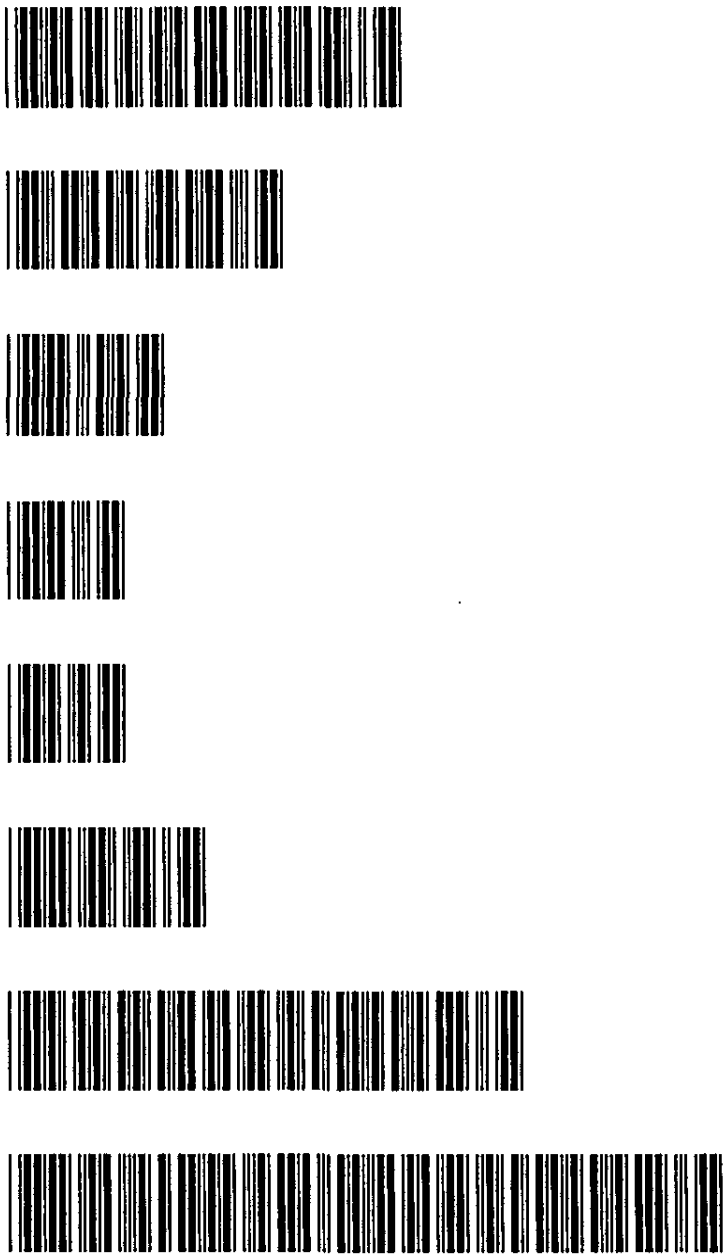
US DISTRICT COURT INDEX SHEET



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DEPUTY

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

'06 CV 0153 JM RBB

ALLTECH, INC., a Kentucky corporation, Plaintiff, v. CENZONE TECH, INC., a California corporation; JUNG FU WU, an individual, Defendants.	Civil Action No. COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff ALLTECH, INC. ("ALLTECH") hereby complains of Defendants CENZONE TECH, INC., ("CENZONE") and JUNG FU WU ("WU"), an individual, and alleges as follows:

JURISDICTION AND VENUE

1. This action arises under the Patent Laws of the United States, Title 35 of the United States Code.

2. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1332 and 1338(a), in that this action involves both a federal question as well as a civil action between citizens of different states in which the amount in controversy exceeds $75,000.

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3. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) in that Defendants CENZONE and WU reside in this judicial district.

THE PARTIES

4. Plaintiff ALLTECH is a corporation organized and existing under the laws of the State of Kentucky, having its principal place of business at 3031 Catnip Hill Pike, Nicholasville, KY 40356.

5. ALLTECH is a multinational biotechnology company involved in the research and development of natural products for the feed industry and food industry. Among the products developed and sold by ALLTECH are natural additives for animal feed products. ALLTECH has conducted extensive research and development in the area of animal feed products and has secured proprietary rights, including U.S. patents, to this technology. ALLTECH is also in the business of selling animal feed products.

6. ALLTECH is informed and believes, and thereon alleges, that Defendant CENZONE is a corporation organized and existing under the laws of the State of California, having a place of business in this judicial district at 2110 Low Chaparral Drive, San Marcos, CA 92069. CENZONE also operates a website at www.cenzone.com advertising its products.

