The “vehicle” involved in the present invention refers to a solvent required for dissolving or dispersing a solid, including, but not limited to water, ethanol, glycerin, etc.

[0129] In some embodiments, the composition further comprises: an additional animal feed additive and/or an animal feed raw material.

15 **[0130]** The “feed additive” involved in the present invention refers to a small or trace amount of substances added during feed processing, production and use, including a nutritive feed additive and/or a general feed additive.

[0131] The “animal” involved in the present invention refers to human or farmed animals that cannot convert inorganic matters into organic matters, but can only utilize organic matters as foods or feeds to perform vital activities such as ingestion, digestion, absorption, respiration, circulation, excretion, sensation, movement, and reproduction. The “farmed animals” include poultry, livestock, aquaculture animals, and other animals that are raised in captivity and are legally captured, including pets such as cats and dogs. The “livestock” refers to, for example, any one of pigs, cattle, horses, goats, sheep, deer, and many useful rodents. The “poultry” includes, for example, chickens, ducks, geese, quails and pigeons. The “aquaculture animals” include, for example, fishes, shrimps, tortoises, and soft-shelled turtles.

20 **[0132]** The “feed” involved in the present invention refers to a product that is industrially processed and made for consumption by animals. Unless otherwise stated, the “feed” or “animal feed” includes animal feed raw materials and one or more animal feed additives.

[0133] The “nutritive feed additive” involved in the present invention refers to a small amount or trace amount of substances that are added to formula feeds for balancing feed nutrients, improving feed utilization, and directly exerting nutritional effects on animals. The nutritive feed additive is selected from an amino acid, an amino acid salt and an analog thereof, a vitamin and a vitamin-like substance, a mineral element and a complex (chelate) thereof, a microbial enzyme preparation or a nonprotein nitrogen.

35 **[0134]** The “general feed additive” involved in the present invention, also known as “non-nutritive additive”, refers to some non-nutritive substances that are added to feeds for improving feed utilization and ensuring feed mass and quality, and are beneficial to animal health or metabolism. The general feed additive includes: a growth promoter, a deworming agent, a flavoring agent and an attractant, a feed conditioning agent, a feed formulation agent, a feed preservative and a Chinese herbal medicine additive.

40 **[0135]** The “animal feed raw material” involved in the present invention is selected

from substances acceptable in feeds, such as grains and processed products thereof, oilseeds and processed products thereof, leguminous crop seeds and processed products thereof, stem tubers, root tubers and processed products thereof, other seed and fruit products and processed products thereof, forage, roughage and processed products thereof, other plants, algae and processed products thereof, dairy products and by-products thereof, terrestrial animal products and by-products thereof, fish, other aquatic organisms and by-products thereof, minerals, microbial fermentation products and by-products thereof, and other feed raw materials.

[0136] The present invention provides a food composition, comprising the above-mentioned ammonium ferric citrate-organic acid complex and/or the salt thereof, and a nutriologically acceptable adjuvant. Preferably, the adjuvant is selected from a nutriologically acceptable inert carrier, an anti-wetting agent, an antioxidant, a wetting agent, a thickening agent, a stabilizer, a multivalent chelating agent, a lubricant, a preservative, a sweetener, and an acidity regulator, or a combination thereof. Preferably, the carrier includes, but is not limited to maltodextrin, starch, calcium sulfate, magnesium sulfate, calcium carbonate, a cellulose derivative, lactose and a derivative thereof, or any mixture of such carriers, and other analogs. Preferably, the above-mentioned ammonium ferric citrate-organic acid complex and/or the salt thereof are/is used as an active ingredient.

[0137] The anti-wetting agent includes, but is not limited to calcium carbonate, microcrystalline cellulose, fatty acid salts (Ca, Na, K, and NH_4), sodium carbonate, sodium bicarbonate, magnesium carbonate, magnesium hydroxide, magnesium oxide, amorphous silicon dioxide, silicon dioxide, calcium silicate, magnesium silicate, talc powder, sodium aluminum silicate, aluminum silicate, etc.

[0138] The wetting agent includes, but is not limited to sodium lactate, potassium lactate, sorbitol and sorbitol syrup, mannitol, glycerin, glycerol, xylitol, polyglucose, etc.

[0139] The antioxidant includes, but is not limited to ascorbic acid, sodium ascorbate, calcium ascorbate, potassium ascorbate, isoascorbic acid, sodium isoascorbate, lecithin, sodium lactate, citric acid, calcium citrate, tricalcium citrate, an ester of citric acid and fatty acid and glycerin, an ester of citric acid and monoglyceride/diglyceride, etc.

[0140] The thickening agent includes, but is not limited to gelatin, alginic acid, sodium alginate, potassium alginate, ammonium alginate, calcium alginate, agar, carrageenan and a salt thereof, jatan gum, carob, guar gum, tragacanth gum, arabic gum, xanthan gum, camphor gum, gellan gum, sorbitol and sorbitol syrup, konjac gum, pectin, amidated pectin, microcrystalline cellulose, methylcellulose, hydroxypropyl cellulose, methylethylcellulose, sodium carboxymethylcellulose, polyglucose, etc.

[0141] The stabilizer includes, but is not limited to sodium caseinate, gelatin, calcium carbonate, calcium acetate, lecithin, monosodium citrate, disodium citrate, sodium citrate, trisodium citrate, potassium citrate, tripotassium citrate, calcium citrate, tricalcium citrate, alginic acid, sodium alginate, potassium alginate, ammonium alginate, calcium alginate, agar, carrageenan and a salt thereof, jatan gum, locust bean, guar gum, tragacanth gum, arabic gum, xanthan gum, karaya gum, gellan gum, mannitol, konjac gum, pectin, amidated pectin, microcrystalline cellulose, methylcellulose, hydroxypropyl cellulose, methylethylcellulose, sodium carboxymethylcellulose, fatty

acid salts (Ca, Na, K, and NH₄), fatty acid monoglyceride and diglyceride, an acetate of fatty acid and glycerin/monoglyceride/diglyceride, a lactate of fatty acid and glycerin/monoglyceride/diglyceride, a citrate of fatty acid and glycerin/monoglyceride/diglyceride, a tartrate of fatty acid and glycerin/monoglyceride/diglyceride, an ester of acetic acid and fatty acid and glycerin, sodium bicarbonate, potassium carbonate, calcium chloride, maltitol, maltitol syrup, polyglucose, etc.

