United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet
https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Document Type:

☒ **National List Petition or Petition Update**

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

☐ **Technical Report**

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

Bio-Gro, Inc. and BOTRY-ZEN

Chitosan | ARMOUR-ZEN ®

National List Petition: Chitosan as an Approved Active Ingredient for Use in Organic Crop Production as Plant Disease Control

Bio-Gro, Inc: Peter Aleman (President & Owner), Breanna Grismer (Systems Coordinator & Quality Control Manager), and Katie Medel (Product Registrations & Compliance). BOTRY-ZEN (2010) Limited: Peter Foster (President & Owner) and Sonia (Microbial Specialist).

10-14-2019

CHITOSAN (ARMOUR-ZEN®)

PETITION INFORMATION PACKET

CHITOSAN (ARMOUR-ZEN®) SUMMARY

On behalf of BOTRYZEN, Bio-Gro, Inc petitions the National Organic Standards Board and National Organic Program to review approval of **Chitosan (ARMOUR-ZEN®)** as an **Approved Active Ingredient for Use in Organic Crop Production as Plant Disease Control**. The manufacturer, Botry-Zen (2010) Limited, of ARMOUR-Zen has **EPA Reg. No.: 75747-3.**

"The National Organic Program (NOP) instituted changes to the sunset review process in the fall of 2013. One goal was to re-instate majority control and thus add stability to the entire material review process. Growers and food companies need significant lead time to make substantive changes in their production processes, and the removal of key production materials on the National List can lead to difficult disruptions of their operations and potential large reductions in supply of certain organic foods, **just the opposite of both the desire of USDA and the general public in terms of growing the organic sector and increasing the supply of U.S. grown organic products."** (Harold Austin, NOSB Member and David Granatstein, WSU, February 11, 2016)

In plants, the chitosan is largely used to mimic biotic and abiotic stresses. The first study of using chitosan as an antipathogen in plants was reported by Allan and Hadwiger, where they demonstrated the fungicidal effects of chitosan on different cell wall compositions of fungi. The improvement of the defense system after applying chitin and chitosan, both in monocotyledon and dicotyledons is the center of addressing this biopolymer in multi-research area. Chitosan has been a bio-fungicide, bio-bactericide, and bio-virucide, which spurs plant defense system against the pathogen, thus inducing the immune system of plants, fruits, and vegetables. Furthermore, the growing demand for food also stimulated the increased use of industrial fertilizer, which causes serious environmental unbalance and is having catastrophic effects on human health. Therefore, the use of chitosan as a biofertilizer is considered. Chitosan has been reported to have a positive effect on rhizobacteria growth, where Chitosan possesses a symbiotic relation with growth promoting rhizobacteria, thus triggered germination rate and improving plant nutrient uptake. (Rahat Sharif, Muhammad Mujtaba, Mati Ur Rahman, Abdulla Shalmani, Husain Ahmad, Toheed Anwar, Deng Tianchan, Xiping Wang, 2018 Apr 10)

Dr. Lee A. Hadwiger, Professor of Plant Pathology, Washington State University says: "I hope that the new systems will make possible the commercial use of natural components even if some modifications involving commercial processing is required to arrive at a compound that is present in nature. My example is chitosan. This material is present in nature and has some very valuable agricultural properties. In nature the compound chitin that is the most prevalent carbohydrate on earth (besides cellulose) is derived converted in nature to chitosan by a chitin deacetylase." (Harold Austin, NOSB Member and David Granatstein, WSU, February 11, 2016)

"Chitin deacetylases, occurring in marine bacteria, several fungi and a few insects, catalyze the deacetylation of chitin, a structural biopolymer found in countless forms of marine life, fungal cell and spore walls as well as insect cuticle and peritrophic matrices. The deacetylases recognize a sequence of four GlcNAc units in the substrate, one of which undergoes deacetylation: the resulting chitosan has a more regular deacetylation pattern than a chitosan treated with hot NaOH. Nevertheless, plain chitin is a poor substrate, but glycolate, reprecipitated or depolymerized chitins are good ones. The marine *Vibrio* sp. colonize the chitin particles and decompose the chitin thanks to the concerted action of chitinases and deacetylases, otherwise they could not tolerate chitosan, a recognized antibacterial biopolymer. In fact, chitosan is used to prevent infections in fishes and crustaceans. Considering that chitin deacetylases play very important roles in the biological attack and defense systems, they may find applications for the biological control of fungal plant pathogens or insect pests

in agriculture and for the biocontrol of opportunistic fungal human pathogens." (Yong Zaho, Ro-Dong Park, and Riccardo A. A. Muzzarelli, 2010., Jan 14)

Dr. Lee A. Hadwiger says: "Commercially chitosan undergoes the same modification of chitin via a chemical deacetylation. The acquisition of chitosan from nature is not feasible but chitin is available in vast quantities as a by-product of crab and shrimp shell wastes and as a result can be attained at a feasible cost for agriculture use. Chitosan can be and has been consumed at rates of 500 to a thousand milligrams per day safely by humans trying to reduce weight. It only seems plausible that its use as a substitute for some copper fungicides would be a boon to the interests of organic growers. Yet chitosan has never been approved for use by the NOP. The logic of their decisions is scientifically illogical." (Harold Austin, NOSB Member and David Granatstein, WSU, February 11, 2016)

"Moreover, chitosan treatment regulates several genes in plants, particularly the activation of plant defense signaling pathways. That includes the elicitation of phytoalexins and pathogenesis-related (PR) protein. Besides that, chitosan has been employed in soil as a plant nutrient and has shown great efficacy in combination with other industrial fertilizers without affecting the soil's beneficial microbes. Furthermore, it is helpful in reducing the fertilizer losses due to its coating ability, which is important in keeping the environmental pollution under check. Based on exhibiting such excellent properties, there is a striking interest in using chitosan biopolymers in agriculture systems. Therefore, our current review has been centered upon the multiple roles of chitosan in horticultural crops that could be useful in future crop improvement programs." (Rahat Sharif, Muhammad Mujtaba, Mati Ur Rahman, Abdulla Shalmani, Husain Ahmad, Toheed Anwar, Deng Tianchan, Xiping Wang, 2018 Apr 10)

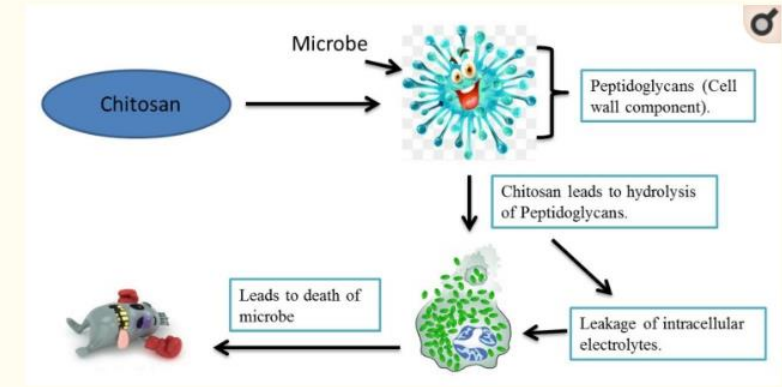


Figure 2

Chitosan acts on the pathogen by breaking the peptidoglycan bond and causing intracellular electrolyte leakage which leads to the death of the microbes.

