

Petition to Amend 7 CFR §205.601 to Add
Polyoxin D Zinc Salt as a Synthetic Substance
Allowed for Use In Organic Crop Production

PUBLIC VERSION

Submitted by
Kaken Pharmaceutical Co., Ltd.
c/o Cynthia Ann Smith
Vice President
Conn & Smith, Inc.
6713 Catskill Road
Lorton, VA 22079 USA
cindy@connsmith.com
703-339-1117

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Introduction

Polyoxin D zinc salt has been used internationally for over 40 years. Polyoxin D zinc salt was first registered for use in the United States on August 20, 1997 to control fungal diseases of turf and ornamentals. On November 19, 2008, uses in the United States were expanded to include disease control for selected food crops. Examples of economically significant plant diseases and pathogens controlled by polyoxin D zinc salt include *Alternaria*, *Anthraco*se, *Botrytis*, Brown Patch, Downy Mildew, Powdery Mildew, and *Rhizoctonia*.

Polyoxin D zinc salt is produced via a fermentation process using a naturally occurring microorganism. The possibility of developing polyoxin D zinc salt for use in organic production was discussed with Mr. Chris Pfeifer of EPA's Biopesticide and Pollution Prevention Division. Based upon Mr. Pfeifer's review of the EPA file, it was his opinion that based upon the manufacturing process alone, polyoxin D zinc salt most probably meets the NOP standards. However, he noted that he would like an opinion from the National Organic Standards Board (NOSB) regarding its status as an antibiotic. Also, the inclusion of zinc would need to be considered.

Ms. Lisa Brines of USDA was consulted. It was explained that the producer, Kaken Pharmaceutical Co., Ltd. (Kaken), has in the past but no longer describes polyoxin D zinc salt as an "antibiotic." Kaken has submitted and EPA has accepted data that demonstrate that polyoxins do not control human and veterinary pathogens. In addition, polyoxin D zinc salt has never been used in human or animal medicine. On August 2, 2011, Ms. Brines advised as follows:

"The term "antibiotic" is not defined under the Organic Foods Production Act of 1990 (OFPA) or the National Organic Program (NOP) regulations, 7 CFR Part 205. Therefore, the NOP is not able to offer you a ruling on whether Polyoxin D salt should be classified as an antibiotic.

In order for this substance to be considered for use in organic production, the NOP would encourage you to submit a petition for Polyoxin D salt to the National Organic Standards Board (NOSB), according to the Federal Register guidelines, [72 FR 2167](#).

The NOSB does not have a formal process to review substances outside of the petition or sunset review process, so the NOSB has historically issued recommendations on the acceptability of specific materials only at these times. Additional information about the NOSB is available on the NOP website at www.ams.usda.gov/nosb."

On December 12, 2011, Cynthia Smith of Conn & Smith, on behalf of Kaken, spoke with Ms. Brines of USDA regarding the section to cite. Specifically, Kaken believed that polyoxin D zinc salt is a non-synthetic material, and as such, none of the section options appear to apply. Ms. Brines agreed that §205.601, §205.602, §205.603, §205.604, and §205.605 do not apply, and there is no section for confirming use of a non-synthetic material proposed for use in organic

production. Ms. Brines further advised Kaken to:

1. Follow the petition outline for §205.601; and
2. Request confirmation that the zinc in polyoxin D zinc salt does not preclude polyoxin D zinc salt from being used in organic production.

The January 25, 2012 petition was prepared in response to the above guidance.

Based upon comments received from Lisa Brines on February 22, 2012, this petition has been amended to:

1. Proposed use of polyoxin D zinc salt as a synthetic substance permitted for use in organic crop production under 7 CFR 205.601 to enable detailed manufacturing data to be retained as confidential business information ; and
2. Delete proposed post-harvest use because the pending tolerance exemption petition that includes post-harvest use has not yet been approved by EPA.

1. Substance's Common Name

The common chemical name of the substance is polyoxin D zinc salt.

2. Manufacturer's Contact Information

The manufacturer's contact information is:

Kaken Pharmaceutical Co., Ltd.
c/o Cynthia Ann Smith
Vice President
Conn & Smith, Inc.
6713 Catskill Road
Lorton, VA 22079 USA
703-339-1117 (office and mobile)
cindy@connsmith.com

3. Current or Intended Use

Polyoxin D zinc salt is registered for use as a foliar spray on food crops, turf and ornamentals to control and/or suppress fungal diseases of plants. Registered uses are summarized in the table below.

Currently Registered Use of Polyoxin D Zinc Salt		
Crop or Crop Group	United States	International
Almond	✓	
Asparagus		✓
Blackberries		✓
Blueberries		✓
Cabbage		✓
Cassis		✓
Cucurbit	✓	
• Cucumber	✓	✓
• Melon	✓	✓
• Watermelon	✓	✓
Fruiting vegetables	✓	
• Eggplant	✓	✓
• Pepper	✓	✓
• Pepper (Hot)	✓	✓
• Tomato	✓	✓
Ginseng	✓	✓
Grape	✓	
Gromwell		✓
Lettuce		✓
Onion (Welsh)		✓
Persimmon		✓
Pistachio	✓	
Pome fruit	✓	
• Apple	✓	✓
Potato	✓	
Raspberry		✓
Rice		✓
Strawberries	✓	✓
Maximum use rates	2.1 to 4.2 oz AI/acre/season	1.5 to 14.3 oz AI/acre/season
Minimum pre-harvest intervals	0 days (365 days for ginseng)	0 to 45 days
NON-FOOD USES		
Turf	✓	✓
Ornamentals (species not specified)	✓	
Gladiolus		✓
Peony		✓

The plants and the associated fungal diseases for which polyoxin D zinc salt is currently registered for use in the United States are summarized in the table below.

Crop	Disease and Pathogen	Control	Suppression
Almond	<ul style="list-style-type: none"> • <i>Alternaria (Alternaria alternata)</i> 	✓	
Cucurbit vegetables	<ul style="list-style-type: none"> • Powdery Mildew (<i>Sphaerotheca</i> sp.) • Gummy Stem Blight (<i>Didymella bryoniae</i>) • Gray Mold (<i>Botrytis</i> sp.) • Corynespora Leaf Spot (<i>Corynespora cassiicola</i>) • Scab (<i>Cladosporium</i> sp.) • Early Blight (<i>Alternaria</i> sp.) 	✓	
Fruiting vegetables	<ul style="list-style-type: none"> • Powdery Mildew (<i>Leveillula taurica, Oidiopsis sipula</i>) • Botrytis Rot (<i>Botrytis</i> sp.) • Early Blight (<i>Alternaria solani</i>) 	✓	
	<ul style="list-style-type: none"> • Anthracnose (<i>Colletotricum coccodes</i>) 		✓
Ginseng	<ul style="list-style-type: none"> • <i>Alternaria</i> Blight (<i>Alternaria panax</i>) • Botrytis Blight (<i>Botrytis cinerea</i>) • <i>Cylindrocarpon</i> Root Rot (<i>Cylindrocarpon destructans</i>) • <i>Rhizoctonia</i> Root and Crown Rot (<i>Rhizoctonia solani</i>) 	✓	
Grapes	<ul style="list-style-type: none"> • Botrytis Bunch Rot (<i>Botrytis cinerea</i>) • Powdery Mildew (<i>Uncinula necator</i>) 	✓	
	<ul style="list-style-type: none"> • Powdery Mildew (<i>Uncinula necator</i>) 		✓
Pistachio	<ul style="list-style-type: none"> • <i>Alternaria (Alternaria</i> sp.) 	✓	
	<ul style="list-style-type: none"> • Botryosphaeria Blight (<i>Botryosphaeria</i> sp.) 		✓
Pome fruit	<ul style="list-style-type: none"> • Powdery Mildew (Apple: <i>Podosphaera leucotricha</i>; Pear: <i>Phyllactinia mali</i>) • <i>Alternaria</i> Leaf Spot (<i>Alternaria mali</i>) • Blotch (<i>Diplocarpon mali</i>) 	✓	
	<ul style="list-style-type: none"> • Scab (<i>Venturia</i> sp.) 		✓
Potato	<ul style="list-style-type: none"> • Early Blight (<i>Alternaria solani</i>) 	✓	
Strawberries	<ul style="list-style-type: none"> • Anthracnose Leaf and Fruit Rot (<i>Colletotricum</i> sp.) • Botrytis Fruit Rot (<i>Botrytis cinerea</i>) • Powdery Mildew (<i>Sphaerotheca macularis</i>) 		

Crop	Disease and Pathogen	Control	Suppression
Ornamentals	<ul style="list-style-type: none"> • Botrytis Blight (<i>Botrytis cinerea</i>) • Alternaria Blight (<i>Alternaria panax</i>) 	✓	
	<ul style="list-style-type: none"> • Anthracnose (<i>Colletotrichum</i>) • Curvularia • Downy Mildew (<i>Pernospora</i> sp. and <i>Plasmopara</i> sp.) • Powdery Mildew (<i>Oidium</i> sp., <i>Erysiphe</i> sp., and <i>Sphaerotheca</i> sp.) • Rhizoctonia Aerial Blight (<i>Rhizoctonia solani</i>) • Apple scab (<i>Venturia inaequalis</i>) • Rhizoctonia Root and Crown Rot (<i>Rhizoctonia solani</i>) 	✓ (WP)	✓ (WDG)
	<ul style="list-style-type: none"> • Petiole Rot (<i>Myrothecium</i>) • Black Root Rot (<i>Thielaviopsis</i>) 		✓
Turf grasses	<ul style="list-style-type: none"> • Brown Patch (<i>Rhizoctonia solani</i>) • Large Patch (<i>Rhizoctonia solani</i>) 	✓	
	<ul style="list-style-type: none"> • Cool Season Brown Patch or Yellow Patch (<i>Rhizoctonia cerealis</i>) • Foliar and Basal Anthracnose (<i>Colletotrichum cereale</i>) • Gray Snow Mold (<i>Typhula ishikariensis</i> and <i>Typhula incarnate</i>) • Leaf Spot/Melting Out (<i>Dreschlera poae</i>) • Pink Snow Mold (<i>Microdochium nivale</i>) • Red Thread (<i>Laetisaria fuciformis</i>) • Rhizoctonia Damping Off (<i>Rhizoctonia solani</i>) • Rhizoctonia Leaf and Sheath Blight (<i>Rhizoctonia zea</i>) • Waitea Patch and Brown Ring Patch (<i>Waitea circinata</i>) • Zoysia Patch (<i>Rhizoctonia solani</i>) • Gray Leaf Spot (<i>Pyricularia grisea</i>) • Fairy Ring (<i>Marasmius</i> sp., <i>Lepiota</i> sp. and <i>Agarius</i> sp.) 		✓

The directions for use for the registered food and non-food uses of polyoxin D zinc salt in the United States are summarized in the table below.

Registered Food and Non-Food Uses of Polyoxin D Zinc Salt the United States						
EPA Reg. No.	Primary Brand Name	Uses	Max. Apps/ Season	Max. Rate/ Application (oz AI/acre)	Max. Rate/ Season (oz AI/acre)	Min. PHI (Days)
• 66330-41 • 68173-2	• Endorse Wettable Powder Fungicide • Endorse Wettable Powder Fungicide	Ginseng	NS	0.96	NS	365
		Turf Grasses	NS	4.4	NS	NA
• 66330-56 • 68173-3	• Endorse Water Dispersible Granules • Endorse Water Dispersible Granules	Almonds	3	0.7	2.1	0
		Cucurbit vegetables	5	0.7	3.5	0
		Fruiting vegetables, excluding Cucurbits	5	0.7	3.5	0
		Ginseng	3	0.7	2.1	0
		Grapes	3	0.7	2.1	0
		Pistachios	3	0.7	2.1	0
		Pome Fruit	6	0.7	4.2	0
		Potatoes	5	0.7	3.5	0
		Strawberries	3	0.7	2.1	0
		Ornamentals	NS	0.96	NS	NA
		Turf grasses	3	4.32	NS	NA
• 68173-1	Polyoxin D Zinc Salt Technical	Manufacturing only	NA	NA	NA	NA

AI = Polyoxin D Zinc Salt

NA = Not Applicable

NS = Not Specified

The maximum registered use rate 4.4 oz polyoxin D zinc salt per acre is equivalent to 0.49 oz zinc per acre.

The most recent EPA stamped approved label for ENDORSE Water Dispersible Granules and for ENDORSE Wettable Powder are provided as [Appendix 1](#) and [Appendix 2](#), respectively.

Polyoxin D Zinc Salt Technical is for manufacturing use only for the production of fungicide formulations for use on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes, strawberries, ornamentals, golf courses, residential lawns, parks, and commercial and institutional grounds. An application for amended registration was recently submitted to EPA. The proposed revised directions for use include use on all crops (pre-harvest and post-harvest). A tolerance exemption petition to expand the current tolerance exemption for the registered crop uses only to the all crops (pre-harvest and post-harvest) was also recently submitted to EPA.

Proposed new uses are summarized in [Confidential Appendix 1](#).

Not an antibiotic

As noted in section 9, 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.

Throughout the world, polyoxin D zinc salt is used exclusively on plants as an anti-fungal agent. Based upon maximum inhibitory concentration evaluations, polyoxin D zinc salt is not effective as an anti-bacterial agent. Polyoxin D zinc salt has never been used as an antibiotic in human medicine or veterinary medicine.

Kaken Pharmaceutical Co., Ltd. has conducted two studies to determine if polyoxin D has any potential for use as an antibiotic. Both studies confirmed that polyoxin D:

1. Is not effective against common human and veterinary pathogens, and
2. Has no significant potential as a human or veterinary antibiotic.

The two studies have been submitted to EPA and are summarized in the table below. The complete study reports are provided as [Appendix 3](#) and [Appendix 4](#).

Summary of Maximum Inhibitory Concentration Data for Polyoxin D			
Pathogen Type	Pathogen	Minimum Inhibitory Concentration (µg/mL)	
		Ref. 1	Ref. 2
Bacteria	<i>Bacillus subtilis</i> ATCC6633		>400
	<i>Bacillus subtilis</i> PCI-219	>100	
	<i>Bacteroides fragilis</i> ATCC25285		>400
	<i>Clostridium perfringens</i> IID520		>400
	<i>Enterobacter aerogenes</i> ATCC13048		>400
	<i>Enterococcus faecalis</i> ATCC19433		>400
	<i>Erwinia aroideae</i>	>100	
	<i>Escherichia coli</i> ATCC25922		>400
	<i>Escherichia coli</i> NIHJ	>100	
	<i>Klebsiella pneumoniae</i> PCI-602	>100	
	<i>Lactobacillus acidophilus</i> ATCC4356		>400
	<i>Micrococcus flavus</i>	>100	
	<i>Mycobacterium phlei</i> CCM-1889	>100	
	<i>Mycobacterium avium</i> ATCC2591		>400
	<i>Pseudomonas aeruginosa</i> ATCC27853		>400
	<i>Pseudomonas fluorescens</i> NRRL-B-10	>100	
	<i>Salmonella enteritidis</i> ATCC13067		>400
	<i>Sarcina lutea</i>	>100	
	<i>Serratia marcescens</i> ATCC13880		>400
	<i>Staphylococcus aureus</i> FDA-209P	>100	
<i>Staphylococcus aureus</i> HEATLEY	>100		
<i>Staphylococcus aureus</i> ATCC25923		>400	
<i>Staphylococcus pneumonia</i> ATCC49619		>400	
<i>Vibrio parahaemolyticus</i> ATCC17802		>400	
<i>Xanthomonas citri</i>	>100		
Yeast	<i>Candida albicans</i> IPCR	>100	
	<i>Candida steratoides</i>	>100	
	<i>Endomyces magnusii</i>	>100	
	<i>Saccharomyces</i> sp.	>100	

Summary of Maximum Inhibitory Concentration Data for Polyoxin D			
Pathogen Type	Pathogen	Minimum Inhibitory Concentration (µg/mL)	
		Ref. 1	Ref. 2
Fungi	<i>Aspergillus fumigatus</i>	>100	
	<i>Aspergillus niger</i>	>100	
	<i>Aspergillus flavus</i>	>100	
	<i>Chaetomium cochliodes</i>	<100	
	<i>Fusarium oxysporum</i> f. <i>niveum</i>	<50	
	<i>Fusarium oxysporum</i> f. sp. <i>lycopersici</i>	>25	
	<i>Fusarium oxysporum</i> f. sp. <i>cucumerinum</i>	<200	
	<i>Fusarium avenaceum</i> f. sp. <i>fabae</i>	>200	
	<i>Fusarium maniliforme</i> var. <i>majus</i>	<50	
	<i>Giberella zeae</i>	>100	
	<i>Mucor recemosus</i> (-)	>10	
	<i>Penicillium citrinum</i>	>100	
	<i>Penicillium crysogenum</i>	>10	
	<i>Rhizopus oryzae</i> IFO-4707	<1.0	

Ref. 1: MRID No. 43261802. Submitted May 27, 1994.

Ref. 2: MRID No. 48653308. Submitted November 9, 2011.

4. List of Crop, Livestock, or Handling Activities for Which the Substance Will Be Used

Please see section 3 above for a list of the registered crop uses.

There are no registered or planned livestock or food handling uses of polyoxin D zinc salt.

5. Source of the Substance and Detailed Description of its Manufacturing or Processing Procedures from its Basic Components to the Final Product

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 is commercially manufactured in a well-controlled fermentation. Following fermentation, polyoxin D zinc salt is isolated from the fermentation broth and then dried.

The detailed description of the production of polyoxin D zinc salt is Confidential Business Information and has been removed [Confidential Appendix 2](#).

6. Summary of Any Available Previous Reviews by State or Private Certification Programs or Other Organizations of the Petitioned Substance

Polyoxin D zinc salt is recommended for Integrated Pest Management for ornamentals. Please see:

http://www.aces.edu/pubs/docs/A/ANR-0500-B/VOL2-2011/commercial_ornamentals_disease2.pdf
http://www.aces.edu/pubs/docs/A/ANR-0500-B/VOL2-2011/commercial_ornamentals_disease3.pdf

The Cornell University Cooperative Extension has recommended polyoxin D zinc salt for use on herbaceous perennials for control of *Botrytis*, downy mildew, fungal leaf spot, powder mildew, and root and stem rots. Please see:

<http://ipmguidelines.org/HerbaceousPerennials/content/CH05/default-1.asp>

The University of California Agriculture & Natural Resources Statewide Integrated Pest Management Program recommends polyoxin D zinc salt for control of fungal diseases of pistachios. Please see:

<http://www.ipm.ucdavis.edu/PMG/r605902111.html>

The Environmental Institute for Golf IPM Planning Guide recommends polyoxin D zinc salt for curative and preventative treatments for turf fungal diseases. Please see:

http://www.eifg.org/sustainability/toolbox/ipmguide/documents/reference_disease.pdf

Frank Wong, Ph.D. of the University of California-Riverside has recommended polyoxin D zinc salt for the control of anthracnose, a disease caused by the fungus *Colletotrichum cereale*. Please see [Appendix 5](#).

The University of Kentucky College of Agriculture Cooperative Extension Service has

recommended polyoxin D zinc salt for control of the following turf grass diseases: Anthracnose, (Brown Patch (= *Rhizoctonia Blight*), Fairy Ring, Gray Leaf Spot, Large Patch of Zoysta (formerly Zoysta Patch), Leaf Spot and Melting Out, Pink Snow Mold/Microdochium Patch (= *Fusarium Patch*), Red Thread, Rhizoctonia Leaf and Sheath Spot, and Yellow Patch (= *Low Temperature Brown Patch*). Please see:

<http://pest.ca.uky.edu/PSEP/Manuals/ppa1.pdf>

California Department of Pesticide Regulation Public Report 2003-7 states:

“Endorse™ Wettable Powder Turf Fungicide is a biochemical-like fungicide that is specific for controlling brown patch and large patch in turf caused by *Rhizoctonia*. The reviewed efficacy data indicates Endorse™ Wettable Powder Turf Fungicide provides equivalent to superior control of these diseases compared to the traditional fungicides. It is a safer alternative to most of the currently registered turf fungicides. However, polyoxin-d does have a specific mode-of-action and there is the potential for development of resistant strains of *Rhizoctonia* from repeated use. Use in conjunction with other turf fungicides is recommended.”

For the full report, please see:

<http://www.cdpr.ca.gov/docs/registration/ais/publicreports/5788.pdf>

High Plains Integrated Pest Management recommends polyoxin D zinc salt for of turf grass diseases. Please see:

<http://wiki.bugwood.org/HPIPM:Other>

The above references are representative (not exhaustive) previous reviews by state or private certification programs.

7. Information Regarding EPA, FDA and State Regulatory Authority Registrations, Including Registration Numbers

Current EPA registrations for products containing polyoxin D zinc salt are summarized in the table below.

Registrant	EPA Reg. No.	Brand Name	Marketed by	State Registrations
Kaken Pharmaceutical Co., Ltd.	68173-1	Polyoxin D Zinc Salt Technical	N/A	No
	68173-2	Endorse Wettable Powder Fungicide	N/A	No
	68173-3	Endorse Water Dispersible Granules	N/A	No
	68173-3-1001	Affirm Water Dispersible Granules	Cleary Chemicals, LLC	Yes
Arysta LifeScience, NA	66330-41	Endorse Wettable Powder Fungicide	Arysta LifeScience, NA	Yes
	66330-56	Endorse Water Dispersible Granules	Arysta LifeScience, NA	Yes
		Ph-D Water Dispersible Granules	Arysta LifeScience, NA	Yes
	66330-56-59807	Veranda O	OHP	Yes

The currently registered formulations containing polyoxin D zinc salt are registered in all states. Most uses are registered in California, but some are not.

A new formulation designed for use in organic production is in development, and the application for registration is planned for submission to EPA in time for use during the 2013 use season. The new formulation is planned for registration and use in all states, including California.

There are no FDA registrations for any products containing polyoxin D or polyoxin D zinc salt.

8. Chemical Abstract Service (CAS) Number or Other Product Numbers

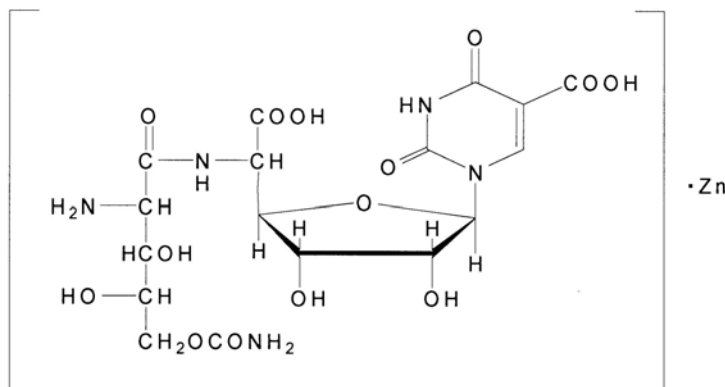
The CAS chemical name (ninth chemical index) for polyoxin D zinc salt is:

B-D-allofuranuronic acid, 5-[[2-amino-5-*O*-(aminocarbonyl)-2-deoxy-L-xyloonyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2*H*)-pyrimidinyl)-1,5-dideoxy-, zinc salt (1:1).

This name can also be expressed as:

zinc 5-[[2-amino-5-*O*-(aminocarbonyl)-2-deoxy-L-xyloonyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2*H*)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronate

The chemical structure of polyoxin D zinc salt is provided below.



Additional identity parameters are summarized below:

- PC Code: 230000
- CAS Number (zinc salt): 146659-78-1
- Empirical formula (1:1 zinc salt): $C_{17}H_{21}N_5O_{14} \cdot Zn$

9. Substance's Physical Properties and Mode of Action

Physical Properties

The physical properties of polyoxin D zinc salt are summarized in the table below.

Gdln. No.	Data Requirement	Description	MRID No.
830.6302	Color	Brown	43261816
830.6303	Physical state	Powder	43261816
830.6304	Odor	Musty	43261816
830.6313	Stability to normal and elevated temperatures, metals and metal ions	122.5 ± 0.1, decomposition at 170 °C. Stable at 0 and 12 °C (96 hrs). Complete degradation (95.8%) at 54 °C for 14 days. No change to metals (zinc and iron foil). Unstable in sunlight 39.3% degradation in 24 hours.	43261816
			43261819
830.6317	Storage stability	100% up to 12 months. Decreased 3% during 24 months. Decreased 5% during 4 years.	43261821
			43823701
830.7000	pH	7.51 (1% solution, 23.2 °C) 6.9 (6.7 - 7.2)	43261816
830.7050	UV/visible light absorption	Absorption maxima: 270.0 nm under neutral conditions 274.0 nm under acidic conditions 268.5 nm under alkaline conditions Extinction coefficient: 18,586 under neutral conditions 24,251 under acidic conditions 17,726 under alkaline conditions	48653302
830.7200	Melting point / melting range	122.5 ± 0.2 °C; decomposes at 170 °C	43261816
830.7220	Boiling point / melting range	NOT APPLICABLE. TGAI is a solid at room temperature.	NA
830.7300	Density / relative density / bulk density	1.8392 g/cc; 2.32441 g/cc (20-27.1 °C)	43261816
830.7520	Particle size, fiber length and diameter distribution	NOT APPLICABLE. TGAI is not water insoluble and is not fibrous.	NA
830.7550	Partition coefficient	NOT APPLICABLE. TGAI is not non-polar. TGAI is very water soluble.	NA

Gdln. No.	Data Requirement	Description	MRID No.
830.7840	Water solubility	1.0 g/100 mL water	43261816
830.7950	Vapor pressure	NOT APPLICABLE. TGAI is a salt.	NA

Mode of Action

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.

9.a. Chemical Interactions with Other Substances, Especially Substances Used in Organic Production

No chemical interactions are anticipated to occur between polyoxin D zinc salt and other substances, including substances used in organic production.

9.b. Toxicity and Environmental Persistence

9.b.1. Toxicity to Non-Target Organisms

Polyoxin D zinc salt is practically non-toxic to birds and non-target insects. Polyoxin D zinc salt is moderately toxic to aquatic organisms. The non-target organism data for polyoxin D zinc salt is summarized in the table below.

Gdln. No.	Study	Results	Description	MRID No.
850.1010	Freshwater invertebrate LC ₅₀ (<i>Daphnia magna</i>)	1.35 ppm polyoxin D zinc salt	Moderately toxic	43261843
850.1075	Freshwater fish 96-hour LC ₅₀ (rainbow trout)	5.06 ppm polyoxin D zinc salt/L	Moderately toxic	43261842
850.2100	Avian acute oral LD ₅₀ (mallard duck)	> 2150 mg/kg	Practically non-toxic	43261840
850.2200	Avian acute dietary LC ₅₀ (mallard duck)	> 5000 ppm	Practically non-toxic	43261841

Gdln. No.	Study	Results	Description	MRID No.
850.5400	Algal growth inhibition	Growth: • E_bC_{50} (0-72 hr) = 6.47 mg/L • $NOEC_b$ (0-72 hr) = 5 mg/L Growth rate: • E_rC_{50} (24-72 hr) = 7.05 mg/L • $NOEC_r$ (24-72 hr) = 5 mg/L	Moderately toxic	48660403
880.4350	Honeybee acute oral LD_{50}	28.774 μ g/bee	Practically non-toxic	48660404

To mitigate the moderate toxicity to aquatic organisms, the product labels state, “Do not contaminate water when cleaning equipment or disposing of equipment washwaters. Do not allow runoff into lakes, streams, ponds or public waterways.”

For all of the above summarized studies, the test substance was polyoxin D zinc salt. Therefore, the studies evaluated the combined toxicity of both polyoxin D and zinc as they would be present under use conditions.

9.b.2. Environmental Persistence

Polyoxin D degrades rapidly under normal environmental conditions. The results of the available degradation data are summarized in the table below.

Degradation Route	Half-life (days)	pH	Conditions
Hydrolysis	32.5	7.0	Neutral, 25 °C
	9.1	9.0	Basic, 25 °C
Aqueous photolysis	4.0	5.0	Acidic, Sterile
	2.3	7.0	Neutral, Sterile
	1.3	9.0	Basic, Sterile
Aerobic soil metabolism	15.9		Microbially active
	59.2		Sterile

Under neutral conditions (pH 7) and in the presence of water and sunlight at normal room temperature, polyoxin D has half-life of 2.3 days. Every 2.3 days, half of the polyoxin D degrades. At temperatures warmer than average room temperature, this degradation will be faster.

9.c. Environmental Impacts from its Use and/or Manufacture

Due to the low toxicity to non-target organisms and the rapid environmental degradation, the use and the manufacture of polyoxin D zinc salt is anticipated to have no significant environmental impact.

9.d. Effects on Human Health

Acute Toxicity

Polyoxin D zinc salt has low acute mammalian toxicity.

Polyoxin D Zinc Salt Acute Toxicology Data Summary			
OPPTS Gdln. No.	Study	Results	MRID No.
870.1100	Acute oral toxicity (rat)	LC ₅₀ ♂: > 15,000 mg/kg bw LC ₅₀ ♀: 10,000 to 15,000 mg/kg bw	43261823
870.1200	Acute dermal toxicity (rat)	LD ₅₀ 2000 mg/kg bw	43261825
870.1300	Acute inhalation toxicity (rat)	LC ₅₀ ♂: > 2.44 mg/L LC ₅₀ ♀: > 2.17 mg/L	43261827
870.2400	Eye irritation (rabbit)	Slight to moderate irritation (Draize)	43261829
870.2500	Dermal irritation (rabbit)	Slight irritation (Draize)	43261831
870.2600	Dermal sensitization (Guinea pig)	Mild sensitizer at 5% TGAI	43261833

Mutagenicity

Based upon Tier I *in vitro* assays, polyoxin D zinc salt ranges from non-mutagenic to equivocal to weakly mutagenic. Based upon a Tier II *in vivo* assay, *i.e.*, a mouse micronucleus test, polyoxin D zinc salt is not mutagenic. This higher tier assay conducted in a whole living mammal with working enzymatic systems is believed to best represent the hazard to humans. The Tier II data support the conclusion that polyoxin D zinc salt is non-mutagenic *in vivo* (in whole body systems).

Polyoxin D Zinc Salt Tier I and Tier II Mutagenicity Data				
OPPTS Gdln. No.	Tier	Assay	Results	MRID No.
870.5100	I	a. REC-assay with <i>B. Subtilis</i> H-17 and M-45	Unacceptable	43261836
		b. Ames Test	Unacceptable	
		c. Host-mediated assay (mice)	Not mutagenic	
		Bacterial reverse mutation test	Weakly mutagenic	43323001
		Bacterial reverse mutation test	Non-mutagenic.	48653313
870.5375	I	Chromosomal aberration, Chinese hamster fibroblast cells	Equivocal at highest dose tested (0.05 mg/mL)	43261835
		Chromosomal Aberration	Non-mutagenic.	48653314
870.5395	II	Micronucleus test	Non-mutagenic. Submitted June 5, 2007 to support petition 7F7252.	47145102

Developmental and Reproductive Toxicity

Polyoxin D zinc salt is not a developmental or reproductive toxicant. Polyoxin D zinc salt has low developmental toxicity rabbits and rats. In both species, no adverse effects were observed in fetuses at the highest dose tested, while maternal effects were observed at lower doses. The NOELs for fetuses were >800 mg/kg/day for rabbits and >1000 mg/kg/day for rats. The NOELs for dams were 50 mg/kg/day in rabbits and 300 mg/kg/day in rats.

Polyoxin D Zinc Salt Tier I and Tier II Developmental and Reproductive Toxicity Data Summary			
OPPTS Gdln. No.	Study	Results	MRID No.
870.3700	Prenatal developmental (rabbit)	From BRAD: NOEL (polyoxin D zinc salt): • Fetal > 800 mg/kg/day • Maternal: 50 mg/kg/day; decreased body weight.	43261837
	Prenatal developmental (rat)	Doses: 0, 100, 300 & 1000 mg/kg/day. NOEL: 1. Fetal: 1000 mg/kg/day. 2. Maternal: 300 mg/kg/day. Maternal LOEL: 1000 mg/kg/day. Thickening of limiting ridge of stomach.	486533135
870.3800	Reproduction and fertility effects (rats)	NOAEL = 1% in diet (HDT).	47120904

Subchronic Toxicity, Immunotoxicity and Chronic Toxicity

Polyoxin D zinc salt has low subchronic toxicity, immunotoxicity, and chronic toxicity.

In the 90-day feeding study in rats, the NOAEL was 133 mg/kg/day (HDT) in females. In males, the NOAEL was 119 mg/kg/day, and decreased body weight gain, food consumption and food efficiency were observed at the LOAEL of 1166 mg/kg/day.

In the 28-day immunotoxicity study, the NOAEL was 1776 mg/kg/day (HDT).

Polyoxin D zinc salt was determined to be non-carcinogenic in both the mouse and the rat. The NOAEL in the mouse is 4% in the diet (HDT). The NOAEL in the rat is 5% in the diet (HDT).

Polyoxin D Zinc Salt Sub-Chronic Toxicity, Immunotoxicity and Chronic Toxicity			
OPPTS Gdln. No.	Study	Results	MRID No.
870.3100	90-Day oral (rat)	♀ NOAEL= 1333 mg/kg/day (HDT). ♂ NOAEL = 119 mg/kg/day. ♂ LOAEL = 1166 mg/kg/day based upon decreased body weight gain, food consumption and food efficiency.	47145101
880.3550	28-Day immunotoxicity (mouse)	NOAEL = 1776 mg/kg/day (HDT).	47120901
870.4200	Carcinogenicity (mouse)	Non-carcinogenic. NOAEL = 4% in diet (HDT). Supplementary.	43261838
	Carcinogenicity (rat)	Non-carcinogenic. NOAEL = 5% in diet (HDT). Supplementary.	43261839

For all of the above summarized studies, the test substance was polyoxin D zinc salt. Therefore, the studies evaluated the combined toxicity of both polyoxin D and zinc as they would be present under use conditions.

Dietary exposure

Dietary exposure to polyoxin D zinc salt residues resulting from both pre-harvest and post-harvest treatment of crops according to good agricultural practices will be very low.

Food

Dietary exposure to polyoxin D zinc salt residues resulting from crops treated pre-harvest according to good agricultural practice will be low based upon:

1. The low measured residues in crops treated pre-harvest in a greenhouse at the maximum seasonal rate;
2. Significant measured residue reduction resulting from rinsing with water; and
3. Rapid environmental degradation of polyoxin D.

Residues resulting from treatments applied post-harvest will similarly be significantly reduced by rinsing the raw agricultural commodity with water. In addition, cooking will further reduce these low level residues to very low level residues.

Drinking water

Residues of polyoxin D zinc salt will be very low. Polyoxin D zinc salt degrades rapidly under normal environmental conditions. The half-life is 32.5 days at pH 7 by hydrolysis, 2.3 days by aqueous photolysis at pH 7, and 15.9 days in microbially active soil by aerobic soil metabolism.

Non-dietary exposure

Polyoxin D zinc salt is registered to control fungal diseases of turf. The use on turf was previously estimated to result in very low non-dietary risk, including hand-to-mouth exposure to infants and children.

Cumulative Effects

Polyoxin D zinc salt is not known to share a toxicological mode of action with any other pesticide.

9.e. Effects on Soil Organisms, Crops, or Livestock

9.e.1. Effects on Soil Organisms

No studies of the effects of polyoxin D zinc salt on soil organisms are available. However, no significant effects on soil organisms are anticipated because:

1. The mode of action of polyoxin D zinc salt is limited to chitin inhibition in fungi; and
2. Polyoxin degrades rapidly in the environment, including in the soil.

9.e.2. Effects on Crops

In over 40 years of use and testing, there have been no reported observations of phytotoxicity or other types of crop damage resulting from exposure to polyoxin D or polyoxin D zinc salt.

Based upon the nature of the data in crops, residues in/on crops will be low and are readily removed by rinsing with water.

9.e.3. Effects on Livestock

Kaken Pharmaceutical Co., Ltd. does not anticipate any adverse effect on livestock due to:

1. The low toxicity to mammals;
2. The low toxicity to birds;
3. The low residues in livestock feeds; and
4. The absence of current or planned future uses of polyoxin D zinc salt on livestock.