[0142] The multivalent chelating agent includes, but is not limited to citric acid, monosodium citrate, disodium citrate, sodium citrate, trisodium citrate, potassium citrate, tripotassium citrate, calcium citrate, tricalcium citrate, sorbitol and sorbitol syrup, an acetate of fatty acid and monoglyceride/diglyceride, a lactate of fatty acid and glycerin/monoglyceride/diglyceride, a citrate of fatty acid and glycerin/monoglyceride/diglyceride, a tartarate of fatty acid and glycerin/monoglyceride/diglyceride, calcium sulfate, etc.

[0143] The acidity regulator includes, but is not limited to calcium carbonate, acetic acid, calcium acetate, lactic acid, malic acid, fumaric acid, sodium lactate, potassium lactate, calcium lactate, citric acid, monosodium citrate, disodium citrate, sodium citrate, trisodium citrate, potassium citrate, tripotassium citrate, calcium citrate, tricalcium citrate, sodium carbonate, sodium bicarbonate, potassium carbonate, ammonium carbonate, ammonium bicarbonate, magnesium carbonate, potassium sulfate, sodium hydroxide, potassium hydroxide, calcium hydroxide, ammonium hydroxide, magnesium hydroxide, calcium oxide, gluconic acid, glucolactone, calcium gluconate, etc.

[0144] The sweetener includes, but is not limited to sucralose, aspartame, acesulfame potassium, sodium saccharin, sodium cyclamate, thaumatin, stevioside, rebaudioside, neohesperidin dihydrochalcone, alitame, or a mixture thereof at any ratio.

[0145] In some embodiments, the food composition further comprises an additional dietary supplement and/or a food additive.

[0146] In particular, the food composition comprises: a vitamin, a mineral, lycopene, lutein, carnitine, creatine, a plant extract, an amino acid, a peptide, and a protein, and further comprises other nutritional ingredients such as vegetable oils containing omega 3, omega 6, and omega 9 and derivatives thereof. Examples of minerals include zinc, calcium, magnesium, phosphorus, potassium, selenium, chromium, copper, manganese, cobalt, molybdenum, iodine, germanium, and a mixture thereof. Examples of vitamins include vitamin C, vitamin A, vitamin D, vitamin E, vitamin B, vitamin K, folic acid, and a mixture thereof.

[0147] Further, the food composition further comprises a food raw material.

[0148] The present invention provides a pharmaceutical composition, comprising the above-mentioned ammonium ferric citrate-organic acid complex and/or the salt thereof, and a pharmaceutically acceptable adjuvant. The pharmaceutically acceptable adjuvant is selected from one or more of a pharmaceutically acceptable carrier, a diluent, an excipient, a dispersant or a suspending agent, a surfactant, an isotonic agent, a thickening agent, an emulsifier, a preservative, a solid adhesive, a lubricant, and a vehicle.

[0149] The carrier refers to a pharmaceutically acceptable substance that has the ability to carry active ingredients and improve their dispersibility, and exhibits good

chemical stability and adsorbability. The carrier includes, but is not limited to different carriers that can be used in preparations of pharmaceutically acceptable compositions and well-known preparation methods therefor.

5 [0150] The diluent refers to a substance that enables additive raw materials to be uniformly distributed in a material and dilutes the high-concentration additive raw materials into a low-concentration premixed agent or premix, which can separate the trace ingredients from each other and reduce the interaction between active ingredients so as to increase the stability of the active ingredients without affecting the physicochemical properties of the material involved.

10 [0151] The excipient is selected from one or more of a wetting agent that induces the inherent viscosity of a substance, an adhesive that binds substances together, a disintegrating agent that breaks the entire sheet of a substance into many fine particles, a retention aid that reduces the friction between particles, or an anti-sticking agent that prevents materials from adhesion. The excipient includes, but is not limited to
15 magnesium stearate, talc powder, vegetable oil, magnesium lauryl sulphate, starch, starch slurry, water, inorganic salts, dextrin, or powdered sugar.

[0152] The vehicle refers to a solvent required for dissolving or dispersing a solid, including but not limited to water, glycerin, and ethanol.

20 [0153] In particular, the above-mentioned pharmaceutically acceptable adjuvant includes, but is not limited to, an ion exchanger, aluminum, aluminum stearate, lecithin, serum protein, a buffer substance such as phosphate, glycine, sorbic acid, potassium sorbate, a mixture of some glycerides of saturated vegetable fatty acids, water, a salt or an electrolyte, sodium dihydrogen phosphate, potassium hydrogen phosphate, sodium chloride, a zinc salt, colloidal silicon, magnesium trisilicate, polyvinylpyrrolidone,
25 polyacrylate, wax, polyethylene-polyoxypropylene-blocking polymer, and lanolin; sugar, such as lactose, glucose and sucrose; starch, such as corn starch and potato starch; cellulose and a derivative thereof such as sodium carboxymethylcellulose, ethylcellulose and cellulose acetate; gum acacia powder; malt; gelatin; talc powder; an adjuvant such as cocoa butter and suppository wax; an oil such as peanut oil, cottonseed oil, safflower
30 oil, sesame oil, olive oil, corn oil, and soybean oil; a diol compound, such as propylene glycol and polyethylene glycol; esters such as ethyl oleate and ethyl laurate; agar; a buffer agent such as magnesium hydroxide and aluminum hydroxide; alginic acid; pyrogen-free water; an isotonic salt; Ringer's solution; and ethanol, a phosphate buffer and other non-toxic suitable lubricants such as sodium laurate and magnesium stearate, a colorant, a
35 releasing agent, a coating material, a sweetener, a flavoring agent, a perfume, a preservative, and an antioxidant.