The Antimicrobial Activity of Chitosan and the elicitation of the defense system in both pre- and post-harvest fruits and vegetables is highly promising. Therefore, regarding the antimicrobial mechanism of chitosan, several researchers have presented their practical point of view. For example, Goy et al. suggested three antibacterial mechanisms of chitosan; firstly, ionic surface interaction resulting in cell wall leakage; secondly, permeation of chitosan into microorganism nuclei inhibits their protein and mRNA synthesis, and thirdly, formation of an external film over the plant surface, limiting the nutrient availability for microorganisms. Liang stated that chitosan is responsible for the destruction of the bacterial cell membrane which causes death due to the leakage

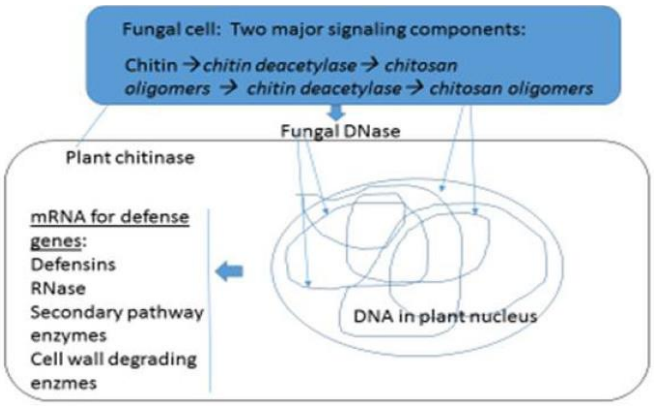
of intracellular substances. It was also found to be involved in altering the growth of fungi and reduced toxin production. However, in recent times, it has been reported that chitosan is responsible for the hydrolysis of peptidoglycans (cell wall component), increasing electrolyte leakage and potentially causing the death of the pathogen). (Rahat Sharif, Muhammad Mujtaba, Mati Ur Rahman, Abdulla Shalmani, Husain Ahmad, Toheed Anwar, Deng Tianchan, Xiping Wang, 2018 Apr 10)

David Granatstein says: "The new sunset process does not change the criteria for determining whether a material should be allowed for use in organic production. A good analogy to the chitin situation is the pheromone used for mating disruption of codling moth in apple. The pheromone is produced by the female codling moth, but it is not feasible to squeeze it out of millions of moths to make a commercial product. A synthetic version is manufactured, and that product had to be petitioned to the NOSB for inclusion on the list of allowed synthetics. The NOSB reviews petitions for such materials, and one cannot predict the outcome, regardless of the scientific merit of the supporting documents." (Harold Austin, NOSB Member and David Granatstein, WSU, February 11, 2016)

The **potato industry could benefit** as "The organic grower can manage potato late blight, caused by Phytophthora infestans (Mont.) de Bary, with natural copper compounds such as copper sulfate pentahydrate, copper dioxide, or copper hydroxide (Lee A. Hadwiger and Pamela O. McBride, 27 Jul 2018)

The **apple industry could benefit** from "Chitosan as a clarifying agent on clear apple juice production for the optimization of process conditions and changes on quality characteristics. Alicyclobacillus acidoterrestris causes significant safety issues in fruit juice industry; therefore, also the antimicrobial effect of chitosan on A. acidoterrestris during the clarification process was examined. The results showed that clear AJ production can be achieved by the clarification step with direct chitosan addition, without the need for enzymatic treatment." (© 2017 Elsevier Ltd)

Chitosan can induce resistant in pea to peat pathogens (Figure 16). (Lee A. Hadwiger, How Plants Resist Disease- A Focus On "Nonhost Resistance" of Pea to Bean Pathogen)



We believe we have good standing and sound scientific justification to support **Chitosan** as an **Approved Active Ingredient for Use in Organic Crop Production as Plant Disease Control**. The manufacturer, Botry-Zen (2010) Limited, of ARMOUR-Zen has **EPA Reg. No.: 75747-3.** We would appreciate the National Organic Standards Board take heavy consideration of Chitosan as it helps with sustainable agriculture and the defense system in both pre-harvest and post-harvest fruits and vegetables and this can be a great success to the Organic program as well as the Food and Beverage Industry as a whole.

4.2 Items to be Included in a Petition as per NOP Guidance Document

Item A.1- Synthetic substances allowed for use in organic crop production (§ 205.601).

Item A.2 -Production Aids

Item A.3 – Not applicable to this petition. Chitosan is currently allowed in organic products as an inert or an adjuvant: July 3, 2006, proposed rule (71 FR 37854)

Item B—Provide concise and comprehensive responses in providing all the following information on the substance being petitioned.

1. Substance Name

Chemical Name:
Poly-D-glucosamine

CAS Number:
9012-76-4

Other names:
Deacetyl chitin

Other Codes:
128930 (EPA/OPP Chemical Code)

2. Petitioner and Manufacturer Information

Manufacturer	Co-Petitioner and Chitosan User	Petitioner
Qingdao Fundchem Co., Ltd. ROOM 24B, Building C, Jindu Garden, No. 37, Donghai Xi Road, 266071, Qingdao, China Tel:86-532-85713787 http://www.fundchem.cn	Botryzen (2010) Ltd Site: 21 Willis Street P O Box 5664 Dunedin 9054 New Zealand DDI: +64 3 4776 447 M: +64 (0)27 477 6447 Email: peter.foster@botryzen.co.nz www.botryzen.co.nz	Bio-Gro, Inc. 681 Glade Road Mabton, WA 98935 Phone: 509-894-4110 ext 102 & 131 Email: registrations@biogro.com peter@biogro.com

3. Intended or Current Use

Please accept our petition to the National Organic Standards Board to amend the National List of Allowed and Prohibited Substances to include Chitosan as an approved active ingredient, section 205.601 "Synthetic substances allowed for use in organic crop production. (i) As plant disease control.". The current use of Chitosan is as an inert ingredient and an adjuvant in organic crop production.

4. Intended Activities and Application Rate

Chitosan is intended as plant disease control for the following targeted diseases at the following recommended application rates:

Application Rates:

Crops	Target Disease	Method	Use Rate per 100 Gallons	Notes
(Brassicas), including: Broccoli, Broccoli Rabe, Brussel Sprouts, Cabbage, Chinese Broccoli, Chinese Cabbage (Bok Choy), Chinese Cabbage (Napa), Chinese Mustard, Cabbage (Gai Choy), Cauliflower Cavalo, Collards, Kale, Kohlrabi, Mizuna, Mustard Greens. Mustard Spinach, Rape Greens, Turnip	Downy Mildew (*Peronospora parasitica)*			Begin application when conditions are conductive to disease development. Repeat on 7 to 10 day intervals or as needed.
		Foliar (Aerial)	1 – 4 quarts	For aerial applications, apply this product in a minimum of 5 gallons of water per acre. Apply preventively or at the first sign of disease symptoms. Repeat applications 7 – 14 day intervals.
Summer Squash: Crookneck Squash, Scallop Squash, Staightneck Squash Vegetable Marrow Zucchini	Powdery Mildew (*Erysiphe cichoracearum)* (*Sphaerotheca fuliginea*)	Foliar (Ground)	1 – 4 quarts	Apply preventatively in 25 – 100 gallons of water per acre or at first sign of disease symptoms. Increase water volume as plant size increases. Reapply on a 7 – 14 day interval depending on plant growth and disease pressure. Use shorter spray intervals for greenhouse cucurbits when under high disease pressure.
		Foliar (Aerial)	1 – 4 quarts	For aerial applications, apply this product in a minimum of 5 gallons of water per acre. Apply preventively or at the first sign of disease symptoms. Repeat applications 7 – 14 day intervals.
Fruiting Vegetables, including: Eggplant Okra Pepper Tomato Tomatillo Ground Cherry	Powdery Mildew (*Erysiphe spp.*) (*Leveillula taurica*) (*Oidopsis taurica*) (*Sphaerotheca spp.*)	Foliar (Ground)	1 – 4 quarts	Apply preventatively in 25 – 100 gallons of water per acre or at first sign of disease symptoms. Increase water volume as plant size increases. Reapply on a 7 – 14 day interval depending on plant growth and disease pressure. Use shorter spray intervals for greenhouse cucurbits when under high disease pressure.
		Foliar (Aerial)	1 – 4 quarts	For aerial applications, apply this product in a minimum of 5 gallons of water per acre. Apply preventively or at the first sign of disease symptoms. Repeat applications 7 – 14 day intervals.
Grapes	Botrytis Bunch Rot (*Botrytis cinerea)*	Foliar	1 – 4 quarts	Apply preventatively in 50 – 100 gallons of water per acre or the first signs of disease symptoms. Reapply applications at 7 – 14 day interval depending on plant growth and disease pressure.
Leafy Vegetables, including: Aruglula, Beet, Celery, Chervil, Cilantro, Corn Salad, Cress, Dandelion, Dock, Edible Chrysanthemum, Endive. Fennel, Garden Peas, Head Lettuce, Leaf Lettuce, Parsley, Purslane. Radicchio, Rhubarb, Spinach, Swiss Chard, Watercress	Downy Mildew (*Bremia lactuca*) (*Peronospora spp.)*	Foliar (Ground)	1 – 4 quarts	Apply preventatively in 50 – 100 gallons of water per acre or when environmental conditions are conducive to rapid disease development. Increase water volume as plant size increases. Reapply on a 7 – 14 day interval or as needed.
		In-Furrow	1 – 4 quarts	Apply as an in-furrow spray at planting at the rate of 1 – 2 quarts per acre or 2.2 – 4.4 fluid ounces per 1000 feet of row. Apply in 5 – 15 gallons of water and direct the spray into the seed furrow just before the seeds are covered.

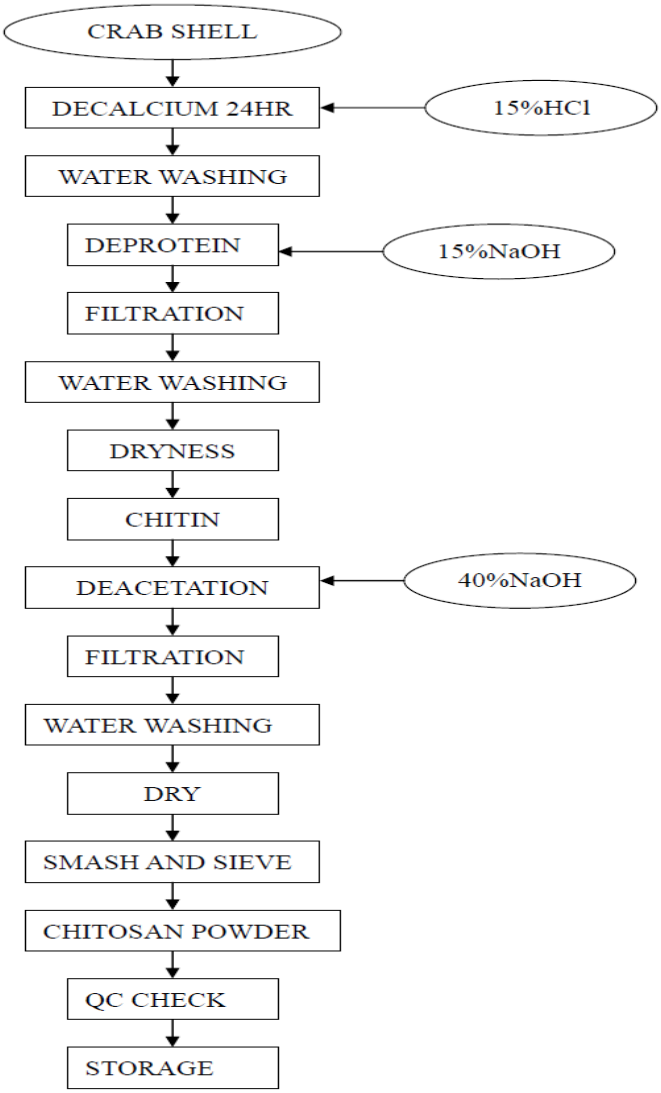
5. Manufacturing Process

Ingredient Supplier Manufacturing process of Chitosan: Crab shell and 3 times amount of HCl (15%) are charged in vessel, stirring for 24hrs to remove calcium, washing by water till pH=7, then 4 times amount of NaOH was added in to remove protein and decoloration, water washing again till pH=7. Chitin was obtained after dryness.

The Chitin and 4 times NaOH (40%) are charged in vessel, heating to 90-95℃, and keeping for 10hrs to deacetylation. Water washing to pH=7 and dryness, the dryness process is in 80℃, for 3hrs. The product was obtained after smash and sieve.

Qingdao Fundchem Co., Ltd.

PROCESSING ROUTE CHART



6. Ancillary Substances

- N/A

7. Previous Reviews

"In the July 3, 2006, proposed rule (71 FR 37854), the NOP stated it "will not propose to specifically add chitosan to the National List as an adjuvant, it is already permitted for use at § 205.601(m) of the National List regulations." Comments were received regarding this statement and, as a result, the NOP is clarifying the use and prohibition of chitosan in organic agriculture. (National Organic Program (NOP); Amendments to the National List of Allowed and Prohibited Substances (Crops and Livestock) Dec 10, 2007, RIN: 0581-AC61, Federal Registration Number E7-23880.)

Chitosan (Poly-D Glucosamine) (CAS #-9012-76-04) was petitioned for use in organic crop production as an adhesive adjuvant to be used with fungicides approved for use under the NOP regulations. At its August 17, 2005, meeting in Washington, DC, the NOSB recommended adding chitosan to the National List for use in organic crop production as an insecticide, with the restriction that it only be used as an adjuvant. In this open meeting, the NOSB evaluated chitosan against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that chitosan is consistent with the OFPA evaluation criteria." (National Organic Program (NOP); Amendments to the National List of Allowed and Prohibited Substances (Crops and Livestock), Publication Date: 12/10/2007, 72 FR 69569, 7 CFR 205).

8. Regulatory Authority

Chitosan is an active ingredient in ARMOUR-Zen with a current EPA Reg. No.: 75747-3

"The NOP consulted with the EPA concerning the NOSB's recommendation to include chitosan on the National List for use as an adjuvant. The EPA stated that, in addition to chitosan being registered as an active ingredient, it is also approved as an EPA List 4B inert ingredient. The EPA further informed the NOP that chitosan, used as an adjuvant, would be considered an inert ingredient. The NOP regulations, at § 205.601(m), permits the use of EPA List 4 inert ingredients with nonsynthetic substances or synthetic substances approved for use under the NOP regulations as an active pesticide ingredient." (National Organic Program (NOP); Amendments to the National List of Allowed and Prohibited Substances (Crops and Livestock), Publication Date: 12/10/2007, 72 FR 69569, 7 CFR 205).

9. Chemical Abstracts Service (CAS) Number and Product Labels

Chitosan is an active ingredient in ARMOUR-Zen with a current EPA Reg. No.: 75747-3 (See label next page)

ARMOUR-Zen

ACTIVE INGREDIENT:

Chitosan	30.00%
OTHER INGREDIENTS:	70.00%
TOTAL:	100.00%

Product contains 2.5 lb (1134 g) of chitosan per gallon.