10. Safety information, including MSDS and report from the National Institute of Environmental Health Studies

Please see [Appendix 6](#) for a copy of the MSDS for Polyoxin D Zinc Salt Technical.

There is no report issued by the National Institute of Environmental Health Studies regarding polyoxin D zinc salt or polyoxin D.

11. Research Information, Including Reviews and Research Bibliographies

The research that has been conducted on polyoxin D Zinc salt has been to support its use as a pesticide. The data submitted to EPA are more extensive than for most biochemicals and are summarized in the table below in guideline number order.

Gdln No.	Guideline Name	Title	MRID No.
	EFFICACY		
810.0000	Efficacy	Minimum Inhibitory Concentrations (MIC) of Polyoxins Against Bacteria, Yeast and Fungi. Unpublished study prepared by Kaken Chemical Co., Ltd. 5 p.	43261802
		Studies on Polyoxin Action Part I: Effect on Respiration and Synthesis in Protein, Nucleic Acids and Cell-Wall of Fungi. Nippon Nogeikagaku Kaishi 42(10):633-638.	43261803
		Studies on the Mode of Action of Polyoxins Part III: Relation of Polyoxin Structure to Chitin Synthetase Inhibition. Agr. Biol. Chem., 35(8):1280-1291.	43261804
		Interaction Between Polyoxin and Active Center of Chitin Synthetase. Agr. Biol. Chem 38(4):699-705.	43261805
		Further Study on the Relation of Polyoxin Structure to Chitin Synthetase Inhibition. Agr. Biol. Chem. 38(4):691-698.	43261806
		Mode of Action of Agricultural Antibiotics Developed in Japan. Residue Reviews 25:93-104.	43261807
		Polyoxin D, A Competitive Inhibitor of UPD-N-Acetylglucosamine: Chitin N-Acetylglucosaminyltransferase in Neurospora crassa. Biochemical and Biophysical Research Communications 37(4):98-102.	43261808
		Mechanism of mode of action of antifungal agent Polyoxin D. Journal of Bacteriology 104(1):189-196.	43372101
		Effect of Polyoxin D on cell wall regeneration and biosynthesis in protoplasts from Pyricularia oryzae. Journal of Pesticide Science 13:213-220.	43372102
		Minimum Inhibitory Concentration (MIC) of Polyoxin D Against Various Bacteria	48653308

Gdln No.	Guideline Name	Title	MRID No.
	PRODUCT CHEMISTRY		
830.SUMM		Polyoxin D Zinc Salt: Product Chemistry Summary for a Tolerance Exemption Petition	48653301
880.1100	Product identity and composition	Polyoxin D Zinc Salt Technical and Polyoxin Z Wettable Powder: Product Identity, Manufacturing Process, Unintentional Ingredients and Certified Limits	43261809
		Studies on Polyoxins, Antifungal Antibiotics Part VII: The Structure of Polyoxins. Journal of the American Chemical Society 91(26):63-78	43261810
		Polyoxin D Zinc Salt Technical and Polyoxin Z Wettable Powder: Product Identity, Manufacturing Process, Unintentional Ingredients, and Certified Limits: (Amended)	44214601
880.1200	Description of starting materials, production and formulation process	Polyoxin D Zinc Salt Technical and Polyoxin Z Wettable Powder: Product Identity, Manufacturing Process, Unintentional Ingredients and Certified Limits	43261809
		Polyoxin D Zinc Salt Technical and Polyoxin Z Wettable Powder: Product Identity, Manufacturing Process, Unintentional Ingredients, and Certified Limits: (Amended)	44214601
880.1400	Discussion of formation of impurities	Polyoxin D Zinc Salt Technical and Polyoxin Z Wettable Powder: Product Identity, Manufacturing Process, Unintentional Ingredients and Certified Limits	43261809
		Polyoxin D Zinc Salt Technical and Polyoxin Z Wettable Powder: Product Identity, Manufacturing Process, Unintentional Ingredients, and Certified Limits: (Amended)	44214601
		Contamination Test and Quality Control Examinations and Method in Fermentation of Polyoxin D	44249801
830.1700	Preliminary analysis	Polyoxin D Zinc Salt Technical Grade Active Ingredient: Analysis of Samples	43261811
		Analysis of Inorganic Salts in Polyoxin D Zinc Salt Technical Grade Active Ingredient	44249701

Gdln No.	Guideline Name	Title	MRID No.
		Contamination Test and Quality Control Examinations and Method in Fermentation of Polyoxin D	44249801
830.1750	Certified limits	Polyoxin D Zinc Salt Technical and Polyoxin Z Wettable Powder: Product Identity, Manufacturing Process, Unintentional Ingredients and Certified Limits	43261809
		Polyoxin D Zinc Salt Technical and Polyoxin Z Wettable Powder: Product Identity, Manufacturing Process, Unintentional Ingredients, and Certified Limits: (Amended)	44214601
830.1800	Enforcement analytical method	Validation of HPLC Analytical Method of Polyoxin D Zinc Salt	43261812
		HPLC Analytical Method of Polyoxin D Zinc Salt	43261813
		The Validity of HPLC Analytical Method of Polyoxin D Zinc Salt	43261814
		Microbiological Assay of Polyoxin D Zinc Salt Using Cylinder Cup/Agar Plant Method	43261815
830.6302	Color	Physical and Chemical Properties of Polyoxin D Zinc Salt Technical Grade Active Ingredient (Color, Physical State, Odor, Melting Point, Density, Solubility, Dissociation Constant, pH, and Stability): Amended Final Report	43261816
830.6303	Physical state	Physical and Chemical Properties of Polyoxin D Zinc Salt Technical Grade Active Ingredient (Color, Physical State, Odor, Melting Point, Density, Solubility, Dissociation Constant, pH, and Stability): Amended Final Report	43261816
830.6304	Odor	Physical and Chemical Properties of Polyoxin D Zinc Salt Technical Grade Active Ingredient (Color, Physical State, Odor, Melting Point, Density, Solubility, Dissociation Constant, pH, and Stability): Amended Final Report	43261816
830.6313	Stability to normal and elevated temperatures, metals and metal ions	Physical and Chemical Properties of Polyoxin D Zinc Salt Technical Grade Active Ingredient (Color, Physical State, Odor, Melting Point, Density, Solubility, Dissociation Constant, pH, and Stability): Amended Final Report	43261816
		Determination of Stability for Polyoxin D Zinc Salt Technical Grade Active Ingredient: Final Report	43261819

Gdln No.	Guideline Name	Title	MRID No.
830.6315	Flammability	Polyoxin D Zinc Salt: Product Chemistry Summary for a Tolerance Exemption Petition	48653301
830.6317	Storage stability	Storage Stability of Polyoxin D Zinc Salt Technical Grade Active Ingredient and Polyoxin Z Wettable Powder	43261821
		Storage Stability of Polyoxin D Zinc Salt Technical Grade Active Ingredient: Final Report	43823701
830.6319	Miscibility	Polyoxin D Zinc Salt: Product Chemistry Summary for a Tolerance Exemption Petition	48653301
830.6320	Corrosion characteristics	Polyoxin D Zinc Salt: Product Chemistry Summary for a Tolerance Exemption Petition	48653301
830.7000	pH	Physical and Chemical Properties of Polyoxin D Zinc Salt Technical Grade Active Ingredient (Color, Physical State, Odor, Melting Point, Density, Solubility, Dissociation Constant, pH, and Stability): Amended Final Report	43261816
830.7050	UV/visible light absorption	Polyoxin D Zinc Salt TGAI: UV/Visible Absorption	48653302
830.7100	Viscosity	Polyoxin D Zinc Salt: Product Chemistry Summary for a Tolerance Exemption Petition	48653301
830.7200	Melting point / melting range	Physical and Chemical Properties of Polyoxin D Zinc Salt Technical Grade Active Ingredient (Color, Physical State, Odor, Melting Point, Density, Solubility, Dissociation Constant, pH, and Stability): Amended Final Report	43261816
830.7220	Boiling point / boiling range	Polyoxin D Zinc Salt: Product Chemistry Summary for a Tolerance Exemption Petition	48653301
830.7300	Density / relative density / bulk density	Physical and Chemical Properties of Polyoxin D Zinc Salt Technical Grade Active Ingredient (Color, Physical State, Odor, Melting Point, Density, Solubility, Dissociation Constant, pH, and Stability): Amended Final Report	43261816
830.7520	Particle size, fiber length and diameter distribution	Polyoxin D Zinc Salt: Product Chemistry Summary for a Tolerance Exemption Petition	48653301
830.7550	Partition coefficient	NOT APPLICABLE. TGAI is not non-polar. TGAI is very water soluble. See: Polyoxin D Zinc Salt: Product Chemistry Summary for a Tolerance Exemption Petition	NA

Gdln No.	Guideline Name	Title	MRID No.
830.7840	Water solubility	Physical and Chemical Properties of Polyoxin D Zinc Salt Technical Grade Active Ingredient (Color, Physical State, Odor, Melting Point, Density, Solubility, Dissociation Constant, pH, and Stability): Amended Final Report	43261816
830.7950	Vapor pressure	NOT APPLICABLE. TGAI is a salt. See: Polyoxin D Zinc Salt: Product Chemistry Summary for a Tolerance Exemption Petition	NA
	ENVIRONMENTAL FATE - TIER II	(In the guideline number order listed in the Federal Register	
835.SUMM		Polyoxin D Zinc Salt: Environmental Fate Summary for a Tolerance Exemption Petition	48653303
835.1230	Sediment and soil adsorption/desorption for parent and degradates	Polyoxin D Zinc Salt: Adsorption/Desorption, Soil Column Leaching, Volatilization from Soil, Aerobic Soil Metabolism and Anaerobic Soil Metabolism	48660401
835.1240	Soil column leaching	Polyoxin D Zinc Salt: Adsorption/Desorption, Soil Column Leaching, Volatilization from Soil, Aerobic Soil Metabolism and Anaerobic Soil Metabolism	48660401
835.1410	Laboratory volatilization from soil	Polyoxin D Zinc Salt: Adsorption/Desorption, Soil Column Leaching, Volatilization from Soil, Aerobic Soil Metabolism and Anaerobic Soil Metabolism	48660401
835.2120	Hydrolysis	A Hydrolysis Study of [¹⁴ C]Polyoxin D in pH 4.0, pH 5.0, pH 7.0 and pH 9.0 Buffer	48653304
835.2240	Photodegradation in water	Photodegradation of [¹⁴ C]Polyoxin D in Sterilized Natural Water and Sterilized Buffer by Simulated Sunlight	48653305
835.4100	Aerobic soil metabolism	Metabolic Fate of [¹⁴ C]Polyoxin D in Aerobic Soil	48653306
835.4300	Aerobic aquatic metabolism	Polyoxin D Zinc Salt: Adsorption/Desorption, Soil Column Leaching, Volatilization from Soil, Aerobic Soil Metabolism and Anaerobic Soil Metabolism	48660401
835.4400	Anaerobic aquatic metabolism	Polyoxin D Zinc Salt: Adsorption/Desorption, Soil Column Leaching, Volatilization from Soil, Aerobic Soil Metabolism and Anaerobic Soil Metabolism	48660401

Gdln No.	Guideline Name	Title	MRID No.
880.4425	Dispenser - water leaching	NOT APPLICABLE. Product is not applied via a passive dispenser.	
	NONTARGET ORGANISM - TIER I		
850.1010	Aquatic invertebrate acute toxicity, freshwater	Polyoxin D Zinc Salt Technical Grade Active Ingredient: Acute EC50 to <i>Daphnia magna</i>	43261843
850.1075	Fish acute toxicity, freshwater	Polyoxin D Zinc Salt Technical Grade Active Ingredient: Acute LC50 to Rainbow Trout (<i>Oncorhynchus mykiss</i>)	43261842
850.2100	Avian acute oral toxicity	Polyoxin D Zinc Salt Technical Grade Material: 21-Day Acute Oral LD50 Study in Mallard Ducks	43261840
850.2200	Avian dietary toxicity	Polyoxin D Zinc Salt Technical Grade Material: 8-Day Acute Dietary LD50 Study in Mallard Ducklings	43261841
850.4100	Terrestrial plant toxicity, seedling emergence	Polyoxin D Zinc Salt: Nontarget Plant Testing	48660402
850.4150	Terrestrial plant toxicity, vegetative vigor	Polyoxin D Zinc Salt: Nontarget Plant Testing	48660402
850.5400	Algal Toxicity	Growth Inhibition Study of Polyoxin D Zinc Salt Technical in Algae	48660403
880.4350	Nontarget insect testing	Effects of Polyoxin D on Two-Spotted Spider Mite, Brown Plant Hopper and Diamond Back Moth	43261844
		Acute Oral Toxicity Study in Honeybee with Polyoxin D Zinc Technical Grade Material	48660404
	NONTARGET ORGANISM - TIER II		
850.4225	Seedling emergence	NOT APPLICABLE. Not a known phytotoxicant.	
850.4250	Vegetative vigor	NOT APPLICABLE. Not a known phytotoxicant.	
	RESIDUE CHEMISTRY		
860.1100	Chemical Identity	Polyoxin D Zinc Salt: Residue Chemistry Summary	48653307
860.1200	Directions for Use	Polyoxin D Zinc Salt: Residue Chemistry Summary	48653307
		Minimum Inhibitory Concentration (MIC) of Polyoxin D Against Various Bacteria	48653308
		Minimum Inhibitory Concentration (MIC) of Polyoxins Against Bacteria, Yeast and Fungi	43216802

Gdln No.	Guideline Name	Title	MRID No.
860.1300	Nature of the residue in plants	Metabolic Fate of [¹⁴ C]Polyoxin D in Grape	48653309
		Metabolism of [¹⁴ C]Polyoxin D in Tomato Plants	48653310
		Metabolic Fate of [¹⁴ C]Polyoxin D in Lettuce Plant	48653311
860.1300	Nature of the residue in livestock	Polyoxin D Zinc Salt: Residue Chemistry Summary	48653307
860.1340	Residue analytical method	Polyoxin D Zinc Salt: Residue Chemistry Summary	48653307
860.1360	Multiresidue method	Polyoxin D Zinc Salt: Residue Chemistry Summary	48653307
860.1400	Magnitude of the residue in potable water, fish and irrigated crops	Polyoxin D Zinc Salt: Residue Chemistry Summary	48653307
860.1460	Food handling	Polyoxin D Zinc Salt: Residue Chemistry Summary	48653307
860.1480	Magnitude of the residue in meat, milk, poultry and eggs	Polyoxin D Zinc Salt: Residue Chemistry Summary	48653307
860.1500	Crop field trials	Polyoxin D Zinc Salt: Residue Chemistry Summary	48653307
860.1520	Processed food/feed	Polyoxin D Zinc Salt: Residue Chemistry Summary	48653307
860.1540	Anticipated residues	Polyoxin D Zinc Salt: Residue Chemistry Summary	48653307
860.1550	Proposed tolerances	Polyoxin D Zinc Salt: Residue Chemistry Summary	48653307
860.1560	Reasonable grounds in support of the petition	Polyoxin D Zinc Salt: Residue Chemistry Summary	48653307
860.1650	Submittal of analytical reference standards	Polyoxin D Zinc Salt: Residue Chemistry Summary	48653307
	MAMMALIAN TOXICOLOGY - TIER I		
870.SUMM		Polyoxin D Zinc Salt: Toxicology Summary for a Tolerance Exemption Petition	48653312
870.1100	Acute oral toxicity	Acute Oral Toxicity Study in Rats with Polyoxin D Zinc Salt Technical Grade Material	43261823

Gdln No.	Guideline Name	Title	MRID No.
870.1200	Acute dermal toxicity	Acute Dermal Toxicity Study of Polyoxin D Zinc Salt in Rats	43261825
870.1300	Acute inhalation toxicity - rat	Polyoxin D Zinc Salt Acute Inhalation Toxicity in Rats: 4-Hour Exposure	43261827
870.2400	Primary eye irritation - rabbit	Primary Eye Irritation Study in Albino Rabbits with Polyoxin D Zinc Salt Technical Grade Material	43261829
870.2500	Primary dermal irritation	Primary Dermal Irritation Study in Albino Rabbits with Polyoxin D Zinc Salt Technical Grade Material	43261831
870.2600	Dermal sensitization	Skin Sensitization Study of Polyoxin D Zinc Salt in the Guinea Pig	43261833
None	Hypersensitivity incidents	No known incidents.	
870.3100	90-day oral (1 species)	Polyoxin D Zinc Salt Technical: Repeated Dose 90-Day Oral Toxicity Study in Rats (A Translated version of the Original Report)	47145101
870.3250	90-day dermal - rat	Waiver granted based upon the 90-day oral toxicity data.	
870.3465	90-day inhalation - rat	Waiver granted based upon the 90-day oral toxicity data.	
870.3700	Prenatal Development (1 st species)	Teratology Study on Polyoxin D Zinc Salt (PSB) in Rabbits	43261837
870.5100	Bacterial reverse mutation test	Reverse Mutation Test of PSB with Bacteria	43323001
		Mutagenicity Testing on Polyoxin D Zinc Salt in Microbial Systems: (1) Rec-Assay with <i>Bacillus subtilis</i> H-17 and M-45, (2) Reverse Mutation Tests With and Without a Liver Metabolic Activation Systems Using Two Strains of <i>Escherichia coli</i> and Four Strands of <i>Salmonella typhimurium</i> , and (3) Host-Mediated Assay with <i>S. typhimurium</i> G-46 in Mice	43261836
		Polyoxin D Zinc Salt: Bacterial Reverse Mutation Test	48653313
870.5375	<i>In vitro</i> mammalian cell assay	Studies on Chromosomal Aberration by Polyoxin D Zinc Salt in CHL Cells	43261835

Gdln No.	Guideline Name	Title	MRID No.
		Polyoxin D Zinc Salt: Chromosome Aberration Test in Cultured Mammalian Cells	48653314
	MAMMALIAN TOXICOLOGY - TIER II		
870.5395	<i>In vivo</i> mammalian cytogenetics	Micronucleus Test of Polyoxin D Zinc Salt Technical in Mice	47145102
870.3700	Prenatal Developmental (2 nd species)	Teratogenicity Study of Polyoxin D Zinc Salt in Rats	48653315
880.3550	Immunotoxicity	A Splenic Antibody Following Dietary Exposure to Polyoxin D Zinc Salt Technical in Female Mice for 28 Days	47120901
	MAMMALIAN TOXICOLOGY - TIER III		
870.3800	Reproduction and fertility effects	Effects of Polyoxin D Salt on Succeeding Generations of Rats	47120904
870.4200	Carcinogenicity - two species - rat and mouse preferred	Summary of Chronic Toxicity Study of Polyoxin D Zinc Salt in Mice	43261838
		Summary of Chronic Toxicity Study of Polyoxin D Zinc Salt in Rats	43261839

Please see [Appendix 7](#) for a copy of the EPA Fact Sheet for polyoxin D zinc salt.

Please see [Appendix 8](#) for a copy of the Biopesticide Registration Action Document (BRAD) prepared by EPA regarding polyoxin D zinc salt.

Please see [Appendix 9](#) for a copy of the final rule regarding the tolerance exemption for polyoxin D zinc salt on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes, and strawberries published in the November 19, 2008 Federal Register.

Please see [Appendix 10](#) for a copy of the notice of filing that was submitted to EPA in support of the pending tolerance exemption petition for use on all crops and for post-harvest use.

12. Petition Justification

The requested addition of polyoxin D zinc salt to the list of synthetic substances allowed for use in organic production under 7 CFR §205.601 is justified on the following grounds:

- Polyoxin D zinc salt is an anti-fungal fermentation product produced by a microorganism that is naturally occurring in the soil. No synthetic materials are present in polyoxin D Zinc Salt Technical.
- Polyoxin D zinc salt has a non-toxic mode of action that is specific to fungi. Polyoxin D zinc salt inhibits cell wall chitin synthesis of fungi. Polyoxin D zinc salt does not kill fungi; it simply stops the fungal growth. Humans and other mammals have cell membranes but do not have cell walls. Humans and other mammals do not have cell structures that contain chitin. Polyoxin D zinc salt is not effective as an anti-bacterial agent. Polyoxin D zinc salt has never been used in human medicine or veterinary medicine.
- The toxicology of polyoxin D zinc salt is well understood and the available data for polyoxin D zinc salt exceed the scope of the data normally available for a biochemical. These data demonstrate that polyoxin D zinc salt:
 - Has low acute toxicity;
 - Has low subchronic toxicity;
 - Has low developmental toxicity;
 - Is not mutagenic *in vivo*;
 - Has low immunotoxicity;
 - Has low reproductive toxicity;
 - Has low chronic toxicity; and
 - Is not oncogenic.
- Based upon the available mammalian toxicology data, it is anticipated that polyoxin D zinc salt is not an endocrine disruptor.
- The residues of polyoxin D zinc salt are exempt from the requirement of a tolerance for the crops for which use is currently registered. A tolerance exemption for all crops (pre-harvest and post-harvest) is pending. If approved, registration for a wide range of crops will be facilitated, including minor use crops.
- Based upon the available crop metabolism data and environmental fate data, residues resulting from the treatment of crops according to good agricultural practice are anticipated to be low in agricultural commodities and in drinking water.

- Based upon the crop metabolism data, significant polyoxin D residues reduction is easily achieved by simply rinsing raw agricultural commodity with water. Based upon the hydrolysis data, further residue reduction is anticipated to be achieved through cooking.
- Polyoxin D zinc salt has both low toxicity and very low dietary exposure. Therefore, the dietary risk of polyoxin D zinc salt residues is very low.
- Polyoxin D zinc salt is an important tool in integrated pest management (IPM) and will not interfere with other products used in organic crop production.
- Formulations containing polyoxin D zinc salt are currently registered in all states.
- There have been no supply interruptions in over 40 years of sales of polyoxin D zinc salt.
- Formulations containing polyoxin D zinc salt have provided reliable control and suppression results of fungal diseases of plants for over 40 years without a single report of pest resistance or adverse effects.

13. Inclusion of Polyoxin D Zinc Salt in Organic Production

13.a. Explanation of Why Polyoxin D Zinc Salt Is Necessary for the Production or Handling of an Organic Product

Polyoxin D zinc salt provides many advantages to the organic grower. Polyoxin D zinc salt:

- Provides good efficacy for control of economically significant fungal diseases and pathogens of plants, including but not limited to, *Alternaria*, *Anthraco*se, *Botrytis*, Downy Mildew, Powdery Mildew, and *Rhizo*ctonia;
- Provides a new mode of action for organic growers;
- Provides scheduling flexibility to the grower because end-use products containing polyoxin D zinc salt:
 - Can be applied on the day of harvest, and
 - Workers can re-enter fields only 4 hours after treatment;
- Has a very selective mode of action that results in low risk to non-target organisms, including honeybees;
- Has no observations of pest resistance, though it been used commercially for over 40 years;
- Is an important integrated pest management (IPM) tool;
- Results in very low residues in food;
- Will not accumulate in the environment;
- Will not contaminate groundwater; and
- Has low toxicity and low risk to humans.

An annotated OMRI Products List of crop products that are described as either fungicides or for disease control is provided as [Appendix 11](#). This publication was used to identify the OMRI listed products that are possible competitors to the proposed product containing polyoxin D zinc salt that has been designed for use in organic production.

The tables below:

- 13.a.1. Copper sulfate;
- 13.a.2. Coppers - fixed;
- 13.a.3. Fungicides - non-synthetic;
- 13.a.4. Microbial pesticides;
- 13.a.5. Microbial products;
- 13.a.6. Neem extracts and derivatives;
- 13.a.7. Plant extracts;
- 13.a.8. Potassium bicarbonate;
- 13.a.9. Steptomycin sulfate;
- 13.a.10. Sulfur - elemental;
- 13.a.11. Tetracycline; and
- 13.a.12. *Trichoderma* spp.

summarize the OMRI listed products, by product type, that are potential competitive products. The tables include hyperlinks to the registered labels and summarize the disease

control provided by polyoxin D zinc salt that is not provided by the subject product.

Please note that:

- The lists of disease control gaps filled by polyoxin D zinc salt:
 - Are not comprehensive; and
 - For simplicity, are limited to food crops, *i.e.*, exclude use on turf and ornamentals;
- There is no OMRI listed product for which the proposed new polyoxin D zinc salt formulation does not have further disease control claims; and
- Polyoxin D zinc salt commonly has more extensive claims regarding control of Alternaria and Rhizoctonia than the current OMRI listed products for disease control on food crops.

Comparative Efficacy 13.a.1. Copper Sulfate		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
Basic Copper 53 (Albaugh, Inc.)	45002-8 http://www.epa.gov/pesticides/chem_search/pls/045002-00008-20110712.pdf	No claims for: <ul style="list-style-type: none"> • Alternaria on almonds; • Anthracnose on strawberries; • Botrytis on cucurbits, ginseng, grapes, pome fruit, and strawberries; • Corynespora leaf spot on cucurbits; • Cylinderocarpon on ginseng; • Leaf blotch on pome fruit; • Powdery mildew on fruiting vegetables, pome fruit, and strawberries; • Scab on pome fruit; • Shots hole on almonds; • Rhizoctonia on almonds, ginseng, and potatoes; and • Southern blight on fruiting vegetables.
Copper Sulfate Crystals (Chem One, Ltd.)	56576-1 http://www.epa.gov/pesticides/chem_search/pls/056576-00001-20110826.pdf	No claims for: <ul style="list-style-type: none"> • Use on brassica, cucurbits, fruiting vegetables, ginseng, pistachios, and strawberries; • Alternaria on almonds and grapes; • Botrytis on grapes; and • Powdery mildew on grapes.
Quimag Quimicos Aguila Copper Sulfate Crystal (Fabrica de Sulfato El Aguila, S.A. de C.V.)	73385-1 http://www.epa.gov/pesticides/chem_search/pls/073385-00001-20100611.pdf	No claims for: <ul style="list-style-type: none"> • Use on brassica, cucurbits, fruiting vegetables, ginseng, pistachios, potatoes, and strawberries; • Alternaria on almonds, and pome fruit; • Botrytis on grapes; • Leaf blotch on pome fruits; • Powdery mildew on grapes, and pome fruit; and • Scab on pome fruit.

Comparative Efficacy 13.a.1. Copper Sulfate		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
Quimag Quimicos Aguila Copper Sulfate Crystal - Crop (Fabrica de Sulfato El Aguila, S.A. de C.V.)	73385-3 http://www.epa.gov/pesticides/chem_search/pls/073385-00003-20100408.pdf	No claims for: <ul style="list-style-type: none"> • Use on brassica, cucurbits, fruiting vegetables, ginseng, grapes (except dormant), pistachios, and strawberries; • Alternaria on pome fruit and potatoes; • Leaf blotch on pome fruit; • Powdery mildew on pome fruit; and • Scab on pome fruit.

* See Confidential Appendix 3 for proposed new uses redacted from this list.

Comparative Efficacy 13.a.2. Coppers - Fixed		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
Chem Copp 50 (American Chemet Corporation)	26883-20 (cuprous oxide) http://www.epa.gov/pesticides/chem_search/pls/026883-00020-20100331.pdf	No claims for: <ul style="list-style-type: none"> • Use on ginseng, and pistachios; • Alternaria on almonds, and pome fruit; • Anthracnose on strawberries; • Botrytis (any crop); • Corynespora leaf spot on cucurbits; • Leaf blotch on pome fruit; • Rhizoctonia (any crop); • Powdery mildew on cucurbits, fruiting vegetables, pome fruit, and strawberries; • Scab on pome fruit; • Shot hole on almonds; and • Southern blight on fruiting vegetables.
Nu-Cop® 50DF (Albaugh, Inc.)	45002-4 (copper hydroxide) http://www.epa.gov/pesticides/chem_search/pls/045002-00004-20110720.pdf	No claims for: <ul style="list-style-type: none"> • Use on pistachios, pome fruit, and potatoes, strawberries; • Alternaria for almonds; • Anthracnose on peppers; • Botrytis for cucurbits, fruiting vegetables, ginseng, and grapes; • Corynespora leaf spot on cucurbits; • Leaf mold on fruiting vegetables; • Powdery mildew for fruiting vegetables; • Rhizoctonia on brassica; • Shot hole for almonds; and • Southern blight on fruiting vegetables.

Comparative Efficacy 13.a.2. Coppers - Fixed		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
Badge® X2 (Isagro USA)	80289-12 (copper hydroxide) http://www.epa.gov/pesticides/chem_search/pls/080289-00012-20110801.pdf	No claims for: <ul style="list-style-type: none"> • Alternaria on almonds and pome fruit; • Botryosphaeria on pistachios; • Botrytis on cucurbits, fruiting vegetables, ginseng, and grapes; • Corynespora leaf spot on cucurbits; • Gummy stem blight on cucurbits; • Leaf blotch on pome fruit; • Powdery mildew on cucurbits, fruiting vegetables, pome fruit; • Rhizoctonia on brassica, ginseng, and potatoes; and • Southern blight on fruiting vegetables.
Camelot O Fungicide/Bactericide (SePRO Corporation)	67702-2-67690 (copper octanoate) http://www.sepro.com/documents/CamelotO_Label.pdf	No claims for: <ul style="list-style-type: none"> • Use on almonds, cucurbits, grapes, pistachios, pome fruit, potatoes, and strawberries; • Alternaria on fruiting vegetables; • Corynespora leaf spot on cucurbits; • Cy lindrocarpon on ginseng; • Gummy stem blight on cucurbits • Powdery mildew on and fruiting vegetables; • Rhizoctonia on brassica, ginseng; and • Southern blight on fruiting vegetables.

Comparative Efficacy 13.a.2. Coppers - Fixed		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
Champ® WG (NuFarm Americas, Inc.)	55146-1 (copper hydroxide) http://www.epa.gov/pesticides/chem_search/ppls/055146-00001-20110511.pdf	No claims for: <ul style="list-style-type: none"> • Alternaria on almonds, fruiting vegetables, pome fruit; • Anthracnose on peppers and strawberries; • Botrytis on cucurbits, fruiting vegetables, ginseng, grapes, and strawberries; • Corynespora on cucurbits; • Leaf mold on peppers; • Leaf blotch on pore fruit; • Powdery mildew on cucurbits, fruiting vegetables, pome fruit, and strawberries; • Rhizoctonia on brassica, ginseng, and potatoes; • Scab on pome fruit; and • Southern blight on fruiting vegetables.
COC WP (Albaugh, Inc.)	45002-17 (copper oxychloride) http://www.epa.gov/pesticides/chem_search/ppls/045002-00017-20110719.pdf	No claims for: <ul style="list-style-type: none"> • Alternaria on almonds, apples; • Anthracnose on strawberries; • Botrytis on cucurbits, fruiting vegetables, ginseng, grapes, and strawberries; • Corynespora leaf spot on cucurbits; • Cyindrocarpon on ginseng; • Leaf blotch on pome fruit; • Leaf mold on fruiting vegetables; • Powdery mildew on fruiting vegetables, pome fruit, and strawberries; • Rhizoctonia on brassica, ginseng, and potatoes; and • Scab on pome fruit.

Comparative Efficacy 13.a.2. Coppers - Fixed		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
CS 2005 Algaecide/Bactericide/Fungicide (Magna-Bon II, LLC)	66675-3 (copper sulfate pentahydrate) http://www.epa.gov/pesticides/chem_search/pls/066675-00003-20110412.pdf	No claims for: <ul style="list-style-type: none"> • Use on ginseng; • Alternaria on almonds and pome fruit; • Anthracnose on strawberries; • Botrytis on cucurbits, grapes, and strawberries; • Corynespora leaf spot on cucurbits; • Leaf mold fruiting vegetables; • Leaf blotch of pome fruit; • Powdery mildew on cucurbits, fruiting vegetables, pome fruit, and strawberries; • Rhizoctonia on brassica and potatoes; and • Southern blight on fruiting vegetables.
CSC Copper Sulfur Dust Fungicide (Martin Operating Partnership, L.P.)	82571-5 (copper oxychloride + basic copper sulfate + sulfur) http://www.epa.gov/pesticides/chem_search/pls/082571-00005-20100720.pdf	Label is limited to powdery mildew and bunch rots on grapes (no other crops or claims)
Cueva Fungicide Concentrate (W Neudorff GmbH KG)	67702-2 (copper octanoate) http://www.epa.gov/pesticides/chem_search/pls/067702-00002-20110926.pdf	(basic registration of the SePRO sub-registration above) No claims for: <ul style="list-style-type: none"> • Use on pistachios; • Alternaria on almonds and pome fruit; • Botrytis on cucurbits; • Corynespora leaf spot on cucurbits; • Cylindrocarpum on ginseng; • Gummy stem blight on cucurbits; • Leaf blotch on pome fruit; • Leaf mold on fruiting vegetables; • Powdery mildew on fruiting vegetables, and pome fruit; • Rhizoctonia on brassica, ginseng, potatoes; • Scab on pome fruit; and • Shot hole on almonds.

Comparative Efficacy 13.a.2. Coppers - Fixed		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
Cueva Fungicide Ready-To-Use (W Neudorff GmbH KG)	67702-1 (copper octanoate) http://www.epa.gov/pesticides/chem_search/pls/067702-00001-20100514.pdf	Food use claims limited to grapes and peaches. No claim for Botrytis on grapes.
NORDOX 30/30 WG (NORDOX AS)	48142-7 (cuprous oxide) http://www.epa.gov/pesticides/chem_search/pls/048142-00007-20101102.pdf	No claims for: <ul style="list-style-type: none"> • Use on brassica, cucurbits, fruiting vegetables, ginseng, potatoes, and strawberries; • Alternaria on almonds, and pome fruit; • Botrytis on grapes; • Leaf blotch on pome fruit; and • Shot hole on almonds.
NORDOX 75 WG (NORDOX AS)	48142-4 (cuprous oxide) http://www.epa.gov/pesticides/chem_search/pls/048142-00004-20010615.pdf	No claims for: <ul style="list-style-type: none"> • Alternaria on almonds, brassica, and pome fruit; • Botrytis on cucurbits, fruiting vegetables, ginseng, grapes, and strawberries; • Corynespora leaf spot on cucurbits; • Cylinderocarpon on ginseng; • Leaf blotch on pome fruit; • Powdery mildew on fruiting vegetables, pome fruit, and strawberries; • Rhizoctonia on brassica, ginseng, and potatoes; • Shot hole on almonds; and • Southern blight on fruiting vegetables.

Comparative Efficacy 13.a.2. Coppers - Fixed		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
Nu Cop® 50 WP (Albaugh, Inc.)	45002-7 (copper hydroxide) http://www.epa.gov/pesticides/chem_search/pls/045002-00007-20111102.pdf	No claims for: <ul style="list-style-type: none"> • Alternaria on almonds, cucurbits, and pome fruit; • Anthracnose on strawberries; • Botrytis on cucurbits, fruiting vegetables, ginseng, grapes, and strawberries; • Cylindrocarpon on ginseng; • Gummy stem blight on cucurbits; • Leaf blotch on pome fruit; • Powdery mildew on cucurbits, fruiting vegetables, pome fruit, and strawberries; • Rhizoctonia on brassica, ginseng, and potatoes; • Scab on pome fruit; • Shot hole on almonds; and • Southern blight on fruiting vegetables.
Ortho® elementals™ Garden Disease Control (The Ortho Group)	67702-1-239 (copper octanoate) http://www.scotts.com/smg/products/ortho-ecosense/PDF/Elementals%20Garden%20Disease%20Control.pdf	Distributor registration of Cueva Fungicide Concentrate (67707-1). See above. Substantial reduction in claims from basic registration.
PHT Copper Sulfur Dust (J.R. Simplot Company)	82571-5-7001 (copper octanoate) http://techsheets.simplot.com/Grower_Solutions/pht_copper_sulfur_dust.pdf	Distributor registration of CSC Copper Sulfur Dust Fungicide (82571-5). See above. Label is limited to powdery mildew and bunch rots on grapes. No other crops or claims.
Ready-To-Use Worry Free® Brand Copper Soap Fungicide (Lilly Miller Brands)	67702-1-33116 (copper octanoate) http://www.worryfreebrand.com/labels/Worry-Free_Copper_Soap_Fungicide_24_oz_RTU_LM131-01_NONOMRI_08-05-08.pdf	Distributor registration of Cueva Fungicide Concentrate (67707-1). See above.