[0154] The pharmaceutical composition of the present invention refers to a collection or a set of compounds comprising one or more compounds. The pharmaceutical composition can be used in the preparation of a drug for animals, which
40 has significant therapeutic effects on diarrhea in an animal, particularly livestock at a weaning stage (such as weaned pigs).

[0155] In some embodiments, the treatment refers to ameliorating the disease or condition (i.e., slowing or restraining or alleviating the development of the disease or at least one of the clinical symptoms thereof) by means of administering to a diseased
45 animal a therapeutic dose of the drug for animals of the present invention; in some other

embodiments, the treatment refers to palliating and/or ameliorating at least one physical parameter, including a physical parameter that may not be perceived by a patient by means of administering to a diseased animal a therapeutic dose of the drug for animals of the present invention; in some other embodiments, the treatment refers to modulating the disease or condition either physically (e.g., stabilization of a perceptible symptom) or physiologically (e.g., stabilization of a physical parameter), or both, by means of administering to a diseased animal a therapeutic dose of the drug for animals of the present invention; and in some other embodiments, the treatment refers to preventing or delaying the onset, occurrence or worsening of the disease or condition by means of administering to a diseased animal a therapeutic dose of the drug for animals of the present invention.

[0156] The term “therapeutic dose” refers to an amount of a compound which, when administered to a diseased animal for treating a disease, is sufficient to provide a treatment effect on such disease and may vary with the compound, the disease, the severity, and the condition, age, weight and gender of the animal to be treated.

[0157] In some embodiments, the pharmaceutical composition further comprises an additional drug for treating diarrhea in an animal.

[0158] The following describes a method of using the drug for animals involved in the present invention. A method of using the drug in the treatment of diarrhea in an animal comprises administering to a diseased animal a therapeutic dose of an ammonium ferric citrate-organic acid complex and/or a salt thereof, or a composition comprising a therapeutic dose of an ammonium ferric citrate-organic acid complex and/or a salt thereof. The pharmaceutical composition of the present invention may be manufactured according to those conventional methods disclosed in the art. The pharmaceutical composition is in a particular target dosage form suitable for therapeutic purposes. The ammonium ferric citrate-organic acid complex is administered in admixture with a suitable pharmaceutical diluent, excipient, carrier, etc. selected in accordance with administration form and conventional pharmaceutical practice, e.g., administered in an oral dosage form via a suitable carrier.

[0159] The pharmaceutical composition is used in the treatment of diarrhea in an animal. The oral dosage form includes, but is not limited to, enteric-coated oral dosage forms of tablets, pills or capsules. The oral dosage form containing the pharmaceutical composition of the present invention is administered to a diseased animal via drenching or in admixture with a feed by a breeder or a veterinarian.

[0160] The dosage regimen of the pharmaceutical composition of the present invention will vary depending on a variety of known factors, such as the pharmacokinetic characteristics, mode, and route of administration of a particular reagent; the type, age, and body weight of a diseased animal; the nature and extent of a symptom; the type of parallel treatment; the frequency of medication in treatment; and the route of administration and the desired therapeutic effect. A veterinarian can make a decision and prescribe an effective amount of a drug to prevent, restrain, alleviate, or slow the development of the symptom of a disease.

[0161] The pharmaceutical composition of the present invention is prepared into a unit dosage form according to a preparation formula, to reduce the dosage and the uniformity of dosage units. Each unit dose of a preparation suitable for administration

may contain from 1 mg to 100 mg of the ammonium ferric citrate-organic acid complex and/or the salt thereof. In these dosage forms, the weight of the active ingredient generally accounts for 0.5%-95% of the total weight of the composition.

- 5 [0162] The above-mentioned “unit dose” refers to a physically discrete unit of a drug required for an appropriate treatment in an organism.

Detailed Description of Embodiments

- 10 [0163] In order to make the purposes, technical solutions and advantages of the present invention clearer, the compounds, compositions and uses of the present invention are further illustrated in detail below by way of examples. It should be understood that the specific examples described herein are merely used to explain the present invention, but are not intended to limit the present invention.

[0164] **Example 1** Preparation scheme for citric acid-fumaric acid complex.

[0165] Reagents involved in the preparation scheme include:

- 15 [0166] ammonium ferric citrate, analytically pure (AR), purchased from Shanghai Aladdin Biochemical Technology Co., Ltd. (Shanghai, China), with elemental analysis data characterized as C 22.62%, H 4.18%, and N 7.31%, an XRD pattern as shown in FIG. 6, and a DSC curve as shown in FIG. 11;

- 20 [0167] fumaric acid, analytically pure (AR), purchased from Shanghai Aladdin Biochemical Technology Co., Ltd. (Shanghai, China), with an XRD pattern as shown in FIG. 7, and a DSC curve as shown in FIG. 13; and

- 25 [0168] a mixture of ammonium ferric citrate raw material and fumaric acid raw material at a molar ratio of 2 : 1 (abbreviated as “mixture”), with an FTIR spectrogram as shown in FIG. 9, an XRD pattern as shown in FIG. 10, and a DSC curve comprising an exothermic peak at 157.41°C as shown in FIG. 14.

[0169] 1. Preparation of ammonium ferric citrate-fumaric acid complex A

[0170] The ammonium ferric citrate-fumaric acid complex A (hereinafter abbreviated as “complex A”) was a product obtained from ammonium ferric citrate and fumaric acid at a feeding molar ratio of 1 : 1 during preparation.