7. ALLTECH is informed and believes, and thereon alleges, that Defendant WU resides within this judicial district.

8. ALLTECH is informed and believes, and thereon alleges, that Defendants CENZONE and WU conduct business throughout the United States, including in this judicial district, and have committed the acts complained of in this judicial district and elsewhere.

ALLEGATIONS FOR ALL CLAIMS FOR RELIEF

9. On April 4, 2000, the PTO duly and lawfully issued U.S. Patent No. 6,045,834 entitled "Compositions and Methods for Removal of Mycotoxins from Animal Feed" (the "834 patent"). ALLTECH is the owner by assignment of the '834 patent. A true and correct copy of the '834 patent is attached hereto as Exhibit A.

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10. ALLTECH is informed and believes, and thereon alleges, that CENZONE through its agents, employees and servants, has infringed ALLTECH's rights in the '834 patent through, *inter alia*, making, using, selling, and/or offering to sell feed additives, including a product referred to as Microbond, that infringe one or more claims of the '834 patent. Upon information and belief, CENZONE has induced others to infringe the '834 patent. Furthermore, this infringement has been willful, CENZONE having received actual notice of ALLTECH's patent rights.

11. ALLTECH is informed and believes, and thereon alleges, that WU, as the president of CENZONE, has personally participated in and/or actively directed the actions of CENZONE complained of herein and has also induced infringement of one or more claims of the '834 patent.

12. ALLTECH has not authorized CENZONE or WU to make, use, sell, offer to sell, or import any product or method claimed in the '834 patent.

I. FIRST CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 6,045,834)

13. ALLTECH repeats, realleges, and incorporates by reference the allegations set forth in paragraphs 1 through 12 of this Complaint as though fully set forth herein.

14. This is a claim for patent infringement against CENZONE and WU and arises under the Patent Laws of the United States, Title 35 of the United States Code.

15. CENZONE, through its agents, employees and servants, has been and is currently infringing the '834 patent by making, using, selling, and/or offering to sell feed additives covered by at least one claim of the '834 patent and/or by inducing others to infringe the '834 patent These acts of CENZONE constitute infringement of the '834 patent in violation of 35 U.S.C. § 271.

16. ALLTECH is informed and believes, and thereon alleges, that WU has been and is currently infringing the '834 patent by making, using, selling, and/or offering to sell feed additives covered by at least one claim of the '834 patent and/or by inducing others to

01/23/2006 13:01 FAX 949 760 9502 KMOB O.C. 008

infringe the '834 patent These acts of WU constitute infringement of the '834 patent in violation of 35 U.S.C. § 271.

17. ALLTECH is informed and believes, and thereon alleges, that CENZONE and/or WU was aware of the '834 patent before introduction of the Microbond product.

18. ALLTECH is informed and believes, and thereon alleges, that the infringement by CENZONE and WU will continue unless enjoined by this Court.

19. ALLTECH is informed and believes, and thereon alleges, that the infringement by CENZONE and WU has been willful.

20. ALLTECH is informed and believes, and thereon alleges, that CENZONE and WU have derived and received, and will continue to derive and receive, gains, profits and advantages from the aforesaid acts of infringement in an amount that is not presently known to ALLTECH. By reason of the aforesaid infringing acts, ALLTECH has been damaged and is entitled to monetary relief in an amount to be determined at trial.

21. Because of the aforesaid infringing acts, ALLTECH has suffered and continues to suffer great and irreparable injury, for which ALLTECH has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, ALLTECH prays that the Court enter judgment in its favor against Defendants CENZONE and WU as follows:

A. Finding that CENZONE and WU have willfully infringed the '834 patent under 35 U.S.C. § 271;

B. Preliminarily and permanently enjoining CENZONE and WU, any officers, agents, servants, employees and attorneys, and those persons in active concert or participation with CENZONE and/or WU, from directly or indirectly infringing the '834 patent in violation of 35 U.S.C. § 271;

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C. Awarding ALLTECH its damages proven at trial, and in no event less than a reasonable royalty, for CENZONE and WU's infringement of the '834 patent pursuant to 35 § U.S.C. 284;

D. Awarding ALLTECH treble damages and/or exemplary damages because of CENZONE and WU's willful conduct pursuant to 35 U.S.C. § 284;

E. Finding this case to be an exceptional case and awarding to ALLTECH against CENZONE and WU its attorneys' fees and costs incurred in connection with this action pursuant to 35 U.S.C. § 285;

F. Awarding pre-judgment and post-judgment interest and costs of this action to ALLTECH against CENZONE and WU; and

G. Such other and further relief as this Court may deem just and proper.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 1/23/06

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Exhibit A

US006045834A

United States Patent [19]

Howes et al.