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If in eyes	• Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call poison control center or doctor for treatment advice.

HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

See back panel for additional precautionary statements and directions for use.

Net Weight: 5 Gallons

Manufactured by:
Botry-Zen (2010) Limited
156 Frederick Street, P.O. Box 1777
Dunedin 9054
New Zealand
www.botryzen.co.nz

EPA Reg. No.: 75747-3
EPA Establishment No.: XXXXX-XX-XX
Use By:
Batch No. / Lot No.:

10. Physical and Chemical Properties. Provide the substance's physical properties and chemical mode of action including the following:

(a) Chemical interactions with other substances, especially substances used in organic

Production: There is minimal potential for a detrimental chemical interaction with another materials used, or adverse biological or chemical interactions, as Chitosan is found naturally in agroecosystems (as shells and cell walls of, for example, snails and fungus) where the other materials are used. Additionally, the soluble form we would be applying is not highly reactive. (Agnes Sri Harti, S. Dwi Sulisetyawati, Atick Murharyati, Meri Oktariani, Ika Budi Wijayanti, International Journal of Pharma Medicine and Biological Sciences Vol. 5, No. 1, January 2016)

(b) Toxicity and environmental persistence: The EPA have exempted it from the requirement for a tolerance limit when used as a pesticide. They cited "Chitosan is not toxic, as demonstrated in acute toxicity studies in mice, rats and rabbits; is naturally occurring in the environment in large concentrations; has been exempted from the requirement of a tolerance in or on barley, beans, oats, peas and wheat when used as a seed treatment at an application rate of 4 oz./100 lbs. seed; has been approved by the State of Oregon for use in unrestricted amounts as a soil amendment (fertilizer), a use regulated by EPA under the Federal Insecticide, Fungicide and Rodenticide Act". Also, the EPA's fact sheet for chitosan notes chitosan is not expected to harm people, pets, wildlife or the environment as it has a very low potential for toxicity and it is naturally abundant in the environment. (EPA Docket Number EPA-HQ-OPP-2007-0566)

(c) Environmental impacts from its use and/or manufacture: Chitosan is a registered pesticide (EPA/OPP chemical code 128930) used as a plant growth enhancer and plant defence booster. It targets pests such as early and late blight, downy and powdery mildew and grey mould. The International Federation of Organic Agriculture Movements (IFOAM), Europe, added Chitosan Hydrochloride to Annex II of Regulation (EC) No. 889/2008. Chitosan was accepted as having no harmful effects, immediate or delayed on human or animal health, nor an unacceptable effect on the environment. Chitin is certified as an organic input, USA (OMRI listed), Canada (COR) and EU.

(d) Effects on human health: Chitosan is not known to be toxic to humans. It is marketed as a dietary supplement for control of obesity and high cholesterol, and many medical fields, so is safe to touch and ingest. The agricultural use fact sheet for chitosan released by the EPA states "No risks to humans are expected when products containing chitosan are used according to label directions. In toxicity tests, the only effect seen was slight skin irritation after chitosan was applied to skin." EPA Docket Number EPA-HQ-OPP-2007-0566

(e) Effects on soil organisms, crops, or livestock: The EPA and FDA, who allow the use of Chitosan, do not provide information to suggest manufacture, use, misuse or disposal will result in contamination. It is a naturally occurring molecule, one of the most common polymers, found in insect shells, crustaceans, fungi, algae and yeast. Chitosan is also biodegradable; plants and soil microbes have enzymes (chitosanases and chitinases) capable of breaking down both chitosan and its precursor chitin into smaller polymers or monomers of the glucose-related molecule chitosan is made of to be used as an energy source. Neither chitosan, chitin nor the break down products persist as they are used as an energy source. (Chitin; Poly0N-acetyl-D-clucosamine (128991 Fact Sheet)

11. Safety Information

Provide safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies. If this information does not exist or is not applicable, the petitioner should state so in the petition.

We are including the Chitosan ingredient certificate of analysis and the safety data sheet for the Chitosan ingredient as well as the safety data sheet for the final product, ARMOUR-ZEN, by BOTRYZEN.

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品 质 证 明 书

CERTIFICATE OF ANALYSIS

编号.
No.
日期.
Date. 2005.11.21

货物标记 Shipping marks	品名 Descriptions
N/M	CHITOSAN CSA#: 9012-76-4

本证明书所列商品的品质经我们检验结果如下特此证明
This is to certify that we, the undersigned, have inspected the quality of the above mentioned goods and found the result of inspection as follows:

BATCH NO.:51112

ITEMS	STANDARD	RESULT
Deacetation (%)	70 min	85.3%
Ash (%)	2.0 max	Pass
Moisture (%)	10.0 max	8.6
Viscosity (1%HAC,25DC, MPA.S)	100 max	50
Particle size (mesh)	80	80

MSDS for Chitosan

****** MATERIAL SAFETY DATA SHEET ******

Section 1 - Chemical Product and Company Identification

MSDS Name: Chitosan
Company Identification: SINOCHEM QINGDAO
20 Xianggangzhong rd.
QingDao,China

Section 2 - Composition, Information on Ingredients

CAS#	Chemical Name	%
9012-76-4	Chitosan	

Hazard Symbols: None Listed.
Risk Phrases: None Listed.

Section 3 - Hazards Identification

EMERGENCY OVERVIEW
Not available.

POTENTIAL HEALTH EFFECTS

Eye:	May cause eye irritation.
Skin:	May cause skin irritation. May be harmful if absorbed through the skin.
Ingestion:	May cause irritation of the digestive tract. May be harmful if swallowed.
Inhalation:	May cause respiratory tract irritation. May be harmful if inhaled.
Chronic:	Not available.

Section 4 - First aid Measures

Eyes:	Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid.
Skin:	Get medical aid. Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
Ingestion:	Get medical aid. Wash mouth out with water.
Inhalation:	Remove from exposure and move to fresh air immediately.
Notes to Physician:	Treat symptomatically and supportively.

Section 5 - Fire Fighting Measures

General Information: As in any fire, wear a self-contained breathing apparatus in

	pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear.
Extinguishing Media:	Use water spray, dry chemical, carbon dioxide, or chemical foam.

Section 6 - Accidental Release Measures

General Information:	Use proper personal protective equipment as indicated in Section 8.
Spills/Leaks:	Vacuum or sweep up material and place into a suitable disposal container.

Section 7 - Handling and Storage

Handling:	Avoid breathing dust, vapor, mist, or gas. Avoid contact with skin and eyes.
Storage:	Store in a cool, dry place. Store in a tightly closed container.

Section 8 - Exposure Controls, Personal Protection

Engineering Controls:	Use adequate ventilation to keep airborne concentrations low.

PERSONAL PROTECTIVE EQUIPMENT

Eyes:	Wear chemical goggles.
Skin:	Wear appropriate protective gloves to prevent skin exposure.
Clothing:	Wear appropriate protective clothing to prevent skin exposure.
Respirators:	Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Always use a NIOSH or European Standard EN 149 approved respirator when necessary.