- 30 [0171] At room temperature, 150 mL of water and fumaric acid (43.8 g, 377 mmol) were sequentially added to a reaction flask to form a reaction solution, and then tan ammonium ferric citrate (100.0 g, 377 mmol) was dissolved in 200 mL of water to obtain a brown solution. The brown solution was added to the reaction flask. The reaction system was heated to 50°C, and then stirred and reacted for 4.0 h until the reaction solution became clear. The reaction system was cooled to room temperature, and then stirred and reacted for another 4 h. The reaction solution was filtered. The filtrate was concentrated and dried. 1000 mL of ethanol was added, and the resulting mixture was stirred and slurried for 3.0 h and then filtered. The filter cake was washed with 500 mL of ethanol, dried at 55°C for 18 h, and sieved to obtain 104.5 g of the complex A as a tan solid powder.

40 [0172] The results of the structural characterization of the complex A are as follows:

[0173] (1) The elemental analysis data are characterized as C 25.14%, H 4.15%, N 5.74%, and O 48.84%, and according to the law of conservation of elements, the content of element iron (Fe) in the complex A is calculated to be about 16.13%.

[0174] (2) The FTIR spectrogram is as shown in FIG. 1.

5 [0175] (3) The XRD pattern is as shown in FIG 4.

[0176] 2. Preparation of ammonium ferric citrate-fumaric acid complex B

[0177] The ammonium ferric citrate-fumaric acid complex B (hereinafter abbreviated as "complex B") is a product obtained from ammonium ferric citrate and fumaric acid at a feeding molar ratio of 2 : 1 during preparation.

10 [0178] At room temperature, 50 mL of water and fumaric acid (21.9 g, 189 mmol) were sequentially added to a reaction flask to form a reaction solution, and then tan ammonium ferric citrate (100.0 g, 377 mmol) was dissolved in 200 mL of water to obtain a brown solution. The brown solution was added to the reaction flask. The reaction system was heated to 50°C, and then stirred and reacted for 1-1.5 h until the reaction
15 solution became clear. The reaction system was cooled to room temperature, and then stirred and reacted for another 5 h. The reaction solution was filtered, and the resulting filtrate was concentrated and dried at 55°C-60°C to provide a tan hard lumpy solid. 500 mL of ethanol was added to the resulting solid, and the mixture was left to stand. The solid was scraped off using a scraper, magnetically stirred and slurried for 3.0 h, and then
20 filtered. The filter cake was dried at 60°C overnight, and sieved to obtain 115 g of a tan solid powder having a moisture content of 2.43% as determined by a moisture dryer.

[0179] The results of the structural characterization of the complex B are as follows:

[0180] (1) The elemental analysis data are characterized as C 25.82%, H 4.09%, N 6.19%, and Fe 18.8%, and according to the law of conservation of elements, the content
25 of element oxygen (O) in the complex B is inferred to be about 42.69%.

[0181] (2) The comparison results of the FTIR spectrograms are as shown in FIG. 2, wherein the samples corresponding to the spectrograms from top to bottom are the ammonium ferric citrate-fumaric acid complex B, ammonium ferric citrate raw material and fumaric acid raw material, respectively; FIG. 2 shows that the spectrogram of the
30 ammonium ferric citrate-fumaric acid complex B does not comprise the characteristic peak of fumaric acid, indicating no free fumaric acid in the sample; and the comparison between FIG. 2 and FIG. 9 shows that the material form of the ammonium ferric citrate-fumaric acid complex B is different from that of the mixture of ammonium ferric citrate raw material and fumaric acid raw material at the same molar ratio (i.e., at a feeding
35 molar ratio of 1 : 1).

[0182] (3) The XRD pattern is as shown in FIG. 5, wherein FIG. 5 shows that the spectrogram of the complex B does not comprise the characteristic peak of fumaric acid, indicating no free fumaric acid in the sample; and the comparison between FIG. 5 and
40 FIG. 10 show that the material form of the complex B is different from that of the mixture of ammonium ferric citrate raw material and fumaric acid raw material at the same molar ratio (i.e., at a feeding molar ratio of 1 : 1).

[0183] (4) The DSC curve is as shown in FIG 12.

[0184] 3. Preparation of ammonium ferric citrate-fumaric acid complex C

[0185] The ammonium ferric citrate-fumaric acid complex C (hereinafter abbreviated as “complex C”) is a product obtained from ammonium ferric citrate and fumaric acid at a feeding molar ratio of 3 : 1 during preparation.

5 [0186] At room temperature, 50 mL of water and fumaric acid (20.0 g, 172 mmol) were sequentially added to a reaction flask, and then tan ammonium ferric citrate (137 g, 517 mmol) was dissolved in 250 mL of water to obtain a brown solution. The brown solution was added to the reaction flask. The reaction solution was heated to 50°C, and then stirred and reacted for 1.5 h. The reaction system was cooled to room temperature, and then stirred and reacted for another 15 h. The reaction solution was filtered. The
10 filtrate was concentrated to dryness. 1000 mL of ethanol was added, and the resulting mixture was stirred and slurried for 4.0 h, and then filtered. The filter cake was washed with 500 mL of ethanol, dried at 55°C for 18 h, and sieved to obtain 149.5 g of a tan solid powder.

[0187] The results of the structural characterization of the complex C are as follows:

15 [0188] (1) The elemental analysis data are characterized as C 23.8%, H 4.29%, N 6.14%, and O 48.61%, and according to the law of conservation of elements, the content of element iron in the solid complex is inferred to be 17.16%.

[0189] (2) The FTIR spectrogram is as shown in FIG. 3.

[0190] (3) The XRD pattern is as shown in FIG. 8.

20 [0191] **Example 2** Study on the stability of ammonium ferric citrate-fumaric acid complex

[0192] 1. Reagents:

25 [0193] Sulfuric acid, hydroxylamine hydrochloride, o-phenanthroline, acetic acid, and sodium acetate (all analytically pure); the ammonium ferric citrate-fumaric acid complex prepared in example 1;

[0194] acetic acid-sodium acetate buffer solution (pH 4.5), prepared by accurately weighing 18 g of sodium acetate, adding 9.8 mL of glacial acetic acid, diluting same with water to 1000 mL, and shaking uniformly; 5% hydroxylamine hydrochloride solution, prepared by accurately weighing 5 g of hydroxylamine hydrochloride, dissolving same
30 in water, adjusting to a constant volume in a 100 mL volumetric flask, and shaking uniformly;

[0195] 0.25% o-phenanthroline solution, prepared by accurately weighing 0.25 g of o-phenanthroline, heating and dissolving same by adding an appropriate amount of water, cooling, adjusting to a constant volume in a 100 mL volumetric flask, and shaking
35 uniformly.