* See Confidential Appendix 3 for proposed new uses redacted from this list.

Comparative Efficacy 13.a.3. Fungicides - Nonsynthetic		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
Contans® WG (Prophyta Biologischer Pflanzenschutz GmbH)	72444-1 (<i>Coniothyrium minitans</i> strain CON/M/91-0B) http://www.epa.gov/pesticides/chem_search/pls/072444-00001-20101122.pdf	Minimal overlap. Claims are limited to <i>Sclerotinia sclerotiorum</i> and <i>Sclerotinia minor</i> .
Mycostop® Biofungicide (Verdera Oy)	64137-5 (<i>Streptomyces griseoviridis</i> strain K61) http://www.epa.gov/pesticides/chem_search/pls/064137-00005-20091030.pdf	Uses limited to seed treatments, seedlings, and field crop use to control seed rot.
Mycostop® Mix (Verdera Oy)	64137-9 (<i>Streptomyces griseoviridis</i> strain K61) http://www.epa.gov/pesticides/chem_search/pls/064137-00009-20110718.pdf	Uses limited to seed treatments and soil treatments to control seed rot.
Oleotrol® - M (NTS Research & Inc.)	FIFRA 25(b) Exempt Product (soybean oil) http://www.naturalforcesllc.com/PDFs/OLEOTR-OL-M.specimenlabel.pdf	No claims for: <ul style="list-style-type: none"> • Use on almonds, brassica, cucurbits, ginseng, pistachios, potatoes and strawberries; • Alternaria on pome fruit; • Leaf blotch on pome fruit; and • Scab on pome fruit.
Prestop® Biofungicide Powder (WP) (Verdera Oy)	64137-11 (<i>Gliocladium catenulatum</i> strain J1446) http://www.epa.gov/pesticides/chem_search/pls/064137-00011-20060124.pdf	Label makes broad claims for crops and diseases; does not match crops with specific diseases. No claim for: <ul style="list-style-type: none"> • Use on almonds, ginseng, grapes, pistachio, and pome fruit; • Anthracnose on fruiting vegetables; • Corynespora on cucurbits; • Leaf mold on fruiting vegetables; • Gummy stem blight on cucurbits; • Powdery mildew on any crop; • Shot hole on almonds; and • Southern blight on fruiting vegetables.
SoilGard® Microbial Fungicide (Certis USA)	70051-3 (<i>Gliocladium virens</i> G-21) http://www.epa.gov/pesticides/chem_search/pls/070051-00003-20100323.pdf	For soil treatment. Not for treatment of foliar diseases.

Comparative Efficacy 13.a.3. Fungicides - Nonsynthetic		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
SPORATEC® (Brandt Consolidated, Inc.)	FIFRA 25(b) Exempt Product (rosemary oil, clove oil, and thyme oil) http://www.cdms.net/LDat/ld93F000.pdf	No claim for: <ul style="list-style-type: none"> • Use on ginseng; • Alternaria on almonds, pistachios, pome fruit, and potatoes; • Anthracnose on fruiting vegetables; and • Botrytis on cucurbits.

* See Confidential Appendix 3 for proposed new uses redacted from this list.

Comparative Efficacy 13.a.4. Microbial Pesticides		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
Serenade® Garden Disease Control Ready to Use (AgraQuest, Inc.)	69592-16 (<i>Bacillus subtilis</i> strain QST 713) http://www.epa.gov/pesticides/chem_search/pls/069592-00016-20100527.pdf	No claim for: <ul style="list-style-type: none"> • Use on ginseng • Disease control (limited to disease suppression of unspecified diseases)
Serenade® MAX™ (AgraQuest, Inc.)	69592-11 (<i>Bacillus subtilis</i> strain QST 713) http://www.epa.gov/pesticides/chem_search/pls/069592-00011-20110303.pdf	No claim for: <ul style="list-style-type: none"> • Use on ginseng; • Alternaria on cucurbit vegetables and pome fruit; • Botrytis on cucurbit vegetables; • Corynespora on cucurbit vegetables; and • Rhizoctonia on brassica vegetables and potatoes.
Taegro® biofungicide (Novozymes Biologicals, Inc.)	70127-5 (<i>Bacillus subtilis</i> var. amyloliquefaciens Strain FZB24) http://www.epa.gov/pesticides/chem_search/pls/070127-00005-20110426.pdf	<ul style="list-style-type: none"> • No claims overlap. • Suppression only of Rhizoctonia.

* See Confidential Appendix 3 for proposed new uses redacted from this list.

Comparative Efficacy 13.a.5. Microbial Products		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs Polyoxin D Zinc Salt*
ArmorTech® Sonnet™ (United Turf Alliance LLC)	69592-11-86064 (<i>Bacillus subtilis</i> strain QST 713) http://www.utaarmortech.com/sites/default/files/ArmorTech%20Sonnet%20Label.pdf	(Distributor registration of Serenade MAX) No claim for: <ul style="list-style-type: none"> • Use on ginseng; • Alternaria on cucurbits and pome fruit; • Botrytis on cucurbits; • Corynespora on cucurbits; and • Rhizoctonia on brassica and potatoes.
ActinoGrow (Natural Industries, Inc.)	73314-1 (<i>Streptomyces lydicus</i> WYEC 108) http://www.epa.gov/pesticides/chem_search/pls/073314-00001-20110727.pdf	Label lists crops and separately lists diseases controlled or suppressed. Possible gaps, but label too loosely written to confirm.
ActinoGrow® ST (Natural Industries, Inc.)	73314-4 (<i>Streptomyces lydicus</i> WYEC 108) http://www.epa.gov/pesticides/chem_search/pls/073314-00004-20071219.pdf	This product is seed treatment only.
ActinoGrow® T&O (Natural Industries, Inc.)	73314-1 (<i>Streptomyces lydicus</i> WYEC 108) http://www.epa.gov/pesticides/chem_search/pls/073314-00001-20110727.pdf	Label lists crops and separately lists diseases controlled or suppressed. Possible gaps, but label too loosely written to confirm.
Actinovate® AG (Natural Industries, Inc.)	73314-1 (<i>Streptomyces lydicus</i> WYEC 108) http://www.epa.gov/pesticides/chem_search/pls/073314-00001-20110727.pdf	Label lists crops and separately lists diseases controlled or suppressed. Possible gaps, but label too loosely written to confirm.
Actinovate® SP (Natural Industries, Inc.)	73314-1 (<i>Streptomyces lydicus</i> WYEC 108) http://www.epa.gov/pesticides/chem_search/pls/073314-00001-20110727.pdf	Label lists crops and separately lists diseases controlled or suppressed. Possible gaps, but label too loosely written to confirm.
Actinovate® for Lawn & Garden (Natural Industries, Inc.)	73314-1 (<i>Streptomyces lydicus</i> WYEC 108) http://www.epa.gov/pesticides/chem_search/pls/073314-00001-20110727.pdf	Label lists crops and separately lists diseases controlled or suppressed. Possible gaps, but label too loosely written to confirm.
Actinovate® STP Fungicide (Natural Industries, Inc.)	73314-4 (<i>Streptomyces lydicus</i> WYEC 108) http://www.epa.gov/pesticides/chem_search/pls/073314-00004-20071219.pdf	This product is for seed treatment only.

Comparative Efficacy 13.a.5. Microbial Products		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs Polyoxin D Zinc Salt*
Ballad® Plus (AgraQuest, Inc.)	69592-13 (<i>Bacillus pumilus</i> strain QST 2808) http://www.epa.gov/pesticides/chem_search/pls/069592-00013-20111202.pdf	No claim for: <ul style="list-style-type: none"> • Alternaria on cucurbits, fruiting vegetables, and pome fruit; • Cylindrocarpon on ginseng; • Leaf blotch on pome fruit; • Leaf mold on fruiting vegetables; • Powdery mildew on pome fruit; • Rhizoctonia on potatoes; • Scab on pome fruit; and • Southern blight on fruiting vegetables.
Bayer Advanced Natria™ Disease Control Ready-to-Spray (Bayer Advanced)	69592-27-72155 (<i>Bacillus subtilis</i> strain QST 713) http://www.bayeradvanced.com/system/product_variants/label_pdfs/000/000/040/original_Natria-Disease-Control-28oz-RTS.pdf	Label makes broad claims for crops and diseases, without matching crops and disease. No claim for: <ul style="list-style-type: none"> • Use on ginseng; • Alternaria control (suppression only); • Downy mildew control (suppression only); • Rhizoctonia on any crop; • Scab control on pome fruit (suppression only); and • Shots hole on almonds.
Bayer Advanced Natria™ Disease Control Ready-to-Use (Bayer Advanced)	69592-16-72155 (<i>Bacillus subtilis</i> strain QST 713) http://www.bayeradvanced.com/system/product_variants/label_pdfs/000/000/039/original_Natria-Disease-Control-24oz-RTU.pdf	Label makes broad claims for crops and diseases, without matching crops and disease. No claim for: <ul style="list-style-type: none"> • Use on ginseng; • Alternaria control (suppression only); • Downy mildew control (suppression only); • Rhizoctonia on any crop; • Scab control on pome fruit (suppression only); and • Shots hole on almonds.

Comparative Efficacy 13.a.5. Microbial Products		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs Polyoxin D Zinc Salt*
CEASE® (BioWorks, Inc.)	69592-19-68539 (<i>Bacillus subtilis</i> strain QST 713) http://www.bioworksinc.com/products/cease/cease-label.pdf	No claim for: <ul style="list-style-type: none"> • Use on food crops except in a greenhouse Greenhouse use excludes: <ul style="list-style-type: none"> • Use on almonds, grapes, pistachios, pome fruit; • Alternaria on cucurbits, and potatoes; • Anthracnose on fruiting vegetables; • Botrytis on cucurbits; • Corynespora on cucurbits; • Leaf mold on fruiting vegetables; • Rhizoctonia on brassica and potatoes; and • Southern blight on fruiting vegetables.
DiPel® 2X DF (Valent BioSciences® Corp.)	This is an insecticide, not a fungicide.	
econem™ (Pasteuria Bioscience, Inc.)	This is a nematicide, not a fungicide.	
JAZZ™ (AgraQuest, Inc.)	69592-11 (<i>Bacillus subtilis</i> strain QST 713) pages 48-55 of the following label: http://www.epa.gov/pesticides/chem_search/pls/069592-00011-20110303.pdf	Claims are limited to green mold control in mushroom production.
Milky Spore Powder Japanese Beetle Control (St. Gabriel Organics)	This is an insecticide, not a fungicide.	
Polyversum® (Biopreparaty Co. Ltd.)	81606-1 (<i>Pythium oligandrum</i> DV 74) http://www.epa.gov/pesticides/chem_search/pls/081606-00001-20100614.pdf	Claims are expressed as “suppress/control” and as “suppresses the growth and antagonistic effects of many soil borne pathogenic fungi.” No specific diseases are claimed for any crop.

Comparative Efficacy 13.a.5. Microbial Products		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs Polyoxin D Zinc Salt*
Rhapsody® ASO (AgraQuest, Inc.)	69592-19 (<i>Bacillus subtilis</i> strain QST 713) http://www.epa.gov/pesticides/chem_search/pls/069592-00019-20100909.pdf	No claims for: <ul style="list-style-type: none"> • Use on almonds, pistachios, pome fruit, • Alternaria on cucurbits, and fruiting vegetables; • Anthracnose on fruiting vegetables; • Botrytis on cucurbits and ginseng; • Corynespora on cucurbits; • Cylindrocarpon on ginseng; • Leaf mold on fruiting vegetables; • Rhizoctonia on brassica, ginseng, and potatoes; and • Southern blight on fruiting vegetables.
RootShield® WP Biological Fungicide (BioWorks, Inc.)	68539-7 (<i>Trichoderma harzianum</i> Rifai strain KRL-AG2) http://www.epa.gov/pesticides/chem_search/pls/068539-00007-20081113.pdf	Limited to sed treatment and soil treatment. No claims for: <ul style="list-style-type: none"> • Use on almonds and pistachios; and • Any specific disease.
Serenade® ASO (AgraQuest, Inc.)	69592-12 (<i>Bacillus subtilis</i> strain QST 713) http://www.agraquest.com/docs/labels-msds/SerASO-Label-US0008-B-007.pdf	Claims limited to soil borne diseases. No claim for: <ul style="list-style-type: none"> • Use on almonds, ginseng, grapes, pome fruit, pistachios, • Alternaria; • Anthracnose; • Botrytis; • Downy mildew; and • Powdery mildew.
Serenade® Garden Disease Control Concentrate (AgraQuest, Inc.)	69592-12 (<i>Bacillus subtilis</i> strain QST 713) http://www.serenadegarden.com/labels-msds/con-label.pdf	
Serenade® Garden Disease Control Ready to Spray (AgraQuest, Inc.)	69592-12 (<i>Bacillus subtilis</i> strain QST 713) http://www.serenadegarden.com/labels-msds/11-0727-Specimen-Serenade%20G%20DC%20RTS.pdf	
Serenade® Garden Lawn Disease Control (AgraQuest, Inc.)	69592-12 (<i>Bacillus subtilis</i> strain QST 713) http://www.serenadegarden.com/labels-msds/lawn-label.pdf	
SERENADE® SOIL (AgraQuest, Inc.)	69592-12 (<i>Bacillus subtilis</i> strain QST 713) http://www.agraquest.com/docs/labels-msds/SerSoil-Label-US0034-B-001.pdf	

Comparative Efficacy 13.a.5. Microbial Products		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs Polyoxin D Zinc Salt*
Sonata® (AgraQuest, Inc.)	69592-13 (<i>Bacillus pumilus</i> strain QST 2808) http://www.epa.gov/pesticides/chem_search/pls/069592-00013-20111202.pdf	No claim for: <ul style="list-style-type: none"> • Alternaria on cucurbits and pome fruit; • Anthracnose on fruiting vegetables; • Botrytis on cucurbits; • Corynespora on cucurbits; • Leaf blotch on pome fruit; • Leaf mold on fruiting vegetables; • Rhizoctonia on brassica vegetables and potatoes; and • Southern blight on fruiting vegetables.

* See Confidential Appendix 3 for proposed new uses redacted from this list.

Comparative Efficacy		
13.a.6. Neem Extract and Derivatives (excluding obvious non-fungicides based on product name)		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
AMAZIN PLUS 1.2% ME (AMVAC Chemical Corp.)	No fungicide uses on this label.	
AZA-Direct® (Gowan Co.)	No fungicide uses on this label.	
AzaGuard™ (BioSafe Systems)	No fungicide uses on this label.	
Concern® Garden Defense Multi-Purpose Spray Concentrate (Woodstream Corporation)	70051-2-50932 (Clarified Hydrophobic Extract of Neem Oil) Basic label: http://www.epa.gov/pesticides/chem_search/pls/070051-00002-20111003.pdf Distributor registration label: http://www.bugspray.net/labels/garden_defense_neem_label.pdf	Basic label: Includes a fungicidal claim but does not list any specific diseases or pathogens (except for citrus).
Ecozin® Plus 1.2% ME (AMVAC Chemical Corp.)	No fungicide uses on this label.	
Fortune AzA Azadirachtin 3% EC (Fortune Biotech, LTD)	No fungicide uses on this label.	
Garden Safe® Brand Fungicide 3® (Schultz® Company)	70051-13-39609 (Clarified Hydrophobic Extract of Neem Oil) http://www.gardensafe.com/~media/Garden%20Safe/Files/Labels/072845104144.ashx	(Distributor registration under a Certis label) Limited to home and garden use. No claim for: <ul style="list-style-type: none"> • Commercial agricultural use; • Alternaria; and • Rhizoctonia.
Green Light® Rose Defense® Ready-to-Use (Green Light Company)	70051-13-869 (Clarified Hydrophobic Extract of Neem Oil) http://www.planetnatural.com/planetnatural/images/rose-defense-rtu-label.pdf	(Distributor registration under a Certis label) Use limited to roses.

Comparative Efficacy		
13.a.6. Neem Extract and Derivatives (excluding obvious non-fungicides based on product name)		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
Green Light® Neem Concentrate (Green Light Company)	70051-2-869 (Clarified Hydrophobic Extract of Neem Oil) Basic label: http://www.epa.gov/pesticides/chem_search/pls/070051-00002-20111003.pdf Distributor registration label: http://www.groworganic.com/media/pdfs/pbt935-b.pdf	Basic label: Includes a fungicidal claim but does not list any specific diseases or pathogens (except for citrus).
Green Light® Rose Defense® (Concentrate) (Green Light Company)	70051-2-869 (Clarified Hydrophobic Extract of Neem Oil) Basic label: http://www.epa.gov/pesticides/chem_search/pls/070051-00002-20111003.pdf Distributor registration label: http://www.planetnatural.com/planetnatural/images/rose-defense-label.pdf	Basic label: Includes a fungicidal claim but does not list any specific diseases or pathogens (except for citrus).
Monterey 70% Neem Oil (Lawn and Garden Products, Inc.)	70051-2-869 (Clarified Hydrophobic Extract of Neem Oil) Basic label: http://www.epa.gov/pesticides/chem_search/pls/070051-00002-20111003.pdf Distributor registration label: http://www.montereylawngarden.com/pdf/70_neem_oil_02_organic.pdf	Basic label: Includes a fungicidal claim but does not list any specific diseases or pathogens (except for citrus).
Monterey Neem Oil RTU (Lawn and Garden Products, Inc.)	70051-13-54705 (Clarified Hydrophobic Extract of Neem Oil) http://www.montereylawngarden.com/pdf/MontereyNeemOilRTU-%2801%29-Label.pdf	(Distributor registration under a Certis label) Label has a generic fungicidal claim that does not specify the disease or pathogen for any crop. The fungicidal claim does not include Alternaria or Rhizoctonia.

Comparative Efficacy		
13.a.6. Neem Extract and Derivatives (excluding obvious non-fungicides based on product name)		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
Neem Oil RTU Fungicide/Miticide/Insecticide (Certis USA)	70051-13 (Clarified Hydrophobic Extract of Neem Oil) http://www.epa.gov/pesticides/chem_search/pls/070051-00013-20081223.pdf	Label has a generic fungicidal claim that does not specify the disease or pathogen for any crop. The fungicidal claim does not include Alternaria or Rhizoctonia.
NeemGard® Fungicide/Miticide/Insecticide (Certis USA)	70051-12 (Clarified Hydrophobic Extract of Neem Oil) http://www.epa.gov/pesticides/chem_search/pls/070051-00012-19960225.pdf	Claims do not include: <ul style="list-style-type: none"> • Alternaria on cucurbits; • Botryosphaeria on fruiting vegetables and pistachios; • Botrytis on cucurbits, ginseng, grapes, and strawberries; • Corynespora on cucurbits; • Gummy stem blight on cucurbits; • Leaf blotch on pome fruit; • Rhizoctonia on brassica, ginseng, and potatoes; and • Shot hole on almonds.
Nimbuz™ Fungicide/Miticide/Insecticide (Certis USA)	70051-2 (Clarified Hydrophobic Extract of Neem Oil) http://www.epa.gov/pesticides/chem_search/pls/070051-00002-20111003.pdf	Includes a fungicidal claim but does not list any specific diseases or pathogens (except for citrus).
Triact® 70 Fungicide/Miticide/Insecticide (Certis USA)	70051-2 (Clarified Hydrophobic Extract of Neem Oil) http://www.epa.gov/pesticides/chem_search/pls/070051-00002-20111003.pdf	Includes a fungicidal claim but does not list any specific diseases or pathogens (except for citrus).
Trilogy® Fungicide/Miticide/Insecticide (Certis USA)	70051-2 (Clarified Hydrophobic Extract of Neem Oil) http://www.certisusa.com/pdf-labels/Trilogy-label-08072009.pdf	Includes a fungicidal claim but does not list any specific diseases or pathogens (except for citrus).
Triple Action Neem Oil (Southern Agricultural Insecticides Inc)	70051-2-829 (Clarified Hydrophobic Extract of Neem Oil) http://www.southernag.com/docs/labels_msds/Neem-pt.pdf	(Distributor registration under the Certis 70051-2 product) Includes a fungicidal claim but does not list any specific diseases or pathogens (except for citrus).

Comparative Efficacy		
13.a.6. Neem Extract and Derivatives (excluding obvious non-fungicides based on product name)		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
UltraStop® 3-in-1 RoseGuard® (Value Garden Supply LLC)	70051-13-192 (Clarified Hydrophobic Extract of Neem Oil) https://apps.sd.gov/doa/PRRS/ImageViewer.aspx?ID=52329&Type=pdf	(Distributor registration under the 70051-13 Certis product) Label has a generic fungicidal claim that does not specify the disease or pathogen for any crop. The fungicidal claim does not include Alternaria or Rhizoctonia.
UltraStop® Fruit Tree 3-In-1 Spray Concentrate (Value Garden Supply LLC)	70051-2-192 (Clarified Hydrophobic Extract of Neem Oil) https://apps.sd.gov/doa/PRRS/ImageViewer.aspx?ID=28574&Type=pdf	(Distributor registration under the Certis 70051-2 product) Includes a fungicidal claim but does not list any specific diseases or pathogens (except for citrus).

* See Confidential Appendix 3 for proposed new uses redacted from this list.

Comparative Efficacy 13.a.7. Plant Extracts - Pesticide		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
ComCat® (AgraForum AG)	Not a pesticide.	
Garden Guys Garden Neem Insecticide • Fungicide Ready to Use (OSM, INC)	no label found	unknown
Regalia® Biofungicide Concentrate (Marrone Bio Innovations)	84059-3 (<i>Reynoutria sachalinensis</i>) http://www.epa.gov/pesticides/chem_search/pls/084059-00003-20111205.pdf	No claim for: <ul style="list-style-type: none"> • Alternaria on ginseng,; • Anthracnose on fruiting vegetables; • Botrytis on cucurbits and fruiting vegetables; • Corynespora on cucurbits; • Dipolcarpon on pome fruit; and • Rhizoctonia on cole crops limited to seed treatment.
Regalia® Maxx Biofungicide Concentrate (Marrone Bio Innovations)	84059-6 (<i>Reynoutria sachalinensis</i>) http://www.epa.gov/pesticides/chem_search/pls/084059-00006-20100818.pdf	No claim for: <ul style="list-style-type: none"> • Alternaria on ginseng; • Anthracnose on fruiting vegetables; • Botrytis on cucurbits and fruiting vegetables; • Leaf blotch on pome fruit; and • Rhizoctonia on cole crops.
Versus 7 (Tecniprosos Biologicos, S.A. de C.V.)	no label found	unknown

* See Confidential Appendix 3 for proposed new uses redacted from this list.

Comparative Efficacy 13.a.8. Potassium Bicarbonate		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt*
Kaligreen® Potassium Bicarbonate Soluble Powder (Otsuka AgriTechno Co., LTD)	11581-2 (potassium bicarbonate) http://www.epa.gov/pesticides/chem_search/ppls/011581-00002-20080730.pdf	Powdery mildew is the only claim.
MilStop® Broad Spectrum Foliar Fungicide (BioWorks, Inc.)	70870-1-68539 (potassium bicarbonate) Basic label: http://www.epa.gov/pesticides/chem_search/ppls/070870-00001-20111116.pdf Distributor registration label: http://www.bioworksinc.com/products/milstop/milstop-label.pdf	Basic label: Label is generic and does not specify diseases or pathogens for each crop grouping.
Monterey Bi-Carb Old Fashioned Fungicide (Lawn and Garden Products, Inc.)	54705-10 (potassium bicarbonate) http://www.epa.gov/pesticides/chem_search/ppls/054705-00010-20090402.pdf	Powdery mildew is the only claim.

* See Confidential Appendix 3 for proposed new uses redacted from this list.

Comparative Efficacy 13.a.9. Streptomycin Sulfate		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt
Agri-Mycin® 17 Agricultural Streptomycin (NuFarm Americas, Inc.)	55146-96 (Streptomycin sulfate) http://www.epa.gov/pesticides/chem_search/ppls/055146-00096-20110203.pdf	No food use claims in common.

Comparative Efficacy 13.a.10. Sulfur - Elemental		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt
Golden Micronized Sulfur (Wilbur-Ellis Company)	2935-407 http://www.epa.gov/pesticides/chem_search/ppls/002935-00407-20111012.pdf	Disease control limited largely to powdery mildew.
ProGanic Micronized Sulfur (Wilbur-Ellis Company)	2935-407 http://www.epa.gov/pesticides/chem_search/ppls/002935-00407-20111012.pdf	Disease control limited largely to powdery mildew.
Cosavet DF® (Sulphur Mills, Ltd.)	70905-1 http://www.epa.gov/pesticides/chem_search/ppls/070905-00001-20100726.pdf	Disease control limited largely to powdery mildew.
CSC 80% Thiosperse (Martin Operating Partnership, L.P.)	82571-4 http://www.epa.gov/pesticides/chem_search/ppls/055429-00004-19960906.pdf	Disease control limited largely to powdery mildew.
CSC Dusting Sulfur (Martin Operating Partnership, L.P.)	82571-3 http://www.epa.gov/pesticides/chem_search/ppls/055429-00003-20030210.pdf	Disease control limited largely to powdery mildew.
Dusting Sulfur (Wilbur-Ellis Company)	2935-48 http://www.epa.gov/pesticides/chem_search/ppls/002935-00048-20101210.pdf	Disease control limited largely to powdery mildew.
Dusting Sulfur Fungicide-Insecticide (Loveland Products, Inc.)	34704-735 http://www.epa.gov/pesticides/chem_search/ppls/034704-00735-20060922.pdf	Disease control limited largely to powdery mildew.
IAP Dusting Sulfur (Independent Agribusiness Professionals)	2935-48-71058 http://pdf.tirmsdev.com/Web/65/31450/65_31450_LABEL_English_.pdf?download=true	Disease control limited largely to powdery mildew.
InteGro Magic Sulfur Dust (InteGro, Inc.)	79702-1 http://www.epa.gov/pesticides/chem_search/ppls/079702-00001-20100603.pdf	Disease control limited largely to powdery mildew.
INTEGRO MAGNETIC SULFUR DUST (InteGro, Inc.)	79702-1 http://www.epa.gov/pesticides/chem_search/ppls/079702-00001-20100603.pdf	Disease control limited largely to powdery mildew.

Comparative Efficacy 13.a.10. Sulfur - Elemental		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt
Kumulus DF (BASF Sparks LLC)	51036-352 http://www.epa.gov/pesticides/chem_search/ppls/051036-00352-20100712.pdf	Disease control limited largely to powdery mildew.
Kumulus DF (Arysta LifeScience North America Corporation)	51036-352-66330 http://www.cdms.net/LDat/ld1R0003.pdf	Disease control limited largely to powdery mildew.
Micro Sulf® (NuFarm Americas, Inc.)	55146-75 http://www.epa.gov/pesticides/chem_search/ppls/055146-00075-20110524.pdf	Disease control limited largely to powdery mildew.
Microthiol Disperss (United Phosphorus Inc.)	70506-187 http://www.epa.gov/pesticides/chem_search/ppls/070506-00187-20100312.pdf	Disease control limited largely to powdery mildew.
pht® Dryout Dust (Britz-Simplot Grower Solutions LLC)	10951-18 http://www.epa.gov/pesticides/chem_search/ppls/010951-00018-20100708.pdf	No claims overlap.
Safer® Brand Garden Fungicide II (Woodstream Corporation)	42697-37 http://www.epa.gov/pesticides/chem_search/ppls/042697-00037-20100114.pdf	Disease control limited largely to powdery mildew.
Special Electric® (Wilbur-Ellis Company)	2935-503 http://www.epa.gov/pesticides/chem_search/ppls/002935-00503-20101216.pdf	Disease control limited largely to powdery mildew.
Sulfur DF (Wilbur-Ellis Company)	51036-352-2935 http://ag.wilburellis.com/Products/Product%20Documents/PlantProtectLABELS/Sulfur%20DF_NVA2009-04-352-0096.pdf	Disease control limited largely to powdery mildew.
Wilbur-Ellis Ben-Sul 85 (Wilbur-Ellis Company)	2935-506 http://www.epa.gov/pesticides/chem_search/ppls/002935-00506-20101216.pdf	Disease control limited largely to powdery mildew.

Comparative Efficacy 13.a.11. Tetracycline		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt
Mycoshield® (NuFarm Americas, Inc.)	55146-97 (Calcium oxytetracycline) http://www.epa.gov/pesticides/chem_search/ppls/055146-00097-20110610.pdf	No claims overlap.

Comparative Efficacy 13.a.12. <i>Trichoderma</i> spp.		
Product Name in OMRI List	EPA Reg. No.	Claims Missing vs. Polyoxin D Zinc Salt
Plant Shield HC Biological Fungicide (BioWorks, Inc.)	68539-4 (<i>Trichoderma harzianum</i> Rifai strain T-22) http://www.epa.gov/pesticides/chem_search/ppls/068539-00004-20110809.pdf	Label does not match crops with diseases. Claims overlap limited to Rhizoctonia and Botrytis.
RootShield Granules (BioWorks, Inc.)	68539-3 (<i>Trichoderma harzianum</i> Rifai strain T-22) http://www.epa.gov/pesticides/chem_search/ppls/068539-00003-20111206.pdf	Label does not match crops with diseases. Claims overlap limited to Rhizoctonia.
RootShield Home & Garden Biological Fungicide (BioWorks, Inc.)	68539-4 (<i>Trichoderma harzianum</i> Rifai strain T-22) http://www.epa.gov/pesticides/chem_search/ppls/068539-00004-20110809.pdf http://www.bioworksinc.com/products/rootshield-hg/rootshield-hg-label.pdf	Label does not match crops with diseases. Claims overlap limited to Rhizoctonia and Botrytis.
T-22 HC Biological Fungicide (BioWorks, Inc.)	68539-4 (<i>Trichoderma harzianum</i> Rifai strain T-22) http://www.epa.gov/pesticides/chem_search/ppls/068539-00004-20110809.pdf http://www.johnnyseeds.com/Assets/Information/9462_T-22HC-PlantShield_Label.pdf	Label does not match crops with diseases. Claims overlap limited to Rhizoctonia and Botrytis.
T-22 Planter Box Biological Fungicide (BioWorks, Inc.)	68539-4 (<i>Trichoderma harzianum</i> Rifai strain T-22) http://fs1.agrian.com/pdfs/T-22_Planter_Box_Label.pdf	Label does not match crops with diseases. Claims overlap limited to Rhizoctonia.
Tenet. WP (Isagro USA)	80289-9 (<i>Trichoderma gamsii</i> Strain ICC 080 and <i>Trichoderma asperellum</i> Strain ICC 012) http://www.epa.gov/pesticides/chem_search/ppls/080289-00009-20110217.pdf	Label does not match crops with diseases. Claims overlap limited to Rhizoctonia.

13.b. List of Alternative Cultural Methods That Could Be Used in Place of the Petitioned Substance

Cultural methods that may be used to reduce the need for fungicides include, but are not limited to:

- Selection of the planting site so that there is:
 - Good soil drainage;
 - Good air flow around the plants; and
 - Direct sunlight exposure of the crops;
- Use of mulch or other soil covering to:
 - Block light reaching the ground between the cultivated plants to control weeds; and
 - Reduce splashing of soil onto the foliar parts of plants due to rainfall and supplemental irrigation;
- Spacing of cultivated plants sufficiently far apart to enable:
 - Good airflow around the plants; and
 - Good sunlight exposure of the plants;
- Avoidance of excessive high nitrogen fertilization, especially in the spring, to reduce the potential for excessive leaf growth;
- Control of weeds to maximize air flow and sun exposure of the plants;
- Prompt removal of infected plants and plant parts;
- Cleaning of tools and gloves used to remove infected plant material to avoid spreading plant pathogens;
- Harvesting and pruning of crops in the morning, after the crops have dried; and
- Limiting supplemental irrigation to shortly before or shortly after sunrise so that plants can dry quickly and remain dry for most of the day.

13.c. Description of the Beneficial Effects to the Environment, Human Health, or Farm Ecosystem from the Use of Polyoxin D Zinc Salt That Support its Use Instead of the Use of an Alternative Non-Synthetic Fungicide or Alternative Cultural Methods

Polyoxin D zinc salt offers the following beneficial effects:

Mode of Action

Polyoxin D zinc salt has a unique, non-toxic mode of action. 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. This unique mode of action makes polyoxin D zinc salt an important component of an integrated pest management (IPM) program.

Resistance Management

In over 40 years of international commercial use, there has never been an observation of pest resistance or the beginning of the development of pest resistance.

Non-Target Organisms

The action of Polyoxin D zinc salt is highly specific. It does not adversely affect bacteria, viruses, mammals, birds, or beneficial insects, including honeybees. Polyoxin D zinc salt is only moderately toxic to aquatic organisms.

Phytotoxicity has never been observed as the result of crop treatments with polyoxin D zinc salt. Use of some of the registered alternatives (*e.g.*, oils and sulfur) can result in phytotoxicity.

Soil and Water

Polyoxin D zinc salt readily degrades under normal environmental conditions. Also, polyoxin D zinc salt is used at low application rates. When used as directed, it is anticipated that polyoxin D zinc salt:

- Will not accumulate in the soil; and
- Will not contaminate groundwater or drinking water.

Human Health

Polyoxin D zinc salt has low toxicity. Based upon laboratory studies, polyoxin D zinc salt:

- Has low acute, subchronic, and chronic toxicity;
- Is not mutagenic in whole animal systems (*in vivo*);
- Does not cause birth defects (is not teratogenic);
- Does not cause infertility (is not a reproductive toxin);
- Does not cause cancer (is not oncogenic); and
- Does not adversely effect the immune system (is not an immunotoxin).

Polyoxin D zinc salt has a carbohydrate-like chemical structure and readily degrades on plants. Also, significant polyoxin D zinc salt residue reduction is achieved by washing treated commodities, and further residue reduction is achieved via cooking.

Polyoxin D zinc salt readily hydrolyzes, and unlike sulfites, does not accumulate in wine.

Dietary exposure to polyoxin D zinc salt is anticipated to be very low.

Dietary risk to polyoxin D zinc salt is anticipated to be very low.

Polyoxin D zinc salt, unlike tetracycline, is not an antibiotic and has never been used as a pharmaceutical in human or veterinary medicine.

Other

In over 40 years of international commercial use, there has never been a supply interruption of polyoxin D zinc salt or its formulations.

Appendix 1. ENDORSE Water Dispersible Granule EPA Stamped Accepted Label

Endorse WDG Master Label Kaken 2009-12-15 with minor changes implemented
EPA Reg. No. 68173-3
Page 1 of 13

- Alternate Brand Names for ENDORSE Water Dispersible Granules:**
- VERANDA™ Water Dispersible Granules
 - AFFIRM™ WDG

ENDORSE® Water Dispersible Granules

For use on Turf, Ornamentals, and Various Crops

GROUP 19 FUNGICIDE

ACTIVE INGREDIENT:	
Polyoxin D zinc salt	11.3%
OTHER INGREDIENTS:	88.7%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE OR BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NOTIFICATION
DEC 16 2009

Date Reviewed: _____
Reviewed By: C. Walsh

EPA Reg. No. 68173-3
EPA Est. No. _____

Kaken Pharmaceutical Co. Ltd.
Agro Chemicals and Animal Health Products Department
28-8, Honkomagome 2-chome
Bunkyo-ku, Tokyo 113-8650, Japan

For Product Information Call _____

Net Content: 1 lb
2 lbs 6.4 oz (2.4 lb)

Endorse WDG Master Label Kaken 2009-12-15 with minor changes implemented
EPA Reg. No. 68173-3
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FIRST AID	
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• 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 a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
<p style="text-align: center;">HOTLINE NUMBERS</p> <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p> <p style="text-align: center;">FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE Call PROSAR at 1-866-303-6952 or 1-651-632-8946 if calling from outside of the U.S.</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through the skin, swallowed or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Avoid breathing dust or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

All mixers, loaders, applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Socks
- Shoes
- Chemical-Resistant gloves

User Safety Requirements

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables are available, use detergent and hot water. Keep and wash PPE separately from other laundry.

