

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: April 27, 2018

Subject: Polyoxin D zinc salt - petitioned

NOSB Chair: Tom Chapman

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: x

Guidance Statement:

Other:

Statement of the Recommendation:

That polyoxin D zinc salt be listed as petitioned at §205.601, synthetic substances allowed for use in organic crop production, (i) as plant disease control.

Rationale Supporting Recommendation (including consistency with OFPA and Organic Regulations):

While other materials are available to organic growers for plant disease control, the petitioner and others in public comments have noted that there are few to no alternatives to control certain fungal diseases on cranberries, grapes, blueberries, strawberries, basil and other fruits and vegetables. Polyoxin D zinc salt potentially provides organic growers a tool for growing crops in areas where other alternatives have failed. Additionally, polyoxin D zinc salt offers growers an additional material to be used in rotation to prevent disease resistance. In April 2013, the NOSB reviewed this product and did not vote to approve its use, based on questions of essentiality and environmental health concerns. The petition, as resubmitted, addressed these concerns. A number of public comments noted the essentiality of the material and research showing no negative effects on soil organisms was cited to address the environmental health issues. Polyoxin D zinc salt, as petitioned, satisfies all three evaluation criteria: Impact on Humans and Environment, Essentiality & Availability, and Compatibility & Consistency.

NOSB Vote:

Classification Motion:

Motion to classify polyoxin D zinc salt as synthetic

Motion by: Jesse Buie

Seconded by: Emily Oakley

Yes: 13 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Listing Motion:

Motion to list polyoxin D zinc salt at §205.601(i)

Motion by: Jesse Buie

Seconded by: Sue Baird

Yes: 11 No: 1 Abstain: 1 Absent: 0 Recuse: 0

Motion Passed

**National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Polyoxin D Zinc Salt
February 19, 2018**

Summary of Polyoxin D Zinc Salt [Petition](#):

Two petitions for polyoxin D zinc salt were submitted to the National Organic Program. Both propose to amend 7 CFR 205.601 to add polyoxin D zinc salt as a synthetic substance allowed for use in organic crop production. The February 2, 2018 petition addendum more precisely specifies that the requested amendment is for 7 CFR 205.601(i). At the April 2013 National Organic Standards Board meeting, the NOSB was unable to reach the required 10 votes to place this material as an approved synthetic on §205.601, by a vote of 9 yes and 6 no. The NOSB found this material non-essential, and there were concerns over its broad-spectrum mode of action as well as environmental concerns for soil bacteria, fungi, and overall environmental health.

The second petition, submitted in May 2016, brought forward data to evaluate the effects on beneficial soil organisms and insects as well as an analysis by the petitioner of grower need.

Summary of Review:

Polyoxin D zinc salt is categorized as a biofungicide or biochemical pesticide. While the polyoxin D might be considered a nonsynthetic product, the addition of the zinc salt makes it a synthetic. The zinc salt makes this product more useful by lessening its water solubility and prevents the product from washing off the application area too quickly to yield significant effectiveness.

The petitioner has made a case that there are few to no alternatives for some fungal diseases on various species of plants, such as cottonball disease on cranberries, black rot, downy mildew, powdery mildew and bunch rot on grapes, mummyberry on blueberries, phomopsis leaf spot on strawberries, downy mildew on basil as well as a host of other fungal diseases on fruits. The petitioner states there are OMRI listed alternatives, but their product is either more effective or offers another tool for producers in rotation to prevent resistance.

While this material is of lower toxicity than some other products used for similar treatments, the Crops Subcommittee expressed varied views regarding its essentiality.

Category 1: Classification

1. For CROP use: Is the substance _____ Non-synthetic or x Synthetic?
Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.

Polyoxin D is converted to polyoxin D zinc salt via a chemical reaction.

2. For CROPS: Reference to appropriate OFPA category:

Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

Polyoxin D zinc salt is a “toxin derived from a naturally bacteria.” Polyoxin D is produced via fermentation of a naturally-occurring (non-GMO) bacteria, *Streptomyces cacaoi* var. *aroensis*, isolated from a soil sample collected in Japan (TR Lines 179 and 187-188).

Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]

The petitioner acknowledges polyoxin D zinc salt could kill beneficial soil fungi, and specific brand name products (Bio-Tam and Rootshield) used by organic producers would be rendered ineffective if they were in contact with polyoxin D zinc salt. However, in their own studies, they found little to no toxic effects on beneficial soil fungi.

2. What is 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? [§6518(m)(2)]

Polyoxin D zinc salt has a unique, non-toxic mode of action. No other active ingredient registered for use in North America has the same mode of action (FRAC Code 19).