[0196] 2. Instruments:

[0197] Drug stability test chamber, Shimadzu UV-1700 spectrophotometer, etc.

[0198] 3. Experimental methods and conditions

40 [0199] Preparation of ammonium ferric citrate standard solution: 0.5 g of an ammonium ferric citrate standard was accurately weighed (accurate to 0.0001 g), added to 25 mL of 1% sulfuric acid solution, and ultrasonically dissolved at 65°C until the solution turned from dark brown to light yellow. The solution was cooled, adjusted to a

- constant volume with 1% sulfuric acid in a 100 mL brown volumetric flask, and shaken uniformly to prepare a standard stock solution having an iron mass concentration of 1000 $\mu\text{g/mL}$. 5 mL of the standard stock solution was accurately measured, placed in a 100 mL brown volumetric flask, adjusted to a constant volume with water, and shaken uniformly to prepare a standard working solution having an iron mass concentration of 50 $\mu\text{g/mL}$, which was stored in a refrigerator at 4°C away from light for later use.

- 5 **[0200]** Plotting of ammonium ferric citrate standard curve: 0, 0.2 mL, 0.5 mL, 1 mL, 2 mL, 3 mL, and 4 mL of the ammonium ferric citrate standard solutions were accurately measured, and placed in 50 mL brown volumetric flasks, respectively. 2 mL of the hydroxylamine hydrochloride solution, 2 mL of the o-phenanthroline solution, and 10 mL of the acetic acid-sodium acetate buffer solution were added. The mixtures were diluted with water to the mark, and shaken uniformly to obtain Fe (II) standard solutions having concentrations of 0.00 $\mu\text{g/mL}$, 0.20 $\mu\text{g/mL}$, 0.50 $\mu\text{g/mL}$, 1.00 $\mu\text{g/mL}$, 2.00 $\mu\text{g/mL}$, 3.00 $\mu\text{g/mL}$, and 4.00 $\mu\text{g/mL}$, respectively. The Fe (II) standard solutions were placed in 10 a thermostat at 37°C for color development for 80 min. Then, by taking the solution having the concentration of 0.00 $\mu\text{g/mL}$ as a blank control, the absorbance of the standard solutions was determined at a wavelength of 510 nm, and a standard curve was plotted with the concentrations of the Fe (II) solutions as the abscissa and the absorbance values as the ordinate.

- 20 **[0201]** Preparation of test solution: 50-100 mg of samples were accurately weighed (accurate to 0.1 mg) and placed in a triangular flask equipped with a plug, and 50 mL of 1% sulfuric acid solution was accurately added into the flask. The flask was plugged, and sealed. The samples were ultrasonically dissolved at 65°C until the solution turned from dark brown to light yellow. The solution was cooled, and immediately detected.

- 25 **[0202]** Preparation of blank test solution: 5.00 mL of the test solution was accurately measured, and placed in a brown volumetric flask, and 10 mL of the acetic acid-sodium acetate buffer solution (pH3.7) was added into the flask. The mixture was diluted with water to the mark, shaken uniformly, and placed in a thermostat at 37°C for 80 min.

- 30 **[0203]** Determination of test solution: 5.00 mL of the test solution was accurately measured, and placed in a brown volumetric flask, and 2 mL of the o-phenanthroline solution and 10 mL of the acetic acid-sodium acetate buffer solution were added into the flask. The mixture was diluted with water to the mark, shaken uniformly, and placed in a thermostat at 37°C for color development for 80 min. Then, by taking the blank test solution as a blank control, the absorbance was measured at a wavelength of 510 nm, and 35 the concentration of Fe (II) in the to-be-tested solution was determined according to the standard curve.

- 40 **[0204]** Stability experiment under high humidity (25°C, 75% $\pm$ 5% RH) and results thereof: samples of ammonium ferric citrate, the complex A, the complex B, and the complex C were placed in petri dishes, and spread into a thin layer of ≤ 5 mm; the petri dishes were placed in a high humidity environment (25°C, 75% $\pm$ 5% RH); and sampling was performed on day 5 and day 10 for detection, wherein each sample was sampled twice in parallel.

- 45 **[0205]** Stability experiment under illumination and results thereof: samples of ammonium ferric citrate, the complex A, the complex B, and the complex C were placed in petri dishes, and spread into a thin layer of ≤ 5 mm; the petri dishes were placed in an

illumination environment (4500 Lx ± 500 Lx); and sampling was performed on day 0, day 5 and day 10 for detection, wherein each sample was sampled twice in parallel. The determination result was the arithmetic mean of the two parallel determination values, and retained to two decimal places, and the percentage change in the content of Fe (II) in the sample was expressed as ΔFe (II) (%). The Fe (II) content (%) expressed as mass percentage was calculated according to formula (1).

$$X = \frac{C \times V \times D}{m \times 1000} \times 100\% \tag{1}$$

[0206] In the formula: C——concentration of Fe (II) in to-be-tested sample calculated according to the standard curve, in micrograms per milliliter (μg/mL); V——total constant volume of sample, in milliliters (mL); D——dilution ratio of sample; and m——mass of sample, in milligrams (mg).