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USER SAFETY RECOMMENDATIONS

- Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

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 washwater 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.

Granules exposed on soil surface may be hazardous to fish and aquatic invertebrates. Collect granules spilled during loading.

Observe the most restrictive of the labeling limitations and precautions of all products used in mixtures.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 4 hours unless wearing appropriate PPE.

PPE required for early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is: coveralls, socks, shoes, chemical resistant gloves.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in the box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses. Keep children and pets out of treated area until sprays have dried.

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GENERAL INFORMATION

ENDORSE Water Dispersible Granules is not for use on turf being grown for commercial seed production.

ENDORSE Water Dispersible Granules is not for homeowner use to treat food crops.

ENDORSE Water Dispersible Granules is for use in controlling or suppressing certain diseases on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes, strawberries, and seedlings or transplants of cucurbit vegetables and fruiting vegetables in a Greenhouse, Lath or Shade house, ornamentals (Field, Nursery, Container, and Residential and Commercial Landscapes), and Turf (including golf courses, sod, residential lawns, parks, athletic fields, and commercial and institutional grounds) composed of cool and warm season grasses such as Bluegrass, Bentgrass, Fescue, Ryegrass, Bermudagrass, St. Augustinegrass, Zoysiagrass, or their mixtures.

Apply ENDORSE Water Dispersible Granules as a preventative or curative treatment in conjunction with good management practices.

RESISTANCE MANAGEMENT RECOMMENDATIONS

ENDORSE Water Dispersible Granules contains a Group 19 fungicide. Fungal isolates with acquired resistance to Group 19 may eventually dominate the fungal population if Group 19 fungicides are used repeatedly in the same field or in successive years as the primary method of control for targeted species. This may result in partial or total loss of control of those species by ENDORSE Water Dispersible Granules or other Group 19 Fungicides.

To delay fungicide resistance, consider:

- Avoiding the consecutive use of ENDORSE Water Dispersible Granules or other target site of action Group 19 fungicides that have a similar target site of action, on the same pathogens.
- Using tank-mixtures or premixes with fungicides from different target site of action Groups as long as the involved products are all registered for the same use and are both effective at the tank mix or prepack rate on the pathogen(s) of concern.
- Basing fungicide use on a comprehensive IPM program.
- Monitoring treated fungal populations for loss of field efficacy.
- Contacting your local extension specialist, certified crop advisors, and/or manufacturer for fungicide resistance management and/or IPM recommendations for specific crops and resistant pathogens.

MIXING AND APPLICATION

When diseases not specified on this label are present or expected, it is appropriate to mix ENDORSE Water Dispersible Granules with appropriately labeled fungicides. When tank mixing ENDORSE Water Dispersible Granules with other products, observe all precautions and limitations on each separate product label. It is always advisable to conduct a tank mix compatibility test when you plan to mix this product with other products. To determine the physical compatibility of this product with other products, use a jar test. Using a quart jar, add the proportionate amounts of the products to approximately one quart of water with agitation. Add dry formulations first, then flowables, then emulsifiable concentrates last. After thorough mixing, allow this mixture to stand for 5 minutes. If the combination remains mixed or can be readily remixed, it is physically compatible. Once compatibility has been proven, use the same procedure for adding required ingredients to the spray tank. To assess the potential for phytotoxicity, test tank mixtures on a small number of plants prior to more widespread application.

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Do not apply this product through any type of irrigation system.

Mixing instructions for ENDORSE Water Dispersible Granules:

- Fill spray tank with water to ½ of the intended final volume.
- Start spray tank agitation.
- Add the appropriate amount of product to the tank according to the rates in the following tables. Follow the directions above for mixing other products in the spray tank.
- Agitate to ensure thorough mixing while adding the remaining required water.
- DO NOT allow the spray mixture to stand without agitation.

Mix only the amount of spray solution needed to treat the desired area.

For optimum control of labeled diseases, apply ENDORSE Water Dispersible Granules with sufficient water to provide a thorough coverage.

ALMONDS		
Disease Control	Rate	Application Notes
<p>Alternaria (<i>Alternaria alternata</i>)</p>	<p>6.2 oz/acre (0.7 oz ai/acre)</p>	<ul style="list-style-type: none"> • Mix in appropriate spray volume appropriate for sufficient coverage (Spray every row to ensure coverage [avoid every other row applications]). • Begin sprays preventatively and repeat on a 10–14 day interval. • 0 day Preharvest Interval. • May be applied by air or ground. • Use of an adjuvant may enhance coverage.
<p>Notes:</p> <ul style="list-style-type: none"> • Use in alternation with fungicides that have different modes of action. • Do not apply more than 3 applications of ENDORSE Water Dispersible Granules (2.1 oz ai/acre) per season. 		

CUCURBIT VEGETABLES		
<p>[Chayote (fruit), Chinese waxgourd (Chinese preserving melon), Citron melon, Cucumber, Gherkin, Gourd, edible (includes hyotan, cucuzza, hechima, Chinese okra), <i>Momordica</i> spp. (includes balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (includes true cantaloupe, cantaloupe, casaba, crenshaw melon, golden pershaw melon, honeydew melon, honey balls, mango melon, Persian melon, pineapple melon, Santa Claus melon, and snake melon), Pumpkin, Squash, summer (includes crookneck squash, scallop squash, straightneck squash, vegetable marrow, zucchini), Squash, winter (includes butternut squash, calabaza, hubbard squash, acorn squash, spaghetti squash), Watermelon]</p>		
Disease Control	Rate	Application Notes
<p>Powdery Mildew (<i>Sphaerotheca</i> sp.)</p> <p>Gummy Stem Blight (<i>Didymella bryoniae</i>)</p>	<p>6.2 oz/acre (0.7 oz ai/acre)</p>	<ul style="list-style-type: none"> • Mix in appropriate spray volume appropriate for sufficient coverage. • For all diseases, spray product preventatively and continue as needed on a 10-14 day interval.

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CUCURBIT VEGETABLES		
[Chayote (fruit), Chinese waxgourd (Chinese preserving melon), Citron melon, Cucumber, Gherkin, Gourd, edible (includes hyotan, cucuzza, hechima, Chinese okra), <i>Momordica</i> spp. (includes balsam apple, balsam pear, bitter melon, Chinese cucumber), Muskmelon (includes true cantaloupe, cantaloupe, casaba, crenshaw melon, golden pershaw melon, honeydew melon, honey balls, mango melon, Persian melon, pineapple melon, Santa Claus melon, and snake melon), Pumpkin, Squash, summer (includes crookneck squash, scallop squash, straightneck squash, vegetable marrow, zucchini), Squash, winter (includes butternut squash, calabaza, hubbard squash, acorn squash, spaghetti squash), Watermelon]		
Disease Control	Rate	Application Notes
Gray Mold (<i>Botrytis</i> sp.) Corynespora leaf spot (<i>Corynespora cassicola</i>) Scab (<i>Cladosporium</i> sp.) Early Blight (<i>Alternaria</i> sp.)		<ul style="list-style-type: none"> • 0 day Preharvest Interval.
Notes: <ul style="list-style-type: none"> • Use in alternation with fungicides that have different modes of action. • Do not apply more than 5 applications of ENDORSE Water Dispersible Granules (3.5 oz ai/acre) per season. 		

FRUITING VEGETABLES (Except Cucurbits)		
[Eggplant, Groundcherry, Pepino, Pepper (includes bell pepper, chill pepper, cooking pepper, pimento, sweet pepper), Tomatillo, Tomato]		
Disease Control	Rate	Application Notes
Powdery Mildew (<i>Leveillula taurica</i> , <i>Oidiopsis sipula</i>) Botrytis Rot (<i>Botrytis</i> sp.) Early Blight (<i>Alternaria solani</i>)	6.2 oz/acre (0.7 oz ai/acre)	<ul style="list-style-type: none"> • Mix in appropriate spray volume appropriate for sufficient coverage. • For all diseases, spray product preventatively and continue as needed on a 10-14 day interval. • 0 day Preharvest Interval.
Disease Suppression		
Anthracnose (<i>Colletotricum coccodes</i>)		
Notes: <ul style="list-style-type: none"> • Use in alternation with fungicides that have different modes of action. • Do not apply more than 5 applications of ENDORSE Water Dispersible Granules (3.5 oz ai/acre) per season. 		

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GINSENG (Except California)		
Foliar Disease Control	Rate	Application Notes
Alternaria blight <i>(Alternaria panax)</i> Botrytis blight <i>(Botrytis cinerea)</i>	6.2 oz/acre (0.7 oz ai/acre)	<ul style="list-style-type: none"> • Apply as a foliar spray every 7–10 days. • Apply prior to disease development and when conditions are conducive for disease.¹
Root and Crown Disease Control	Rate	Application Notes
Cylindrocarpon root rot <i>(Cylindrocarpon destructans)</i>	6.2 oz/acre (0.7 oz ai/acre)	<ul style="list-style-type: none"> • Apply as a drench every 14 days.
Rhizoctonia root and crown rot <i>(Rhizoctonia solani)</i>		<ul style="list-style-type: none"> • Apply as a drench every 14–28 days.
Notes: <ul style="list-style-type: none"> • Apply within 2 weeks following plant emergence and continue throughout the season. • ¹Consult your local extension agent or local recommendations for information relating to proper timing for control of these diseases. • Use in alternation with fungicides that have different modes of action. • Do not apply more than 3 applications of ENDORSE Water Dispersible Granules (2.1 oz ai/acre) per season. 		

GRAPES		
Disease Control	Rate	Application Notes
Botrytis Bunch Rot <i>(Botrytis cinerea)</i> Powdery Mildew <i>(Uncinula necator)</i>	6.2 oz/acre (0.7 oz ai/acre)	<ul style="list-style-type: none"> • Mix in appropriate spray volume appropriate for sufficient coverage. • For Botrytis Bunch Rot control, spray product at veraison and 7 days prior to harvest. • For Powdery Mildew control, begin sprays preventatively and continue as needed on a 14 day interval. • 0 day Preharvest Interval. • Do not apply by air.
Notes: <ul style="list-style-type: none"> • Use in alternation with fungicides that have different modes of action. • Do not apply more than 3 applications of ENDORSE Water Dispersible Granules (2.1 oz ai/acre) per season. 		

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PISTACHIOS		
Disease Control	Rate	Application Notes
Alternaria (<i>Alternaria</i> sp.)	6.2 oz/acre (0.7 oz ai/acre)	<ul style="list-style-type: none"> • Mix in appropriate spray volume appropriate for sufficient coverage (Spray every row to ensure coverage (avoid every other row applications)). • For both diseases, begin sprays preventatively and continue as needed on a 10–14 day interval. • 0 day Preharvest Interval. • Do not apply by air. • Use of an adjuvant may enhance coverage.
Disease Suppression		
Botryosphaeria blight (<i>Botryosphaeria</i> sp.)		
Notes: <ul style="list-style-type: none"> • Use in alternation with fungicides that have different modes of action. • Do not apply more than 3 applications of ENDORSE Water Dispersible Granules (2.1 oz ai/acre) per season. 		

POME FRUITS		
[Apple, Crabapple, Loquat, Mayhaw, Pear, Oriental Pear, Quince]		
Disease Control	Rate	Application Notes
Powdery Mildew (Apple: <i>Podosphaera leucotricha</i> Pear: <i>Phyllactinia mali</i>)	6.2 oz/acre (0.7 oz ai/acre)	<ul style="list-style-type: none"> • Mix in appropriate spray volume appropriate for sufficient coverage. • Start sprays for scab control at green tip and continue as needed on a 7-10 day interval. • For Powdery Mildew control, begin preventatively and repeat as necessary on a 10-14 day interval. Use of an alternation program with a sterol inhibiting fungicide is recommended. • 0 day Preharvest Interval.
Alternaria Leaf Spot (<i>Alternaria mali</i>)		
Blotch (<i>Diplocarpon mali</i>)		
Disease Suppression		
Scab (<i>Venturia</i> sp.)		
Notes: <ul style="list-style-type: none"> • Use in alternation with fungicides that have different modes of action. • Do not apply more than 6 applications of ENDORSE Water Dispersible Granules (4.2 oz ai/acre) per season. 		

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POTATOES		
Disease Control	Rate	Application Notes
Early Blight (<i>Alternaria solani</i>)	6.2 oz/acre (0.7 oz ai/acre)	<ul style="list-style-type: none"> Mix in appropriate spray volume appropriate for sufficient coverage. For all diseases, spray product preventatively and continue as needed on a 10-14 day interval. 0 day Preharvest Interval.
Notes: <ul style="list-style-type: none"> Use in alternation with fungicides that have different modes of action. Do not apply more than 5 applications of ENDORSE Water Dispersible Granules (3.5 oz ai/acre) per season. 		

STRAWBERRIES		
Disease Control	Rate	Application Notes
Anthracnose Leaf and Fruit Rot (<i>Colletotricum</i> sp.) Botrytis Fruit Rot (<i>Botrytis cinerea</i>) Powdery Mildew (<i>Sphaerotheca macularis</i>)	6.2 oz/acre (0.7 oz ai/acre)	<ul style="list-style-type: none"> Mix in appropriate spray volume appropriate for sufficient coverage. Begin applications preventatively and continue as needed on a 7-10 day interval. 0 day Preharvest Interval. Do not apply by air. Use of adjuvant may enhance coverage.
Notes: <ul style="list-style-type: none"> Use in alternation with fungicides that have different modes of action. Do not apply more than 3 applications of ENDORSE Water Dispersible Granules (2.1 oz ai/acre) per season. 		

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ORNAMENTALS		
Foliar Diseases	Rate	Application Notes
Anthracnose (<i>Colletotrichum</i>) *Botrytis blight (<i>Botrytis cinerea</i>) Curvularia Downy Mildew (<i>Pernospora sp.</i>) (<i>Plasmopara sp.</i>) Powdery Mildew (<i>Oidium sp.</i>) (<i>Erysiphe sp.</i>) (<i>Sphaerotheca sp.</i>) Rhizoctonia aerial blight (<i>Rhizoctonia solani</i>)	0.25 – 0.5 lb/100 gal/acre (0.03 – 0.06 lb ai/100 gal/acre)	<ul style="list-style-type: none"> • Apply as a full coverage foliar spray every 7 – 10 days with sufficient water for plant type and maturity (50-300 gallons/acre). • Apply prior to disease development and when conditions are conducive to disease development. Consult your local extension agent or local recommendations for recommendations for information relating to proper timing for control of these diseases.
*Alternaria blight (<i>Alternaria panax</i>) Apple scab (<i>Venturia inaequalis</i>)	0.5 lb/100 gal/acre (0.06 lb ai/100 gal/acre)	
Root and Crown Diseases	Rate	Application Notes
*Rhizoctonia root and crown rot (<i>Rhizoctonia solani</i>)	0.25 – 0.5 lb/100 gal/acre (0.03 – 0.06 lb ai/100 gal/acre)	<ul style="list-style-type: none"> • Apply as a soil drench every 14 – 28 days.
Notes: <ul style="list-style-type: none"> • * Control • Use in alternation with fungicides that have different modes of action. 		

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TURF GRASSES		
Disease	Rate	Application Notes
Control	2.4 lbs /acre (0.27 lb ai/acre)	<ul style="list-style-type: none"> • Repeat treatment on a 7-14 day schedule where environmental conditions are conducive to development of diseases. Consult your local extension agent or local recommendations for information relating to proper timing for control of these diseases. • When symptoms are present, best control will be achieved by using a shorter interval. • For best results apply after mowing. • Apply to obtain thorough plant coverage in a minimum of 44 gallons water per acre.
Brown Patch (<i>Rhizoctonia solani</i>)		
Large Patch (<i>Rhizoctonia solani</i>)		
Aids in Control (except California)		
Cool Season Brown Patch (Yellow Patch) (<i>Rhizoctonia cerealis</i>)		
Foliar and Basal Anthracnose (<i>Colletotrichum-cereale</i>)		
Gray Snow Mold (<i>Typhula ishikariensis</i> and <i>Typhula incarnate</i>)		
Leaf Spot/Melting Out (<i>Dreschlera poae</i>)		
Pink Snow Mold (<i>Microdochium nivale</i>)		
Red Thread (<i>Laetisaria fuciformis</i>)		
Rhizoctonia Damping Off (<i>Rhizoctonia solani</i>)		
Rhizactonia Leaf and Sheath Blight (<i>Rhizoctonia zeae</i>)		
Waitea Patch (Brown Ring Patch) (<i>Waitea circinata</i>)		
Zoysia Patch (<i>Rhizoctonia solani</i>)		
Aids in Suppression (except California)	1 oz/1000 sq ft in minimum of 1 gallon of water (0.27 lb ai/acre in 44 gallons of water)	<ul style="list-style-type: none"> • Make two-three applications on a 7-day interval schedule. • Use a penetrating wetting agent. • Immediately following application, water in the treatment with sufficient irrigation (1/8-1/4") to wet the active root zone.
Gray Leaf Spot (<i>Pyricularia grisea</i>)		
Suppression and Short Term Control:		
Fairy Ring (including <i>Marasmius</i> spp., <i>Lepiota</i> , spp. and <i>Agarius</i> spp.)		

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TURF GRASSES		
Disease	Rate	Application Notes
Notes: <ul style="list-style-type: none">• With the exception for treatment of Fairy Ring, irrigation or rainfall soon after treatment with ENDORSE Water Dispersible Granules will decrease disease control. For best control, do not irrigate for 12 hours after treatment.• Use in alternation with fungicides that have different modes of action.		

STORAGE AND DISPOSAL
Do not contaminate water, food or feed by storage or disposal.
PESTICIDE STORAGE: Store in dry place away from food or feed.
PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Offer for recycling, if available, or dispose of empty bag in a sanitary landfill or by incineration, or, if allowed, by State and local authorities, by burning. If burned, stay out of smoke.

**FOR 24-HOUR CHEMICAL EMERGENCY (Spill, Leak, Fire or Accident) ASSISTANCE:
CALL CHEMTREC 1-800-424-9300**

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Warranty and Disclaimer Statement

1. The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Such risks may arise from weather conditions, soil factors, off-target movement, unconventional farming techniques, the presence of other materials, the manner of use or application, or other unknown factors, all of which are beyond the control of Kaken Pharmaceutical Co. Ltd. ("Kaken"), and can cause crop injury, injury to non-target crops or plants, ineffectiveness of the product, or other unintended consequences. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.
2. Kaken warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks described above, when used in accordance with the Directions for Use under normal conditions.
3. This warranty does not extend to the use of this product contrary to label instructions or under conditions not reasonably foreseeable to Kaken, and is subject to the inherent risks described above. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, KAKEN DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, KAKEN, MANUFACTURER, AND SELLER DISCLAIM AND SHALL NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE, HANDLING, APPLICATION, STORAGE, OR DISPOSAL OF THIS PRODUCT OR FOR DAMAGES IN THE NATURE OF PENALTIES, AND THE USER AND BUYER WAIVE ANY RIGHT THAT THEY MAY HAVE TO SUCH DAMAGES. NO AGENT, REPRESENTATIVE OR EMPLOYEE OF KAKEN IS AUTHORIZED TO MAKE ANY WARRANTY, GUARANTEE OR REPRESENTATION BEYOND THOSE CONTAINED HEREIN OR TO MODIFY THE WARRANTIES CONTAINED HEREIN.**
4. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE TOTAL LIABILITY OF KAKEN, MANUFACTURER, AND SELLER, SHALL BE LIMITED TO THE PURCHASE PRICE PAID, OR AT KAKEN'S ELECTION, THE REPLACEMENT OF THE PRODUCT.**

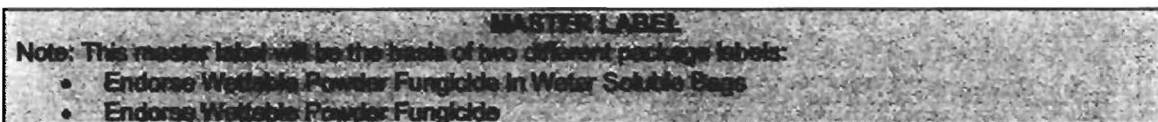
ENDORSE® is a registered trademark of Arysta LifeScience North America, LLC.

VERANDA™ is a trademark of Arysta LifeScience North America, LLC.

AFFIRM™ is a trademark of Cleary Chemical, LLC.

Appendix 2. ENDORSE Wettable Powder EPA Stamped Accepted Label

ENDORSE Wettable Powder Fungicide Kaken Master AD 022707- Notif DB101207 - Clean PR Not 2007-4 Storage & Disposal 052808
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ENDORSE® Wettable Powder Fungicide

For use on Turf, Ornamentals and Non-Food Ginseng

Prohibited for Any Food or Feed Use

GROUP	19	FUNGICIDE
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ACTIVE INGREDIENT:

Polyoxin D zinc salt (1:1) ¹ ,	
Zinc 5-[[2-amino-5-O-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2H)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronate.....	2.5 %
OTHER INGREDIENTS:	97.5 %
TOTAL	100.0%

¹Equivalent to 2.2% polyoxorim and 0.3% metallic zinc

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE/BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 68173-2
EPA Est. No. _____

Produced by:
Kaken Pharmaceutical Co. Ltd.
Agro Chemicals and Animal Health Products Department
28-8, Honkomagonme 2-chome
Bunkyo-ku, Tokyo 113-8650, Japan

For Product Use Information Call: 1-866-761-9397

Net Weight: 1 pound, 1.6 ounces
11 lbs



ENDORSE® Wettable Powder Fungicide

IN WATER SOLUBLE PACKS

For Use on Turf, Ornamental and Non-Food Ginseng

Prohibited for Any Food or Feed Use

GROUP	19	FUNGICIDE
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ACTIVE INGREDIENT:

Polyoxin D zinc salt (1:1) ¹ ,	
Zinc 5-[[2-amino-5-O-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2H)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronate.....	2.5 %
OTHER INGREDIENTS:.....	97.5 %
TOTAL.....	100.0%

¹Equivalent to 2.2% polyoxorim and 0.3% metallic zinc

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE/BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

EPA Reg. No. 68173-2
EPA EST. No. _____

Produced by:
Kaken Pharmaceutical Co. Ltd.
Agro Chemicals and Animal Health Products Department
28-8, Honkomagonme 2-chome
Bunkyo-ku, Tokyo 113-8650, Japan

For Product Use Information Call: 1-866-761-9397

Net weight: 1 pound, 1.6 ounces
Each water soluble pack contains 1 lb, 1.6 ounces of product. There is one pack per bag and 10 bags per case.

ENDORSE Wettable Powder Fungicide Kaken Master AD 022707- Notif DB101207 - Clean PR Not 2007-4 Storage & Disposal 052808
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FIRST AID	
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• 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 a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
<p style="text-align: center;">HOTLINE NUMBERS</p> <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p> <p style="text-align: center;">FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE: Call PROSAR at 1-866-303-6952 or 1-651-632-8946 if calling from outside of the U.S.</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin, swallowed or inhaled. Causes moderate eye irritation. Avoid breathing dust or spray mist. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse. Wear the appropriate Personal Protective Equipment (PPE).

PERSONAL PROTECTIVE EQUIPMENT (PPE)

All mixers, loaders, applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Socks
- Shoes
- Chemical-Resistant gloves

User Safety Requirements

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables are available, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This product 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 washwaters 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.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Carefully read and understand the Directions for Use and restrictions before applying this product.

Do not apply this product in any way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribe responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 4 hours unless wearing appropriate PPE.

PPE required for early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is: coveralls, socks, shoes, chemical resistant gloves.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep children and pets out of treated area until sprays have dried.

GENERAL INFORMATION

ENDORSE® Wettable Powder Fungicide is not for use on turf being grown for commercial seed production.

ENDORSE Wettable Powder Fungicide is a systemic foliar applied fungicide for use in controlling or suppressing certain diseases on golf courses, residential lawns, parks and commercial and institutional grounds composed of cool and warm season grasses such as bluegrass, bentgrass, fescue, ryegrass, zoysiagrass, or their mixtures. ENDORSE Wettable Powder Fungicide is also for use on ornamentals and ginseng. (Refer to the TURF GRASSES, GINSENG and ORNAMENTALS tables below for specific diseases.)

Apply ENDORSE Wettable Powder Fungicide as a preventive or curative treatment in conjunction with good turf and ornamental management practices.

RESISTANCE MANAGEMENT DIRECTIONS

ENDORSE Wettable Powder Fungicide contains a Group 19 fungicide. Fungal isolates with acquired resistance to Group 19 may eventually dominate the fungal population if Group 19 fungicides are used repeatedly in the same field or in successive years as the primary method of control for targeted species. This may result in partial or total loss of control of those species by ENDORSE Wettable Powder Fungicide or other Group 19 Fungicides.

To delay fungicide resistance, consider:

- Avoiding the consecutive use of ENDORSE Wettable Powder Fungicide or other target site of action Group 19 fungicides that have a similar target site of action, on the same pathogens.
- Using tank-mixtures or premixes with fungicides from different target site of action Groups as long as the involved products are all registered for the same use and are both effective at the tank mix or prepack rate on the pathogen(s) of concern.
- Basing fungicide use on a comprehensive IPM program.
- Monitoring treated fungal populations for loss of field efficacy.
- Contacting your local extension specialist, certified crop advisors, and/or manufacturer for fungicide resistance management and/or IPM recommendations for specific crops and resistant pathogens.

MIXING AND APPLICATION

When tank mixing ENDORSE Wettable Powder Fungicide with other products, observe all precautions and limitations on each separate product label. It is always advisable to conduct a spray compatibility test when you plan to mix this product with other products. To determine the physical compatibility of this product with other products, use a jar test. Using a quart jar, add the proportionate amounts of the products to approximately one quart of water with agitation. Add dry formulations first, then flowables, then emulsifiable concentrates last. After thorough mixing, allow this mixture to stand for 5 minutes. If the combination remains mixed or can be readily remixed, it is physically compatible. Once compatibility has been proven, use the same procedure for adding required ingredients to the spray tank. Use combinations on a small number of plants to check for phytotoxicity and disease control before treating large areas. Do not use the combination if adverse affects are observed.

Do not apply this product through any type of irrigation system.

Mixing instructions for ENDORSE Wettable Powder Fungicide in water soluble pack:

- Fill spray tank ¾ full
- Start spray tank agitation
- Drop water soluble pack(s) in tank
- Direct the balance of water at the floating pack(s)
- Pack(s) must be dissolved before recycling through spray tank

Mix only the amount of spray solution needed to treat the desired area.

For optimum control of labeled diseases, apply ENDORSE Wettable Powder Fungicide with sufficient water to provide a thorough coverage.

With the exception for treatment of Fairy Ring, irrigation or rainfall soon after treatment with ENDORSE Wettable Powder Fungicide will decrease disease control. For best control, do not irrigate for 12 hours after treatment.

TURF GRASSES		
Disease	Rate	Application Notes
Control: Brown Patch Large Patch	1 pack/4,400 square feet in a minimum of 44 gallons of water (0.275 lb ai/acre)	Repeat treatment on a 7-14 day schedule where environmental conditions are conducive to development of diseases. ¹
Aids in Control: (Except California) Cool Weather Brown Patch (Yellow Patch) (<i>Rhizoctonia cerealis</i>) Foliar and Basal Anthracnose (<i>Collectotrichum graminicola</i>) Gray Snow Mold (<i>Typhula ishikariensis</i> and <i>Typhula incarnate</i>) Leaf Spot/Melting Out (<i>Dreschlera poae</i>) Pink Snow Mold (<i>Microdochium solani</i>) Red Thread (<i>Laetisaria fuciformis</i>) Rhizoctonia Damping Off (<i>Rhizoctonia solani</i>) Zoysia Patch (<i>Rhizoctonia solani</i>) on cool and warm season turf grasses		

ENDORSE Wettable Powder Fungicide Kaken Master AD 022707- Notif DB101207 - Clean PR Not 2007-4 Storage & Disposal 052808
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TURF GRASSES		
Disease	Rate	Application Notes
Aids in Suppression: (Except California) Gray Leaf Spot (<i>Pyricularia grisea</i>)		
Suppression and Short Term Control: Fairy Ring (including <i>Marasmius</i> spp., <i>Lepiota</i> , spp. and <i>Agarius</i> spp.)	1 pack/4,400 square feet in a minimum of 88 gallons of water (0.275 lb ai/acre)	Make two-three applications on a 7-day interval schedule. Use a penetrating wetting agent. Immediately following application, water in the treatment with sufficient irrigation (0.5-1") to wet the active root zone.
Notes: <ul style="list-style-type: none"> • Use in alternation with fungicides that have different modes of action. • ¹ Consult your local extension agent or local recommendations for information relating to proper timing for control of these diseases. 		

GINSENG (Except California)		
Foliar Disease Control	Rate	Application Notes
Alternaria blight (<i>Alternaria panax</i>) Botrytis blight (<i>Botrytis cinerea</i>)	1 pack/0.5 – 1 acre in 100 gallons of water (0.03 - 0.06 lb ai/100 gal/acre)	Apply as a foliar spray every 7 – 10 days. Apply prior to disease development and when conditions are conducive for disease. ¹
Root and Crown Disease Control	Rate	Application Notes
Cyliandrocarpon root rot (<i>Cyliandrocarpon destructans</i>)	1 pack/0.5 acre in 100 gallons of water (0.06 lb ai/100 gal/acre)	Apply as a drench every 14 days.
Rhizoctonia root and crown rot (<i>Rhizoctonia solani</i>)	1 pack/0.5 – 1 acre in 100 gallons of water (0.03 – 0.06 lb ai/100 gal/acre)	Apply as a drench every 14 – 28 days.
Notes: <ul style="list-style-type: none"> • Do not use for food or feed purposes within 1 year of treatment. • Apply within 2 weeks following plant emergence and continue throughout the season. • Use in alternation with fungicides that have different modes of action. • ¹ Consult your local extension agent or local recommendations for information relating to proper timing for control of these diseases. 		

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ORNAMENTALS		
Foliar Disease Control	Rate	Application Notes
Anthracnose <i>(Colletotrichum)</i> Botrytis blight <i>(Botrytis cinerea)</i> Curvularia Downy Mildew Pernospora sp. Plasmopara sp. Powdery Mildew Oidium sp. Erysiphe sp. Sphaerotheca sp. Rhizoctonia aerial blight <i>(Rhizoctonia solani)</i>	1-2 pack/100 gallons	Apply as a full coverage foliar spray every 7 – 14 days in sufficient water for plant type and maturity (50-300 gallons/acre). Apply prior to disease development and when conditions are conducive for disease. ¹
Alternaria blight <i>(Alternaria panax)</i> Apple scab <i>(Venturia inaequalis)</i>	2 packs/100 gallons	
Root and Crown Disease Control	Rate	Application Notes
Rhizoctonia root and crown rot <i>(Rhizoctonia solani)</i>	1-2 pack/100 gallons	Apply as a drench every 14 – 28 days.
Notes: <ul style="list-style-type: none"> • Use in alternation with fungicides that have different modes of action. • ¹ Consult your local extension agent or local recommendations for information relating to proper timing for control of these diseases. 		

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in dry place away from food or feed.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Offer for recycling, if available, or dispose of empty outer packaging (bag) in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. Offer for recycling, if available.

Warranty and Disclaimer Statement

1. Kaken Pharmaceutical Co. Ltd. ("Kaken") warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with the Directions for Use under normal conditions of use.
2. This warranty does not extend to the use of this product contrary to label instructions and is subject to the inherent risks described below. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, KAKEN DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, KAKEN, THE MANUFACTURER, AND THE SELLER DISCLAIM AND SHALL NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE, HANDLING, APPLICATION, STORAGE, OR DISPOSAL OF THIS PRODUCT OR FOR DAMAGES IN THE NATURE OF PENALTIES, AND THE BUYER AND THE USER WAIVE ANY RIGHT THAT THEY MAY HAVE TO SUCH DAMAGES. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, KAKEN AND THE SELLER'S LIABILITY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE. KAKEN DOES NOT AUTHORIZE ANY AGENT OR REPRESENTATIVE TO MAKE ANY OTHER WARRANTY, GUARANTEE OR REPRESENTATION CONCERNING THIS PRODUCT.**
3. The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Kaken. All such risks shall be assumed by the user or buyer.

NON WATER SOLUBLE PACK PACKAGING, SUB-LABEL

ENDORSE® Wettable Powder Fungicide

For use on Turf, Ornamentals and Non-Food Ginseng

Prohibited for any Food or Feed Use

GROUP	19	FUNGICIDE
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ACTIVE INGREDIENT:

Polyoxin D zinc salt (1:1) ¹ ,	
Zinc 5-[[2-amino-5-O-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2H)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronate.....	2.5 %
OTHER INGREDIENTS:.....	97.5 %
TOTAL.....	100.0%

¹Equivalent to 2.2% polyoxorim and 0.3% metallic zinc

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE/BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

EPA Reg. No. 68173-2
EPA EST. No. _____

Produced by:
Kaken Pharmaceutical Co. Ltd.
Agro Chemicals and Animal Health Products Department
28-8, Honkomagonme 2-chome
Bunkyo-ku, Tokyo 113-8650, Japan

For Product Use Information Call: 1-866-761-9397

Net contents: 11 lbs

FIRST AID	
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• 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 a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
HOTLINE NUMBERS	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE: Call PROSAR at 1-866-303-6952 or 1-651-632-8946 if calling from outside of the U.S.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin, swallowed or inhaled. Causes moderate eye irritation. Avoid breathing dust or spray mist. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse. Wear the appropriate Personal Protective Equipment (PPE).

PERSONAL PROTECTIVE EQUIPMENT (PPE)

All mixers, loaders, applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Socks
- Shoes
- Chemical-Resistant gloves

User Safety Requirements

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables are available, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This product 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 washwaters 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.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Carefully read and understand the Directions for Use and restrictions before applying this product.

Do not apply this product in any way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribe responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow entry into treated areas during the restricted entry interval (REI) of 4 hours unless wearing appropriate PPE.

PPE required for early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is: coveralls, socks, shoes, chemical resistant gloves.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep children and pets out of treated area until sprays have dried.

GENERAL INFORMATION

ENDORSE® Wettable Powder Fungicide is not for use on turf grown for commercial seed production.

ENDORSE Wettable Powder Fungicide is a systemic foliar applied fungicide for use in controlling or suppressing certain diseases on golf courses, residential lawns, parks and commercial and institutional grounds composed of cool and warm season grasses such as bluegrass, bentgrass, fescue, ryegrass, zoysiagrass, or their mixtures. ENDORSE Wettable Powder Fungicide is also for use on ornamentals and ginseng. (Refer to the TURF GRASSES, GINSENG and ORNAMENTALS tables below for specific diseases.)

Apply ENDORSE Wettable Powder Fungicide as a preventive or curative treatment in conjunction with good turf and ornamental management practices.

RESISTANCE MANAGEMENT DIRECTIONS

ENDORSE Wettable Powder Fungicide contains a Group 19 fungicide. Fungal isolates with acquired resistance to Group 19 may eventually dominate the fungal population if Group 19 fungicides are used repeatedly in the same field or in successive years as the primary method of control for targeted species. This may result in partial or total loss of control of those species by ENDORSE Wettable Powder Fungicide or other Group 19 Fungicides.

To delay fungicide resistance, consider:

- Avoiding the consecutive use of ENDORSE Wettable Powder Fungicide or other target site of action Group 19 fungicides that have a similar target site of action, on the same pathogens.
- Using tank-mixtures or premixes with fungicides from different target site of action Groups as long as the involved products are all registered for the same use and are both effective at the tank mix or prepack rate on the pathogen(s) of concern.
- Basing fungicide use on a comprehensive IPM program.
- Monitoring treated fungal populations for loss of field efficacy.
- Contacting your local extension specialist, certified crop advisors, and/or manufacturer for fungicide resistance management and/or IPM recommendations for specific crops and resistant pathogens.