[11] **Patent Number: 6,045,834**

[45] **Date of Patent: Apr. 4, 2000**

[54] **COMPOSITIONS AND METHODS FOR REMOVAL OF MYCOTOXINS FROM ANIMAL FEED**

[75] Inventors: **A. Dean Howes**, Nampa, Id.; **Kyle E. Newman**, Corinth, Ky.

[73] Assignee: **Alltech, Inc.**, Nicholasville, Ky.

[21] Appl. No.: **09/293,068**

[22] Filed: **Apr. 16, 1999**

Related U.S. Application Data

[60] Provisional application No. 60/082,134, Apr. 17, 1998.

[51] **Int. Cl.**[7] **A23K 1/06**

[52] **U.S. Cl.** **426/2**; 426/656; 426/807

[58] **Field of Search** 424/406, 442; 435/259, 255.1; 426/2, 286, 335, 656, 655, 623, 807

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,961,080	6/1976	Sugimoto et al.	426/60
4,251,519	2/1981	Robbins et al.	424/180
4,765,992	8/1988	Gencix et al.	426/15
5,149,549	9/1992	Beggs	426/2
5,165,946	11/1992	Taylor et al.	426/74
5,192,547	3/1993	Taylor	424/438
5,639,492	6/1997	Turk et al.	426/2
5,922,373	7/1999	Johnston	426/2

FOREIGN PATENT DOCUMENTS

0551331B1	11/1995	European Pat. Off. .
0721741	1/1996	European Pat. Off. .

OTHER PUBLICATIONS

H.J. Peppler, "Production of Yeasts and Yeasts Products," Microbial Technology, 2nd ed., Academic Press, Inc., p. 159–185, (1979) vol. 1.

Primary Examiner—Keith D. Hendricks
Attorney, Agent, or Firm—King and Schickli, PLLC

[57] **ABSTRACT**

A method of removing mycotoxins from animal feeds is described whereby a combination of a modified yeast cell wall extract and a mineral clay is fed to animals in amounts sufficient to inactivate mycotoxins present in the feeds. The yeast cell wall extract/clay mixture may be admixed with feeds, incorporated directly into pelleted feeds, or fed directly to animals.

21 Claims, No Drawings

EXHIBIT A PAGE 1 OF 5

COMPOSITIONS AND METHODS FOR REMOVAL OF MYCOTOXINS FROM ANIMAL FEED

This application claims the benefit of priority in provisional application Ser. No.: 60/082,134, filed on Apr. 17, 1998.

FIELD OF THE INVENTION

The present invention is directed to compositions and methods for reducing or ameliorating the absorption of a variety of mycotoxins in animal feeds, thus improving nutritional quality of the feeds and subsequent health and performance of animals consuming them. In particular, the compositions of the invention are comprised of a combination of a modified yeast cell wall extract and a clay, e.g., a zeolite, bentonite, or other aluminosilicate clay. This combination has a surprising and unexpected additive binding effect for reducing mycotoxin contamination in animal feedstuffs.

BACKGROUND OF THE INVENTION

Every year a substantial percentage of the world's grain and hay supply for animal feeds is contaminated by toxins produced by invading molds. Decreased feed nutritive value and instances of animal poisoning are most often traced to growth of various species of Aspergillus, Fusarium, and Penicillium in stored grain or other feeds. Mycotoxins affect feed nutritive value, livestock performance, and animal health. Mycotoxin contaminated feeds are considerably less palatable to the animal, and the resulting decreased intake levels may exacerbate poor performance and/or toxicity problems.

Mycotoxin formation may occur when the causative fungi grow on crops in the field, at harvest, in storage, or during feed processing; essentially whenever favorable conditions for their formation prevail. Generalizations about geographical distribution of particular types of mycotoxins are difficult due to widespread distribution of the causative fungi. However, aflatoxins and fumonisin tend to prevail in warmer climates, while cooler regions with higher moisture are subject to ochrutoxin, zearalenone, vomitoxin (deoxynivalenol, DON), T2 toxin, and others. Each mycotoxin has its own particular effect, and all can be devastating. Co-contamination by one or more types of mycotoxin occurs naturally, and exerts a greater negative impact on health and productivity of livestock than contamination by individual mycotoxins.