[0207] 4. Results and conclusions

[0208] (1) With regard to the physical stability of ammonium ferric citrate and the complex B thereof, the samples were mainly investigated for weight gain after moisture absorption and appearance change under high humidity conditions of 75% ± 5% RH, and the study results were as shown in Table 1. The results showed that on day 10 of the experiment, the moisture absorption of the ammonium ferric citrate-fumaric acid complex was improved by 41.3% [this value = [(weight gain of ammonium ferric citrate after moisture absorption)-(weight gain of ammonium ferric citrate-fumaric acid complex B after moisture absorption)]/(weight gain of ammonium ferric citrate after moisture absorption)*100%] compared to that of ammonium ferric citrate. During the experiment, the sample appearance of the ammonium ferric citrate-fumaric acid complex substantially remained unchanged, whereas the ammonium ferric citrate turned from a rust-colored powder to a black colloidal liquid due to moisture absorption.

[0209] Table 1 Study results of stability of ammonium ferric citrate and ammonium ferric citrate-fumaric acid complex B under high humidity

Sample	Day 0		Day 5		Day 10	
	Weight gain after moisture absorption/%	Sample appearance	Weight gain after moisture absorption/%	Sample appearance	Weight gain after moisture absorption/%	Sample appearance
Ammonium ferric citrate	0	Rust-colored powder	19.99	Black colloidal liquid	19.83	Black colloidal liquid
Ammonium ferric citrate-fumaric acid complex B	0	Tan powder	11.67	Tan powder	11.64	Tan powder

[0210] (2) With regard to the chemical stability of ammonium ferric citrate and ammonium ferric citrate-fumaric acid complex B, the samples were mainly investigated

for the content change of Fe (II) in ammonium ferric citrate and the complex thereof under illumination conditions, and the results were as shown in Table 2. The results showed that under the illumination conditions, the $\Delta\text{Fe (II)}$ content in the ammonium ferric citrate-fumaric acid complex B on day 10 was reduced by about 16.25% (this value = $[\Delta\text{Fe (II) in ammonium ferric citrate} - \Delta\text{Fe (II) in ammonium ferric citrate-fumaric acid complex}] / \Delta\text{Fe (II) in ammonium ferric citrate} * 100\%$) compared to that of ammonium ferric citrate, indicating obviously enhanced stability.

[0211] Table 2 Study results of stability of ammonium ferric citrate and ammonium ferric citrate-fumaric acid complex B under illumination

	Day 0		Day 5		Day 10	
	Fe (II) content/%	$\Delta\text{Fe (II)}/\%$	Fe (II) content/%	$\Delta\text{Fe (II)}/\%$	Fe (II) content/%	$\Delta\text{Fe (II)}/\%$
Ammonium ferric citrate	0.37	0	1.09	0.72	1.17	0.80
Ammonium ferric citrate- fumaric acid complex B	0.27	0	0.75	0.48	0.94	0.67

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[0212] **Example 3** Effect of ammonium ferric citrate-fumaric acid complex on growth performance and diarrhea of piglets

[0213] One hundred and forty of 45-day-old Duroc×Landrace×Yorkshire heterozygous lean piglets with similar weights were randomly divided into 7 treatment groups, with 2 replicates per group and 10 piglets per replicate (half male and half female). The specific grouping was as shown in Table 3. Pigsty and utensils were disinfected before the experiment. In the experimental period, the animals were held in separate pens in the same pigsty under the same raising and management conditions. During the experiment, the experimental piglets had free access to food and water. Group A was the blank control group, and provided with nursery feeds only; and experimental groups B-D were provided with nursery feeds containing different addition amounts of ammonium ferric citrate respectively; and experimental groups E-G were provided with nursery feeds containing different addition amounts of the ammonium ferric citrate-fumaric acid complex B (abbreviated as “complex B”) prepared in example 1. No additional antioxidant ingredients and growth promoters were added to each experimental group throughout the raising process. The experimental period was 28 days, and the growth performance of the experimental piglets was recorded. The average daily feed intake (ADFI, g/d*the number of piglets), average daily gain (ADG, g/d*the number of piglets), feed conversion ratio (FCR) and diarrhea rate of the experimental piglets were expressed as “mean values”, as shown in Table 3.

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[0214] Feed conversion ratio (FCR) = average daily feed intake/average daily gain;

[0215] Weight gain rate = (experimental group ADG - control group ADG)/control group ADG*100%;

[0216] Feed intake increase rate = (experimental group ADFI - control group ADFI)/control group ADFI*100%;

[0217] Feed conversion ratio decrease rate = (control group FCR - experimental group FCR)/control group FCR*100%;

- 5 [0218] Diarrhea ameliorating rate = (diarrhea rate of experimental group-diarrhea rate of control group)/diarrhea rate of control group*100%.

[0219] Table 3 Effect of ammonium ferric citrate-fumaric acid complex on growth performance of piglets

Item	Sample/addition amount (g/kg)	Number of experiments	ADFI	ADFI increase rate (%)	ADG	Weight gain rate (%)	FCR	Feed conversion ratio decrease rate (%)	Diarrhea rate (%)	Diarrhea ameliorating rate (%)
Group A	0	10*2	713	-	366	-	1.95	-	33.33	-
Group B	Ammonium ferric citrate/250	10*2	808	13.32	449	22.68	1.80	7.69	25.54	23.37
Group C	Ammonium ferric citrate/500	10*2	814	14.17	461	25.96	1.77	9.23	18.37	44.88
Group D	Ammonium ferric citrate/1000	10*2	822	15.29	477	30.33	1.72	11.79	10.32	69.04
Group E	Complex B/250	10*2	823	15.43	452	23.50	1.82	6.67	27.53	17.40
Group F	Complex B/500	10*2	830	16.41	472	28.96	1.76	9.74	20.51	38.46
Group G	Complex B/1000	10*2	815	14.31	486	32.79	1.68	13.85	10.28	69.16