MIXING AND APPLICATION

When tank mixing ENDORSE Wettable Powder Fungicide with other products, observe all precautions and limitations on each separate product label. It is always advisable to conduct a spray compatibility test when you plan to mix this product with other products. To determine the physical compatibility of this product with other products, use a jar test. Using a quart jar, add the proportionate amounts of the products to approximately one quart of water with agitation. Add dry formulations first, then flowables, then emulsifiable concentrates last. After thorough mixing, allow this mixture to stand for 5 minutes. If the combination remains mixed or can be readily remixed, it is physically compatible. Once compatibility has been proven, use the same procedure for adding required ingredients to the spray tank. Use combinations on a small number of plants to check for phytotoxicity and disease control before treating large areas. Do not use the combination if adverse effects are observed.

Do not apply this product through any type of irrigation system.

Mixing instructions for ENDORSE Wettable Powder Fungicide:

- Fill spray tank to ¾ of the intended final volume.
- Start spray tank agitation.
- Add the appropriate amount of product to the tank (refer to Rate and Schedule section of label). Follow the directions above for mixing other products in the spray tank.
- Agitate to ensure thorough mixing while adding the remaining required water.
- DO NOT allow the spray mixture to stand without agitation.

Mix only the amount of spray solution needed to treat the desired area.

For optimum control of labeled diseases, apply ENDORSE Wettable Powder Fungicide with sufficient water to provide a thorough coverage.

With the exception for treatment of Fairy Ring, irrigation or rainfall soon after treatment with ENDORSE Wettable Powder Fungicide will decrease disease control. For best control, do not irrigate for 12 hours after treatment.

TURF GRASSES		
Disease	Rate	Application Notes
Control: Brown Patch Large Patch	11 lbs/acre (0.275 lb ai/acre in a minimum of 44 gallons of water)	Repeat treatment on a 7-14 day schedule where environmental conditions are conducive to development of diseases. ¹ When symptoms are present, best control will be achieved by using a shorter interval. For best results apply after mowing.
Aids in Control: (Except California) Cool Weather Brown Patch (Yellow Patch) (<i>Rhizoctonia cerealis</i>) Foliar and Basal Anthracnose (<i>Collectotrichum graminicola</i>) Gray Snow Mold (<i>Typhula ishikariensis</i> and <i>Typhula incarnate</i>) Leaf Spot/Melting Out (<i>Dreschlera poae</i>) Pink Snow Mold (<i>Microdochium solani</i>) Red Thread (<i>Laetisaria fuciformis</i>) Rhizoctonia Damping Off (<i>Rhizoctonia solani</i>) Zoysia Patch (<i>Rhizoctonia solani</i>) on cool and warm season turf grasses		

TURF GRASSES		
Disease	Rate	Application Notes
<p>Aids in Suppression: (Except California)</p> <p>Gray Leaf Spot (<i>Pyricularia grisea</i>)</p>		
<p><u>Suppression and Short Term Control:</u></p> <p>Fairy Ring (including <i>Marasmius</i> spp., <i>Lepiota</i>, spp. and <i>Agarius</i> spp.)</p>	<p>4 ozs/1000 square feet in minimum of 2 gallons of water (0.275 lb ai/acre in a minimum of 88 gallons of water)</p>	<p>Make two-three applications on a 7-day interval schedule.</p> <p>Use a penetrating wetting agent.</p> <p>Immediately following application, water in the treatment with sufficient irrigation (0.5-1") to wet the active root zone.</p>
<p>Notes:</p> <ul style="list-style-type: none"> • Use in alteration with fungicides that have different modes of action. • ¹ Consult your local extension agent or local recommendations for information relating to proper timing for control of these diseases. 		

GINSENG (Except California)		
Foliar Disease Control	Rate	Application Notes
<p>Alternaria blight (<i>Alternaria panax</i>)</p> <p>Botrytis blight (<i>Botrytis cinerea</i>)</p>	<p>1.1 – 2.2 lb/100 gal/acre (0.03 - 0.06 lb ai /100 gal/acre)</p>	<p>Apply as a foliar spray every 7 – 10 days.</p> <p>Apply prior to disease development and when conditions are conducive for disease.¹</p>
Root and Crown Disease Control	Rate	Application Notes
<p>Cylindrocarpon root rot (<i>Cylindrocarpon destructans</i>)</p>	<p>2.2 lb/100 gal/acre (0.06 lb ai/100 gal/acre)</p>	<p>Apply as a drench every 14 days.</p>
<p>Rhizoctonia root and crown rot (<i>Rhizoctonia solani</i>)</p>	<p>1.1 - 2.2 lb/100 gal/acre (0.03 – 0.06 lb ai/100 gal/acre)</p>	<p>Apply as a drench every 14 – 28 days.</p>
<p>Notes:</p> <ul style="list-style-type: none"> • Do not use for food or feed purposes within 1 year of treatment. • Apply within 2 weeks following plant emergence and continue throughout the season. • Use in alternation with fungicides that have different modes of action. • ¹ Consult your local extension agent or local recommendations for information relating to proper timing for control of these diseases. 		

ORNAMENTALS		
Foliar Disease Control	Rate	Application Notes
Anthracnose <i>(Colletotrichum)</i> Botrytis blight <i>(Botrytis cinerea)</i> Curvularia Downy Mildew Pernospora sp. Plasmopara sp. Powdery Mildew Oidium sp. Erysiphe sp. Sphaerotheca sp. Rhizoctonia aerial blight <i>(Rhizoctonia solani)</i>	1-2 pack/100 gallons	Apply as a full coverage foliar spray every 7 – 14 days in sufficient water for plant type and maturity (50-300 gallons/acre). Apply prior to disease development and when conditions are conducive for disease. ¹
Alternaria blight <i>(Alternaria panax)</i> Apple scab <i>(Venturia inaequalis)</i>	2 packs/100 gallons	
Root and Crown Disease Control	Rate	Application Notes
Rhizoctonia root and crown rot <i>(Rhizoctonia solani)</i>	1-2 pack/100 gallons	Apply as a drench every 14 – 28 days.
Notes: <ul style="list-style-type: none"> • Use in alternation with fungicides that have different modes of action. • ¹ Consult your local extension agent or local recommendations for information relating to proper timing for control of these diseases. 		

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in dry place away from food or feed.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Offer for recycling, if available, or dispose of empty bag in a sanitary landfill or by incineration, or, if allowed, by State and local authorities, by burning. If burned, stay out of smoke. Offer for recycling, if available.

Warranty and Disclaimer Statement

1. Kaken Pharmaceutical Co. Ltd. ("Kaken") warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with the Directions for Use under normal conditions of use.
2. This warranty does not extend to the use of this product contrary to label instructions and is subject to the inherent risks described below. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, KAKEN DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, KAKEN, THE MANUFACTURER, AND THE SELLER DISCLAIM AND SHALL NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE, HANDLING, APPLICATION, STORAGE, OR DISPOSAL OF THIS PRODUCT OR FOR DAMAGES IN THE NATURE OF PENALTIES, AND THE BUYER AND THE USER WAIVE ANY RIGHT THAT THEY MAY HAVE TO SUCH DAMAGES. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, KAKEN AND THE SELLER'S LIABILITY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE. KAKEN DOES NOT AUTHORIZE ANY AGENT OR REPRESENTATIVE TO MAKE ANY OTHER WARRANTY, GUARANTEE OR REPRESENTATION CONCERNING THIS PRODUCT.**
3. The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Kaken. All such risks shall be assumed by the user or buyer.

**Appendix 3. Minimum Inhibitory Concentrations (MIC) of Polyoxins Against Bacteria, Yeast and
Fungi**

Minimum Inhibitory Concentrations (MIC) of Polyoxins against Bacteria, Yeast and Fungi

Keiji Takahashi
The Third Laboratory, Research Laboratories,
Kaken Chemical Co., Ltd.
April 1972

1. Determination of MIC

1) Bacteria

Agar streak method using peptone-glucose agar was employed.
Determination was made after incubation at 31 °C for 18-24 hr.

2) Yeast

Agar streak method using potato sucrose agar was employed.
Determination was made after incubation at 26 °C for 48 hr.

3) Fungi

Agar streak method using potato sucrose agar was employed.
Determination was made after incubation at 26 °C for 48-65 hr.
(For *Fusarium* spp., Hopkins agar was used instead of potato sucrose agar.)

2. Test substance

Polyoxin D, E and F mixture (purity 80 % up as polyoxin D activity)

3. Results

1) Bacteria

	MIC (μg/ml)
<i>Bacillus subtilis</i> PCI-219	>100
<i>Staphylococcus aureus</i> FDA-209P	>100
<i>S. aureus</i> HEATLEY	>100
<i>Escherichia coli</i> NIHJ	>100
<i>Pseudomonas fluorescens</i> NRRL-B-10	>100
<i>Klebsiella pneumoniae</i> PCI-602	>100
<i>Mycobacterium phlei</i> CCM-1889	>100
<i>Micrococcus flavus</i>	>100
<i>Sarcina lutea</i>	>100
<i>Xanthomonas citri</i>	>100
<i>Erwinia aroideae</i>	>100

2) Yeast

	MIC (μg/ml)
<i>Candida albicans</i> IPCR	>100
<i>C. steratoides</i>	>100
<i>Endomyces magnusii</i>	>100
<i>Saccharomyces</i> sp.	>100

Minimum Inhibitory Concentration (MIC) of Polyoxins Against Bacteria, Yeast and Fungi

3) Fungi

	MIC(μ g/ml)
<i>Aspergillus flavus</i>	>100
<i>A. fumigatus</i>	>100
<i>A. niger</i>	>100
<i>Penicillium citrinum</i>	>100
<i>P. crysogenum</i>	> 10
<i>Mucor racemosus</i> (-)	> 10
<i>Rhizopus oryzae</i> IFO-4707	< 1.0
<i>Giberella zeae</i>	>100
<i>Fusarium avenaceum</i> f. sp. fabae	>200
<i>F. maniliforme</i> var. majus	< 50
<i>F. oxysporum</i> f. sp. cucumerinum	<200
<i>F. oxysporum</i> f. sp. lycopersici	> 25
<i>F. oxysporum</i> f. niveum	< 50
<i>Chaetomium cochliodes</i>	<100

Appendix 4. Minimum Inhibitory Concentration (MIC) of Polyoxin D Against Various Bacteria

KPD05-043
Sep. 14, 2006

Minimum Inhibitory Concentration (MIC) of Polyoxin D Against Various Bacteria

ABSTRACT

Growth inhibitory concentration of Polyoxin D against pathogenic, intestinal and other general bacteria existing widely in nature was measured by the agar plate dilution method. From the results obtained, the level of MIC was found to be higher than 400 µg/mL and it was concluded that Polyoxin D was inactive to bacteria.

STUDY REPORT

Starting date: March 18, 2004
Finishing date: June 25, 2004

STUDY SITE

Mitsubishi Kagaku Bio-Chemical Laboratories, Inc.
Main Reference Laboratory in Tokyo
30-1, Shimura 3-chome, Itabashi-ku, Tokyo 174-8555, Japan

STUDY DIRECTOR

Intetsu Kobayashi, Ph.D.
General Manager
Clinical Microbiological Department

MATERIALS AND METHODS

1. Test Substance

Name: Polyoxin D (Lot PDWS-001)
Purity: 94.6% (HPLC)

2. Test Concentration in Agar Plate Medium

In a range from 400 to 0.025 µg/mL (15 different levels prepared by 2 times sequential dilution)

3. Test Microbial Strains

(1) Aerobic bacteria

Staphylococcus aureus ATCC25923
Enterococcus faecalis ATCC19433
Streptococcus pneumoniae ATCC49619
Bacillus subtilis ATCC6633
Escherichia coli ATCC25922
Enterobacter aerogenes ATCC13048
Serratia marcescens ATCC13880
Salmonella choleraesuis serotype Enteritidis (*Salmonella enteritidis*) ATCC13076
Vibrio parahaemolyticus ATCC17802
Pseudomonas aeruginosa ATCC27853

(2) Anaerobic bacteria

Clostridium perfringens IID520
Lactobacillus acidophilus ATCC4356
Bacteroides fragilis ATCC25285

(3) Acid-Fast bacteria

Mycobacterium avium ATCC25291

KPD05-043
Sep. 14, 2005

4. Inoculum Size

Aerobic bacteria: approx 10⁶ CFU/mL of medium
 Anaerobic bacteria: approx 10⁸ CFU/mL of medium
 Acid-fast bacterium: approx 10⁸ CFU/mL of medium

5. Assay Media

Agar plate media used for the drug sensitivity test was shown in Table 1.

6. Drug Sensitivity Test Method

The test was carried out according to the Agar Plate Dilution Method described in the Standard Operation Procedure of the Japanese Society of Chemotherapy^{1),2)}. The culture conditions were shown in Table 1.

Table-1 Test Bacteria, Assay Media and Culture Conditions

Test bacteria	Assay media	Culture conditions
<i>S. aureus</i>	Mueller Hinton Agar (MHA)	Aerobic culture at 35°C for 18 to 20 hr
<i>E. faecalis</i>	"	"
<i>B. subtilis</i>	"	"
<i>E. coli</i>	"	"
<i>E. aerogenes</i>	"	"
<i>S. marcescens</i>	"	"
<i>S. enteritidis</i>	"	"
<i>V. parahaemolyticus</i>	"	"
<i>P. aeruginosa</i>	"	"
<i>S. pneumonia</i>	MHA with addition of 5% horse blood	"
<i>C. perfringens</i>	Brucella agar ^a with addition of 5% horse blood	Anaerobic culture at 35°C for 40 to 48hr
<i>L. acidophilus</i>	"	"
<i>B. fragilis</i>	"	"
<i>M. avium</i>	Middlebrook 7H10 Agar ^b	Aerobic culture at 35°C for 3 to 10hr

^aFive (5) mg of hemin and 1 mg of vitamin K₁ were added in 1L of the assay medium.

^bFive (5) g of glycerol and 100 mL of OADC enrich were added in 1L of the assay medium.

7. Determination of MIC

After confirming the growth of each bacterial strain in a control medium prepared without addition of the test substance, the MIC was determined from the lowest concentration of test substance at which no bacterial growth in the assay medium was observed.

RESULTS

The results were shown in Table 2. The values of MIC of Polyoxin D against all the tested aerobic, anaerobic and acid-fast bacteria were higher than 400 µg /mL.

KPD05-043
Sep. 14, 2006

Table-2 MIC of Polyoxin D Against Various Bacteria

Strain of test bacteria	MIC (µg/mL)
<i>Staphylococcus aureus</i> ATCC25923	>400
<i>Enterococcus faecalis</i> ATCC19433	>400
<i>Streptococcus pneumoniae</i> ATCC49619	>400
<i>Bacillus subtilis</i> ATCC6633	>400
<i>Escherichia coli</i> ATCC25922	>400
<i>Enterobacter aerogenes</i> ATCC13048	>400
<i>Serratia marcescens</i> ATCC13880	>400
<i>Salmonella enteritidis</i> ATCC13076	>400
<i>Vibrio parahaemolyticus</i> ATCC17802	>400
<i>Pseudomonas aeruginosa</i> ATCC27853	>400
<i>Clostridium perfringens</i> IID520	>400
<i>Lactobacillus acidophilus</i> ATCC4356	>400
<i>Bacteroides fragilis</i> ATCC25285	>400
<i>Mycobacterium avium</i> ATCC25291	>400

DISCUSSION

Polyoxin D is an antifungal agent and the primary site of action is inhibition of the cell wall chitin synthesis of plant-pathogenic fungi ^{3), 4), 5), 6), 7), 8)}. Since bacteria contain no chitin, this compound has been known to be inactive to any bacteria. The present test results indicate that the levels of MIC of Polyoxin D against the various tested bacteria are higher than 400 µg/mL and, in conclusion, no effect of this compound on bacterial growth is reconfirmed.

REFERENCES

- 1) CHEMOTHERAPY 29, 76, (1981)
- 2) CHEMOTHERAPY 27, 559, (1979)
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- 7) M. Hori, K. Kakiki, and T. Misato: *Agricultural Biological Chemistry*, 38, 691, (1974)
- 8) M. Hori, K. Kakiki, and T. Misato: *Agricultural Biological Chemistry*, 38, 699, (1974)

Appendix 5. Recommendation by Frank Wong, Ph.D. of the University of California-Riverside



Media Contact: Felicia Gillham, Gillham & Associates
619-482-8820; Fax: 619-482-8825; Cell: 619-341-3054

FOR APPROVAL ONLY
First Draft: 7-7-08

PACE Turf Meeting Provides Realistic Tools for Implementing IPM

“Integrated pest management, or IPM, is sometimes seen as more of an academic endeavor than as an approach that can work in the real world,” said Wendy Gelernter, Ph.D., co-director of PACE Turf at the company’s recent PACE Turfgrass Research Institute annual seminar in San Diego. More than 160 superintendents and turf managers attended the meeting that provided the latest information on new tools, products and practices for developing turf IPM programs that work. “Our goal is to translate science into practice,” Gelernter said, “so you can go back to work tomorrow with information that you can immediately put to use.”

Recent advances in cultural management practices can significantly reduce pest infestations, said Gelernter, the first speaker of the day. Management of soil moisture, nitrogen and sand topdressing can reduce damage from diseases, insects and weeds, sometimes in unexpected ways. One of the most surprising findings that she presented showed how low soil moisture plays a role in a variety of turf problems, including disease. “Most people think of fungal disease as the result of overly wet conditions, but there are several important diseases—including gray leaf spot, anthracnose and brown ring patch—that are promoted when soils are too dry,” she said.

Recycled water also has an impact on IPM programs. “In this time of ever-limited resources and ever-increasing expenses, there isn’t much controversy over the question of whether you want recycled water at your facility,” Larry Stowell, Ph.D. said, “because you do.” But the fellow PACE Turf co-director stressed the importance of recognizing that recycled water can be difficult to manage, especially if it is of lower quality than your current irrigation source.

Stowell extensively studied recycled water for more than 10 years as he consulted with golf courses around the country. A key finding of his work concludes that monitoring trends in soil chemistry is the best way to track the changes brought about by using recycled water. “We’ve seen that the most common problems associated with recycled water come in the form of excess salinity, nitrogen and sodium,” Stowell said. “But by keeping close tabs on these factors, and by leaching when necessary, turf damage can be avoided.”

Turf managers using recycled water should test their soils twice a year, Stowell said, and to compare the results against the PACE Turf Soil Chemistry Guidelines, which can be found free-of-charge on the PACE Turf website at www.paceturf.org.

Management of difficult turf pests in IPM programs was addressed by Frank Wong, Ph.D. of the University of California-Riverside and Mike McClure, Ph.D. of the University of Arizona. Wong addressed anthracnose, a disease caused by the fungus *Colletotrichum cereale*. Three years of efficacy field trials yielded some clear pest control winners, including conventional fungicides, such as Medallion (fludioxinil), Banner (propiconazole) and combinations with Signature (aluminum tris) or Daconil (chlorothalonil). But there were also some unexpected stars among biological pesticides, such as Endorse (polyoxin-D), Ecoguard (*Bacillus licheniformis*) and Huma-balance (*Bacillus subtilis*).

McClure addressed another stubborn pest, the stem gall nematode (*Anguina pacifica*). A devastating pest of poa greens, this unique nematode is a problem only in the coastal strip of Central and Northern California. But despite its limited geographical range, its impact is huge; since there have been no viable controls available for many years, golf courses that are infested with the nematode must either switch to bentgrass (which is much more tolerant of *Anguina* damage) or suffer unacceptable levels of damage.

For the last several years, McClure has studied the nematode's life cycle, habits and control and has shed some insight on what has been a confusing and very difficult problem for superintendents. One of the most interesting findings from his lab, McClure said, was of the activity of a fungicide — Cleary's 3336 (thiophanate-methyl) against the nematode. McClure has also been conducting a multi-year bentgrass screening trials to determine which varieties are most tolerant of *Anguina*.

Summaries of each of these talks, as well as the full presentations, are available to subscribers of PACE Turf on the organization's "Member Edition" website. Subscription information is available on the PACE Turf website at: www.paceturf.org.

PACE Turf is a membership organization that provides research, education and information services to the turf management community. Founded in 1993 by its research directors Wendy Gelernter, Ph.D. and Larry Stowell, Ph.D., the PACE Turf mission is to generate and share independent and objective agronomic information among turf professionals so they may develop management programs that are effective, practical and scientifically sound.

##

Appendix 6. MSDS for Polyoxin D Zinc Salt Technical

REVISION DATE 24/01/2011

SAFETY DATA SHEET Polyoxin D Zinc Salt

1 IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

PRODUCT NAME	Polyoxin D Zinc Salt		
CAS-NO.	146659-78-1		
SYNONYMS, TRADE NAMES	PSB		
APPLICATION	,		
SUPPLIER	Importer:	MANUFACTURER	Kaken Pharmaceutical Co.,Ltd. 28-8, Honkomagome 2-chome, Bunkyo-ku, Tokyo 113-8650, Japan TEL 81-3-5977-5034
CONTACT PERSON	ag_rd@kaken.co.jp		
EMERGENCY TELEPHONE	Tel:		

2 HAZARDS IDENTIFICATION

CLASSIFICATION (67/548)	Xn;R20. N;R51/53. R43.		
CLASSIFICATION (EC 1272/2008)	Physical and Chemical Hazards	Not classified.	
	Human health	Acute Tox. 4 - H332;Skin Sens. 1 - H317	
	Environment	Aquatic Acute 2 - H401;Aquatic Chronic 2 - H411	

LABEL IN ACCORDANCE WITH (EC) NO. 1272/2008



SIGNAL WORD Warning

HAZARD STATEMENTS

H317	May cause an allergic skin reaction.
H332	Harmful if inhaled.
H401	Toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENTS

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P302+352	IF ON SKIN: Wash with plenty of soap and water.
P333+313	If skin irritation or rash occurs: Get medical advice/attention.

SUPPLEMENTARY PRECAUTIONARY STATEMENTS

P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P304+340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P363	Wash contaminated clothing before reuse.
P391	Collect spillage.
P321	Specific treatment (see statements on this label).
P501	Dispose of content/container to licensed waste site in accordance with local Waste Disposal Authority.

3 COMPOSITION/INFORMATION ON INGREDIENTS

REVISION DATE 24/01/2011

Polyoxin D Zinc Salt

CAS-NO. 146659-78-1

4 FIRST-AID MEASURES

INHALATION

Move the exposed person to fresh air at once. Rinse nose and mouth with water. Get medical attention if any discomfort continues.

INGESTION

NEVER MAKE AN UNCONSCIOUS PERSON VOMIT OR DRINK FLUIDS! Immediately rinse mouth and drink plenty of water (200-300 ml). Induce vomiting, if person is conscious. Get medical attention if any discomfort continues.

SKIN CONTACT

Remove affected person from source of contamination. Remove contaminated clothing. Wash the skin immediately with soap and water. Get medical attention if any discomfort continues.

EYE CONTACT

Make sure to remove any contact lenses from the eyes before rinsing. Promptly wash eyes with plenty of water while lifting the eye lids. Continue to rinse for at least 15 minutes. Get medical attention if any discomfort continues.

5 FIRE-FIGHTING MEASURES

EXTINGUISHING MEDIA

Small fires: Water spray, fog or mist. Carbon dioxide (CO₂). Dry chemicals, sand, dolomite etc. Larger fires: Foam.

SPECIAL FIRE FIGHTING PROCEDURES

Keep up-wind to avoid fumes. Keep run-off water out of sewers and water sources. Dike for water control.

PROTECTIVE MEASURES IN FIRE

Wear full protective clothing.

6 ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

Wear protective clothing as described in Section 8 of this safety data sheet. Provide adequate ventilation.

ENVIRONMENTAL PRECAUTIONS

Do not discharge onto the ground or into water courses.

SPILL CLEAN UP METHODS

Stop leak if possible without risk. Remove spillage with vacuum cleaner. If not possible, collect spillage with shovel, broom or the like. Collect in containers and seal securely.

7 HANDLING AND STORAGE

USAGE PRECAUTIONS

Do not use in confined spaces without adequate ventilation and/or respirator. Provide good ventilation. Avoid handling which leads to dust formation. Avoid inhalation of dust and contact with skin and eyes.

STORAGE PRECAUTIONS

Store in tightly closed original container in a dry, cool and well-ventilated place. Keep away from heat, sparks and open flame. Protect from light, including direct sunrays.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

PROTECTIVE EQUIPMENT



ENGINEERING MEASURES

Provide adequate general and local exhaust ventilation.

RESPIRATORY EQUIPMENT

Dust mask/respirator.

HAND PROTECTION

Use protective gloves made of: Rubber or plastic.

EYE PROTECTION

Wear goggles/face shield.

REVISION DATE 24/01/2011

Polyoxin D Zinc Salt

OTHER PROTECTION

Wear appropriate clothing to prevent any possibility of skin contact.

HYGIENE MEASURES

Wash promptly if skin becomes contaminated. Promptly remove any clothing that becomes contaminated. When using do not eat, drink or smoke. Wash at the end of each work shift and before eating, smoking and using the toilet.

9 PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE	Powder, dust
COLOUR	Brownish Grey
ODOUR	Odourless
SOLUBILITY	Insoluble in water Soluble in: Hydrochloric acid (HCl).
MELTING POINT (°C)	> 240 °C
SOLUBILITY VALUE (g/100g H ₂ O@20°C)	0.01

10 STABILITY AND REACTIVITY

STABILITY

Stable under normal temperature conditions.

CONDITIONS TO AVOID

Avoid excessive heat for prolonged periods of time.

MATERIALS TO AVOID

Strong alkalis.

HAZARDOUS DECOMPOSITION PRODUCTS

Fire creates: Carbon monoxide (CO). Carbon dioxide (CO₂). Nitrous gases (NO_x).

11 TOXICOLOGICAL INFORMATION

TOXIC DOSE 1 - LD 50	> 9600 mg/kg (oral rat)
TOXIC DOSE 2 - LD 50	> 2000 mg/kg (dermal rat)
TOXIC CONC. - LC 50	> 2440 mg/m ³ /30h (inh-rat)

INHALATION

Harmful by inhalation.

INGESTION

No specific health warnings noted.

SKIN CONTACT

May cause sensitisation by skin contact.

EYE CONTACT

Particles in the eyes may cause irritation and smarting.

OTHER HEALTH EFFECTS

Micronucleous test (-)
chromosomal aberration (-)

This substance has no evidence of carcinogenic properties.

12 ECOLOGICAL INFORMATION

ECOTOXICITY

The product is mildly toxic to aquatic organisms.

LC 50, 96 Hrs, FISH mg/l > 100

EC 50, 48 Hrs, DAPHNIA, mg/l 7

IC 50, 72 Hrs, ALGAE, mg/l 7.19

MOBILITY

The product is insoluble in water.

BIOACCUMULATION

No data available on bioaccumulation.

REVISION DATE 24/01/2011

Polyoxin D Zinc Salt

DEGRADABILITY

There are no data on the degradability of this product.

13 DISPOSAL CONSIDERATIONS

DISPOSAL METHODS

Dispose of waste and residues in accordance with local authority requirements.

14 TRANSPORT INFORMATION

GENERAL

The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

15 REGULATORY INFORMATION

EU DIRECTIVES

Dangerous Substance Directive 67/548/EEC. Dangerous Preparations Directive 1999/45/EC. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, including amendments. (EC) No 1272/2008 (CLP).

STATUTORY INSTRUMENTS

The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (S.I 2009 No. 716).

APPROVED CODE OF PRACTICE

Safety Data Sheets for Substances and Preparations. Classification and Labelling of Substances and Preparations Dangerous for Supply.

GUIDANCE NOTES

CHIP for everyone HSG(108). Workplace Exposure Limits EH40.

16 OTHER INFORMATION

REVISION COMMENTS

This is first issue.

REVISION DATE 24/01/2011

DISCLAIMER

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.

Appendix 7. EPA Fact Sheet for Polyoxin D Zinc Salt



http://www.epa.gov/oppbppd1/biopesticides/ingredients/factsheets/factsheet_230000.htm
Last updated on Wednesday, February 16, 2011

Pesticides: Regulating Pesticides

You are here: [EPA Home](#) [Pesticides](#) [Regulating Pesticides](#) [Biopesticides](#) [Active Ingredient Index P - S](#) [Polyoxin D Zinc Salt \(230000\) Fact Sheet](#)

Polyoxin D Zinc Salt (230000) Fact Sheet

Issued: 8/01

On This Page

- I. [Description of the Active Ingredient](#)
- II. [Use Sites, Target Pests, And Application Methods](#)
- III. [Assessing Risks to Human Health](#)
- IV. [Assessing Risks to the Environment](#)
- V. [Regulatory Information](#)
- VI. [Registrant Information](#)
- VII. [Additional Contact Information](#)

Related Information

- [Regulating Biopesticides](#)
- [Active Ingredient Index](#)

Information related to this page:

- [Federal Register Notices](#)
- [Technical Doc \(PDF\)](#)
(24 pp, 200 K, about PDF)

Summary

Polyoxin D Zinc Salt is used as a fungicide for turf on golf courses, parks, home lawns, and the grounds of commercial and institutional buildings. Given the lack of toxicity and limited use sites, this active ingredient is not expected to harm people, pets, wildlife, or the environment when used according to label directions.

I. Description of the Active Ingredient

Active Ingredient Name: Polyoxin D Zinc Salt

OPP Chemical Code: 230000; (CAS# 146659-78-1)

Polyoxins are a family of chemicals produced by a specific bacterium naturally found in soil. The bacteria are grown commercially, and the polyoxins are then purified in the form of Polyoxin D Zinc Salt. This active ingredient inhibits the action of an enzyme needed by the target fungi for making chitin, a component of the cell wall. Without chitin, susceptible fungi are unable to continue growing and infecting plant cells.

II. Use Sites, Target Pests, And Application Methods

- **Use Sites:** Turf and lawns that are not intended for commercial use as sod, commercial seed production, or research.
- **Target pests:** The fungus species *Rhizoctonia solani*, which causes brown patch and large patch disease.
- **Application Methods:** Applied as a spray every one to two weeks, as needed.

III. Assessing Risks to Human Health

Based on required toxicity tests, no risks to humans are expected when products containing

this active ingredient are used according to label directions.

IV. Assessing Risks to the Environment

There was no toxicity to land mammals, insects, or birds in various tests. The product label reflects the concern for possible harm to freshwater invertebrates and fish by prohibiting the use or disposal of Polyoxin D Zinc Salt in bodies of water.

V. Regulatory Information

Year registered (licensed for sale) as active ingredient: 1997

Number of end products, January 2001: 1

VI. Registrant Information

Kaken Pharmaceutical Co., Ltd., Japan

U.S. Contact: Dr. Premjit P. Halanker

Tomen Agro, Inc.

Suite 1610

100 First Street

San Francisco, CA 94105

VII. Additional Contact Information

Ombudsman, Biopesticides and Pollution Prevention Division (7511P)

Office of Pesticide Programs

Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, D.C. 20460

Appendix 8. EPA Biopesticide Registration Action Document (BRAD) for Polyoxin D Zinc Salt



US Environmental Protection Agency Office of Pesticide Programs

BIOPESTICIDE REGISTRATION ACTION DOCUMENT MEMORANDUM

**Consideration of Eligibility for Registration of
the New Pesticide Active Ingredient Polyoxin D
Zinc Salt-DECISION MEMORANDUM-**

MEMORANDUM

SUBJECT: Consideration of Eligibility for Registration of the New Pesticide Active Ingredient Polyoxin D Zinc Salt
-DECISION MEMORANDUM-

FROM: Janet L. Andersen, Director
Biopesticides and Pollution Prevention Division (7511W)

TO: Daniel M. Barolo, Director
Office of Pesticide Programs (7501C)

ISSUE

Should the Agency grant registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) § 3(c)(5) for the technical product and the end-use product containing the new biochemical-like active ingredient, polyoxin D zinc salt (PC Code 230000), for use on turf sites including golf courses, home lawns, parks and commercial and institutional grounds for control of Brown Patch and Large Patch disease caused by *Rhizoctonia solani*?

CONCLUSION

Data requirements for granting these registrations under Section 3(c)(5) of FIFRA have been fulfilled. Available and submitted data have been reviewed and the Biopesticides and Pollution Prevention Division (BPPD) has made a determination of reasonable certainty of no harm to humans, especially infants and children, and the environment from the use of this active ingredient. BPPD recommends unconditional registration.

BASES FOR CONCLUSION

A. DATA GAPS

There are no data gaps. There exists a potential risk to aquatic species. However, exposure to aquatic species is considered minimal to negligible when the end-use product containing the active ingredient is used according to label instructions.

B. SUMMARY OF FINDINGS

(1) Product Identity

Polyoxin D Zinc Salt Technical and the end-use product, STOPIT™ Wettable Powder Turf Fungicide (EPA File Symbols 068173-R and 068173-E, respectively), are the first products containing the biochemical-like active ingredient polyoxin D zinc salt (PC Code 230000).

Polyoxin D (also known as polyoxorim), the active portion of the polyoxin D zinc salt compound, is an antibiotic and acts to inhibit the growth of phytopathogenic fungal cell wall chitin by competitively inhibiting chitin synthetase. Polyoxin D is produced via a fermentation process using *Streptomyces cacaoi* var. *asoensis*, which was isolated from a soil sample collected in Japan. Polyoxin D is very water soluble so it is formulated as the zinc salt to give longer residence time on plant surfaces. The compound is fungistatic and reportedly has no residual effects after the compound has degraded or washed off surfaces.

The technical product, Polyoxin D Zinc Salt Technical, is used for the manufacture of the end-use product. The end-use product, STOPIT™ Wettable Powder Turf Fungicide, contains 2.5% polyoxin D zinc salt.

(2) Use Sites/Usage

The proposed end-use involves ground and hand spray foliar applications of wettable powder to turf sites including golf courses, home lawns, parks and commercial and institutional grounds. STOPIT™ Wettable Powder Turf Fungicide is not for use on turf being grown 1) for sale or other commercial use as sod, 2) for commercial seed production, or 3) for research purposes.

(3) Human Health Risk Assessment

(a) Toxicological Endpoints

No toxicological endpoints were identified. No unreasonable adverse human health effects were identified.

(b) Human Exposure

All data requirements have been fulfilled for the active ingredient. No numeric tolerance or exemption from the requirement of a tolerance is needed since polyoxin D zinc salt will not be registered for uses on food.

The acute oral toxicity studies, acute inhalation studies and primary dermal

irritation studies indicated Toxicity Category IV for both Polyoxin D Zinc Salt Technical and STOPIT™ Wettable Powder Turf Fungicide. The acute dermal toxicity studies indicated Toxicity Category III for Polyoxin D Zinc Salt Technical and for STOPIT™ Wettable Powder Turf Fungicide. The primary eye irritation study indicated Toxicity Category III for polyoxin D zinc salt and for STOPIT™ Wettable Powder Turf Fungicide. The hypersensitivity study indicated polyoxin Z zinc salt was a mild sensitizer at a 5% dose, and that the end-use product was a non-sensitizer. To date, there have been no hypersensitivity incidents reported in handlers of the technical or end-use product.

(c) Risk Assessment

The battery of acute and chronic toxicological studies indicates polyoxin D zinc salt induces minimal toxic effects to humans through oral, dermal, ocular or inhalation exposure. We have also considered polyoxin D zinc salt in light of the nine safety factors listed in the Food Quality Protection Act (FQPA) and have made a determination of reasonable certainty of no harm. In short, BPPD has not identified any subchronic, chronic, immune, endocrine, or non-dietary cumulative exposure issues as they may affect infants and children and the general population.

(4) Ecological Risk Assessment

(a) Ecological Toxicity Endpoints

No unreasonable adverse ecological or environmental fate effects on avian, aquatic or other nontarget organisms were identified.