Section 9 - Physical and Chemical Properties

Physical State:	Powder
Color:	off-white to beige - yellow
Odor:	Not available.
pH :	Not available.
Vapor Pressure:	Not available.
Viscosity:	Not available.
Boiling Point:	Not available.
Freezing/Melting Point:	Not available.
Autoignition Temperature:	Not available.
Flash Point:	Not available.
Explosion Limits, lower:	Not available.
Explosion Limits, upper:	Not available.
Decomposition Temperature	
Solubility in water :	

Specific Gravity/Density
Molecular Formula: C6H11NO4
Molecular Weight : 161

Section 10 - Stability and Reactivity

Chemical Stability : Stable.
Conditions to Avoid :. Keep away from oxidizing agents
Incompatibilities with Other Materials: Not available.
Hazardous Decomposition Products: Nitrogen oxides, carbon monoxide, carbon dioxide.
Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

RTECS#: CAS# 9012-76-4: FM6300000
Acute oral LD50(Mice): 10g/kg min.
Acute toxicity: No effect at 20400 µ/l dose rate
Carcinogenicity Chitosan - Not listed by ACGIH, IARC, NIOSH, NTP, or OSHA.
See actual entry in RTECS for complete information.

Section 12 - Ecological Information

Other : Biodegradable.

Section 13 - Disposal Considerations

Dispose of in a manner consistent with federal, state, and local regulations.

Section 14 - Transport Information

	IATA	IMO	RID/ADR
Shipping Name:	No information available.	No information available.	No information available.
Hazard Class:	-	-	-
UN Number:	-	-	-
Packing Group:	-	-	-

Section 15 - Regulatory Information

European/International Regulations
European Labeling in Accordance with EC Directives
Hazard Symbols: Not available.
Risk Phrases:
Safety Phrases:
S 24/25 Avoid contact with skin and eyes.

WGK (Water Danger/Protection)

CAS# 9012-76-4: 0

United Kingdom Occupational Exposure Limits

United Kingdom Maximum Exposure Limits

Canada

CAS# 9012-76-4 is listed on Canada's NDSL List.

CAS# 9012-76-4 is not listed on Canada's Ingredient Disclosure List.

Exposure Limits

US FEDERAL

TSCA

CAS# 9012-76-4 is listed on the TSCA inventory.

Section 16 - Additional Information

MSDS Creation Date 5/26/2000

Revision #0 Date Original.

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no way shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages. ----------

ZHEJIANG NEW CENTURY INT'L TRADE CO., LTD.

ADD: B/22. 168 BAIZHANG ROAD, NINGBO, CHINA
TEL: 0086-574-27858348 / 27858206
E-mail: chinaj-s@hotmail.com
FAX: 0086-574-27858205

Certificate of Analysis

Product Name:	**Compact Chitosan Food Grade**	**Manufacture Date:**	**2005-10-29**
Latin Name:		**Testing Date:**	**2005-10-30**
Batch Number:	**CC051029**	**Expire Date:**	**2006-10-29**
Quantity:	**1000KGS**	**Shelf Life:**	**12 months**

TEST ITEM	SPECIFICATION	TEST RESULT
DESCRIPTION:		
APPEARANCE	OFF-WHITE POWDER	COMPLIES
DAC DEGREE	≥95%	96.12%
MOISTURE	≤10.0%	8.12%
ASH CONTENT	≤1.5%	0.91%
DENSITY	≥0.65 g/ml	0.73 g/ml
VISCOSITY	50MPA.S - 200MPA.S	100MPA.S
MESH SIZE	100 MESH	COMPLIES
HEAVY METALS	≤10ppm	COMPLIES
ARSENIC	< 0.5ppm	COMPLIES
INSOLUBLE	<1.0%	COMPLIES
TOTAL PLATE COUNT	≤1000cfu/g	COMPLIES
YEAST AND MOLD	≤100cfu/g	COMPLIES
E. COLI	NEGATIVE	COMPLIES
SALMONELLA	NEGATIVE	COMPLIES
STORAGE	KEEP THE GOODS COOL AND DRY AWAY FROM STRONG LIGHT AND HEAT.	

QUALITY ASSURANCE OFFICER **CORRECTOR** **ANALYST**

BOTRYZEN 2010 LTD
proven natural science

21 Willis Street, PO Box 5664, DUNEDIN. Phone: 64 3 477 6447. Fax: 64 3 477 9605

SAFETY DATA SHEET

1. Identification

Product: **ARMOUR-Zen®**

License Classification:
New Zealand: Registered pursuant to the ACVM Act 1997, No: P7570

Recommended Use: for the control of *Botrytis cinerea* and *Sclerotinia sclerotiorum*
Permitted Crops: grapes and ornamentals

Supplier: Botry-Zen (2010) Limited
PO Box 5664
21 Willis Street
Dunedin
New Zealand

Ph: +64 (3) 477 - 6447
Fax: +64 (3) 477 - 9605
E-mail: info@botryzen.co.nz

2. Hazard Identification

Classification of the substance: ARMOUR-Zen® is ecotoxic.

HSNO classification 9.1A.

Precautions:
- Avoid contamination of the water supply with the product or empty container.
- In the case of a spill, contain the spill and remove contaminated material to be disposed of in an approved landfill.
- Keep out of reach of children.
- Store in original container, tightly closed away from foodstuffs.
- Avoid contact with skin and eyes and inhalation of spray mist and/or concentrate.
- When mixing or applying wear protective eyewear and waterproof gloves.
- Wash hands and exposed skin before meals and after using.

3. Composition / Information on Ingredients:

COMMON NAME: Chitosan
CAS NUMBER: 9012-76-4

4. First-Aid Measures:

Eyes: Flush eyes immediately with a continuous gentle stream of water for 15 minutes. Get medical attention if irritation persists.
Skin: Immediately wash the affected area with soap and water. Get medical attention if irritation persists.
Ingestion: Wash mouth out with clean water. Do not induce vomiting unless instructed to do so by qualified medical personnel. Get medical attention if discomfort occurs,
Inhalation: Remove individual to fresh air. If breathing difficulty occurs, get medical attention.
Note to physician: There is no specific antidote. Employ supportive care. Treatment should be based on judgment of the physician in response to reactions of the patient.

5. Fire-Fighting Measures:

Extinguishing media: Water, fog, foam, CO_2, sand.
Flammable limits: Not available
Auto-ignition temperature: Not available
Sensitivity to mechanical impact / static discharge: Not available

6. Accidental Release Measures:

If the spill occurs out of doors, cover it with an absorbent material to prevent dispersion of the spilled material until recovery can begin. Soak up material from broken containers, and store collected material in secure containers until safe disposal can be arranged.

7. Handling and Storage:

Handling: Practice good care and good safety precautions when handling this product. Avoid contact with eyes, skin and clothing. Contaminated clothing should be washed separately from domestic laundry and line-dried. Users should wash hands before eating and drinking.

Storage: Store in original containers only. Keep containers tightly closed when not in use.

8. Exposure controls/personal protection

For brief contact during manufacture, warehousing and transport, wear clean body-covering clothing. During operations where direct contact with ARMOUR-Zen® may occur additional protection maybe required. This includes mask, gloves, coveralls, and safety glasses.

9. Physical and chemical properties:

Appearance:	golden brown
Odour:	vinegar
Odour threshold:	not available
pH:	4.5 – 5.5
Melting point/freezing point:	not available
Initial boiling point and boiling range:	not available
Flash point:	not available
Evaporation rate:	not available
Flammability:	not available
Upper/lower flammability of explosive limits:	not available
Vapour pressure:	does not apply
Vapour density:	does not apply
Relative density:	1.1
Solubility:	soluble
Partition coefficient: n-octanol/water:	not available
Auto-ignition temperature:	does not apply
Decomposition temperature:	not available
Viscosity:	not available

10. Stability and Reactivity

Reactivity: Avoid oxidizing materials
Stability: This product is stable under normal storage conditions.
Hazardous decomposition products: Oxides of nitrogen and carbon are produced under fire conditions.
Hazardous polymerization: Not known to occur.