The physical effects of mycotoxins range from reduced feed intake and poor feed conversion to a general inability of an animal to thrive. Symptoms vary according to toxin. Vomitoxin, called the feed refusal factor, affects mainly pigs. Zearalenone affects the reproductive organs of pigs and dairy cattle. Fumonisin causes a nervous disorder in horses due to its impact in the brain. Ochratoxin causes kidney damage. Poultry and pigs are sensitive to ochratoxin, whereas dairy cattle can tolerate higher levels of ochratoxin because of its biotransformation into a nontoxic form by ruminal bacteria. Aflatoxins, the most common mycotoxin, cause increased susceptibility to disease. At the organ or cellular level mycotoxins differ in their effects with severe damage done to the liver and kidney by aflatoxins and on reproductive organs by zearalenone. Other indices of mycotoxicosis include mammary gland swelling and ovarian atrophy (zearalenone), oral lesions in chicks (T2 toxins), nervous system disorders and necrosis of the extremities

(ergot alkaloids). Mycotoxins may also impact human health, as many are transferred into milk or meat following ingestion by the animal. For example, aflatoxins appear in milk as aflatoxin M1, a metabolite.

Acute symptoms of mycotoxicosis are often relatively easy to identify. However, chronic symptoms including slightly diminished performance and/or immunosuppression may result in greater economic losses. Traditional methods of dealing with mycotoxins include use of mold inhibitors to prevent mold growth in stored feeds. However, particularly in the livestock industries, economic circumstances force producers to find ways to use mycotoxin-contaminated feeds. Common methods have included dilution of contaminated feeds with feedstuffs known to be free of mycotoxins, physical separation to remove highly contaminated feeds, and ammoniation or heating to detoxify the feeds. These methods are labor-intensive and uneconomical, and may be ineffective against certain mycotoxins.

A more viable method of dealing with mycotoxin-contaminated feeds is to blend in substance capable of binding out the toxins, thus preventing absorption of the toxins into the animal's bloodstream. Few chemicals have proven successful enough to use commercially. Among these, use of mineral clays as binders has proven common. For example, U.S. Pat. No. 5,149,549 teaches the use of a montmorillonite clay, particularly a bentonite clay, admixed with animal feeds as a mycotoxin binder. U.S. Pat. No. 5,165,946 teaches the use of a montmorillonite clay in combination with a suitable sequestrant, particularly phosphate and polyphosphate salts, as a mycotoxin binder. U.S. Pat. No. 5,639,492 further refines the art, teaching the use of an acid-activated calcium bentonite clay admixed with animal feeds to reduce effects of mycotoxin contamination. However, clays as mycotoxin binders have significant limitations. Clays must be included in animal feeds at high levels to effect significant mycotoxin binding. Additionally, most clays have a limited binding efficacy range, binding only aflatoxins to any significant extent Further, in domestic livestock production situations, excreted clays may cause problems with clogging of manure handling equipment. Thus, a need exists for a mycotoxin-binding agent, effective against a wide range of mycotoxins, which can be admixed with animal feeds at lower inclusion rates than is currently possible with substances commonly used to bind mycotoxins in feeds.

SUMMARY OF THE INVENTION

Accordingly, it is a primary object of the present invention to provide a method for binding and consequent inactivation of mycotoxins present in common animal feedstuffs.

It is a further object of the present invention to provide a method for binding and inactivation of mycotoxins present in animal feeds comprising a combination of a modified yeast cell wall extract and a mineral clay such as a zeolite or bentonite clay, or aluminum silicate.

Yet another object of the present invention is to provide a composition comprising a combination of a modified yeast cell wall extract and a mineral clay as described above which provides a surprising and unexpected additive binding effect for reducing mycotoxin contamination in animal feedstuffs.

Still another object of the present invention is to provide a composition comprising a combination of modified yeast cell wall extract and a mineral clay as described above which may be admixed with animal feeds at lower inclusion rates than are required for other commonly available mycotoxin-binders suitable for inclusion in animal feeds.

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Additional objects, advantages and other novel features of the invention will be set forth in part in the description that follows and in part will become apparent to those skilled in the art upon examination of the following or may be learned with the practice of the invention. The objects and advantages of the invention may be realized and obtained by means of the instrumentalities and combinations particularly pointed out in the appended claims.

To achieve the foregoing and other objects, and in accordance with the purposes of the present invention as described herein, a novel method is described for binding mycotoxins present in animal feeds. In particular, in a preferred embodiment, the invention provides a method and a composition for binding mycotoxins present in animal feed rations encompassing a modified yeast cell wall extract and aluminosilicate. The yeast cell wall is extracted from a yeast organism which can be any of a number of yeasts. The aluminosilicate is a standard commercial grade available from a variety of sources.

The compositions provided by the invention can be fed to any animal including, but not limited to, avian, bovine, porcine, equine, ovine, caprine, canine, and feline species. When admixed with feed or fed as a supplement, the compositions with their surprisingly increased mycotoxin-binding capacity, decrease absorption or uptake of the mycotoxins by the affected animal, thereby improving performance and health, and reducing the incidence of mycotoxin-associated diseases.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is based upon the surprising discovery that a yeast cell wall-derived extract in combination with a mineral clay provides an unexpected additive binding effect on mycotoxins in animal feeds. Thus, the invention provides a method and a composition for binding mycotoxins present in animal feeds utilizing a yeast cell wall extract/clay combination.