(b) Ecological Exposure

Potential exposure to freshwater invertebrates and fish, via runoff after application, will be minimized by mitigating Environmental Hazards label text.

(C) Risk Assessment

Ecological effects studies were performed on mallard duck, freshwater invertebrates and rainbow trout and non-target insects including two-spotted spider mites, brown plant hoppers, and diamond back moths. Toxicological studies indicated that there is no significant toxicity to rodents from acute oral testing at the maximum hazard dose. Therefore, risk to mammalian wildlife is expected to be minimal to nonexistent. Polyoxin D zinc salt was found to be practically non-toxic to the mallard duck, which is a representative species for avian risk assessment. Based on the results of the non-target insect study, exposure to polyoxin D zinc salt is not expected to pose significant increased risks to terrestrial insects. In the studies submitted, moderate toxicity to aquatic species (freshwater invertebrates and rainbow trout) was observed. No unreasonable adverse ecological or environmental fate effects were identified by the duck, mite and insect testing. Potential exposure to freshwater invertebrates and fish will be minimized by appropriate precautionary labeling.

OFFICE DIRECTOR CONCURRENCE

The Biopesticides and Pollution Prevention Division (BPPD) recommends that the biochemical-like pesticide technical and end-use products containing the new active ingredient polyoxin D zinc salt be unconditionally registered under 3(c)(5) of FIFRA for the specified terrestrial non-food turf use sites including golf courses, home lawns,

parks, commercial and institutional grounds for control of Brown Patch and Large Patch disease caused by *Rhizoctonia solani*.

Concurrence: _____

Non Concurrence: _____

Date: _____

Polyoxin D Zinc Salt
(PC Code 230000)

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I. Executive Summary

A. IDENTITY

The Agency has classified polyoxin D zinc salt as a biochemical-like pesticide. Polyoxin D, the active portion of the polyoxin D zinc salt compound [zinc 5-[[2-amino-5-O-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2H)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronate], is produced via a fermentation process using *Streptomyces cacaoi* var. *asoensis*, which was isolated from a soil sample collected in Japan. Polyoxin D (also known as polyoxorim) is an antibiotic and acts to inhibit the growth of phytopathogenic fungal cell wall chitin by competitively inhibiting chitin synthetase. Polyoxin D is very water soluble, so it is formulated as the zinc salt to give longer residence time on plant surfaces. The compound is fungistatic and reportedly has no residual effects after the compound has degraded or washed off surfaces.

The technical product, Polyoxin D Zinc Salt Technical, is used for the manufacture of the end-use product. The end-use product, STOPIT™ Wettable Powder Turf Fungicide, contains 2.5% polyoxin D zinc salt.

B. USE/USAGE

The proposed end-use involves ground and hand spray foliar applications of the wettable powder formulation to turf sites.

C. RISK ASSESSMENT

There is a reasonable certainty that no harm will result from aggregate exposure to the active ingredient polyoxin D zinc salt. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

1. Human Health Risk Assessment

a. Toxicological Endpoint

No toxicological endpoints were identified.

b. Human Exposure

Mammalian toxicology data have been submitted and adequately satisfy data requirements to support the registration. The acute dermal and primary eye toxicity tests submitted using polyoxin D zinc salt and using the end-use product STOPIT™ Wettable Powder Turf Fungicide all resulted in Toxicity Category III classification. Other toxicity tests submitted (the acute oral, acute inhalation, and primary dermal irritation tests) using both the technical grade active ingredient and the end-use product resulted in Toxicity Category IV. Results of hypersensitivity studies indicated the technical grade active ingredient was a mild sensitizer and the end-use product was a non-sensitizer. In addition, the registrant submitted results of chronic exposure and oncogenicity studies indicating Polyoxin D Zinc salt did not produce significant toxic or oncogenic responses in mice or rats after dietary exposure at various doses for a 24 month period.

c. Risk Assessment

Polyoxin D zinc salt has been considered in light of the nine safety factors listed in the Food Quality Protection Act (FQPA) and a determination of reasonable certainty of no harm has been made. In short, BPPD has not identified any subchronic, chronic, immune, endocrine, or nondietary cumulative exposure issues that might affect infants and children or the general population.

2. Ecological Risk Assessment

a. Ecological Toxicity Endpoint

Ecological effects studies were performed on mallard duck, freshwater invertebrates, rainbow trout and non-target insects including two-spotted spider mites, brown plant hoppers, and diamond back moths.

No unreasonable adverse ecological or environmental fate effects on avian, aquatic or other nontarget organisms were identified.

b. Ecological Exposure

Data waivers were granted for non-target plants and honeybee toxicity studies based on the limited turf only application sites and expected minimal exposure to pollinating insects, i.e. honeybees. In the studies submitted, moderate toxicity to aquatic species (freshwater invertebrates and rainbow trout) was the only observed toxicity. Exposure to daphnids, other aquatic invertebrates and fish could occur based on current label use directions, however, the acute risk to aquatic organisms will be minimized via mitigating label language.

c. Risk Assessment

Non-target organism toxicity studies, in conjunction with exposure considerations for the use pattern, indicate no unreasonable adverse effects.

D. DATA GAPS/LABELING RESTRICTIONS

There are no data gaps. There exists a potential risk to aquatic species. However, exposure and therefore risk to aquatic species is considered minimal to negligible when the end-use product containing the active ingredient is used in accordance with the limitations specified in the label.

II. OVERVIEW

A. ACTIVE INGREDIENT OVERVIEW

Common Name:	Polyoxin D Zinc Salt
Chemical Name:	zinc 5-[[2-amino-5-O-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2H)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronate
Chemical Family:	Polyoxins - agricultural antifungal antibiotic complex
CAS Registry Number:	146659-78-1 (1:1 zinc salt) 22976-86-9 (polyoxin D, or polyoxorim)
OPP Chemical Code:	230000 Polyoxin D Zinc Salt
Empirical Formula:	$C_{17}H_{21}N_5O_{14} \cdot Zn$ (1:1 zinc salt) $C_{17}H_{23}N_5O_{14}$
Trade and Other Names:	Polyoxin D Zinc Salt Technical STOPIT™ Wettable Powder Turf Fungicide
Basic Manufacturer:	Kaken Pharmaceutical Co., Ltd. Agrochemicals and Animal Health Products Division 3-4-10, Nihonbashi Honcho Chuo-ku, Tokyo 103, Japan

B. USE PROFILE

The following is information on the proposed uses with an overview of use sites and application methods.

Type of Pesticide: Biochemical-like pesticide, a phytopathogenic fungal wall chitin synthetase inhibitor

Use Sites: The end-use product, STOPIT™ Wettable Powder Turf Fungicide, is for use on turf sites including golf courses, home lawns, parks and commercial and institutional grounds. It is not for use on turf being grown 1) for sale or other commercial use as sod, 2) for commercial seed production, or 3) for research purposes.

Target Pests: *Rhizoctonia solani*, the causative agent of Brown Patch or Large Patch disease

Formulation Types: The technical grade product, Polyoxin D Zinc Salt Technical, is a powder. The end-use product, STOPIT™ Wettable Powder Turf Fungicide, is a wettable powder.

Method and Rates of Application: 0.006 lb ai/1000 ft² (117 g ai/acre) in a minimum of 0.5 gallons of water per 1000 ft² (21.8 gpa).

Treatment should be repeated on a 7-14 day schedule as necessary when environmental conditions are conducive to development of disease. The shorter

interval should be used when disease symptoms are present.

Type of Treatment: foliar spray

Equipment: ground-based sprayer

Use Practice Limitations: Do not use STOPIT™ Wettable Powder Turf Fungicide through any type of irrigation system.

C. ESTIMATED USAGE

None used yet since these will be the first registered products.

D. DATA REQUIREMENTS

For polyoxin D zinc salt, the mammalian toxicology data requirements for the technical product have been fulfilled. Product analysis data requirements are adequately satisfied. All ecological effects data requirements for polyoxin D zinc salt have been adequately fulfilled. The data requirements for granting this registration under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD). Based on available information, the Agency foresees no unreasonable adverse effects to human health and the environment from the use of this biochemical-like pesticide.

E. REGULATORY HISTORY

Kaken Pharmaceutical Company, Ltd., represented by Stewart Pesticide Registration Associates, Inc., submitted applications for registration of Polyoxin D Zinc Salt Technical and the end-use product STOPIT™ Wettable Powder Turf Fungicide to the Registration Division on May 26, 1994. The application was subsequently transferred to the Biopesticides and Pollution Prevention Division (BPPD) to be considered as a "biochemical-like" substance for registration. Polyoxin D zinc salt was classified by BPPD as a "gray area pesticide" on May 16, 1995. The receipt of the applications for registration was published in the **Federal Register** on September 27, 1995, (60 FR 49838). There were no comments received in response to the notice of application.

F. FOOD CLEARANCES/TOLERANCES

A numeric tolerance or exemption from the requirement of a tolerance is not required for polyoxin D zinc salt since there are no food uses associated with the registration. Safety factors from the Food Quality Protection Act of 1996 (FQPA) were considered.

III. Science Assessment

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for polyoxin D zinc salt technical grade active ingredient are satisfied. These data support a registration eligibility decision.

1. Product Identity

Polyoxin D (also known as polyoxorim), the active portion of the polyoxin D zinc salt compound (zinc 5-[[2-amino-5-O-(aminocarbonyl)-2-deoxy-L-xyloxy]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2H)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronate), is produced via a fermentation process using *Streptomyces cacaoi* var. *asoensis*, which was isolated from a soil sample collected in Japan. Polyoxin D is very water soluble, so it is formulated as the zinc salt to give longer residence time on plant surfaces. The compound is fungistatic and reportedly has no residual effects after the compound has degraded or washed off surfaces.

Mode of Action: Polyoxin D is an antibiotic and acts to inhibit the growth of phytopathogenic fungal cell wall by competitively inhibiting chitin synthetase.

2. Food Clearances/Tolerances

Polyoxin D zinc salt is a fungicide intended for turf uses only. Therefore, a numeric tolerance or exemption from the requirement of a tolerance is not an issue for these non-food uses.

Safety factors from FQPA were evaluated. BPPD has considered, among other relevant factors, available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide residue and exposure from non-occupational sources. Given the low toxicity of polyoxin D zinc salt as indicated by both the acute and chronic mammalian toxicity studies, a determination of reasonable certainty of no harm for the general population as well as subgroups including infants and children was made.

3. Physical and Chemical Properties Assessment

The generic data requirements for physical and chemical characteristics of the technical grade active ingredient are summarized in Table 1.

Table 1. Product Chemistry Data Requirements

Guideline no.	STUDY	RESULTS	MRID no.
151-10	Product Identity	polyoxin D is an agricultural antifungal antibiotic complex discovered in cultural broths of <i>Streptomyces cacaoi</i> var. <i>asoensis</i> ATCC 19093	432618-09, 4327618-10
151-11	Manufacturing Process	Technical manufactured by a batch fermentation process using <i>Streptomyces cacaoi</i> var. <i>asoensis</i> ATCC 19093	432618-09
151-12	Discussion of formation of unintentional ingredients	impurities were identified via HPLC/UV analytical method and microbiological assay	432618-09, 442498-01
151-13	Analysis of Samples	X-ray diffraction analysis was used to identify impurities	432618-11, 442497-01
151-15	Certification of Limits	Limits listed in the CSF are adequate	CSF, 442497-01
151-16	Analytical Method	HPLC/UV analytical method and microbiological assay were used	432618-13, 432618-14, 432618-15
151-17	Physical and Chemical Properties	Results, Method/MRID No. of Technical Grade Active Ingredient	
	color	brown	Munsell/432618-16,17
	Physical State	powder	visual/432618-16, -17
	Odor	musty	432618-16, 17
	Melting Point	122.5 ± 0.1, decompose at 170° C	432618-16
	Density (20 - 27.1°C)	1.8392 g/cm ³ , 2.32441 g/cm ³	gas pycnometer/432618-16, -17
	Solubility: (g/100 ml)	solvents: at 25° C water 1.0, methanol,* octanol [†]	432618-16
	Dissociation Constant	3.25, 4.16, 8.0, 9.56, and 10.5	pH meter/432618-16
	pH (23.2°C)	1% solution = 7.51 6.9 (6.7 - 7.2)	pH meter/432618-16 pH meter/432618-18
	Stability	stable at 0 and 12°C (96 hrs); complete degradation (95.8%) at 54°C for 14 days; no change to metals zinc and iron foil; unstable in sunlight 39.3% degradation in 24 hrs	432618-19
	Storage Stability	100% up to 12 months, slightly decreased 3% during 24 months, and in 4 yrs decreased about 5%	HPLC/432618-21

* The solubility in organic solvents was not reliable and changed with time. Therefore, octanol/water partition coefficient was not performed.

B. HUMAN HEALTH ASSESSMENT

Mammalian toxicology data have been submitted and adequately satisfy the requirements as set forth in 40 CFR 158.690 for biochemical pesticides for non-food, domestic outdoor uses.

1. Toxicology Assessment

Adequate mammalian toxicology data are available to support registration of the active ingredient polyoxin D zinc salt.

a. Acute Toxicology

The following toxicity studies were submitted for registration of polyoxin D zinc salt technical grade active ingredient and are acceptable for purposes of registration.

Table 2. Mammalian Toxicity Studies with Polyoxin D Zinc Salt

Guideline No.	Study	Results	Toxicity Category	MRID No.
152-10	Acute Oral LD ₅₀ (rat)	male: > 15,000 mg/Kg bodyweight female: 10,000 to 15,000 mg/Kg bodyweight	IV	432618-23
152-11	Acute Dermal LD ₅₀ (rat)	> 2,000 mg/Kg bodyweight	III	432618-25
152-12	Acute Inhalation LC ₅₀ (rat)	> 2.44 mg/L for males > 2.17 mg/L for females	IV	432618-27
152-13	Primary Eye Irritation (rabbit)	slight to moderate irritation (Draize)	III	432618-29
152-14	Primary Dermal Irritation (rabbit)	slight irritation (Draize)	IV	432618-31
152-15	Hypersensitivity Study (guinea pigs)	mild sensitizer at 5% TGAI (GPMT)	N/A	432618-33
152-16	Hypersensitivity Incidents	none reported	N/A	N/A

The following studies were submitted in fulfillment of requirements for registration of the end-use product STOPIT™ Wettable Powder Turf Fungicide and are acceptable for purposes of registration.

Table 3. Mammalian Toxicity Studies with STOPIT™ Wettable Powder Turf Fungicide

Guideline No.	Study	Results	Category	MRID No.
152-10	Acute Oral LD ₅₀ (rat)	> 5,000 mg/Kg bodyweight	IV	432618-24
152-11	Acute Dermal LD ₅₀ (rat)	> 2,000 mg/Kg bodyweight	III	432618-26
152-12	Acute Inhalation LC ₅₀ (rat)	> 4.93 mg/L for males and females combined	IV	432618-28

152-13	Primary Eye Irritation (rabbit)	mild irritation (Draize)	III	432618-30
152-14	Primary Dermal Irritation (rabbit)	non-irritant (Draize)	IV	432618-32
152-15	Hypersensitivity Study (guinea pigs)	non-sensitizer (modified Buehler method)	N/A	432618-34
152-16	Hypersensitivity Incidents	none reported	N/A	N/A

b. Mutagenicity and Developmental Toxicity

Genotoxicity studies are conditionally required to support non-food uses only if the use is likely to result in significant human exposure, or the active ingredient or its metabolites are structurally related to a known mutagen, or the active ingredient belongs to any chemical class of compounds containing known mutagens. Although the triggers for genotoxicity studies were not met by polyoxin D zinc salt, the registrant submitted mutagenicity and developmental toxicity studies to support registration.

Results of the mutagenicity studies indicated Polyoxin D Zinc Salt Technical was weakly mutagenic in an Ames Assay (MRID # 433230-01) and not mutagenic in a host mediated assay (MRID # 432618-36). If a food/feed use is ever sought, the test results will require a review of the mutagenicity data base to determine the need for additional studies. However, for this registration, since polyoxin D zinc salt is to be used solely as a turf fungicide, the mutagenicity question is not an issue and the data base is acceptable to support registration.

No maternal toxicity or developmental toxicity was observed at any dose in the developmental toxicity study, MRID # 432618-37.

Table 4. Mutagenicity and Developmental Toxicity Studies

Guideline No.	Study	Results	MRID No.
152-17	Ames Test	weakly mutagenic*	433230-01
152-19	Three Mutagenicity Tests		432618-36
	a. REC-Assay with <i>B. subtilis</i> H-17 and M-45	unacceptable **	"
	b. Ames Test	unacceptable **	"
	c. Host-mediated Assay (mice)	not mutagenic ***	"

152-23	Developmental Toxicity	maternal NOEL = 50 mg/Kg/day polyoxin D zinc salt****; maternal LOEL = 50 mg/Kg/day polyoxin D zinc salt; developmental toxicity NOEL is > 800 mg/Kg/day polyoxin D zinc salt	432618-37
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* in two separate assays, a comparison of the revertant colonies in the test groups with those treated with positive control chemicals indicates that the test substance is only weakly positive

** these studies were classified as unacceptable due to lack of pertinent detail and data or for protocol deficiencies

*** this study is no longer used to satisfy requirements for gene mutation study, however, it can be used to support the negative conclusions of MRID # 433230-01

**** maternal NOEL based on decreased body weight; developmental toxicity studies based on polyoxin D zinc salt (25.7 - 26.1 % active ingredient)

c. Subchronic Assessment Tests

A 90-day feeding study is not required because the non-food non-feed uses do not require a numeric tolerance or an exemption from the requirement of a tolerance; and the uses are not likely to result in repeated human exposure by the oral route. Likewise, the 90-day dermal and inhalation toxicity studies are not required because the use pattern does not result in a long-term inhalation exposure at concentrations that are likely to be toxic, and there is no purposeful application to human skin, nor is prolonged dermal exposure likely.

d. Chronic Exposure and Oncogenicity Assessment

Chronic exposure studies are conditionally required to support non-food uses only if the potential for adverse chronic effects are indicated based on 1) the subchronic effect levels established in the Tier I subchronic oral toxicity, subchronic dermal or subchronic inhalation, 2) the pesticide use pattern or 3) the frequency and level of repeated human exposure that is expected. Oncogenicity studies are required to support non-food uses only if 1) the active ingredient or any of its metabolites, degradation products or impurities produce in Tier I studies morphologic effects in any organ that potentially could lead to neoplastic change. Although the triggers for chronic exposure and oncogenicity studies were not met by polyoxin D zinc salt, the registrant submitted results of a chronic exposure study and an oncogenicity study to support registration.

Results of the chronic toxicity/oncogenicity studies indicated Polyoxin D Zinc Salt Technical did not produce significant toxic or oncogenic responses after mice were fed polyoxin D zinc salt at 0, 0.04%, 0.4% and 4% dose levels, beginning when the mice were six weeks old, and continuing for 24 months (MRID 432618-38). Furthermore, no significant toxic or oncogenic responses in rats were found after daily administration of polyoxin D zinc salt at 0, 0.01%, 0.1% 1.0% and 5% dose levels beginning when the rats were seven weeks old and continuing for 24 months (MRID 432618-39).

Table 5. Chronic Exposure and Oncogenicity Studies

Guideline No.	Study	Results	MRID No.
152-26/152-29	Chronic Exposure and Oncogenicity	NOEL = 3591 mg/Kg/day polyoxin D zinc salt in male mice and 4177 mg/Kg/day polyoxin D zinc salt in female mice	432618-38
152-26/152-29	Chronic Exposure and Oncogenicity	NOEL = 2058.7 mg/Kg/day in male rats and 2469.8 mg/Kg/day in female rats	432618-39

e. Effects on Immune and Endocrine Systems

The Agency is not requiring information on the endocrine effects of this biochemical pesticide at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects. However, BPPD has considered, among other relevant factors, available information concerning whether the biochemical-like compound may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. The active ingredient, polyoxin D zinc salt, acts as a fungal chitin synthetase inhibitor. There is no known evidence so far that this compound acts as an endocrine disrupter in humans. Available developmental toxicity data do not indicate that polyoxin D zinc salt has any endocrine effects. Furthermore, results from chronic exposure and oncogenicity studies showed no significant toxic or oncogenic responses from polyoxin D zinc salt. Therefore, no adverse effects to the endocrine or immune systems are known or expected.

2. Dietary Exposure and Risk Characterization

The proposed use pattern for STOPIT™ Wettable Turf Fungicide, turf uses only, will not likely result in dietary exposure and does not require a numeric tolerance or an exemption from the requirement of a tolerance. Acute exposure could occur from small children ingesting treated turf foliage, or transferring residues from turf to hand to mouth, but would be very low because of the low application rates. In the absence of any toxicological endpoints, risk from the consumption of residues is not expected for both the general population and infants and children.

3. Occupational, Residential, School and Daycare Exposure and Risk Characterization

No indoor residential, school or daycare uses currently appear on the label. The proposed use pattern is for turf sites only. There is a potential for dermal exposure at these sites where children are present but the health risk is expected to be minimal to nonexistent based on evaluations of the submitted toxicological studies and the relatively low application rate.

a. Occupational Exposure and Risk Characterization

Based on the application methods, the potential for dermal, eye, and inhalation exposures to STOPIT™ Wettable Powder Turf Fungicide exists for applicators and handlers. However, because of the lack of significant mammalian acute and chronic toxicity, the specific mode of action as a fungal chitin synthetase inhibitor and the low use rates at 117 grams ai/acre, data on worker exposure (i.e. occupational exposure data) to the active ingredient are not required at this time. Risks from occupational exposure will be mitigated through the appropriate precautionary labeling.

b. Residential, School and Daycare Exposure and Risk Characterization

No indoor residential, school or daycare uses currently appear on the label. The proposed use pattern is for turf sites only. Non-dietary exposure at these sites could occur where children are present, but the health risk is expected to be minimal to nonexistent based on evaluations of the submitted studies and the low toxicity of polyoxin D zinc salt.

4. Drinking Water Exposure and Risk Characterization

Although the potential exists for a minimal amount of polyoxin D zinc salt to enter ground water or other drinking water sources if, after application, weather patterns are such that significant rainfall and surface water runoff occur, the health risk to humans is considered negligible based on the evaluations of the submitted toxicity studies, and the low application rate of the active ingredient.

5. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

There are no food uses associated with the registration of Polyoxin D Zinc Salt Technical and STOPIT™ Wettable Powder Turf Fungicide. Therefore, acute and chronic dietary risks should be minimal based on lack of exposure. Furthermore, results from mammalian acute and chronic toxicity studies indicate lack of toxicity, adding further weight to the lack of risk from exposure to polyoxin D zinc salt.

It is feasible that infants and children could incur minimal dietary exposure if, when they come into contact with recently treated turf, they either ingest treated turf foliage or transfer residues from turf to hand to mouth. However, the Agency has no information to indicate that children or infants would be more sensitive than adults to effects caused by polyoxin D zinc salt. Therefore, based on the lack of chronic and acute toxicity in the submitted studies, the potential risks to infants and children are considered negligible.

6. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

Aggregate exposure would primarily occur in the mixer/loader/applicator subpopulation, via dermal and inhalation routes. Risks associated with dermal and inhalation aggregate exposure are measured via the acute toxicity studies submitted to support registration. Because the pulmonary studies for both the technical and end-use product showed no adverse effects (both Toxicity Category IV), the risks anticipated for this route of exposure are considered minimal. Results of the acute dermal studies using the

technical and using the end-use product indicated low toxicity (Toxicity Category III), and no significant dermal irritation (Toxicity Category IV). Based on these results, the anticipated risks from dermal exposure are also considered minimal. Therefore, the risks from aggregate exposure via dermal and inhalation exposure are a compilation of two low risk exposure scenarios and are considered negligible.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

Ecological effects studies were performed on mallard duck, freshwater invertebrates, rainbow trout, and non-target insects including two-spotted spider mites, brown plant hoppers, and diamond back moths. In the studies submitted, moderate toxicity to aquatic species (freshwater invertebrates and rainbow trout) was observed. The freshwater invertebrates study, MRID # 432618-43 indicated that polyoxin D zinc salt was highly toxic to neonate (6 hour old) freshwater invertebrates, but showed no effects during a range finding test with 20 hour old freshwater invertebrates. The rainbow trout study indicated moderate toxicity to rainbow trout with a 96 hr LC₅₀ of 5.06 ppm polyoxin D zinc salt. As a mitigation measure to protect aquatic species, the end-use product label will include the following statement under the "Environmental Hazards" heading: "This product 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 cleaning equipment or disposing of equipment washwaters. Do not allow runoff into lakes, streams, ponds or public waterways."

The non-target insect study was considered to be supplemental because the study did not follow EPA Guidelines and the insects used were Asian insect pests of agricultural crops instead of beneficial insects usually tested. However, the results of the study indicate that polyoxin D zinc salt was not toxic to two-spotted spider mites, diamond back moths and brown plant hoppers at rates up to 400 ppm. This rate represents slightly over 10 times the estimated field application rate. When making a risk determination, the Agency considers the whole body of evidence presented for registration. Therefore, the Agency believes the limited, turf only application sites, and the results of the supplementary non-target insect study, provide enough information to conclude that risks to non-target insects are expected to be minimal.

The registrant was granted data waivers for non-target plants and honeybee toxicity studies based on the limited turf only application sites and expected minimal exposure to pollinating insects, i.e. honeybees.

Table 5. Non-target Toxicity Studies with Polyoxin D Zinc Salt

Guideline No.	Study	Results	MRID
154-6	Avian Acute Oral LD ₅₀ (Mallard Duck)	> 2150 mg/Kg	432618-40
154-7	Avian Acute Dietary LC ₅₀ (Mallard Duck)	> 5000 ppm	432618-41
154-8	Freshwater Fish LC ₅₀ (Rainbow Trout)	96 hr LC ₅₀ : 5.06 (3.5-10) ppm polyoxin D zinc salt/L; 1.02 (0.73 - 2.1) p.m. polyoxin D/L	432618-42
154-9	Freshwater Invertebrate LC ₅₀ (<i>Daphnia magna</i>)	probit LC ₅₀ 1.35 (1.12 - 1.78) ppm polyoxin D zinc salt	432618-43
154-10	Non-target Plant Test	data waiver request	waived
154-11	Non-target Insect Test	supplemental	432618-44
154-11	Honeybee Test	data waiver request	waived

2. Environmental Fate and Ground Water Data

The need for environmental fate and ground water data was not triggered under current requirements for the proposed products due to the use pattern, application methods, and mitigation of nontarget aquatic organism toxicity with appropriate precautionary label statements under "Environmental Hazards."

Estimated environmental concentrations were made based on the application rate and usage patterns: estimated concentration from runoff of residues into surrounding aquatic habitats from a 10 acre drainage basin into a 6 foot deep 1 acre pond would be approximately 1.6 ppb per 1% residue runoff. However, any effects from runoff residues in aquatic environments will be mitigated through the label language triggered by the aquatic non-target toxicity studies.

Estimated environmental concentrations are expected to reach maximum residue levels of from 9 ppm to 62 ppm for foliar surfaces of most plant types. These levels are expected to pose minimal levels of risk to mammalian and avian wildlife based on present toxicological data.

3. Ecological Exposure and Risk Characterization

a. Exposure and Risk to Non-target Terrestrial Animals

Toxicological studies indicated that there is no significant toxicity to rodents from acute oral testing at the maximum hazard dose. Therefore, risk to mammalian wildlife is expected to be minimal to nonexistent. Based on the results of the non-target insect study, exposure to polyoxin D zinc salt is not expected to pose significant increased risks to terrestrial insects.

b. Exposure and Risk to Aquatic Animals

Exposure to aquatic invertebrates and vertebrates could occur based on current label use directions. Results of submitted aquatic non-target studies indicated polyoxin D zinc salt is moderately toxic to rainbow trout and freshwater invertebrates. However, with the appropriate aquatic mitigating label language, the exposure and therefore risk to aquatic species is expected to be minimal.

c. Exposure and Risk to Non-target Plants

Exposure to non-target plants is unlikely based on the turf only use pattern and the relatively low application rates, 117 g/A of polyoxin D zinc salt. Furthermore, the mode of action is specific to certain fungi and should not pose risk to other plants.

d. Exposure and Risk to Endangered Species

Threatened or endangered species commonly inhabit undisturbed ecosystems. The end-use product, STOPIT™ Wettable Powder Turf Fungicide is for use only on turf. Turf sites are commonly intensely managed areas and as such are undesirable habitat for threatened or endangered species. Therefore, exposure to threatened or endangered species is considered unlikely. In addition, the low application rate of polyoxin D zinc salt, at 117 g/A, further reduces the possibility of exposure to threatened or endangered species. Therefore, risk to threatened or endangered species from exposure to polyoxin D zinc salt is considered minimal to non-existent.

Polyoxin D Zinc Salt Technical and STOPIT™ Wettable Powder Turf Fungicide pose practically no threat to threatened or endangered species when used according to label directions. Polyoxin D zinc salt was found to be practically non-toxic to the mallard duck, which is a representative species for avian risk assessment. These findings indicate minimal-to-no risk to threatened or endangered birds. The intended use pattern is turf use only and is not intended for use on commercial turf crops.

The ecological risk assessment indicated moderate toxicity to rainbow trout with a 96-hr LC₅₀ of approximately 5.06 ppm polyoxin D zinc salt/L for rainbow trout and an EC₅₀ of 1.4 mg/polyoxin D zinc salt/L for neonate freshwater invertebrates. In order to mitigate possible risks to aquatic threatened or endangered species, the ecological risk assessment recommended that the end-use product label include the following precautionary language within a statement titled "Environmental Hazards": "This product 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 cleaning equipment or disposing of equipment washwaters. Do not allow runoff into lakes, streams, ponds or public waterways."

IV. Risk Management Decision

A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (1) its composition is such as to warrant the proposed claims for it; (2) its labeling and other material required to be submitted comply with the requirements of FIFRA; (3) it will perform its intended function without unreasonable adverse effects on the environment; and (4) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

All FIFRA Section 3(c)(5) criteria have been satisfied in the course of the risk characterization. All risk considerations have been adequately addressed and are reflected in the appropriate label language.

Therefore, STOPIT™ Wettable Powder Turf Fungicide and Polyoxin D Zinc Salt Technical are eligible for registration. The proposed uses are turf sites including golf courses, home lawns, parks and commercial and institutional grounds and are listed in Table 4, Appendix A. The uses do not include use on turf being grown 1) for sale or other commercial use as sod, 2) for commercial seed production, or 3) for research purposes.

B. REGULATORY POSITION

1. Conditional/Unconditional Registration

All data requirements are fulfilled and the Biopesticides and Pollution Prevention Division recommends unconditional registration of Polyoxin D Zinc Salt Technical and STOPIT™ Wettable Powder Turf Fungicide.

2. Tolerance Reassessment

There are no food uses pertaining to the registration of polyoxin D zinc salt and therefore are no tolerance issues.

3. CODEX Harmonization

There are no Codex harmonization considerations since there is currently no Codex tolerance for polyoxin D zinc salt residues.

4. Non-food Re/Registrations

There are no non-food use issues at this time. The non-food uses are listed in Table 4, Appendix A.

5. Risk Mitigation

Since there are no risk issues, no risk mitigation measures are required at this time for dietary risk, occupational and residential risk, risks to most non-target organisms (plants and wildlife), or ground and surface water contamination for these products. Both product labels will, however, bear Environmental Hazards text to mitigate the potential risk to aquatic species.

6. Endangered Species Statement

Currently, the Agency is developing a program (The Endangered Species Protection Program) to identify all pesticides whose use may cause potential adverse impacts on threatened or endangered species and their habitats. To aid in the identification of threatened or endangered species and their habitats, several companies have formed an Endangered Species Task Force (EST) under the direction of the American Crop Protection Association (ACPA). Moreover, the EST will assist in providing species location information at the subcounty level, and particularly if a threatened or endangered species occurs in areas where pesticides would be used. This information will be useful once the Endangered Species Protection Program has been implemented.

Prior to the implementation of the Endangered Species Protection Program, the Agency will not impose specific labeling on those pesticides that pose risks to threatened or endangered species and their habitats but will defer imposing specific labeling language until the implementation of the Program.

C. LABELING RATIONALE

1. Human Health Hazard

a. Worker Protection Standard

This product does not fall under the Worker Protection Standard (WPS), therefore there are no human health hazard labeling issues associated with the WPS.

b. Non-Worker Protection Standard

There are no non-WPS human health hazard issues.

c. Precautionary Labeling

The Agency has examined the toxicological data base for polyoxin D zinc salt and concluded that the following proposed labeling (i.e. Signal Word CAUTION for both Polyoxin D Zinc Salt Technical and STOPIT™ Wettable Powder Turf Fungicide) is appropriate:

For Polyoxin D Zinc Salt Technical, "CAUTION" and "Causes moderate eye irritation. Harmful if absorbed through the skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling."

For STOPIT™ Wettable Powder Turf Fungicide, "CAUTION" and "Causes moderate eye irritation. Harmful if absorbed through the skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling."

d. Spray Drift Advisory

A spray drift advisory statement is not needed on the labeling for the proposed uses of Polyoxin D Zinc Salt Technical or STOPIT™ Wettable Powder Turf Fungicide, due to the composition of the end-use product and its domestic, noncommercial use pattern.

2. Environmental Hazards Labeling

Provided the following statements are placed into the Environmental Hazards section, the risk of polyoxin D zinc salt is minimal to nonexistent to non-target organisms, including threatened or endangered species.

a. End-Use Product Environmental Hazards Labeling

"This product 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 cleaning equipment or disposing of equipment washwaters. Do not allow runoff into lakes, streams, ponds or public waterways."

b. Manufacturing-Use Product Environmental Hazards Labeling

"This product is moderately toxic to aquatic invertebrates and fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

3. Application Rate

It is the Agency's position that the labeling for the end-use pesticide product containing polyoxin D zinc salt complies with the current pesticide labeling requirements. The Agency has not imposed a maximum number of allowable applications for the active ingredient. However, a maximum quantity of end-use product

per application (four ounces of end-use product, or 0.006 pounds of active ingredient) per 1,000 square feet is specified on the label.

D. LABELING

(1) Product name: **Polyoxin D Zinc Salt Technical**

The signal word is "Caution," based on the submitted acute toxicity study results. A copy of the proposed label is attached.

(2) Product name: **STOPIT™ Wettable Powder Turf Fungicide**

The signal word is "Caution," based on the submitted acute toxicity study results. A copy of the proposed label is attached.

V. Actions Required by Registrants

Reporting of adverse effects to humans or domestic animals under FIFRA, Section 6(a)2 and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16 is required.

VI. Appendix A

Table 4 lists the uses sites for each product. The proposed labels for the products are also attached.

TABLE # 4: Nonfood Use Site Registrations

<p>Polyoxin D Zinc Salt Technical</p> <p><u>Nonfood Use Sites</u> For manufacturing use only for the production of fungicide formulations for use on turf of golf courses, home lawns, parks, and commercial and institutional grounds.</p> <p>STOPIT™ Wettable Powder Turf Fungicide</p> <p><u>Nonfood Use Sites</u> The end-use product, STOPIT™ Wettable Powder Turf Fungicide, is not for use on turf being grown 1) for sale or other commercial use as sod, 2) for commercial seed production, or 3) for research purposes. It is for use on turf on all other turf sites including golf courses, home lawns, parks and commercial and institutional grounds.</p>	<p>Official Date: registered,</p>
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Appendix 9. Tolerance Exemptions for Polyoxin D Zinc Salt (Final Rule)

duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and

other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 5, 2008.

Debra Edwards,
Director, Office of Pesticide Programs.