As described in the 2012 petition (page 18):

“The active portion of polyoxin D zinc salt is polyoxin D which is produced by a microorganism that is naturally occurring in the soil. Polyoxin D inhibits the growth of phytopathogenic fungal cell wall chitin by competitively inhibiting chitin synthetase. Without chitin, susceptible fungi are unable to continue growing and infecting plant cells. Polyoxin D zinc salt does not kill the fungi; it simply stops the fungal growth. The action of Polyoxin D is highly specific; it does not affect bacteria, viruses, or mammals.”

Per comments from the members of the NOSB during the 2013 public hearing, further information regarding the elucidation of the mode of action is included in the May 31, 2016 petition.

The December 12, 2017 TR states (lines 206-210):

“Soil half-life from aerobic microbial metabolism is reported to be 15.9 days (Esteem Report). Polyoxin D Zinc Salt was shown to undergo aqueous abiotic hydrolysis at pH = 7 and pH= 9 (Esteem Report). Photolytic degradation was observed, DT₅₀ = 1.6 d in spring conditions (Esteem Report). Data reviewed by EPA indicated that polyoxin D Zinc Salt biodegrades within 2-3 days of application, with a low toxicity profile [73 FR 69559].”

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]

There is no concern during the manufacture, use, or disposal other than that this product should not be used nearby to, or in, water since it is moderately toxic to aquatic invertebrates and fish. A brand name product label (VEGGIETURBO 5SC Suspension Concentrate Fungicide) containing polyoxin D zinc salt has this warning:

“For terrestrial use. This pesticide is moderately toxic to aquatic invertebrates and fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate. Do not allow runoff into lakes, streams, ponds or public waterways. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Observe the most restrictive labeling limitations and precautions of all products used in mixtures.”

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].

The Technical Review of polyoxin D zinc salt from December 2017 states there is very low acute toxicity to humans by oral, dermal, or inhalation routes, and it did not demonstrate mutagenic potential. However, there are warnings on the label about possible skin irritation effects, as well as eye irritation.

Specifically, the TR states (lines 218-230):

*“In animal models, Polyoxin D Zinc Salt was shown to have very low acute toxicity by oral, dermal, and inhalation routes. Only very minor skin irritation was observed for Polyoxin D Zinc Salt, which was not sufficient to warrant classification. Polyoxin D Zinc Salt was shown to cause mild eye irritation. Polyoxin D Zinc Salt was shown not to be a contact sensitizer. Polyoxin D did not demonstrate a mutagenic potential though it did reveal some clastogenic potential with and without metabolic activation. In general, low toxicity was observed for Polyoxin D Zinc Salt in all investigations. During toxicity studies, Polyoxin D Zinc Salt is poorly absorbed with the vast majority of the product (>90%) being excreted unchanged directly in the feces. Polyoxin D Zinc Salt has been used for many years without any notable, consistent adverse human reactions being recorded. Polyoxin D Zinc Salt has been in use as an antifungal agent for over 40 years in Japan on rice, and approved in the USA and Mexico on food crops for over 5 and 3 years respectively and for non-food crops in the USA for over 16 years. The product is derived naturally in Japan from *Streptomyces cacaoi* var *asoensis* and has a unique mode of activity by inhibiting fungal cell wall synthesis. The risk to humans is considered to be extremely low.”*

5. Discuss any effects the substance may have 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. [§6518(m)(5)]

In response to NOSB questions of toxicity to beneficial soil fungi, honeybees, or ladybird beetles, the petitioner, Kaken, commissioned their own studies and found no negative effects on any of these organisms. (See petition from May 2016)

6. Are there any adverse impacts on biodiversity? (§205.200)

The technical review states this product rapidly degrades in the environment, approximately 2-3 days, and therefore it was concluded there was low environmental risk.

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

There are numerous OMRI and certifier-approved materials that can be used as alternatives, as well as cultural methods, to control fungal disease. The petitioner has stated that practices and OMRI-listed alternative materials are insufficient to meet organic grower needs.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

Yes, in balancing the responses to the criteria above, polyoxin D zinc salt to other products is compatible with a system of sustainable agriculture.

Classification Motion:

Motion to classify polyoxin D zinc salt as a synthetic substance.

Motion by: Jesse Buie

Seconded by: Emily Oakley

Yes: 6 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add polyoxin D zinc salt as petitioned at §205.601(i).

Motion by: Jesse Buie

Seconded by: Sue Baird

Yes: 3 No: 1 Abstain: 2 Absent: 1 Recuse: 0

Approved by Steve Ela, Crops Subcommittee Chair, to transmit to NOSB February 23, 2018