- 10 [0220] From the above-mentioned experimental results, it could be seen that the experimental groups provided with the nursery feeds containing ammonium ferric citrate or the fumaric acid complex thereof had obvious effects on improving the feed intake, average daily gain, feed conversion ratio and diarrhea rate of the experimental piglets compared to those in the blank control group.
- 15 [0221] The experimental piglets provided with the nursery feeds containing ammonium ferric citrate had an increase of 13.62%-15.29% in the feed intake, an increase of 22.68%-30.33% in the body weight, a feed conversion ratio decrease rate of 7.69%-11.79%, and a decrease of 23.37%-69.04% in the diarrhea rate.
- 20 [0222] The experimental piglets provided with the nursery feeds containing the ammonium ferric citrate-fumaric acid complex had an increase of 14.31%-16.41% in the feed intake, an increase of 23.50%-32.79% in the body weight, a feed conversion ratio decrease rate of 6.67%-13.85%, and a decrease of 17.40%-69.16% in the diarrhea rate.
- 25 [0223] From the effect of the ammonium ferric citrate-organic acid complex on the growth performance and diarrhea rate of the experimental piglets, it could be seen that the ammonium ferric citrate-organic acid complex has farming effects comparable to or even more excellent than ammonium ferric citrate, particularly had a better effect at 500-1000 ppm, and could be used as an equivalent substitute of ammonium ferric citrate in feeds for pigs. In addition, the results of comparison with the blank control group further showed that the ammonium ferric citrate-fumaric acid complex increased the growth rate

of the experimental piglets and increased the feed reward by increasing the feed intake and feed conversion rate of the experimental piglets, and could be used as a new feed additive in the farming of pigs.

5 [0224] **Example 4** Effect of ammonium ferric citrate-fumaric acid complex on growth performance of broilers

[0225] In the experiment, single-factor randomized design was used. Two hundred and forty of 1-day-old three-yellow broilers (yellow-feather broilers) with similar weights (average weight of 50 g) were randomly divided into 4 treatment groups, with 3 replicates per group and 20 three-yellow broilers (yellow-feather broilers) per replicate 10 (half male and half female). The grouping was as shown in Table 4. Chicken houses and utensils were disinfected before the experiment. In the experimental period, the animals were caged in the same chicken house under the same raising and management conditions. The basal diet was mainly corn-soybean meal, and no additional antioxidant ingredients and growth promoters were added throughout the raising process. Experimental group A 15 was the blank control group, and provided with the basal diet only, and experimental groups B-D were provided with the basal diet plus different doses of the ammonium ferric citrate-fumaric acid complex B respectively, as shown in Table 4. The experimental period was 20 days in total. The experimental broilers had free access to food and water, and were fed twice a day. With each replicate as one unit, the broilers were weighed at 20 21 days of age (withholding feeds for 12 h, but allowing access to water), the feed consumption of the experimental broilers was recorded, and the average daily feed intake (ADFI, g/d*the number of broilers), average daily gain (ADG, g/d*the number of broilers) and feed conversion ratio (FCR) of the experimental broilers in each group were calculated according to the following calculation formulas:

25 [0226] Feed conversion ratio (FCR) = average daily feed intake/average daily gain;

[0227] Weight gain rate = (experimental group ADG - control group ADG)/control group ADG*100%;

[0228] Feed intake increase rate = (experimental group ADFI - control group ADFI)/control group ADFI*100%;

30 [0229] Feed conversion ratio decrease rate = (control group FCR - experimental group FCR)/control group FCR*100%.

[0230] The experimental results were as shown in Table 4. It could be seen from the results that compared to the control group,

35 [0231] the experimental broilers in the experimental groups provided with the basal diet plus the ammonium ferric citrate-fumaric acid complex B had an increase of 6.96%-22.47% in the feed intake and an increase of 11.72%-32.03% in the average daily gain, which displayed an upward trend with the increase of the doses, and had a decrease of about 4.45%-7.29% in the feed conversion ratio, indicating an increase in the feed conversion rate.

40 [0232] It could be seen therefrom that the use of the ammonium ferric citrate-fumaric acid complex B in the feed for broilers could effectively promote the growth of the experimental broilers, increase the feed reward, and be used as a feed additive (for effectively promoting the growth of broilers) in feeds for broilers, thereby improving the farming efficiency and benefits.

[0233] Table 4 Application effect of ammonium ferric citrate-fumaric acid complex B in feeds for broilers

Item	Sample/addition amount (g/t)	ADFI (g/d*the number of broilers)	ADFI increase rate (%)	ADG (g/d*the number of broilers)	Weight gain rate (%)	FCR	Feed conversion ratio decrease rate (%)
Group A	0	31.6	-	12.8	-	2.47	-
Group B	Complex/100	33.8	6.96	14.3	11.72	2.36	4.45
Group C	Complex/200	34.9	10.44	15.1	17.97	2.31	6.48
Group D	Complex/400	38.7	22.47	16.9	32.03	2.29	7.29

[0234] **Example 5** Study on use of ammonium ferric citrate-fumaric acid complex B in feeds for meat ducks

[0235] Single-factor experimental design was used. Four hundred and eighty of 1-day-old Cherry valley meat ducks with substantially the same weight and good health status were selected and randomly divided into 4 treatment groups, with 6 replicates per group and 20 ducks per replicate. The control group was a blank feed group, and fed with a basal diet (corn-soybean meal type); and the other 4 treatment groups were all sample addition groups, and provided with the basal diet plus different doses of the ammonium ferric citrate-organic acid complex B respectively. The experimental period was 42 days in total. See Table 5 for specific animal grouping. During the experiment, the experimental ducks had free access to food and water, and were immunized according to conventional immunization procedures, and the feed intake, feed consumption, preclusion due to death, etc. in each group were observed and recorded every day. The ducks were weighed on an empty stomach at the beginning and end of the experiment. After the end of the experiment, with each replicate as one unit, the average daily gain, average daily feed intake and feed conversion ratio were statistically analyzed for each treatment group, and the results were as shown in Table 5.