11. Toxicological Information

Acute toxicity: Not available
Skin corrosion/irritation: May cause skin irritation.
Serious eye damage/irritation: May cause eye irritation.
Respiratory or skin sensitization: Not available
Germ cell mutagenicity: Not available
Carcinogenicity: Not available
Reproductive toxicity: Not available
STOST-single exposure: Not available
STOST-repeated exposure: Not available
Aspiration hazard: Not available

Note: Normal or casual exposure to this product is not expected to cause unusual acute or chronic health risks to workers, bystanders or consumers.
Chronic effects: Chronic exposure may aggravate existing medical conditions.

12. Ecological Information

ARMOUR-Zen® is an aquatic toxicant and should not come into contact with waterways.

ARMOUR-Zen®, once taken up by plants is converted to naturally occurring substances that present no hazards to the environment.

13. Disposal considerations

Triple rinse empty containers and dispose of at an AgRecovery site

14. Transport information

Proper shipping name environmentally hazardous substance liquid, NOS (chitosan)
Hazard Class 9 Miscellaneous Goods
UN No 3082
Packing Group III

According to the amendments publicised on the 1st of January 2015 of the 56th edition of the IATA regulations (A197), UN#3082 is to be shipped as "not restricted", as long as the net quantity in each receptacle does not exceed 5L/kg and the packaging meets the defined standards.

Also the transport of dangerous goods by sea - IMDG code edition 2014, states that UN#3082 is not subject to the IMDG code (no marking, labeling or documentation required) provided that inner packaging is 5 litres or less, and the packaging is strong and rigid.

15. Regulatory information

Registered pursuant to the ACVM Act 1997, No P7570

16. Other Information

Contact Person: Kirstin Bevin	Issue: 10	Date: February 2017

12. Research Information

This item should include research information about the substance. The research should include comprehensive substance research reviews and research bibliographies, including reviews and bibliographies that present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List.
For petitions to include nonorganic agricultural substances on the National List for organic handling, this information should include research on why the substance should be permitted in the handling of an organic product, including the availability of organic alternatives.
If research information does not exist for the petitioned substance or for the contrasting position, the petitioner should state so in the petition.

"In nature chitin (N-acetyl glucosamine), the precursor, may be de-acetylated to chitosan (glucosamine), although not by the same technique - application of NaOH - as used commercially.

Chitin is the name for polymers of both chitin and chitosan molecules linked together in chains that can reach up to 5000 molecules long. A solution is named chitin when most of the molecules are chitin, if the proportion changes and chitosan is more numerous, it is renamed chitosan. Chitin is first harvested from the naturally occurring animal source; crab and shrimp shells. Chitin is extracted by demineralisation (acid treatment to remove calcium carbonate, the shells) and deproteinization (alkaline treatment to remove proteins). These chemical treatments cause some deacetylation - producing a little chitosan. Further deacetylation is carried out to produce a higher percentage chitosan solution. A mild organic acid, such as lactic or acetic acid, can be applied to adjust chitosan's pH to mildly acidic, making it water soluble.

In summary, chitosan molecules are present in polymers of chitin, present in the naturally occurring source. The polymers are chemically treated to change most chitin monomers to chitosan monomers, by removing some of the acetyl group. This changes the proportions of the substance that was extracted from the naturally occurring source." (*Lee A. Hadwiger*, 2013 Elsevier Ireland Ltd)

13. Petition Justification Statement

Please accept our petition to the National Organic Standards Board to amend the National List of Allowed and Prohibited Substances to include Chitosan as an approved active ingredient, section 205.601 "Synthetic substances allowed for use in organic crop production. (i) As plant disease control.".

Chitin is the precursor molecule of chitosan. In nature and after chemical treatment, they exist together. The definition of "chitin" or "chitosan" depends on the percentage of each molecule present. Chitin is listed as non-synthetic and organic under the classification "Crop Fertilizers and Soil Amendments" (NOP reference 205.105(a).

Botry-zen®/BotryStop®, one of Botry-Zen (2010) Ltd.'s, organic products, could be repeatedly applied, although it would become expensive as it's not designed for the niche market that Armour-Zen®, our product containing chitosan, is. There are some other organic products available for purchase, although several are sulfur-based, which can be environmentally damaging, particularly to the resident microbes, and is often phytotoxic or damaging to plants when overused. It is possible to approach the problem of fungus overgrowth by physically investigating each grape vine and removing contaminated bunches or grapes. This need to be carried out regularly if contamination frequently returns, especially after a heavy rain-event which could spread the spores and result in vineyard-wide contamination.

If chitosan is approved as organic for use as a fungicide, our chitosan containing product, Armour-zen®, would fill the need for an organic product that's flexible in the timing of use, cost effective and considerably easier to use, than physically controlling fungal infection.

A. Inclusion of a Synthetic on the National List (7 C.F.R. §§ 205.601, 205.603, 205.605(b))

• Explain why the synthetic substance is necessary for the production or handling of an organic product: Chitosan is a registered pesticide (EPA/OPP chemical code 128930) used as a plant growth enhancer and plant defence booster. It targets pests such as early and late blight, downy and powdery mildew and grey mould.

The International Federation of Organic Agriculture Movements (IFOAM), Europe, added Chitosan Hydrochloride to Annex II of Regulation (EC) No. 889/2008. Chitosan was accepted as having no harmful effects, immediate or delayed on human or animal health, nor an unacceptable effect on the environment.

Chitin is certified as an organic input, USA (OMRI listed), Canada (COR) and EU.

• Describe any non-synthetic substances, synthetic substances on the National List, or alternative cultural method that could be used in place of the petitioned synthetic substance: It is possible to approach the problem of fungus overgrowth by physically investigating each grape vine and removing contaminated bunches or grapes. This need to be carried out regularly if contamination frequently returns, especially after a heavy rain-event which could spread the spores and result in vineyard-wide contamination.

Chitosan use, in fungicide products, is an alternative to currently available products, such as those that are sulphur-based, which can cause damage to the microbial communities and the plants themselves. This is less damaging to the environment, an organic farming target. (Laura Orzali, Beatrice Corsi, Cinzia Forni, and Luca Riccioni, January 11, 2017)

• Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a non-synthetic substance or alternative cultural method. Chitosan is not known to be toxic to humans. It is marketed as a dietary supplement for control of obesity and high cholesterol, and many medical fields, so is safe to touch and ingest. The agricultural use fact sheet for chitosan released by the EPA states "No risks to humans are expected when products containing chitosan are used according to label directions. In toxicity tests, the only effect seen was slight skin irritation after chitosan was applied to skin."

The EPA has exempted it from the requirement for a tolerance limit when used as a pesticide. They cited "Chitosan is not toxic, as demonstrated in acute toxicity studies in mice, rats and rabbits; is naturally occurring in the environment in large concentrations; has been exempted from the requirement of a tolerance in or on barley, beans, oats, peas and wheat when used as a seed treatment at an application rate of 4 oz./100 lbs. seed; has been approved by the State of Oregon for use in unrestricted amounts as a soil amendment (fertilizer), a use not regulated by EPA under the Federal Insecticide, Fungicide and Rodenticide Act". Also, the EPA's fact sheet for chitosan notes chitosan is not expected to harm people, pets, wildlife or the environment as it has a very low potential for toxicity and it is naturally abundant in the environment. EPA Docket Number EPA-HQ-OPP-2007-0566

Chitosan has, in fact, many documented physiological effects on plants and soil organisms which are regarded as beneficial to crop production, including plant growth enhancement, and antimicrobial (antimicrobial, antifungal, and antiviral effects) ability.