The yeast organism used for the composition of the present invention may be any of a number of edible yeasts including, but not limited to, Saccharomyces, Candida, Kluyveromnyces, or Torulaspora species. In a preferred embodiment, the yeast used is *Saccharomyces cerevisiae* strain 1026. The yeast cell wall extract is obtained by methods commonly known in the art (See, Peppler, H. J. 1979. Production of yeasts and yeast products. Page 157 in: Microbial Technology & Microbial Processes, Vol.1 (2d Ed.), Academic Press).

Briefly, the yeast organism is grown following common techniques used in food-related fermentations and the beverage industries. Any of a number of common sugar-containing media, such as diluted molasses, may be used to provide a source of sugars for growth of the yeasts. Other media which may be employed include wood sugars, sulfite waste liquor, and whey. The yeast biomass may then be separated and washed by centrifugation to yield a yeast cream.

Following separation, the organism is lysed. Any of a number of methods common in the art may be utilized to lyse the yeast organisms, including autolysis and hydrolysis. A preferred embodiment of the current invention allows the yeast organisms to autolyse at room temperature and pressure over a 12–24 hr period. A protease such as papain or any of a number of alkaline or neutral proteases may be added during the lysis phase to accelerate solubilization of yeast proteins and prevent agglutination of intracellular components. Following autolysis, the resultant yeast cell wall extract is washed several times by centrifugation to remove intracellular components and concentrate the extract. The resulting extract concentrate may be dried by any of a number of methods common in the art, including spray-drying or drum drying to form a hygroscopic, water-soluble powder.

The present invention also provides a method of enhancing and improving the mycotoxin-binding characteristics of a yeast cell wall extract comprising modification of the mannanoligosaccaride (MOS) portion of the cell wall by an alcohol shocking of the yeast organism during growth, e.g. during fermentation, resulting in a thickening of the yeast cell wall and an increase in the surface area available for mycotoxin binding of the resultant cell wall extract Any of a number of standard commercially available alcohols may be used, including, but not limited to methyl, ethyl, and isopropyl alcohols. In a preferred embodiment of the current invention, the alcohol-shock of the yeast organism is accomplished using ethyl alcohol. The alcohol shock of the yeast organisms can be performed by exposing the yeast organism to an environment comprising between about 5% and about 20% alcohol during growth. In a further embodiment the yeast organism is exposed to an environment comprising between 8% to 15% alcohol during growth. In a presently preferred embodiment, the yeast organism is exposed to an environment comprising between 10% and about 12% alcohol during growth.

The mineral clays used in the composition of the present invention may be any of a number of standard commercial grade clays suitable for inclusion in animal diets, including, but not limited to, zeolite and bentonite clays, or aluminosilicate. Clays may be obtained from a variety of commercial sources. In a particularly preferred embodiment, the invention comprises inclusion of alunminosilicate, available from a variety of commercial sources.

In a preferred embodiment, the composition of the present invention comprises between about 1% and about 10% aluminum silicate, and between about 90% and about 99% modified yeast cell wall extract A preferred composition of the invention comprises from between about 4% to about 8% aluminum silicate and between about 92% and about 96% yeast cell wall extract. An especially preferred embodiment of the invention comprises from between 5% to about 7% aluminum silicate and between about 93% and about 95% yeast cell wall extract. The preferred physical form of the invention is a dry, free-flowing powder suitable for direct inclusion into animal feeds or as a supplement to a total mixed ration.

The compositions provided by the present invention can be added to any commercially available feedstuffs for livestock or companion animals including, but not limited to, grains or pelleted concentrates. The composition provided by the present invention may be incorporated directly into commercially available pelleted feeds or fed supplementally to commercially available feeds. When incorporated directly into animal feeds, the present invention may be added to such feeds in amounts ranging from 0.25 to about 4 kilograms per ton of feed. In a preferred composition, the invention is added to feeds in amounts ranging from 0.5 to about 3 kilograms per ton of feed. In an especially preferred composition, the invention is added to feeds in amounts ranging from 1 to 2 kilograms per ton of feed. The composition contained in the present invention may be fed to any animal, including but not limited to, avian, bovine, porcine, equine, ovine, caprine, canine, and feline species.