[0236] It could be seen from the results as shown in Table 5 that the addition of the ammonium ferric citrate-fumaric acid complex B to the feed for 1-42 day-old Cherry valley meat ducks could significantly improve the production performance of the meat ducks, and at the experimental doses, the feed intake, weight gain rate and feed conversion ratio decrease rate were 2.40%-6.24%, 7.64%-15.72% and 4.78%-8.26% respectively. It could be seen that the ammonium ferric citrate-fumaric acid complex B could increase the feed intake and reduce the feed conversion ratio of the experimental ducks, that is, increase the feed conversion rate, thereby promoting the growth of the experimental ducks by increasing the feed intake and feed conversion thereof, and further increasing the feed reward, and could be used as a feed additive for promoting the growth of meat ducks.

[0237] Table 5 Application effect of ammonium ferric citrate-fumaric acid complex B in feeds for meat ducks

Item	Sample/addition amount (ppm)	Average daily feed intake (g/d)	Feed intake increase rate (%)	Average daily gain (g/d)	Weight gain rate (%)	Feed conversion ratio	Feed conversion ratio decrease rate (%)
Group A	0	178.06	-	77.35	-	2.30	-
Group B	Complex/100	182.33	2.40	83.26	7.64	2.19	4.78
Group C	Complex/200	183.95	3.31	86.57	11.92	2.12	7.83
Group D	Complex/400	189.17	6.24	89.51	15.72	2.11	8.26

[0238] The above examples merely represent several embodiments of the present invention, giving specifics and details thereof, but should not be understood as limiting the scope of the present patent of invention thereby. It should be noted that a person of ordinary skill in the art could also make several alterations and improvements without departing from the spirit of the present invention and these would all fall within the scope of protection of the present invention. Therefore, the scope of protection of the present patent of invention shall be in accordance with the appended claims.

Claims

1. An ammonium ferric citrate-organic acid complex or a salt thereof, wherein the complex comprises ammonium ferric citrate and an organic acid, wherein the organic acid is selected from fumaric acid, maleic acid, succinic acid, malonic acid, oxalic acid, benzoic acid, sorbic acid, or an acidic amino acid, wherein the acidic amino acid is selected from glutamic acid or aspartic acid; preferably, the organic acid is fumaric acid or maleic acid; and more preferably, the salt of the ammonium ferric citrate-organic acid complex is a sodium salt of the ammonium ferric citrate-organic acid complex.
2. The ammonium ferric citrate-organic acid complex or the salt thereof according to claim 1, wherein the complex or the salt thereof further comprises at least one solvent capable of solvating ammonium ferric citrate and the organic acid; preferably, the solvent is selected from water, methanol, ethanol, an aqueous methanol solution, or an aqueous ethanol solution; more preferably, the ammonium ferric citrate-organic acid complex or the salt thereof is used as a drug, a feed, or a food; and further preferably, the ammonium ferric citrate-organic acid complex or the salt thereof is used as a drug for preventing and treating diarrhea in an animal.
3. A method for preparing the ammonium ferric citrate-organic acid complex or the salt thereof according to claim 1 or 2, comprising the following steps:
- (1) dissolving an organic acid or a salt thereof to obtain a solution of the organic acid or the salt thereof;
 - (2) dissolving ammonium ferric citrate to obtain a solution of ammonium ferric citrate;
 - (3) adding the solution of ammonium ferric citrate to the solution of the organic acid or the salt thereof to obtain a reaction solution, and stirring the reaction solution for 1-4 h while heating;
 - (4) stirring the reaction solution obtained in step (3) at room temperature for 4-15 h; and
 - (5) filtering the reaction solution obtained in step (4), and concentrating and drying the resulting filtrate to obtain the ammonium ferric citrate-organic acid complex or the salt thereof.
4. The preparation method according to claim 3, wherein the molar ratio of the ammonium ferric citrate to the organic acid in the preparation method is 1:1-3:1; preferably, the molar ratio of the ammonium ferric citrate to the organic acid is 2:1; preferably, the heating is performed at a temperature of 25°C-60°C; and more preferably, the organic acid is fumaric acid or maleic acid.
5. A composition, wherein the composition comprises the ammonium ferric citrate-organic acid complex or the salt thereof according to claim 1 or 2; and preferably, the composition is used as a drug, a feed, or a food.

6. A composition acceptable in feeds, wherein the composition comprises the ammonium ferric citrate-organic acid complex or the salt thereof according to claim 1 or 2, and one or more of a carrier, an excipient, a diluent, or a vehicle acceptable in feeds;
5 and preferably, the composition further comprises an additional feed additive and/or a feed raw material, and more preferably, the feed additive is selected from a nutritive feed additive or a non-nutritive feed additive.
7. An edible composition, wherein the edible composition comprises the ammonium
10 ferric citrate-organic acid complex or the salt thereof according to claim 1 or 2, and a nutriologically acceptable adjuvant; and preferably, the composition further comprises an additional dietary supplement and/or a food additive and/or a food raw material.
8. A pharmaceutical composition, wherein the pharmaceutical composition comprises
15 the ammonium ferric citrate-organic acid complex or the salt thereof according to claim 1 or 2, and a pharmaceutically acceptable adjuvant, and preferably, the composition further comprises an additional drug for treating diarrhea in an animal.
9. Use of the ammonium ferric citrate-organic acid complex or the salt thereof
20 according to claim 1 or 2 or the composition according to any one of claims 5-8 as an animal feed additive or in the preparation of an animal feed additive, wherein preferably, the animal feed additive is selected from an animal iron supplement and/or an animal growth promoter.
10. Use of the ammonium ferric citrate-organic acid complex or the salt thereof
25 according to claim 1 or 2 or the composition according to any one of claims 5-8 as a food additive or in the preparation of a food additive, wherein preferably, the food additive is a food iron fortifier.
11. Use of the ammonium ferric citrate-organic acid complex or the salt thereof
30 according to claim 1 or 2 or the composition according to any one of claims 5-8 in the preparation of a drug for preventing and treating diarrhea in an animal.
12. A method for feeding an animal, comprising applying to the animal the ammonium
35 ferric citrate-organic acid complex and/or the salt thereof according to claim 1 or 2, or the composition according to any one of claims 5-8.