I. Adding, amending, or removing an annotation for a listed substance (all sections). Provide detailed information on why a new annotation is needed.

(1) The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems.

Chitosan, as one of the most common polymers, has been intensely researched for decades and applied to many different fields. Agriculturally chitosan is used as a natural seed treatment, plant growth enhancer and bio-pesticide, boosting the innate ability of plants to defend themselves against fungal infections. Chitosan products are EPA-approved and allowed for use outdoors and indoors on plants and crops grown commercially and by consumers. "In agriculture, chitosan and is used as a plant growth enhancer and as a substance that boosts the ability of plants to defend against fungal infections." (Biopolymer Electrolytes Fundamentals and Applications in Energy Storage, Y.N Sudhakar, M. Selvakumar, D. Krishna Bhat, 2018)

As a "plant growth enhancer" it's thought to; help the plant resist insects, pathogens, and soil-borne diseases when applied to foliage or the soil; increase photosynthesis; stimulate nutrient uptake and increase germination and sprouting. In some crops it has been found to stimulate an innate immunity in newly developing roots which destroys parasitic cyst nematodes without harming the beneficial nematodes and organisms. Using chitosan can reduce environmental stress due to drought and soil deficiencies. It can strengthen seed vitality, improve stand quality, increase yields, and reduce fruit decay. Horticultural application of chitosan has been shown to increase the number of blooms and extends the life of cut flowers and Christmas trees. It has even been used to protect plants in space; NASA completed an experiment growing adzuki beans aboard the space shuttle and Mir space station in 1997, which showed it increased growth and pathogen resistance.

(2) The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.

It can be used in water filtration processes by causing fine sediment particles to stick together before being removed, reducing turbidity. Chitosan is used to remove heavy minerals, dyes, oils and heavy metals from water this way. For example, is also used as a fining agent to clarify wine, mead and beer (Post-Fermentation Clarification: Wine Fining Process, Allison Corriveau, Lindsey Wilson, Professor Stephen J. Kmiotek, 2015). In other, more varied fields, modified chitosan has been embedded in cotton as an antibacterial agent to prevent bacterial colonization in clothes; for medical services or sportswear. Alone or with other components chitosan is showing promise as a bioactive film in food packaging to maintain quality and extend shelf life. Food containers or utensils bio-printed from a chitosan base will biodegrade. (Fibers and Polymers 2016, Vol.17, No 11, 1782-1789 DOI 10.1007-s12221-016-6609-2)

(3) The probability of environmental contamination during manufacture, use, misuse or disposal of the substance.

There is minimal potential for a detrimental chemical interaction with another materials used, or adverse biological or chemical interactions, as Chitosan is found naturally in agroecosystems (as shells and cell walls of, for example, snails and fungus) where the other materials are used. Additionally, the soluble form we would be applying is not highly reactive.

(4) The effect of the substance on human health.

In the medical field it has been used in wound dressings to decrease bleeding and assist post-surgery wound healing, in patches and bandages as antimicrobial dressings after burning and to give prosthesis an antimicrobial coating. Chitosan can act as a drug carrier. Antimicrobial chitosan nanoparticles have been studied in the

emerging Nano Bio pharmaceutics field targeting various microorganisms. It's been used as an inactive vehicle for solid dose drug delivery as a coating, a disintegrate (to cause tablets to disintegrate on contact with moisture), a tablet binder and a mucoadhesive for at least 25 years. It's been investigated in delivery of antibiotics. More recently, it's been found to form complexes easily with DNA and so could be of great benefit in gene therapy. Chitosan has been marketed as a tablet to limit fat absorption but appears to have little or no clinically measurable ability to lower cholesterol or body weight. It has also been sold as a soluble dietary fiber. (J. Am Diet Association, 2005 Jan;105 (1):72-7, U.S National Library of Medicine National Institutes of Health).

(5) The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops, and livestock.

Firstly, it is made from a natural, sustainable resource; the crab shell waste of the seafood industry. Chitosan use, in fungicide products, is an alternative to currently available products, such as those that are sulphur-based, which can cause damage to the microbial communities and the plants themselves. This is less damaging to the environment, an organic farming target.

There is minimal potential for a detrimental chemical interaction with another materials used, or adverse biological or chemical interactions, as Chitosan is found naturally in agroecosystems (as shells and cell walls of, for example, snails and fungus) where the other materials are used. Additionally, the soluble form we would be applying is not highly reactive.

Chitosan has, in fact, many documented physiological effects on plants and soil organisms which are regarded as beneficial to crop production, including plant growth enhancement, and antimicrobial (antimicrobial, antifungal, and antiviral effects) ability.

It is also worth noting that producing chitosan from crab shell waste is reducing the environmental contamination associated with crab shell waste disposal.

In summary, chitosan and its breakdown products are not toxic; chitosan is commonly found in the environment and is broken down by enzymes commonly found in the environment and used as an energy source.

(6) The alternatives to using the substance in terms of practices or other available materials.

Botry-zen®/BotryStop®, one of Botry-Zen (2010) Ltd.'s, organic products, could be repeatedly applied, although it would become expensive as it's not designed for the niche market that Armour-Zen®, our product containing chitosan, is. There are some other organic products available for purchase, although several are sulfur-based, which can be environmentally damaging, particularly to the resident microbes, and is often phytotoxic or damaging to plants when overused. It is possible to approach the problem of fungus overgrowth by physically investigating each grape vine and removing contaminated bunches or grapes. This need to be carried out regularly if contamination frequently returns, especially after a heavy rain-event which could spread the spores and result in vineyard-wide contamination.

Chitosan use, in fungicide products, is an alternative to currently available products, such as those that are sulphur-based, which can cause damage to the microbial communities and the plants themselves. This is less damaging to the environment, an organic farming target.

If chitosan is approved as organic for use as a fungicide, our chitosan containing product, Armour-Zen®, would fill the need for an organic product that's flexible in the timing of use, cost effective and considerably easier to use, than physically controlling fungal infection.

(7) Its compatibility with a system of sustainable agriculture.

Firstly, it is made from a natural, sustainable resource; the crab shell waste of the seafood industry. Chitosan use, in fungicide products, is an alternative to currently available products, such as those that are sulphur-based, which can cause damage to the microbial communities and the plants themselves. This is less damaging to the environment, an organic farming target. In nature chitin (N-acetyl glucosamine), the precursor, may be de-acetylated to chitosan (glucosamine), although not by the same technique - application of NaOH - as used commercially.

Chitin is the name for polymers of both chitin and chitosan molecules linked together in chains that can reach up to 5000 molecules long. A solution is named chitin when most of the molecules are chitin, if the proportion changes and chitosan is more numerous, it is renamed chitosan. Chitin is first harvested from the naturally occurring animal source; crab and shrimp shells. Chitin is extracted by demineralisation (acid treatment to remove calcium carbonate, the shells) and deproteinization (alkaline treatment to remove proteins). These chemical treatments cause some deacetylation - producing a little chitosan. Further deacetylation is carried out to produce a higher percentage chitosan solution. A mild organic acid, such as lactic or acetic acid, can be applied to adjust chitosan's pH to mildly acidic, making it water soluble. In summary, chitosan molecules are present in polymers of chitin, present in the naturally occurring source. The polymers are chemically treated to change most chitin monomers to chitosan monomers, by removing some of the acetyl group. This changes the proportions of the substance that was extracted from the naturally occurring source. Chitosan is found naturally in agroecosystems (as shells and cell walls of, for example, snails and fungus) where the other materials are used. Additionally, the soluble form we would be applying is not highly reactive. (Youling Yuan, Betsy M. Chessnut, Warren O. Haggard and Joel D. Bumgardner, 12 August 2011)

Synthetic substances petitioned for use in organic processing are evaluated pursuant to additional criteria in 7 C.F.R. § 205.600(b).