The methods of the invention comprise increasing binding and removal of mycotoxins from animal feedstuffs,

01/23/2006 13:02 FAX 949 760 9502 KMOB O.C. 014

including, but not limited to, Aflatoxin, Zearalenone, Vomitoxin, Fumonisins, T2 toxin, and Ochratoxin, thereby increasing safety and nutritional value of the feed and the overall health and performance of the animal. The compositions of the invention are especially effective in increasing binding of Aflatoxin, Zearalenone, and Fumonisin compared to binding obtained with individual components of the invention alone.

The composition contained in the present invention may be added to mycotoxin-contaminated animal feedstuffs in amounts from about 0.0125% to 0.4% by weight of feed. In a preferred embodiment, the composition is added to mycotoxin-contaminated animal feedstuffs in amounts from about 0.025% to 0.2% by weight of feed. In an especially preferred embodiment, the invention is added to mycotoxin-contaminated animal feedstuffs in amounts from about 0.04% to 0.1% by weight of feed.

Alternatively, the composition contained in the present invention may be directly fed to animals as a supplement in amounts ranging from 2.5 to 20 grams per animal per day. An especially preferred embodiment comprises feeding the composition contained in the present invention to animals in amounts ranging from 10 to 15 grams per animal per day. One of skill in the art can appreciate that the amount of the composition fed can vary depending upon the animal species, size of the animal and the type of feedstuff to which the composition is to be added.

EXAMPLES

The following examples are intended to be illustrative of the invention, and are not to be considered restrictive of the scope of the invention as otherwise described herein.

Example 1

The following experiments demonstrate the in vitro mycotoxin-binding capacity of the compositions provided by the current invention. All experiments were done in aqueous solution. The specified toxins were added at concentrations of 2 μg/ml. One mg the modified yeast cell wall extract/aluminosilicate combination in a ratio of about 94% yeast cell wall extract to about 6% aluminum silicate was added to the mixture and held for one hour with vortexing. Adsorbents were removed by centrifugation.

TABLE 1

IN VITRO BINDING OF MYCOTOXINS[a]

Mycotoxin[b]	% Bound[c]
Aflatoxin B1	95.2
Fumonisin B1	19.9
Vomitoxin	9.6
T2 Toxin	26.6
Zearalenone	44.7
Ochratoxin	8.8

[a]Binding assay carried out in aqueous media over a 1 hour incubation period. Mycotoxin concentrations were analyzed using standard HPLC procedures. Adsorbent added at 1 mg/culture tube.
[b]Toxin concentration = 2 μg/ml.
[c]Compared to adsorbent-free control cultures.

The composition provided by the present invention was most effective in binding Aflatoxin, followed by Zearalenone, T2 toxin, and Fumonisin. Binding of Vomitoxin (DON) and Ochratoxin was roughly equivalent. In similar experiments, the binding capacity of the composition provided by the present invention was tested for a range of mycotoxins in contaminated feed (TABLE 2). Similar results were observed, except that binding of Fumonisin was more efficient than T2 toxin.

TABLE 2

IN VITRO ADSORPTION OF MYCOTOXINS IN CONTAMINATED FEED

Mycotoxin	Strong Binding (%)[a]
Aflatoxins	85.23
Zearalenone	66.66
Vomitoxin	12.58
Ochratoxin	12.49
T2 Toxin	33.39
Fumonisin	67.00

[a]Compared to nonspecific binding in negative control cultures.

Example 2

The following experiments compare the mycotoxin-binding capacity of the composition provided by the present invention to other adsorbents. Table 3 illustrates comparative binding of mycotoxins by the present invention compared to yeast cell debris alone. Assay procedures were similar as described for data presented in Table 1, except that mycotoxin concentrations in solution were determined using a commercially available direct competitive enzyme-linked immunosorbent assay (Veratox® Quantitative mycotoxin test).

TABLE 3

COMPARATIVE BINDING OF MYCOTOXINS[a]

	Adsorbent[b]	
Mycotoxin	Yeast Cell Wall Extract/Aluminosilicate	Yeast Cell Debris
Aflatoxin	84	24
T2 Toxin	0	5
Vomitoxin	12	0
Ochratoxin	42	0
Zearalenone	71	79

[a]Expressed as % bound compared to adsorbent-free control. Mycotoxins were added at a concentration of 2 μg/ml. Toxin concentrations were analyzed using a commercial ELISA test kit (Veratox ® Quantitative mycotoxin test).
[b]Adsorbents added at 1 mg per culture.

Compared to yeast cell debris alone, the composition provided by the present invention bound significantly more of all mycotoxins tested except for Zearalenone. Table 4 demonstrates a comparison of in vitro mycotoxin-binding capacity of the composition provided by the present invention compared to other commercial binding agents.