■ Therefore, 40 CFR Chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.646 is added to subpart C to read as follows:

§ 180.646 Ipconazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of ipconazole, (2-[(4-chlorophenyl)methyl]-5-(1-methylethyl)-1-(1H-1,2,4-triazole-1-ylmethyl) cyclopentanol) from seed treatment in or on the following commodities:

Commodity	Parts per million
Cotton, gin byproducts	0.01
Cotton, undelinted seed	0.01
Grain, cereal, forage, fodder and straw, group 16, except rice	0.01
Grain, cereal group 15, except rice	0.01
Pea and bean, dried shelled, except soybean, subgroup 6C	0.01
Peanut	0.01
Soybean, forage	0.01
Soybean, seed	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. E8-27310 Filed 11-18-08; 8:45 am]
BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0417; FRL-8389-5]

Polyoxin D Zinc Salt; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the polyoxin D zinc salt (zinc 5-[[2-amino-5-o-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2H)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronatein) on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes and strawberries when applied/used as a biochemical

pesticide to control and suppress fungal diseases. Arysta LifeScience North America Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of polyoxin D zinc salt (zinc 5-[[2-amino-5-o-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2H)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronatein).

DATES: This regulation is effective November 19, 2008. Objections and requests for hearings must be received on or before January 20, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0417. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Chris Pfeifer, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0031; e-mail address: pfeifer.chris@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially

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affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDC A, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2008-0417 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before January 20, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2

may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2008-0417, by one of the following methods.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of July 31, 2008 (73 FR 44719) (FRL-8374-3), EPA issued a notice pursuant to section 408(d)(3) of FFDC A, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 7F7252) by Arysta LifeScience North America Corporation, 15401 Weston Parkway, Suite 150, Cary, NC 27513. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of polyoxin D zinc salt (zinc 5-[[2-amino-5-o-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2H)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronatein). This notice included a summary of the petition prepared by the petitioner Arysta LifeScience North America Corporation. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDC A allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDC A defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDC A, in

establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDC A, which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ." Additionally, section 408(b)(2)(D) of FFDC A requires that the Agency consider "available information concerning the cumulative effects of a particular pesticide's residues " and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDC A, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Polyoxin D zinc salt is a brown musty smelling powder derived through the fermentation of the microbe *Streptomyces cacaoi var. asoenis*, which was isolated from a soil sample collected in Japan. It is registered with EPA's Biopesticides and Pollution Prevention Division (BPPD) as a biochemical active ingredient, intended for incorporation into sprayable fungicides for turf. As an active ingredient, it has a non-toxic mode of action, which acts against fungi; not by killing it, but by inhibiting chitin growth in the cell walls, and thus precluding the development of fungal colonies. Its effects are considered fungi-exclusive in that it has no mode of action relative to mammals. Polyoxin D zinc salt does not persist in the environment, biodegrading readily within 2 to 3 days. Finally, polyoxin D zinc salt has a well understood low toxicity profile.

Polyoxin-D zinc salt was first assessed by EPA in 1997 with regard to the

human health risks associated with its fungicidal use on turf. The risk assessment concluded that the commercial turf uses of polyoxin D zinc salt posed no health risks to either occupational users or to any non-occupational populations that might be exposed. A battery of acute and chronic toxicological studies, submitted in support of this non-food use, showed that polyoxin D zinc salt induced "minimal toxic effects to humans through oral, dermal, ocular or inhalation routes of exposure." These studies included all acute toxicity studies, mutagenicity studies, developmental studies, and exposure and oncogenicity studies. Additionally, EPA's risk assessment considered the active ingredient in light of the requirements of the Food Quality Protection Act (FQPA) and made a determination of "reasonable certainty of no harm to human health." Altogether, the Agency's 1997 risk assessment of polyoxin D zinc salt concluded that there are no risks expected for acute, subchronic, chronic, immune, endocrine, or non-dietary cumulative exposures due to the negligible toxicity associated with the active ingredient.

New toxicity data have since been submitted in support of the request by the applicant to allow food uses (detailed in this rule) of this registered non-food use active ingredient. These data have been incorporated into a comprehensive risk assessment on polyoxin D zinc salt and provide sufficient grounds for this exemption from the requirement of a tolerance. The new data include a new mutagenicity study, a 90-day subchronic oral toxicity study, a 2-generation developmental toxicity study, an immunotoxicity study, and calculations for terrestrial residues. All new data confirm a lack of human health hazard associated with dietary exposures. These new toxicity data, coupled with the data to support the original non-food uses, allow for a comprehensive dietary risk analysis, and fully demonstrate polyoxin D zinc salt's lack of acute, subchronic, and/or chronic toxicity with regard to dietary exposure. All data substantiate the lack of dietary risk associated with the food use of polyoxin D zinc salt.

All data supporting the use of polyoxin D zinc salt on the food crops mentioned in this rule confirm that the dietary risks to humans are negligible for the following reasons:

i. The fungistatic mode of action of this active ingredient is specific to fungi and poses no risk to mammals.

ii. Polyoxin D zinc salt is not digestible by mammals and passes through the digestive system.

iii. Theoretical (potential) residues are substantially less than the doses that were actually used in polyoxin D zinc salts' toxicity studies, which showed virtual non-toxicity.

iv. A complete battery of toxicological studies show no toxicological endpoints and confirm the active ingredient's very low toxicity. For the reasons listed in this unit, any potential residues of polyoxin D zinc salt are considered to be safe with regard to dietary risk. Summaries of the supporting toxicological information are found in this unit.

1. *Acute toxicity.* Acute toxicity studies were submitted to support the initial registration of polyoxin D zinc salt. These studies show a lack of significant acute toxicological endpoints, and support the finding that polyoxin D zinc salt poses no significant human health risk with regard to food uses listed in the summary section of this document. A précis of the acute toxicity studies follows:

i. The acute oral LD₅₀ is greater than 10,000 milligrams/kilograms (mg/kg) in rats, a result that confirms acute non-toxicity through the oral route, and undergirds the risk assessment finding that any amount of residues of polyoxin D zinc salt, if consumed, is not a health concern.

ii. The acute dermal LD₅₀ in rats is greater than 2,000 mg/kg in rats, and demonstrates very low toxicity through dermal exposure. While no significant dermal exposure is expected as a result of pesticidal applications associated with these new food uses, these data substantiate polyoxin D zinc salt's relative non-toxicity to both occupational users and the general public.

iii. The acute inhalation LC₅₀ is greater than 2.17 mg/L in rats, and shows no significant inhalation toxicity. Again, no significant new inhalation exposure is expected; and relatedly, no risks are expected for occupational users or the general public as a result of these new food uses.

iv. Primary dermal irritation in rabbits was considered slight, which finding bolsters the information presented in the acute dermal toxicity study.

v. A hypersensitivity study on guinea pigs further demonstrated that the active ingredient was not a dermal sensitizer. The acute toxicity studies demonstrate that even if there were residues present in food, there would be negligible toxic effects associated with polyoxin D zinc salt.

2. *Mutagenicity.* Data demonstrate that polyoxin D zinc salt is non-mutagenic. Accordingly, residues associated with the new pesticidal food uses of polyoxin D zinc salt are not expected to pose any risk to humans with regard to mutagenicity. Studies submitted in support of the original 1997 registration of polyoxin D zinc salt first showed the active ingredient to be without mutagenic effect. While an Ames Assay (Master Record Identification Number (MRID 433230-01)) showed polyoxin D to be weakly mutagenic, a battery of three complementary mutagenicity tests supported negative conclusions for mutagenicity. In further support of that finding of non-mutagenicity, no maternal toxicity or developmental toxicity were observed in a developmental toxicity study submitted at that time (MRID 432618-36). More recently, two additional studies were submitted in support of non-mutagenicity with regard to a food use. A Tier II Mammalian Erythrocyte Micronucleus Study (OPPTS 870.5395; MRID 47145102) showed no mutagenic effect. The test material was not toxic to male mice at any dose tested, and there were no reported sex differences in response to the test. In a second study, polyoxin D zinc salt was tested to the limit dose of 2,000 mg/kg on mice. The mice showed no clinical signs or mortality, and there was no significant increase in the frequency of micronucleated PCEs, further indicating no mutagenic effect. The mutagenicity studies are sufficient to confirm that there are no expected dietary, occupational, or non-occupational risks of mutagenicity with regard to new food uses.

3. *Subchronic toxicity.* Polyoxin D zinc salt has very low subchronic oral toxicity, and demonstrates a lack of dietary risk at the subchronic level. In a 90-Day Oral Toxicity study on rats (OPPTS 870.3100; MRID 47145101), polyoxin D zinc salt technical was administered to ten rats. There were no toxicologically significant treatment-related effects on mortality. Neurological assessments, urinalysis, ophthalmology, hematology, clinical chemistry, and gross and histologic pathology found no clinical signs of toxicologically significant treatment-related effects. The no-observed-adverse-effect level (NOAEL) in this study is 20,000 parts per million (ppm) (1,333 mg/kg/day) in females and 2,000 ppm (119 mg/kg/day) in males. The lowest-observed-adverse-effect level (LOAEL) in males is 20,000 ppm (1,166 mg/kg/day) based on decreased body

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weight (bw) gain, food consumption and food efficiency; a LOAEL was not observed in females. Based on the lack of meaningful subchronic toxicological endpoints for the technical grade active ingredient (TGAI), the fungi-exclusive mode of action as a chitin synthetase inhibitor, and the related lack of toxic oral effect in mammals, there are no subchronic oral toxicity concerns with polyoxin D zinc salt. It is further noted that the proposed use patterns for this active ingredient are not expected to result in any repeated and/or long-term exposure by either the dermal or inhalation routes; and as a result, no dermal or inhalation subchronic studies are required to establish this food use.

4. *Developmental toxicity.* Data demonstrate that polyoxin D zinc salt is not a developmental or reproductive toxicant. These findings further confirm polyoxin D zinc salt's lack of mammalian toxicity, and demonstrate a lack of dietary effect consistent with its fungi-exclusive mode of action. A Tier III Two Generation Reproduction Toxicity Study (OPPTS 870.3800; MRID 47120904) on rats showed no parental systemic toxicity or differences in bw gain of either generation. No abnormal clinical signs were observed during the study period in any generation. No significant differences were found between treated and control groups with regard to the average number of live births per litter, average bw of live pups, ossification failure of the chest ossification center, or bone variation. No differences were found in the number of stillbirths and weaning rate. No specific abnormalities in postnatal growth or general behavior was found between treated and control groups. No differences were detected in mating, pregnancy, delivery, or nursing rate by generation between the treated and control groups. No chemical effects were found in males or females. The reproductive NOAEL for polyoxin D zinc salt is 1%; a LOAEL was not identified. Again, the data indicate the fungistatic nature of active ingredient and the capacity of polyoxin D zinc salt to pass through mammalian digestive systems. In sum, the study demonstrated a clear lack of reproductive toxicity regarding dietary exposure and supports the Agency's conclusion that there is no risk of developmental toxicity associated with the new food uses.

5. *Immunotoxicity.* Polyoxin D zinc salt is not immunotoxic on a dietary basis. No meaningful immunotoxicity endpoints (i.e., dietarily possible) for polyoxin D zinc salt were identified. In an immunotoxicity study based on dietary exposure (OPPTS 870.7800;

MRID 47120901), polyoxin D zinc salt technical was administered to mice in their diet for 28 days at various concentrations. There were no compound-related deaths or effects on clinical observations, bw or food consumption. There were no compound-related macroscopic findings noted, and organ weights were unaffected. There were no compound-related effects on the humoral immune response to the T-dependent antigen, sRBC. This study shows the lack of dietary risk posed by the immunotoxicity of polyoxin D zinc salt residues, and supports the exemption from the requirement of a tolerance by further demonstrating a lack of toxic endpoints.

6. *Chronic exposure/oncogenicity.* Based on the data, polyoxin D zinc salt is not a chronic toxicant or oncogen. Results of chronic toxicity/oncogenicity studies (MRIDs 432618–38 and -39) indicated that there were no significant toxicity or oncogenic responses in mice dosed with polyoxin D zinc salt over 2 years. The NOAEL was determined to be 2,058.7 mg TGAI/kg bw/day in males and 2,469.8 mg TGAI/kg bw/day in females. The data show the lack of chronic toxicity/oncogenicity posed by dietary exposure to polyoxin D zinc salt, and further demonstrate the fungistatic nature of the active ingredient – i.e. polyoxin D zinc salt can pass through the mammalian digestive system regularly without toxic effect.

7. *Effects on immune and endocrine systems.* There is no available evidence demonstrating that polyoxin D zinc salt acts as an endocrine disruptor in humans. Based on negative responses obtained from developmental toxicity studies, chronic exposure studies, and oncogenicity studies (MRIDs 432618–36, -38 and -39), no adverse effects to the endocrine or immune systems are known or expected. The lack of evidence of endocrine disruption is consistent with polyoxin D zinc salt's non-toxic profile, and supports this exemption from the requirement of a tolerance.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

Dietary risks to humans are considered negligible based on the lack of dietary toxicological endpoints for polyoxin D zinc salt, and its non-toxic mode of action as a fungi-specific chitin synthetase inhibitor that passes through mammalian digestive systems. No acute, subchronic, mutagenic, immunotoxic, reproductive, or chronic dietary toxicity hazards were identified in any of the studies used to support this exemption from the requirement of a tolerance. Based on polyoxin D zinc salt's virtual dietary non-toxicity for mammals, no aggregate dietary exposure concerns are expected.

1. *Food.* A Terrestrial Exposure Model (T-Rex, v. 1.2.3; EPA, 2005) used to calculate terrestrial residue data confirms that it is highly unlikely that there will be adverse effects resulting from the use of polyoxin D zinc salt via the oral route of exposure. EPA's T-Rex calculations delimit aggregate consumption of residues to no more than 40 ppm polyoxin D zinc salt, a level that is far below the highest doses used in any of the toxicity testing. T-Rex residue modeling, findings of negligible toxicity, and information confirming polyoxin D zinc salt's fungi-specific mode of action demonstrate a lack of aggregate dietary risk sufficient to support this exemption from the requirement of a tolerance.

2. *Drinking water exposure.* There is a small potential for trace amounts of polyoxin D zinc salt to enter ground water or other drinking water sources after a significant rainfall and surface water runoff, and from incidental spray drift. While the active ingredient does degrade in water over days, it still has the remote potential to reach drinking water sources. Nonetheless, any residues resulting from the scenarios in this unit are expected to be so diluted as to be negligible. As a result, even if there is drinking water exposure, a health risk to humans is considered negligible. Again, based on the lack of toxicological endpoints for polyoxin D zinc salt, and its non-toxic fungi-specific mode of action as a chitin synthetase inhibitor, no dietary risks are expected with regard to drinking water exposure.

B. Other Non-Occupational Exposure

No new non-occupational exposure is expected to result from the new agricultural uses of polyoxin D zinc salt. However, the Agency notes that no health risks are expected from any exposure to this active ingredient in any event. A 1997 risk assessment of polyoxin D zinc salt makes clear that

even the expected non-agricultural non-occupational exposures that are associated with this active ingredient pose negligible risks. Polyoxin D zinc salt is characterized by its negligible toxicity; it has a non-toxic, fungistatic, fungi-specific mode of action, and it demonstrates no mammalian dietary effects.

1. *Dermal exposure.* No new non-occupational dermal exposures are expected to result from the new agricultural uses of polyoxin D zinc salt. Any new dermal exposure associated with this new agricultural use pattern is expected to be occupational in nature.

2. *Inhalation exposure.* No new non-occupational inhalation exposures are expected to result from the new agricultural uses of polyoxin D zinc salt. Any new inhalation exposure associated with this new agricultural use pattern is expected to be occupational in nature.

V. Cumulative Effects

Pursuant to section 408(b)(2)(D)(v) of FFDCA, EPA has considered available information concerning the cumulative effects of polyoxin D zinc salt residues and other substances that have a common mechanism of toxicity. These considerations include the cumulative effects on infants and children of polyoxin D zinc salt residues and other substances with a common mechanism of toxicity. Because there is no indication of mammalian toxicity, the Agency concludes that there are no cumulative effects arising from polyoxin D zinc salt residues in or on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes and strawberries.

VI. Determination of Safety for U.S. Population, Infants and Children

Health risks to humans, including infants and children are considered negligible. There is a lack of meaningful toxicological endpoints for polyoxin D zinc salt. Moreover, polyoxin D zinc salt is defined by its fungistatic non-toxic mode of action, and demonstrates no mammalian effect. Accordingly, it is considered to have negligible toxicity, and there are no acute or chronic dietary risk concerns for sensitive subpopulations.

1. *U.S. population.* The Agency has determined that there is reasonable certainty that no harm will result to the U.S. population from aggregated exposure to residues of polyoxin D zinc salt. This includes all dietary exposures and other exposures for which there is reliable information. The Agency has arrived at this conclusion based on polyoxin D zinc salt's non-toxic fungi-specific mode of action, and its

observed non-toxic effect on mammals. The Agency finds that the combination of registered turf use and the proposed crop uses of polyoxin D zinc salt has a reasonable certainty of no harm to the U.S. population.

2. *Infants and children.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless the EPA determines that a different margin of exposure (safety) will be safe for infants and children. Based on all the reliable available information the Agency reviewed on polyoxin D zinc salt, the Agency concludes that there are no residual uncertainties for prenatal/postnatal toxicity resulting from polyoxin D zinc salt, and that polyoxin D zinc salt has relatively low toxicity to mammals from a dietary standpoint, including infants and children. Accordingly, there are no threshold effects of concern and an additional margin of safety is not necessary to protect infants and children. Indeed, the available data indicate that polyoxin D zinc salt has very low toxicity, including to infants and children, and no increased sensitivity of infants or children was indicated in any of the laboratory studies. In sum, there is a reasonable certainty of no harm to infants and children with regard to the proposed food uses of polyoxin D zinc salt.

VII. Other Considerations

A. Endocrine Disruptors

Based on available data, no endocrine system-related effects have been identified with the consumption of polyoxin D zinc salt. No evidence of endocrine system effects was observed in the immunotoxicity, subchronic, chronic, teratology or reproduction studies.

B. Analytical Method

Through this action, the Agency proposes an exemption from the requirement of a tolerance of polyoxin D zinc salt when used on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes and/or strawberries, without any numerical limitations for residues. EPA has determined that residues resulting from the pesticidal uses of polyoxin D zinc salt would as a matter of viable application be low, and that there are no significant toxicity concerns regarding this active ingredient. As a result, the Agency has concluded that an analytical method is

not required for enforcement purposes for this proposed use of polyoxin D zinc salt.

C. Codex Maximum Residue Level

Through this action, the Agency proposes an exemption from the requirement of a tolerance of polyoxin D zinc salt when used on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes and/or strawberries, without any numerical limitations for residues. EPA has determined that residues resulting from the pesticidal uses of polyoxin D zinc salt would as a matter of viable application be low, and that there are no significant toxicity concerns regarding this active ingredient. As a result, the Agency has concluded that an analytical method is not required for enforcement purposes for this proposed use of polyoxin D zinc salt.

VIII. Conclusions

Based on the information submitted, and other information available to the Agency, EPA is establishing an exemption from the tolerance requirements pursuant to section 408(c) of FFDCA for residues of polyoxin D zinc salt in or on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes and strawberries.

IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCFA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCFA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: November 11, 2008.

Debra Edwards,
Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1285 is added to subpart D to read as follows:

§ 180.1285 Polyoxin D zinc salt; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of the biochemical pesticide polyoxin D zinc when used as a fungicide on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes and strawberries.

[FR Doc. E8-27485 Filed 11-18-08; 8:45 am]

BILLING CODE 6560-50-S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 65

[Docket No. FEMA-B-1019]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the Base (1% annual-chance) Flood Elevations (BFEs) is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified BFEs for new buildings and their contents.

DATES: These modified BFEs are currently in effect on the dates listed in the table below and revise the Flood Insurance Rate Maps (FIRMs) in effect prior to this determination for the listed communities.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Mitigation Assistant Administrator of FEMA reconsider the changes. The

modified BFEs may be changed during the 90-day period.

ADDRESSES: The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: William R. Blanton, Jr., Engineering Management Branch, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3151.

SUPPLEMENTARY INFORMATION: The modified BFEs are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection is provided.

Any request for reconsideration must be based on knowledge of changed conditions or new scientific or technical data.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by the other Federal, State, or regional entities. The changes BFEs are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This interim rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility

**Appendix 10. Notice of Filing for the EPA Petition for Exemption from Tolerance for
Polyoxin D Zinc Salt Used on All Growing Crops and for Post-Harvest Uses**



**EPA BIOPESTICIDES AND POLLUTION PREVENTION DIVISION
COMPANY NOTICE OF FILING FOR PESTICIDE PETITIONS PUBLISHED IN
THE FEDERAL REGISTER**

EPA Biopesticides and Pollution Prevention Division contact: [insert name and telephone number with area code]

INSTRUCTIONS: Please utilize this outline in preparing the pesticide petition. In cases where the outline element does not apply, please insert “NA-Remove” and maintain the outline. Please do not change the margins, font, or format in your pesticide petition. Simply replace the instructions that appear in green, i.e., “[insert company name],” with the information specific to your action.

SUBMISSION: E-mail the completed template to: hollis.linda@epa.gov.

TEMPLATE:

[Kaken Pharmaceutical Co., Ltd.]

[Insert petition number]

EPA has received a pesticide petition ([for an exemption from the requirement of a tolerance for residues of polyoxin D zinc salt in/on all agricultural commodities]) from [Kaken Pharmaceutical Co., Ltd.], [c/o Conn & Smith, Inc., Agent, 6713 Catskill Road, Lorton, VA 22079] requesting, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an amendment/expansion of an existing tolerance exemption for the biochemical pesticide [polyoxin D zinc salt].

Pursuant to section 408(d)(2)(A)(i) of FFDCA, as amended, [Kaken Pharmaceutical Co., Ltd.] has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by [Conn & Smith, Inc. and Kaken Pharmaceutical Co., Ltd.] and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA’s position and not the position of the petitioner.

I. [Kaken Pharmaceutical Co., Ltd.] Petition Summary

[Insert petition number]

A. Product Name and Proposed Use Practices

[Polyoxin D zinc salt is the active ingredient in ENDORSE Water Dispersible Granules and other brand name formulations and is proposed for use on all crops both pre-harvest and post-harvest according to good agricultural practices. The active portion of polyoxin D zinc salt is polyoxin D which is produced by a bacterium 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.]

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* [The CAS name for polyoxin D zinc salt is zinc 5-[[2-amino-5-*O*-(aminocarbonyl)-2-deoxy-L-xylonyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2*H*)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronate.]

2. *Magnitude of residues at the time of harvest and method used to determine the residue.* [The magnitude of the residue has been evaluated as part of the evaluation of the nature of the residue in grapes, tomatoes, and lettuce. Each of the crops received three pre-harvest treatments at 7-day to 10-day intervals, and the total application rate was the maximum seasonal rate. Polyoxin D and uracil-5-carboxylic acid were determined to be the primarily metabolites. The sum of the measured polyoxin D and uracil-5-carboxylic acid residues were consistently low when the crops were treated at the maximum seasonal rate (0.40 mg eq/kg in grape berries harvested 1 day after last treatment, 0.01 mg eq/kg in tomatoes harvest 14 days after last treatment, and 0.02 mg eq/kg in head lettuce with the outer leaves removed and harvested 7 days after last treatment. These measured residues are worst case residues. These nature of the residue studies demonstrated that a large percentage of the residue is removed by rinsing the harvested raw agricultural commodity with water (84% for grapes harvested 1 day after treatment, 96% for tomatoes harvested 1 day after last treatment, and 85% from head lettuce outer leaves harvested 7 days after last treatment). Also, the nature of the residue studies were conducted in greenhouses, and the plants were irrigated so that water did not contact the aerial portion of the plant. Under field conditions, residues on crops would be even lower due to reduction of residues by rainwater and irrigation water. Also, polyoxin D degrades very rapidly in the environment. The half-life is 32.5 days at pH 7 by hydrolysis, 2.3 days by aqueous photolysis at pH 7, and 15.9 days in microbially active soil by aerobic soil metabolism. Cooking (hydrolysis at elevated temperature) will also reduce the magnitude of the residues in the diet.]

3. *A statement of why an analytical method of detecting and measuring the levels of the pesticide residue are not needed.* [A tolerance exemption is proposed. Therefore, no tolerance enforcement method is proposed.]

C. Mammalian Toxicological Profile

[1. Acute Toxicity: Technical grade polyoxin D zinc salt has very low acute toxicity. The acute oral LD₅₀ was determined to be greater than 10,000 mg/kg in rats. Polyoxin D is not teratogenic in the rabbit and rat. In a teratology study in rabbits, no adverse effects were observed in the pups while body weight reduction was observed in the dams at the highest dose tested (800 mg TGAI/kg/day). In a teratology study in rats, no treatment related adverse effects were observed in the pups while thickening of the limiting ridge of the stomach was observed in dams. Also, no statistically significant adverse effects in the offspring were observed in a 2-generation reproduction study at dietary intake levels greater than 10,000 mg TGAI.

2. Subchronic Toxicity: Technical grade polyoxin D zinc salt has very low subchronic toxicity. For 90 days, rats were fed a diet containing up to 20,000 ppm technical grade polyoxin D zinc salt. The NOAEL was determined to be 2000 ppm (119mg TGAI/kg bw/day in males and 135 mg TGAI/kg bw/day in females). At 20,000 ppm, decreased body weight gain and decreased food consumption were observed. In a 28-day study to evaluate immunotoxicity, female mice were fed a diet containing up to 40,000 ppm technical grade polyoxin D zinc salt, and no adverse effects were observed. The NOAEL was determined to be approximately 8000 mg TGAI/kg/day.

3. Chronic Toxicity: Technical grade polyoxin D zinc salt has very low chronic toxicity. For 24 months, rats were fed a diet containing up to 5% technical grade polyoxin D zinc salt and evaluated the toxicity, including oncogenicity. No statistically significant effects were observed at the highest dose tested. The NOAEL was determined to be 2,058.7 mg TGAI/kg bw/day in males and 2,469.8 mg TGAI/kg bw/day in females.

4. Mutagenicity: Based upon the weight of evidence, technical grade polyoxin D zinc salt is not mutagenic. Technical grade polyoxin D zinc salt was determined to be non-mutagenic in an Ames test, a Rec-assay with *Bacillus subtilis* H-17 and M-45, and a host mediated Assay with *S. typhimurium* G-46 in mice. Equivocal results were obtained in a chromosome aberration study, and data indicating weak mutagenicity were obtained in a second Ames test. However, in a repeat chromosome aberration study, technical grade polyoxin D zinc salt was determined to be non-mutagenic. Also, in a repeat Ames study, technical grade polyoxin D zinc salt was determined to be non-mutagenic. Even more importantly, in an *in vivo* (whole animal) study, technical grade polyoxin D zinc salt was determined to be not mutagenic. Technical grade polyoxin D zinc salt was determined to be not mutagenic at the highest dose tested (2000 mg TGAI/kg) in the mouse micronucleus test. Most importantly, technical grade polyoxin D zinc salt is not teratogenic and not oncogenic. These results are consistent with a non-mutagenic material.]

D. Aggregate Exposure

1. Dietary exposure. [Dietary exposure to polyoxin D zinc salt residues resulting from both pre-harvest and post-harvest treatment of crops according to good agricultural

practices will be very low.]

i. *Food*. [Based upon (a) the low measured residues in crops treated pre-harvest in a greenhouse at the maximum seasonal rate, (b) significant measured residue reduction resulting from rinsing with water, and (c) rapid environmental degradation of polyoxin D, dietary exposure to polyoxin D zinc salt residues resulting from crops treated pre-harvest according to good agricultural practice will be low. Residues resulting from treatments applied post-harvest will similarly be significantly reduced by rinsing the raw agricultural commodity with water. In addition, cooking will further reduce these low level residues to very low level residues.]

ii. *Drinking water*. [Residues of polyoxin D zinc salt will be very low. Polyoxin D zinc salt degrades rapidly under normal environmental conditions. The half-life is 32.5 days at pH 7 by hydrolysis, 2.3 days by aqueous photolysis at pH 7, and 15.9 days in microbially active soil by aerobic soil metabolism.]

2. *Non-dietary exposure*. [Polyoxin D zinc salt is registered to control fungal diseases of turf. The use on turf was previously estimated to result in very low non-dietary risk, including hand-to-mouth exposure to infants and children.]

E. Cumulative Effects

[Polyoxin D zinc salt is not known to share a toxicological mode of action with any other pesticide.]

F. Safety Determination

1. *U.S. population*. [Based upon the combination of very low mammalian toxicity and very low aggregate exposure, the sum of all registered uses and potential new uses of polyoxin D zinc salt to control or suppress fungal diseases in crops according to good agricultural practices has a reasonable certainty of no harm to the U.S. population.]

2. *Infants and children*. [The available data indicate that polyoxin D zinc salt has very low toxicity, including to infants and children. No increased sensitivity by infants or children was indicated in any of the laboratory studies. Therefore, the sum of all registered uses and potential new uses of polyoxin D zinc salt to control or suppress fungal diseases in crops according to good agricultural practices has a reasonable certainty of no harm to infants and children.]

G. Effects on the Immune and Endocrine Systems

[In a 28-day study to evaluate immunotoxicity (splenic antibody study), female mice were fed a diet containing up to 40,000 ppm technical grade polyoxin D zinc salt, and no adverse effects were observed. The NOEL was determined to be approximately

8000 mg TGAI/kg bw/day. No evidence of endocrine system effects was observed in the subchronic, chronic, teratology, or reproduction studies.]

H. Existing Tolerances

[There is an existing exemption from the requirement of a tolerance for residues of polyoxin D zinc salt on almonds, cucurbits vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes, and strawberries when applied as a biochemical pesticide to control and suppress fungal diseases. See 40 CFR §180.1285.]

I. International Tolerances

[There are no current CODEX MRLs or other international tolerances for polyoxin D zinc salt or polyoxin D. Polyoxin D zinc salt is registered for food uses in Japan, Korea, Taiwan, and Mexico, and the regulatory authorities in these countries have each determined that no tolerance (MRL) is needed.]

Appendix 11. OMRI List of Crop Products for Disease Control

OMRI Products List. Web Edition

Crop Products

Wetting Agents

- Down To Earth Foliar Agent (Down To Earth Distributors, Inc.)
- Natural Wet® (JH Biotech, Inc.)
- Organagrow (DANCO, Inc.)
- Phyto-Plus® Brand Foliar Friend (Baicor, L.C.)
- QL Agri (Desert King International, LLC)
- Quillaja Powder QP (Desert King International, LLC)
- SaferGro® Natural Wet (JH Biotech, Inc.)
- Surfact 50™ (Northwest Agricultural Products™ Inc.)
- ThermX™ 15M (American Extracts)
- ThermX™ 70 (American Extracts)
- Yucca Ag-Aide (Desert King International, LLC)

Yucca

- B'cuzz® Foliar Boost (Atami America, Inc.)
- Tecno-nina (Aromaticos Quimicos Potosinos, S.A. de C.V. (Grupo Tecnaal))
- Tension-Free (Agro-Ux Biocontrol, S. de R. L. de C.V.)
- Yucca Ag-Aide™ Powder (Desert King International, LLC)
- YUCCA SD POWDER (Desert King International, LLC)

Crop Pest, Weed, and Disease Control

Azadirachta indica

May be used as a pesticide if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

- NeemAzad® 1% EC Insect Growth Regulator (Certis USA)

Bacillus thuringiensis

May be used as a pesticide if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

- ✘ Bactur 2X WP (Valent BioSciences® Corp.)
- Monterey B.t. Easy-to-Mix Liquid Concentrate (Lawn and Garden Products, Inc.)
- ✘ Sequra® 32 (Valent BioSciences® Corp.)
- Thuricide® HPWP (Certis USA)
- Able® 50 WDG Biological Insecticide (Certis USA)
- Agree® WG Biological Insecticide (Certis USA)
- ✘ Astuto® (Valent BioSciences® Corp.)
- ✘ Aztron WDG (Valent BioSciences® Corp.)
- Bactospeine DF (Valent BioSciences® Corp.)
- ✘ Bazthu • 32® (Valent BioSciences® Corp.)
- Biobit® HP (Valent BioSciences® Corp.)
- ✘ Biobit® 32 (Valent BioSciences® Corp.)
- BT 320 Sulfur 25 Dust (Wilbur-Ellis Company)
- Condor® WP Wettable Powder Bioinsecticide (Certis USA)
- Costar® Biological Insecticide (Certis USA)
- Delfin® WG Biological Insecticide (Certis USA)
- Deliver® Biological Insecticide (Certis USA)
- DiPel® 2X Biological Insecticide Wettable Powder (Valent BioSciences® Corp.)
- DiPel® DF (Valent BioSciences® Corp.)
- DiPel® PRO DF (Valent BioSciences® Corp.)
- ✘ FlorBac® (Valent BioSciences® Corp.)
- Foray® 48B (Valent BioSciences® Corp.)
- ✘ Geoda® (Valent BioSciences® Corp.)
- Gnatrol® WDG (Valent BioSciences® Corp.)
- Green Light® BT Worm Killer 2 (Green Light, A Valent U.S.A. Company)
- Javelin® WG Biological Insecticide (Certis USA)

- Organocide™ Worm & Caterpillar Control (Organic Laboratories, Inc.)
- pht® Bt Dust (Britz-Simplot Grower Solutions LLC)
- Safer® Brand Garden Dust (Woodstream Corporation)
- Thuricide® HPC-O for Home & Gardens (Easy-to-Mix Liquid Concentrate) (Certis USA)
- VectoBac® WDG (Valent BioSciences® Corp.)
- XenTari® W. D. G. (Valent BioSciences® Corp.)
- XenTari® Dry Flowable (Valent BioSciences® Corp.)
- ✘ Xtream Dry Flowable (Valent BioSciences® Corp.)

Beauveria spp.

May be used for disease control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

- Mycotrol® O (Laverlam International Corp.)

Biological Controls

- Grub Guard (North Country Organics)
- NINJA SC (Agro-Ux Biocontrol, S. de R. L. de C.V.)

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Δ: Products with this symbol are certified 'organic' or '100% organic' by a USDA accredited certifier.

✘: Products with this symbol are not permitted for use as a pesticide in the USA.

OMRI Products List, Web Edition

Crop Products

Biological Pesticides

For use as a pest lure, repellent, or as part of a trap, or as a disease control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

- ✳ MBI - 203 SC (Marrone Bio Innovations)
Actino-Iron® Biological Fungicide (Natural Industries, Inc.)
- ✳ Baktillis® Biological Fungicide (Biokrone, S.A. de C.V.)
Carpovirusine (Arysta LifeScience North America Corporation)
DiTera® DF (Valent BioSciences® Corp.)
- ✳ JUQ (Gauri Lab-Microorganismos Beneficos)
- ✳ MBI - 203 EP (Marrone Bio Innovations)
MeloCon® WG Biological Nematicide (Prophyta Biologischer Pflanzenschutz GmbH)
Semaspore Bait™ (Planet Natural)
VectoLex® WDG (Valent BioSciences® Corp.)

Biopesticides

For use as a pest lure, repellent, or as part of a trap, or as a disease control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

- Bloomtime Biological™ FD Biopesticide (Northwest Agricultural Products™ Inc.)
- BOTRY-Zen® (Botry-Zen Limited)
- Natular™ 2EC (Clarke Mosquito Control Products, Inc.)

Boric Acid

May be used as an insecticide for structural pest control provided there is no direct contact with food or crops being certified. May be used for plant disease control if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

- MotherEarth® Granular Scatter Bait (Whitmire Micro-Gen Research Laboratories, Inc.)
- NiBan® Granular Bait (Nisus Corporation)

Botanical Pesticides

May be used as a pest lure, repellent, or as part of a trap, or as a disease control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

- GC-3™ (JH Biotech, Inc.)

Calcium Polysulfide

May be used as insecticide (acaricide) and for plant disease control only if the requirements of 205.206(e) are met.

- BSP Lime-Sulfur Solution (Ag Formulators, Inc.)
- Green Cypress® Lime-Sulfur Solution (Monterey AgResources)

Copper Sulfate

For use as an algicide in aquatic rice systems and for tadpole shrimp control in aquatic rice systems; use is not to exceed one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a time frame agreed upon by the producer and accredited certifying agent.