Chitosan has already been approved as adjuvant and inert ingredient by the NOP and evaluated against the following criteria. Please accept our petition to the National Organic Standards Board to amend the National List of Allowed and Prohibited Substances to include Chitosan as an approved active ingredient, section 205.601 "Synthetic substances allowed for use in organic crop production. (i) As plant disease control.".
Chitin is the precursor molecule of chitosan. In nature and after chemical treatment, they exist together. The definition of "chitin" or "chitosan" depends on the percentage of each molecule present. Chitin is listed as non-synthetic and organic under the classification "Crop Fertilizers and Soil Amendments" (NOP reference 205.105(a).We are putting forward this petition to the National Organics Standards Board, for Chitosan to be included on the National List as an active ingredient, so that products that include Chitosan as part of their formulation can then be a certified as an organic input.

- The substance cannot be produced from a natural source and there are no organic substitutes;
- The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;

- The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations;
- The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;
- The substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and
- The substance is essential for the handling of organically produced agricultural products.

14. References

- Lee A. Hadwiger, Plant science review: Multiple effects of chitosan on plant systems: Solid Science or hype, 2013 Elsevier Ireland Ltd.
- Lee A. Hadwiger, How Plants Resist Disease- A Focus On "Nonhost Resistance" of Pea to Bean Pathogen
- *Chitosan* by Peter Foster and Sonia, BotryZen 2010
- National Organic Program (NOP); Amendments to the National List of Allowed and Prohibited Substances (Crops and Livestock). Dec 10, 2007, RIN: 0581-AC61, Federal Registration Number E7-23880.
- (National Organic Program (NOP); Amendments to the National List of Allowed and Prohibited Substances (Crops and Livestock), Publication Date: 12/10/2007, 72 FR 69569, 7 CFR 205).
- (International Journal of Pharma Medicine and Biological Sciences Vol. 5, No. 1, January 2016) The Effectiveness of Snail Slime and Chitosan in Wound Healing, Agnes Sri Harti, S. Dwi Sulisetyawati, Atick Murharyati, Meri Oktariani, Ika Budi Wijayanti)
- Deacetylation of Chitosan: Material Characterization and in vitro Evaluation via Alubimin Adsorption and Pre-Osteblastic Cell Cultures) Youling Yuan, Betsy M. Chessnut, Warren O. Haggard and Joel D. Bumgardner, 12 August 2011
- Annex II of Regulation (EC) No. 889/2008
- EPA/OPP chemical code 128930
- "Crop Fertilizers and Soil Amendments" (NOP reference 205.105(a).
- Chitosan in Agriculture: A New Challenge for Managing Plant Disease. (Laura Orzali, Beatrice Corsi, Cinzia Forni, and Luca Riccioni, submitted: April 19th, 2016 Reviewed: November 11th, 2016, January 11, 2017 DOI: 10.8772/66840)
- Post-Fermentation Clarification: Wine Fining Process, Allison Corriveau, Lindsey Wilson, Professor Stephen J. Kmiotek, 2015
- Durable Antibacterial Cotton Modified by Silver Nanoparticles and Chitosan Derivatives Binder, QingBo Xu, Yong Hong Wu, Yan Yan Zhang, Fei Ya Fu and Xiang Dong Liu, Fibers and Polymers 2016, Vol.17, No 11, 1782-1789 DOI 10.1007-s12221-016-6609-2
- J. Am Diet Association, 2005 Jan;105 (1):72-7, U.S National Library of Medicine National Institutes of Health
- Biopolymer Electrolytes Fundamentals and Applications in Energy Storage, Y.N Sudhakar, M. Selvakumar, D. Krishna Bhat, 2018
- Chitin; Poly0N-acetyl-D-clucosamine (128991 Fact Sheet https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/fs_PC-128991_1-Mar-01.pdf
- USDA NOP Technical Report for Chitosan as an adjuvant. https://www.ams.usda.gov/sites/default/files/media/Chitosan%20TR.pdf
- EPA Docket Number EPA-HQ-OPP-2007-0566
- EPA Substance Registry Services (SRS) Chitosan https://iaspub.epa.gov/sor_internet/registry/substreg/searchandretrieve/advancedsearch/externalSearch.do?p_type=CASNO&p_value=9012-76-4

- FDA GRAS Notices https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GrASNotices&id=397&sort=Date_of_closure&order=ASC&startrow=1&type=basic&search=chitosan
- FREEDOM OF INFORMATION SUMMARY ORIGINAL REQUEST FOR ADDITION TO THE INDEX OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGS FOR MINOR SPECIES MIF 900-012 https://www.fda.gov/media/83661/download
- Agriculture Label with Chitosan as an Active Ingredient in Canada http://www.ez-gro.com/product/ez-gro-chitosan/
- https://www.federalregister.gov/documents/2007/12/10/E7-23880/national-organic-program-nop-amendments-to-the-national-list-of-allowed-and-prohibited-substances
- U.S National Library of Medicine National Center for Biotechnology Compound https://pubchem.ncbi.nlm.nih.gov/compound/Chitosan
- U.S National Library of Medicine National Center for Biotechnology Data Sheet https://pubchem.ncbi.nlm.nih.gov/compound/Chitosan
- Chitosan Active Ingredient Agriculture Label for Canada http://www.ez-gro.com/product/ez-gro-chitosan/
- https://www.intechopen.com/books/biological-activities-and-application-of-marine-polysaccharides/chitosan-in-agriculture-a-new-challenge-for-managing-plant-disease
- Formal Recommendation By The National Organic Standards Board (NOSB) To The National Organic Program (NOP) Chitosan https://www.ams.usda.gov/sites/default/files/media/NOP%20Rec%20Chitosan.pdf
- http://www.fundchem.cn/en/index.html
- National Organic Program (NOP); Amendments to the National List of Allowed and Prohibited Substances (Crops and Livestock) https://www.regulations.gov/document?D=AMS-TM-07-0112-0001
- The “Sunset Review” Process of the National Organics Standards Board, Posted by David Granatstein, February 11, 2016. Written by Harold Austin, NOSB Member and David Granatstein, WSU
- Chitin Deacetylases: Properties and Applications. Mar Drugs. 2010 Jan; 8(1): 24–46. Published online 2010 Jan 14. doi: 10.3390/md8010024. Yong Zaho, Ro-Dong Park, and Riccardo A. A. Muzzarelli, 2010., Jan 14
- Low-Level Copper Plus Chitosan Applications Provide Protection Against Late Blight of Potato (Lee A. Hadwiger and Pamela O. McBride, 27 Jul 2018)
- Chitosan as a novel clarifying agent on clear apple juice production: Optimization of process conditions and changes on quality characteristics Food Chem. 2017 Dec 15;237:818-824. doi: 10.1016/j.foodchem.2017.06.025. Epub 2017 Jun 12. Copyright © 2017 Elsevier Ltd. All rights reserved.
- The Multifunctional Role of Chitosan in Horticultural Crops; A Review. Molecules 2018 Apr 23(4):872. Published online 2018 Apr 10. doi.: 10.3390/molecules23040872 Rahat Sharif, Muhammad Mujtaba, Mati Ur Rahman, Abdulla Shalmani, Husain Ahmad, Toheed Anwar, Deng Tianchan, Xiping Wang, 2018 Apr 10