TABLE 4

COMPARATIVE MYCOTOXIN-BINDING CAPACITIES OF VARIOUS ADSORBENTS IN VITRO

	Mycotoxin			
Adsorbent	Aflatoxin	Zearalenone	Fumonisin	Vomitoxin
Yeast cell wall extract/ aluminosilicate	95	52	45	10
Diatomaceous Earth	47	12	17	ND[a]
Aluminosilicate	58	5	5	ND

[a]Not Done.

The composition provided by the present invention showed marked improvements in strong mycotoxin binding

EXHIBIT A PAGE 4 OF 5

compared to other binders tested. Similarly, the composition provided by the present invention markedly improved in vitro binding of Aflatoxin in contaminated poultry feed compared to binding by hydrated sodium calcium aluminosilicate (HSCAS) alone (TABLE 5).

TABLE 5

COMPARATIVE BINDING OF AFLATOXIN IN CONTAMINATED POULTRY FEED[a]

	Adsorbent: Yeast cell wall extract/aluminosilicate HSCAS[c]					
Aflatoxin[b]	0.0125	0.025	0.05	0.1	0.2	0.4
50	33	58	83	3	26	54
100	48	58	69	14	47	78
200	51	62	79	25	65	78

[a]Results expressed as % bound compared to control without adsorbent.
[b]Parts per billion.
[c]Hydrated sodium calcium aluminosilicate.

Improvements in mycotoxin binding by the composition provided by the present invention were observed at significantly lower concentrations than were required for HSCAS.

These results show that the composition provided by the present invention, i.e. a modified yeast cell wall extract in combination with a suitable mineral clay, provides an effective method for removal of mycotoxins in contaminated animal feeds at lower inclusion rates than are required for other commonly used binders.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. Obvious modifications or variations are possible in light of the above teachings. The embodiment was chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitable entitled.

What is claimed is:

1. A composition for binding and thereby inactivating a mycotoxin in an animal feed, comprising a modified yeast cell wall extract and a mineral clay.

2. The composition of claim 1, wherein the yeast cell wall is extracted from a yeast selected from the group consisting of Saccharomyces, Candida, Kluyveromyces, Torulaspora or a combination thereof.

3. The composition of claim 2, wherein the yeast cell wall extract is extracted from a *Saccharomyces cerevisiae* yeast.

4. The composition of claim 1, wherein the yeast cell wall is modified prior to extraction.

5. The composition of claim 4, wherein the yeast cell wall is modified by an alcohol shocking of the yeast thereby increasing the mycotoxin-binding capacity of the yeast cell wall.

6. The composition of claim 5, wherein the yeast cell wall is modified by exposing the yeast to a growth environment comprising from between about 5% and about 20% alcohol.

7. The composition of claim 6, wherein the yeast cell wall is modified by exposing the yeast to a growth environment comprising from between about 10% and about 12% alcohol.

8. The composition of claim 1, wherein the mineral clay is selected from the group consisting of a zeolite, a bentonite, an aluminosilicate or mixtures thereof.

9. The composition of claim 8, wherein the mineral clay is an aluminosilicate clay.

10. The composition of claim 1, wherein the composition comprises from between about 1% to about 10% of the mineral clay and from between about 90% to about 99% of the yeast cell wall extract.

11. The composition of claim 10, wherein the composition of the invention comprises form between about 2% to about 4% of the mineral clay, and from between about 96% to about 98% o the yeast cell wall extract.

12. The composition of claim 1, formulated for feeding to an animal selected from the group consisting of avian, bovine, porcine, equine, ovine, and caprine species.

13. The composition of claim 1, wherein at least a portion of the composition is bound to a mycotoxin.

14. The composition of claim 13, wherein the mycotoxin is selected from the group consisting of Aflatoxin, Zearalenone, Vomitoxin, Fumonisins, T2 toxin, and Ochratoxin.

15. An animal feed comprising a composition comprised of a modified yeast cell wall extract and a mineral clay in an amount effective to bind and thereby inactivate a mycotoxin present in the animal feed.

16. The animal feed of claim 15, wherein the effective amount of the composition comprises from between about 0.0125% to between about 4% by weight of the feed.

17. A method for reducing mycotoxin contamination of an animal consuming a feedstuff, comprising feeding to an animal an effective amount of a composition comprising a modified yeast cell wall extract and a mineral clay thereby binding and inactivating the mycotoxin in the animal feed.

18. The method of claim 17, wherein the effective amount of the composition comprises from between about 0.0125% to between about 4% by weight of the animal's daily feed ration.

19. The method of claim 17, wherein the animal is selected from the group consisting of avian, bovine, porcine, equine, ovine, and caprine species.

