

68173-1

8/29/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Kaken Pharmaceutical Co., Ltd.  
c/o Cynthia Ann Smith  
Conn & Smith, Inc.  
6713 Catskill Road  
Lorton, VA 22079-1113

**AUG 29 2012**

Subject: Registration Amendment to expand the tolerance exemption to all food commodities for the active ingredient, polyoxin D zinc salt, and add all food commodities to the label.  
Polyoxin D Zinc Salt Technical  
EPA Reg. No.: 68173-1  
Your submission dated November 15, 2011  
Decision Number: 457591, PRIA Category B631

Dear Ms. Smith:

The amendment referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(5), is acceptable provided that you:

- 1) Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2) Submit two (2) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Should you have any questions, you may contact Mr. Colin Walsh directly at (703) 308-0298 or via email at [walsh.colin@epa.gov](mailto:walsh.colin@epa.gov).

Sincerely,

Linda A. Hollis, Chief  
Biochemical Pesticides Branch

CONCURRENT BUSINESS Pesticides and Pollution

SYMBOL	7511P						
SURNAME	Walsh						
DATE	8/29/12						

Polyoxin D Zinc Salt Technical (EPA Reg. No. 68173-1)  
 August 24, 2012 revised proposed label based upon comments received by email on August 23, 2012 regarding the  
 November 15, 2011 proposed amended label to permit use on all for and feed crops  
 Changes implemented.  
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**ACCEPTED**

Polyoxin D Zinc Salt Technical

AUG 29 2012

For Manufacturing Use Only

Under the Federal Insecticide, Fungicide,  
 and Rodenticide Act, as amended, for  
 the pesticide registered under  
 EPA Reg. No. 68173-1

<b>GROUP</b>	<b>19</b>	<b>FUNGICIDE</b>
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<b>Active Ingredient:</b>	
Polyoxin D zinc salt (1:1) <sup>1</sup> ,	
Zinc 5-[[2-amino-5-O-(aminocarbonyl)-2-deoxy-L-xylonyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2H)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronate	23.8%
<b>Other Ingredients:</b>	76.2%
<b>Total:</b>	100.0%

Equivalent to 21.1% polyoxorim and 2.65% metallic zinc.

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

<b>FIRST AID</b>	
If on skin or clothing	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
If in eyes	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
If swallowed	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
If inhaled	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferable by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>HOTLINE NUMBER</b>	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
<p align="center"><b>FOR 24-HOUR EMERGENCY MEDICAL ASSISTANCE:</b>            Call CHEMTREC at 1-800-424-9300 or POISON CONTROL CENTER at 1-800-222-1222            or 1-703-527-3887 if calling from outside of the U.S.</p>	

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**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

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

**ENVIRONMENTAL HAZARDS**

This pesticide 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.

**DIRECTIONS FOR USE**

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

Polyoxin D Zinc Salt Technical is for manufacturing use only for the production of fungicide formulations for use on all food and feed crops (pre-harvest and post-harvest), ornamentals, golf courses, residential lawns, parks, and commercial and institutional grounds.

**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 HANDLING:** Nonrefillable container. Do not reuse or refill this container. Completely empty bag into manufacturing equipment. Then 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 ASSISTANCE:**

(Spill, leak, fire, exposure or accident), call CHEMTREC 1-800-424-9300  
or 1-703-527-3887 if calling from outside of the U.S.

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### 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 in the Directions for Use, subject to the inherent risks described above, when used in accordance with the Directions for Use under normal conditions.
2. 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.**
3. **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.**

EPA Reg. No: 68173-1

EPA Est. No: 68173-JP-001

Net Contents:

Produced by:

Kaken Pharmaceutical Co., Ltd.

Agrochemicals & Animal Health Products Division

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