When used for plant disease control must be used in a manner that minimizes accumulation of copper in the soil. May be used as an algicide, insecticide, or disease control if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

- Basic Copper 53 (Albaugh, Inc.)
- Copper Sulfate Crystals (Chem One, Ltd.)
- Quimag Quimicos Aguila Copper Sulfate Crystal (Fabrica de Sulfato El Aguila, S.A. de C.V.)
- Quimag Quimicos Aguila Copper Sulfate Crystal - Crop (Fabrica de Sulfato El Aguila, S.A. de C.V.)

Coppers – fixed

May be used for plant disease control if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices. Must be used in a manner that minimizes copper accumulation in the soil and shall not be used as herbicides.

- Chem Copp 50 (American Chemet Corporation)
- Nu-Cop® 50DF (Albaugh, Inc.)
- Badge® X2 (Isagro USA)
- Camelot O Fungicide/Bactericide (SePRO Corporation)
- Champ® WG (NuFarm Americas, Inc.)
- COC WP (Albaugh, Inc.)
- CS 2005
- Algaecide/Bactericide Fungicide (Magna-Bon II, LLC)
- CSC Copper Sulfur Dust Fungicide (Martin Operating Partnership, L.P.)
- Cueva Fungicide Concentrate (W Neudorff GmbH KG)
- Cueva Fungicide Ready-To-Use (W Neudorff GmbH KG)
- NORDOX 30/30 WG (NORDOX AS)
- NORDOX 75 WG (NORDOX AS)
- Nu Cop® 50 WP (Albaugh, Inc.)
- Ortho® elementals™ Garden Disease Control (The Ortho Group)
- PHT Copper Sulfur Dust (J.R. Simplot Company)
- Ready-To-Use Worry Free® Brand Copper Soap Fungicide (Lilly Miller Brands)

Cytokinins – nonsynthetic

May be used as a plant growth regulator if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

- Cytex™ (Atlantic & Pacific)
- Nitrozyme™ Concentrate (Atlantic Laboratories, Inc.)
- SeaCrop 16 (North American Kelp)
- Stimplex® Crop Biostimulant (Acadian AgriTech (A Division of Acadian Seaplants Ltd.))

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OMRI Products List, Web Edition

Crop Products

Diatomaceous Earth

For use as a pest lure, repellent, or as part of a trap, or as a disease control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

Safer® Brand Ant & Crawling Insect Killer (Woodstream Corporation)

Ferric Phosphate

May be used as slug and snail bait if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

Bayer Advanced Natria™ Snail & Slug Killer Bait Ready-to-Use (Bayer Advanced)
 Bug-N-Sluggo® Insect, Slug and Snail Bait (W Neudorff GmbH KG)
 First Choice® Sluggo® Snail and Slug Bait (Loveland Products, Inc.)
 Garden Safe® Brand Slug & Snail Bait (Schultz® Company)
 Monterey Sluggo® (Lawn and Garden Products, Inc.)
 Monterey Sluggo®-AG (Lawn and Garden Products, Inc.)
 Ortho® elementals™ Slug & Snail Killer (The Ortho Group)
 Sluggo® Slug & Snail Bait (W Neudorff GmbH KG)
 Sluggo® Slug & Snail Bait (Omex Agriculture, Inc.)
 Whitney Farms® Slug & Snail Killer (Swiss Farms Products, Inc.)
 Worry Free® Brand by Lilly Miller® Ferramol™ Slug & Snail Bait (Lilly Miller Brands)

Fungicides – nonsynthetic

May be used as a pesticide for disease control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

Contans® WG (Prophyta Biologischer Pflanzenschutz GmbH)
 Mycostop® Biofungicide (Verdera Oy)
 Mycostop® Mix (Verdera Oy)
 Oleotrol® - M (NTS Research & Inc.)
 Prestop® Biofungicide Powder (WP) (Verdera Oy)
 SoilGard® Microbial Fungicide (Certis USA)
 SPORATEC® (Brandt Consolidated, Inc.)

Garlic

For use as a pest lure, repellent, or as part of a trap, or as a disease control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

Ajick® (Biokrone, S.A. de C.V.)
 ✖ Bio Crack® + Plus (Bemi Labs. S. de R.L. Microindustrial)
 BioLink® Insect Repellent Garlic Juice (Westbridge)
 BioRepel™ (JH Biotech, Inc.)
 ✖ EDOCA ALLIUM® control de plagas en cultivo (Organica Premier S.A. de C.V.)
 Garlic Barrier AG+ (Garlic Research Labs)
 PHC® Bug Balancer® (Plant Health Care de México, S. de R.L. de C.V.)
 SaferGro® Biorepel (JH Biotech, Inc.)
 ✖ XtraGarlic (Agrobiologica S.A. de C.V.)

Gibberellic Acid

May be used as a pesticide if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

✖ Activo! 40% GS (Valent BioSciences® Corp.)
 Falgro® 20SP (Fine Americas, Inc.)
 Falgro® 4L (Fine Americas, Inc.)
 GA3 20% Plant Growth Regulator Soluble Powder (CP Bio, Inc.)
 GibGro® 20% Powder (NuFarm Americas, Inc.)
 GibGro® 4LS (NuFarm Americas, Inc.)
 GibGro® 5% Powder (NuFarm Americas, Inc.)
 N-Large™ (Stoller Enterprises, Inc.)
 Novagib™ 10L (Fine Americas, Inc.)
 Plant Growth Regulator Release® Soluble Powder (Valent BioSciences® Corp.)
 ProGibb® 4% Solution (Valent BioSciences® Corp.)
 ProGibb® 40% (Valent BioSciences® Corp.)
 ProGibb® T&O (Valent BioSciences® Corp.)
 Pro-Gibb® Plus 2X Soluble Powder (Valent BioSciences® Corp.)
 ProVide® 10 SG (Valent BioSciences® Corp.)
 Release® LC (Valent BioSciences® Corp.)
 RYZUP 40 SG (Valent BioSciences® Corp.)
 RyzUp SmartGrass™ (Valent BioSciences® Corp.)
 RyzUp® (Valent BioSciences® Corp.)

Growth Regulators for Plants

May be used if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

✖ agrizest® (Indigo)
 ✖ agrizest® plus (Indigo)
 ✖ GroundsKeeper's® Pride Kelp Meal 1-0.15-1.5 (Westland Ltd.)
 ✖ Nature's Curator® (Indigo)
 ProTone™ SG (Valent BioSciences® Corp.)

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OMRI Products List, Web Edition

Crop Products

Herbicides – nonsynthetic

May be used if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

- ✘ BioLink® Herbicide Liquid Concentrate Biolink Herbicide (Westbridge)
- MATRATEC® (Brandt Consolidated, Inc.)
- SaferGro® WeedZap (JH Biotech, Inc.)
- Summerset AllDown® Concentrate Non-Selective Broadleaf and Grass Herbicide (KPT, LLC dba Summerset Products)
- Weed Zap™ (JH Biotech, Inc.)
- Worry Free® Brand Weed & Grass Killer (Concentrate) (Lilly Miller Brands)
- Worry Free® Brand Weed & Grass Killer (Ready To Use) (Lilly Miller Brands)

Horticultural Oils – animal or plant derived

For use as a pest lure, repellent, or as part of a trap, or as a disease control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

- Aramite (Bright Organics Corp)
- BG-VG (Bgreen Limited)
- St Gabriel Organics Moss Killer Ready To Use (St. Gabriel Organics)
- St Gabriel Organics Poison Ivy Fast Acting Defoliant (St. Gabriel Organics)

Hydrogen Peroxide

May be used for plant disease control or as an algicide, disinfectant, or sanitizer if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices. May be used as an adjuvant or inert ingredient in passive pheromone dispensers.

- Di-Oxy Solv Plus™ Broad Spectrum Algaecide / Bactericide / Fungicide (Flo-Tec, Inc.)
- GreenClean® Broad Spectrum Algaecide/Bactericide Liquid (BioSafe Systems)
- OxiDate® Broad Spectrum Bactericide / Fungicide (BioSafe Systems)
- PERpose Plus™ (A Growing Alternative, Inc.)

Lime Sulfur

May be used in pest control as insecticides, including acaricides or mite control, and for plant disease control if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

- Rex Lime Sulfur Solution (OR-Cal, Inc.)
- Tetrasul 4s5 (OR-Cal, Inc.)

Limonene

For use as a pest lure, repellent, or as part of a trap, or as a disease control. May be used for other pesticidal purposes, including use as an insecticide, if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

- Avenger AG Burndown Herbicide (Cutting Edge Formulations, Inc.)
- Avenger® Ready To Use (RTU) Weed Killer (Cutting Edge Formulations, Inc.)
- Avenger® Weed Killer Concentrate (Cutting Edge Formulations, Inc.)
- Moss Avenger (Cutting Edge Formulations, Inc.)
- Orange Guard® Ornamental Plants (Orange Guard, Inc.)
- Ready to Spray Worry Free® Brand Moss & Algae Control (Lilly Miller Brands)

Microbial Pesticides

May be used for pesticidal purposes only if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

- Serenade® Garden Disease Control Ready to Use (AgraQuest, Inc.)
- Serenade® MAX™ (AgraQuest, Inc.)
- Taegro® biofungicide (Novozymes Biologicals, Inc.)

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OMRI Products List, Web Edition

Crop Products

Microbial Products

May be used as a pest lure, repellent, or as part of a trap, or as a **disease** control. May only be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- ArmorTech® Sonnet™ (United Turf Alliance LLC)
- ActinoGrow (Natural Industries, Inc.)
- ActinoGrow® ST (Natural Industries, Inc.)
- ActinoGrow® T&O (Natural Industries, Inc.)
- Actinovate® AG (Natural Industries, Inc.)
- Actinovate® SP (Natural Industries, Inc.)
- Actinovate® for Lawn & Garden (Natural Industries, Inc.)
- Actinovate® STP **Fungicide** (Natural Industries, Inc.)
- Ballad® Plus (AgraQuest, Inc.)
- Bayer Advanced Natria™ **Disease** Control Ready-to-Spray (Bayer Advanced)
- Bayer Advanced Natria™ **Disease** Control Ready-to-Use (Bayer Advanced)
- CEASE® (BioWorks, Inc.)
- DiPel® 2X DF (Valent BioSciences® Corp.)
- econem™ (Pasteuria Bioscience, Inc.)
- JAZZ™ (AgraQuest, Inc.)
- Milky Spore Powder Japanese Beetle Control (St. Gabriel Organics)
- Polyversum® (Biopreparaty Co. Ltd.)
- Rhapsody® (AgraQuest, Inc.)
- Rhapsody® ASO (AgraQuest, Inc.)
- RootShield® WP Biological **Fungicide** (BioWorks, Inc.)
- Serenade® ASO (AgraQuest, Inc.)
- Serenade® Garden **Disease** Control Concentrate (AgraQuest, Inc.)
- Serenade® Garden **Disease** Control Ready to Spray (AgraQuest, Inc.)
- Serenade® Garden Lawn **Disease** Control (AgraQuest, Inc.)
- SERENADE® SOIL (AgraQuest, Inc.)
- Sonata® (AgraQuest, Inc.)

Mined Minerals – unprocessed

For use as a pest lure, repellent, or as part of a trap, or as a **disease** control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- Surround® WP Crop Protectant (Tessenderlo Kerley Inc.)

Mulch – plastic

Must be removed at the end of the season. Plastic mulches in perennial crops may be left for more than one season, but must be removed before the plastic decomposes or breaks into pieces so that it is not possible to effectively remove all pieces from the soil. May be used to control weed problems if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- Brite'Nup (Pacific Coating Technologies, Inc.)

Neem Extract and Derivatives

May be used as a pest lure, repellent, or as part of a trap, or as a **disease** control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- Azatrol® Hydro Botanical Insecticide (PBI/Gordon Corp.)
- Debug® Turbo (Agro Logistic Systems, Inc.)
- AMAZIN PLUS 1.2% ME (AMVAC Chemical Corp.)
- AZA-Direct® (Gowan Co.)
- AzaGuard™ (BioSafe Systems)
- AzaMax® Botanical Insecticide, Miticide, and Nematicide (Parry America Inc.)
- Azatrol® EC Insecticide (PBI/Gordon Corp.)
- Concern® Garden Defense Multi-Purpose Spray Concentrate (Woodstream Corporation)
- EcoGarden™ Botanical Insecticide, Miticide, and Nematicide (Parry America Inc.)
- Ecozin® Plus 1.2% ME (AMVAC Chemical Corp.)
- Fortune AzA Azadirachtin 3% EC (Fortune Biotech, LTD)
- Garden Safe® Brand **Fungicide** 3® (Schultz® Company)
- Garden Safe® Brand **Fungicide** 3® Concentrate (Schultz® Company)
- GOS Neem 7 Way Spray Biological Insecticide (Georgia Organic Solutions, LLC)
- Green Light® Rose Defense® Ready-to-Use (Green Light Company)
- Green Light® Neem Concentrate (Green Light Company)
- Green Light® Rose Defense® (Concentrate) (Green Light Company)
- Meen Insect Growth Regulator (Certis USA)
- Molt-X™ Botanically Based Insecticide/Nematicide (BioWorks, Inc.)
- Monterey 70% Neem Oil (Lawn and Garden Products, Inc.)
- Monterey Neem Oil RTU (Lawn and Garden Products, Inc.)
- * N8 (Empresas Organicas N8 S.A. de C.V.)
- Neem Oil RTU **Fungicide/Miticide/Insecticide** (Certis USA)

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NeemGard®

Fungicide/Miticide/Insecticide
(Certis USA)

Neemix® 4.5 Insect Growth Regulator (Certis USA)

Nimbuz™

Fungicide/Miticide/Insecticide
(Certis USA)

Plasma Neem® Oil (azadirachtin 3000 ppm) BIOLOGICAL INSECTICIDE (Plasma Power Private Limited)

Safer® Brand BioNEEM® Multi-purpose Insecticide & Repellent Concentrate (Woodstream Corporation)

Safer® Brand End All™ Insect Killer (Woodstream Corporation)

Safer® Brand Grub Killer Ready-To-Spray (Woodstream Corporation)

TreeAzin Systemic Insecticide (BioForest Technologies Inc)

Triact® 70

Fungicide/Miticide/Insecticide
(Certis USA)

Trilogy®

Fungicide/Miticide/Insecticide
(Certis USA)

Triple Action Neem Oil (Southern Agricultural Insecticides Inc)

UltraStop® 3-in-1 RoseGuard® (Value Garden Supply LLC)

UltraStop® Fruit Tree 3-In-1 Spray Concentrate (Value Garden Supply LLC)

Nematicides – nonsynthetic

May be used as a pesticide if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

Dragonfire-CPP™ (Poulenger USA, Inc. NaEx Corp.)

Nema-Q® (Monterey AgResources)

Quillaja Extract (Desert King Chile)

Oils – nonsynthetic sources

May be used as a pesticide if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

Bayer Advanced Natria™ Multi-Insect Control Concentrate (Bayer Advanced)

Bayer Advanced Natria™ Multi-Insect Control Ready-to-Spray (Bayer Advanced)

Concentrate Worry Free® Brand Vegol™ Year-Round Pesticidal Oil (Lilly Miller Brands)

ECO E-RASE™ (IJO Products, LLC)

EcoLogic Pro™ Blaze™ (Marrone Bio Innovations)

✳ EPA 90® (Biokrone, S.A. de C.V.)

Golden Pest Spray Oil™ (Stoller Enterprises, Inc.)

GreenMatch® EX Bumdown Herbicide (Marrone Bio Innovations)

Permatrol™ (Soil Technologies Corp.)

SeaCide® (Omega Protein, Inc.)

St Gabriel Organics Bum Out II Concentrate (St. Gabriel Organics)

St Gabriel Organics Bum Out II Ready to Use (St. Gabriel Organics)

Vegol™ Insecticidal Oil (W Neudorff GmbH KG)

Oils, Petroleum-Based – narrow range

May be used for plant disease control or as an insecticide (including acaricide or mite control) if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

Leaf Life® Gavicide Green® 415 (Loveland Products, Inc.)

Leaf Life® Gavicide Green® 440 (Loveland Products, Inc.)

OMNI SUPREME SPRAY (Helena Chemical Co.)

TresOil™ (Brandt Consolidated, Inc.)

TriTek™ (Brandt Consolidated, Inc.)

BVA Spray 10 (BVA, Inc.)

BVA Spray 13 (BVA, Inc.)

CIVITAS™ (Petro Canada Lubricants Inc.)

Glacial® Spray Fluid (Loveland Products, Inc.)

Master Nursery® Pest Fighter® Year-Round Spray Oil (Summit Responsible Solutions®)

Monterey Horticultural Oil (Lawn and Garden Products, Inc.)

Monterey SAF-T-SIDE® Spray Oil Emulsion Insecticide, Fungicide and Miticide (Lawn and Garden Products, Inc.)

Organic JMS Stylet-Oil® (JMS Flower Farms, Inc.)

pht 440 Supreme Spray Oil (Britz-Simplot Grower Solutions LLC)

Pure Spray Green Concentrate (Petro Canada Lubricants Inc.)

PureSpray™ Green (Petro Canada Lubricants Inc.)

Saf-T-Side® (Brandt Consolidated, Inc.)

✳ SPARROW 888 PLUS® (Sparrow Oilz P., Ltd.)

SuffOil-X® (BioWorks, Inc.)

Summit® Year-Round™ Spray Oil (Summit Responsible Solutions®)

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Crop Products

Paper

May only be used as a mulch or compost feedstock.

- EarthLine Garden Essentials (DeWitt Company)
- DeWitt Garden Weed-Barrier® (DeWitt Company)
- Landmaster™ Biodegradable Paper Mulch (Easy Gardener Products, Inc.)
- Weed Block® Biodegradable Mulch (Easy Gardener Products, Inc.)
- WeedGuardPlus® (SunShine Paper Company, LLC)

Peracetic Acid

May be used as a pesticide to control fireblight and to disinfect equipment, seed and asexually propagated planting material (i.e., bulbs, corms, tubers) if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- GreenClean® FX Moss, Mold, and Mildew Treatment (BioSafe Systems)
- OXICURE (Advance Research Chemicals, Inc.)
- OxiDate® Ready to Spray **Fungicide** Bactericide (BioSafe Systems)

Pheromones

May be used if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- Biomite™ (Natural Plant Protection)
- CheckMate® OFM Dispenser (Suterra, LLC)
- Checkmate® OFM-SL+ (Suterra, LLC)
- ISOMATE® - C Plus (Pacific Biocontrol Corp.)
- ISOMATE® - C TT (Pacific Biocontrol Corp.)
- ISOMATE® - CM FLEX (Pacific Biocontrol Corp.)
- ISOMATE® - CM RING (Pacific Biocontrol Corp.)
- ISOMATE® - CM/OFM TT (Pacific Biocontrol Corp.)
- ISOMATE® - EGVM (Pacific Biocontrol Corp.)
- ISOMATE® - M Rosso (Pacific Biocontrol Corp.)
- ISOMATE® - OFM TT (Pacific Biocontrol Corp.)
- ISOMATE® - OFM/PTB TT (Pacific Biocontrol Corp.)
- ISOMATE® - OmLR (Pacific Biocontrol Corp.)
- ISOMATE® - PTB TT (Pacific Biocontrol Corp.)
- NoMate® CM-O Spiral (Scentry Biologicals, Inc.)
- PB - Rope L (Pacific Biocontrol Corp.)

Plant Extracts – pesticide

May be used as a pest lure, repellent, or as part of a trap, or as a **disease** control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- ComCat® (AgraForum AG)
- Garden Guys Garden Neem Insecticide • **Fungicide** Ready to Use (OSM, INC)
- Regalia® **Biofungicide** Concentrate (Marrone Bio Innovations)
- Regalia® Maxx **Biofungicide** Concentrate (Marrone Bio Innovations)
- Versus 7 (Tecniprocessos Biologicos, S.A. de C.V.)

Plant Pesticides

May be used as a pest lure, repellent, or as part of a trap, or as a **disease** control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- Ant Out® (JH Biotech, Inc.)
- Cedar Gard™ (Natural Resources Group)
- DEFAN-100® (INVENTISA De Mexico, S.A. de C.V.)
- Ecotec - G Ready-to-use Granular Broad Spectrum Insecticide (Brandt Consolidated, Inc.)
- ECOTEC® (Brandt Consolidated, Inc.)
- GC-Mite™ (JH Biotech, Inc.)
- Heads Up® Plant Protectant (HeadsUp Plant Protectants, Inc.)
- ✳ Honcobacter (Ankarte)
- HUMA GRO® Promax™ (Bio Huma Netics, Inc®)
- HUMA GRO® Proud 3® (Bio Huma Netics, Inc®)
- Mildew Cure® (JH Biotech, Inc.)
- Nature Shield **Fungicide** (Apra SA de CV)
- No Moss® (JH Biotech, Inc.)
- Orange Guard® Fire Ant Control (Orange Guard, Inc.)
- Organocide™ Insecticide and **Fungicide** For Organic Production (Organic Laboratories, Inc.)
- Pest Out® (JH Biotech, Inc.)
- SaferGro® Ant Out (JH Biotech, Inc.)
- SaferGro® Mildew Cure® (JH Biotech, Inc.)
- SaferGro® No Moss® (JH Biotech, Inc.)
- SaferGro® Pest Out (JH Biotech, Inc.)

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OMRI Products List, Web Edition

Crop Products

Potassium Bicarbonate

May be used for **disease** control if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

Kaligreen® Potassium Bicarbonate Soluble Powder (Otsuka AgriTechno Co., LTD)

MilStop® Broad Spectrum Foliar Fungicide (BioWorks, Inc.)

Monterey Bi-Carb Old Fashioned Fungicide (Lawn and Garden Products, Inc.)

✳ PHC® MilStop Plus® (Plant Health Care de México, S. de R.L. de C.V.)

Potassium Silicate, aqueous

May be used if the requirements of 205.206(e) are met.

Si-MATRIX™ Fungicide/Miticide/Insecticide (PQ Corporation)

Pseudomonas

May be used for **disease** control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

Blight Ban® A506 (NuFarm Americas, Inc.)

Pyrethrum

May be used as a pest lure, repellent, or as part of a trap, or as a **disease** control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

Concern® Multi-Purpose Insect Killer II (Woodstream Corporation)

Concern® Rose & Flower Insect Killer II (Woodstream Corporation)

Concern® Tomato & Vegetable Insect Killer II (Woodstream Corporation)

Concern® Multi-Purpose Insect Killer Concentrate (Woodstream Corporation)

PyGanic® Crop Protection EC 1.4 II (MGK Co.)

PyGanic® Crop Protection EC 5.0 II (MGK Co.)

Safer® Brand End All™ Insect Killer (Woodstream Corporation)

Safer® Brand Houseplant Insect Killer (Woodstream Corporation)

Safer® Brand Houseplant Insect Killer III (Woodstream Corporation)

Safer® Brand Pyrethrin & Insecticidal Soap Concentrate II (Woodstream Corporation)

Safer® Brand Tomato & Vegetable Insect Killer II (Woodstream Corporation)

Safer® Brand Wasp & Hornet Killer (Woodstream Corporation)

Safer® Brand Yard & Garden Insect Killer II (Woodstream Corporation)

Safer® Brand Ant & Roach Killer (Woodstream Corporation)

Safer® Brand Bug Patrol Lawn & Landscape Insecticide Concentrate (Woodstream Corporation)

Safer® Brand Flying Insect Killer (Woodstream Corporation)

Safer® Brand Mosquito and Tick Killer (Woodstream Corporation)

Repellents

May be used only if the requirements of 205.206(e) are met.

DeFence™ by Havahart Rabbit & Deer Repellent (Woodstream Corporation)

Havahart® Critter Ridder® (Woodstream Corporation)

Havahart® Critter Ridder® Concentrate (Woodstream Corporation)

Havahart® Deer Away® Deer & Rabbit II (Woodstream Corporation)

Havahart® Deer-Off® II Ready-To-Use (Woodstream Corporation)

Havahart® Deer-Off® II Concentrate (Woodstream Corporation)

Havahart® Deer-Off® III Concentrate (Woodstream Corporation)

Havahart® Critter Ridder® Ready to Use (Woodstream Corporation)

Havahart® Deer Away® Deer & Rabbit Concentrate (Woodstream Corporation)

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OMRI Products List, Web Edition

Crop Products

Repellents, Vertebrate Animal – nonsynthetic

DeFence™ by Havahart Rabbit and Deer Repelling Pellets (Woodstream Corporation)
 Havahart® Deer Off® Deer & Rabbit Repelling Pellets (Woodstream Corporation)
 Nature's Best Coyote Urine Granules (Nature's Best Products LLC)
 Nature's Best Coyote/Fox Urine Granules (Nature's Best Products LLC)
 Nature's Best Fox Urine Granules (Nature's Best Products LLC)
 Plantskydd® Repellent Deer • Rabbits • Elk Soluble Powder Concentrate (Tree World Plant Care Products, Inc. dba Tree World®)
 Plantskydd® Repellent Rabbits & Small Critters (RTU Granules) (Tree World Plant Care Products, Inc. dba Tree World®)
 Shake Away® Coyote Urine Granules (Shake Away Inc.)
 Shake Away® Coyote/Fox Urine Granules (Shake Away Inc.)
 Shake Away® Fox Urine Granules (Shake Away Inc.)
 St Gabriel Organics Holy Moley (St. Gabriel Organics)
 Uncle Ian's Dog & Cat Repellent (Ian Enterprises)
 Uncle Ian's Mole & Gopher, Deer, Rabbit & Squirrel Repellent (Ian Enterprises)

Soap – pesticide

May be used as an algicide/demosser, herbicide or insecticide if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices. When used as an herbicide may only be used for farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops, nonfood crop uses only; use on any food crop or fallow fields is prohibited.

NEU1128 (W Neudorff GmbH KG)
 Final-San-O (Certis USA)
 Bayer Advanced Natria™ Insecticidal Soap Ready-to-Use (Bayer Advanced)
 ✕ Bioshampoo Plaguisin (Ankarte)
 Concern® Multi-Purpose Insect Killer II (Woodstream Corporation)
 Concern® Rose & Flower Insect Killer II (Woodstream Corporation)
 Concern® Tomato & Vegetable Insect Killer II (Woodstream Corporation)
 Concern® Insect Killing Soap II (Woodstream Corporation)
 Concern® Multi-Purpose Insect Killer Concentrate (Woodstream Corporation)
 DES-X™ Insecticidal Soap Concentrate (Certis USA)
 EARTH OPTIONS BY Raid™ insecticidal soap (S.C. Johnson & Son Inc)
 Finalsan Concentrate Grass and Weed Killer (W Neudorff GmbH KG)
 Finalsan Ready-to-Use Herbicidal Soap (W Neudorff GmbH KG)
 Garden Safe® Brand Insecticidal Soap Insect Killer (Schultz® Company)
 Moss-Aside Moss Killer (W Neudorff GmbH KG)
 M-Pede® (Dow Agrosciences, LLC)
 M-Pede® Insecticide Miticide Fungicide (Gowan Co.)
 Neudorff® H01 Concentrate Herbicidal Soap (W Neudorff GmbH KG)
 Neudorff's Insecticidal Soap Concentrate (W Neudorff GmbH KG)
 Neudorff's Insecticidal Soap Ready-to-Use (W Neudorff GmbH KG)
 Neudosan™ Insecticidal Soap Ready-to-Use (W Neudorff GmbH KG)

Opal-Insecticidal Soap (Omex Agriculture, Inc.)
 Ortho® elementals™ Insecticidal Soap (The Ortho Group)
 Pathway K+ Neem™ Insecticide - Fungicide II (Concentrate) (Pathway Holdings, LLC)
 Pathway Ready To Use K+ Neem™ Insecticide - Fungicide II (Pathway Holdings, LLC)
 Racer® Concentrate Non-selective Herbicide (Falcon Lab LLC)
 Ready To Use Worry Free® Brand Insecticidal Soap (Lilly Miller Brands)
 Safer® Brand 3- in-1 Concentrate II (Woodstream Corporation)
 Safer® Brand 3-in-1 Garden Spray II (Woodstream Corporation)
 Safer® Brand End All™ Insect Killer (Woodstream Corporation)
 Safer® Brand Fast Acting Weed & Grass Killer (Woodstream Corporation)
 Safer® Brand Fruit & Vegetable Insect Killer II (Woodstream Corporation)
 Safer® Brand Houseplant Insect Killer (Woodstream Corporation)
 Safer® Brand Houseplant Insect Killer III (Woodstream Corporation)
 Safer® Brand Houseplant Insect Killing Soap II (Woodstream Corporation)
 Safer® Brand Insect Killing Soap Concentrate II (Woodstream Corporation)
 Safer® Brand Insect Killing Soap with Seaweed Extract II (Woodstream Corporation)
 Safer® Brand Moss & Algae Killer & Surface Cleaner Ready to Spray II (Woodstream Corporation)
 Safer® Brand Moss & Algae Killer & Surface Cleaner Ready to Use II (Woodstream Corporation)
 Safer® Brand Rose & Flower Insect Killer II (Woodstream Corporation)
 Safer® Brand Tomato & Vegetable Insect Killer II (Woodstream Corporation)
 Safer® Brand Wasp & Hornet Killer (Woodstream Corporation)
 Safer® Brand Yard & Garden Insect Killer II (Woodstream Corporation)

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Crop Products

- Safer® Brand Ant & Roach Killer (Woodstream Corporation)
- Safer® Brand Bug Patrol Lawn & Landscape Insecticide Concentrate (Woodstream Corporation)
- Safer® Brand Flying Insect Killer (Woodstream Corporation)
- ✘ Safer's® Insecticidal Soap Concentrate (Woodstream Canada Corporation)
- ✘ Safer's® Insecticidal Soap Ready To Use (Woodstream Canada Corporation)
- ✘ Safer's® Rose & Flower Insecticide Ready to Use (Woodstream Canada Corporation)
- ✘ Safer's® Tomato & Vegetable Insecticide Ready To Use (Woodstream Canada Corporation)
- Whitney Farms® Insecticidal Soap (Swiss Farms Products, Inc.)

Sodium Carbonate Peroxyhydrate

Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label. May only be used as a pesticide if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- Algae-Off® Pro85 (Winston Company Inc.)
- GreenClean® Granular Algaecide (BioSafe Systems)
- GreenClean® PRO (BioSafe Systems)

Sodium Chloride

May be used as a pest lure, repellent, or as part of a trap, or as a **disease** control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- ADIOS READY-TO-USE WEED CONTROL (HerbaNatur Inc.)

Spinosad

May be used as a pest lure, repellent, or as part of a trap, or as a **disease** control. May be used for other pesticidal purposes if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- Regard™ Insecticide (Syngenta Crop Protection, LLC)
- Conserve Naturallyte Insect Control (Southern Agricultural Insecticides Inc)
- Conserve® Fire Ant Bait XT (Dow Agrosciences, LLC)
- Conserve® Fire Ant Bait (Dow Agrosciences, LLC)
- Entrust® Naturalyte® Insect Control (Dow Agrosciences, LLC)
- GF-120® NF Naturalyte® Fruit Fly Bait (Dow Agrosciences, LLC)
- Green Light Fire Ant Killer with Spinosad (Green Light Company)
- Green Light® Lawn & Garden Spray with Spinosad® (Green Light Company)
- Green Light® Lawn & Garden Spray with Spinosad® 2 (Concentrate) (Green Light, A Valent U.S.A. Company)
- Green Light® Lawn & Garden Spray with Spinosad® 2 (Ready-to-Spray) (Green Light, A Valent U.S.A. Company)
- Green Light® Fire Ant Control with Conserve® (Green Light Company)
- Justice™ Insect Control (Dow Agrosciences, LLC)
- Monterey Garden Insect Spray (Lawn and Garden Products, Inc.)
- Natular T30 (Clarke Mosquito Control Products, Inc.)
- Natular XRT (Clarke Mosquito Control Products, Inc.)
- Natular™ G30 (Clarke Mosquito Control Products, Inc.)
- Natular™ G (Clarke Mosquito Control Products, Inc.)
- Neudorff Bug Bait (W Neudorff GmbH KG)
- Ortho® ecosense™ brand fire ant bait granules (The Ortho Group)
- Seduce® Insect Bait (Certis USA)
- Spinosad 0.5% SC (Dow Agrosciences, LLC)

Sticky Traps and Barriers

May be used as an insecticide if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- Tangle-Trap® Sticky Coating Paste Formula (The Tanglefoot Co.)
- Tree Tanglefoot Insect Barrier (The Tanglefoot Co.)

Streptomycin Sulfate

May be used to control fireblight on apples and pears if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- Agri-Mycin® 17 Agricultural Streptomycin (NuFarm Americas, Inc.)

Sucrose Octanoate Ester (CAS #s 49522-74-7; 58064-47-4)

May only be used in accordance with approved labeling and only if the requirements of 205.206(e) are met.

- Natural Forces SucraShield™ (Natural Forces LLC)

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OMRI Products List, Web Edition

Crop Products

Sulfur – elemental

May be used as a plant **disease** control or an insecticide (including acaricide or mite control) if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- Golden Micronized Sulfur (Wilbur-Ellis Company)
- ProGanic Micronized Sulfur (Wilbur-Ellis Company)
- Cosavet DF® (Sulphur Mills, Ltd.)
- CSC 80% Thiosperse (Martin Operating Partnership, L.P.)
- CSC Dusting Sulfur (Martin Operating Partnership, L.P.)
- Dusting Sulfur (Wilbur-Ellis Company)
- Dusting Sulfur **Fungicide** Insecticide (Loveland Products, Inc.)
- IAP Dusting Sulfur (Independent Agribusiness Professionals)
- InteGro Magic Sulfur Dust (InteGro, Inc.)
- INTEGRO MAGNETIC SULFUR DUST (InteGro, Inc.)
- Kumuluf DF (BASF Sparks LLC)
- Kumuluf DF (Arysta LifeScience North America Corporation)
- Micro Sulf® (NuFarm Americas, Inc.)
- Microthiol Dispers (United Phosphorus Inc.)
- pht® Dryout Dust (Britz-Simplot Grower Solutions LLC)
- Safer® Brand Garden **Fungicide** II (Woodstream Corporation)
- Special Electric® (Wilbur-Ellis Company)
- Sulfur DF (Wilbur-Ellis Company)
- Wilbur-Ellis Ben-Sul 85 (Wilbur-Ellis Company)

Tetracycline

For use as a fire blight control and for use only until October 21, 2012, if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- Mycoshield® (NuFarm Americas, Inc.)

Trichoderma spp.

May be used if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- ✘ Bioben (Biokrone, S.A. de C.V.)
- ✘ NatuControl® (Biokrone, S.A. de C.V.)
- ✘ PHC® PlanterBox® (Plant Health Care de México, S. de R.L. de C.V.)
- ✘ PHC® T-22® (Plant Health Care de México, S. de R.L. de C.V.)
- Plant Shield® HC Biological **Fungicide** (BioWorks, Inc.)
- RootShield® Granules (BioWorks, Inc.)
- RootShield® Home & Garden Biological **Fungicide** (BioWorks, Inc.)
- T-22™ HC Biological **Fungicide** (BioWorks, Inc.)
- T-22™ Planter Box Biological **Fungicide** (BioWorks, Inc.)
- Tenet™ WP (Isagro USA)

Virus Sprays

For use as a pest lure, repellent, or as part of a trap, or as a **disease** control. May be used for other pesticidal purposes only if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- CYD-X® Insecticidal Virus (Certis USA)
- CYD-X® HP Insecticidal Virus (Certis USA)
- Gemstar® LC Insecticidal Virus (Concentrate) (Certis USA)
- Spod-X® LC Insecticidal Virus (Concentrate) (Certis USA)
- Virosoft CP4 (Biotepp, Inc.)

Vitamin D3

May be used as a pesticide if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and **disease** management practices.

- Agri3® Bait Chunx® (Motomco)
- Agri3® Pelleted Bait (Motomco)
- Terad3® Ag Blox (Bell Laboratories, Inc.)
- Terad3® Ag Pellets (Bell Laboratories, Inc.)

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