20. The method of claim 17, wherein the mycotoxin is selected from the group consisting of Aflatoxin, Zearalenone, Vomitoxin, Fumonisins, T2 toxin, and Ochratoxin.

21. The method of claim 17, wherein the composition is admixed with the animal feed prior to feeding.

* * * * *

EXHIBIT A PAGE 5 OF 5

AO 120 (Rev.3/04)

TO: Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court San Diego on the following Patents or Trademarks:

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
06cv153-JM(RBB)	1/23/06	United States District Court, Southern District of California
PLAINTIFF		DEFENDANT
Alltech, Inc		Cenzone Tech, Inc and Jung Fu Wu

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	6,045,834	4/4/2000	Alltech, Inc
2			
3			
4			
5			

In the above-entitled case, the following patent(s)/trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1			
2			
3			
4			
5			

In the above-entitled case, the following decision has been rendered or judgment issued:

DECISION/JUDGMENT		
CLERK	(BY) DEPUTY CLERK T. LEE	DATE 1/24/06

Copy 1 - Upon initiation of action, mail this copy to Director
Copy 2 - Upon filing document adding patent(s), mail this copy to Director
Copy 3 - Upon termination of action, mail this copy to Director
Copy 4 - Case file copy

ORIGINAL

JS 44
(Rev. 07/89)

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE SECOND PAGE OF THIS FORM.)

I. (a) PLAINTIFFS
Alltech, Inc., a Kentucky corporation

DEFENDANTS
Cenzone Tech, Inc., a California corporation; Jung Fu Wu, an individual.

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF (EXCEPT IN U.S. PLAINTIFF CASES)

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT (IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
Knobbe, Martens, Olson & Bear LLP
2040 Main Street
Fourteenth Floor
Irvine, California 92614
Phone (949)760-0404; Fax (949)760-9502

ATTORNEYS (IF KNOWN)
'06CV 0153 JM RBB

II. BASIS OF JURISDICTION (PLACE AN 'X' IN ONE BOX ONLY)
- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN 'X' IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)
(For Diversity Cases Only)

	PT	DEF		PT	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business in This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY.)
This action arises under the Patent Laws of the United States, Title 35 of the United States Code.
35:145

V. NATURE OF SUIT (PLACE AN "X" IN ONE BOX ONLY)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury - Medical Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881	PROPERTY RIGHTS	☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	☐ 820 Copyrights	☐ 450 Commerce/ICC Rates/etc.
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☒ 830 Patent	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 840 Trademark	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health	SOCIAL SECURITY	☐ 810 Selective Service
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other	☐ 861 HIA (1395ff)	☐ 850 Securities/Commodities/ Exchange
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	LABOR	☐ 862 Black Lung (923)	☐ 875 Customer Challenge 12 USC 3410
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 710 Fair Labor Standards Act	☐ 863 DIWC/DIWW (405(g))	☐ 891 Agricultural Acts
☐ 195 Contract Product Liability			☐ 720 Labor/Mgmt. Relations	☐ 864 SSID Title XVI	☐ 892 Economic Stabilization Act
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 730 Labor/Mgmt. Reporting & Disclosure Act	☐ 865 RSI (405(g))	☐ 893 Environmental Matters
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motion to Vacate Sentence	☐ 740 Railway Labor Act	FEDERAL TAX SUITS	☐ 894 Energy Allocation Act
☐ 220 Foreclosure	☐ 442 Employment	HABEAS CORPUS:	☐ 790 Other Labor Litigation	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 895 Freedom of Information Act
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General	☐ 791 Empl. Ret. Inc. Security Act	☐ 871 IRS - Third Party 26 USC 7609	☐ 900 Appeal of Fee Determination Under Equal Access to Justice
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty			☐ 950 Constitutionality of State Statutes
☐ 245 Tort Product Liability	☐ 440 Other Civil Rights	☐ 540 Mandamus & Other			☐ 890 Other Statutory Actions
☐ 290 All Other Real Property		☐ 550 Civil Rights			
		☐ 555 Prison Conditions			

VI. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)
- ☒ 1 Original Proceeding
- ☐ 2 Removal from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from another district (specify)
- ☐ 6 Multidistrict Litigation
- ☐ 7 Appeal to District Judge from Magistrate Judgment

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND $
CHECK YES only if demanded in complaint: JURY DEMAND: ☐ YES ☒ NO

VIII. RELATED CASE(S) IF ANY (See Instructions): JUDGE _____ Docket Number _____

DATE: January 23, 2006.
SIGNATURE OF ATTORNEY OF RECORD: Sheila Swaroop

::ODMA\PCDOCS\WORDPERFECT\22816\1 January 24, 2000 (3:10pm)

PAID $250.00 1/23/06
BH RCPT# 120641