

endothall. Endothall appears to be chemically and toxicologically dissimilar to existing chemical substances. Therefore, cumulative risk should not be an issue for this chemical.

#### *E. Safety Determination*

1. *U.S. population.* For chronic dietary risk, two scenarios were used. Scenario 1 used tolerance values on all registered and proposed crops, as well as secondary residues in meat, milk, and eggs, shellfish, fish, catfish, and crayfish. Under this scenario, less than 5% of the RfD for the total U.S. population was utilized. Because of the high milk consumption by children ages 1–6, this group represents the highest exposed subgroup. For children ages 1–6, approximately 12.4% of the RfD is utilized. In the second scenario which included the above food exposure from above plus tap water and non-food based water, 28.3% of the RfD was utilized for the total U.S. population. Because of high water consumption likely from reconstituted formula, all infants utilized 103.7% of the RfD and non-nursing infants utilized 130.7% of the RfD. This scenario, however, is not considered a realistic estimate of risk. It is unlikely that endothall residues would be significant in water considering its intermittent and seasonal use pattern, lack of movement in surface water, rapid degradation and label restriction for application within 600 feet of a potable water intake. The acute dietary risk analysis has been performed using TAS-Exposure software which gives a distributional analysis of exposure. For the total U.S. population, children ages 7–12, and women ages 13 to 50 all MOEs exceeded 1,000 at the 95<sup>th</sup> percentile of exposure for the first scenario (excluding water). Under this scenario, all infants, non-nursing infants <1-year and children ages 1–6 had MOEs of 935, 852, and 988, respectively. When tap water and non-food based water are included in the analysis at tolerance level (0.2 ppm), the highest exposed subpopulation is again non-nursing infants with an MOE of 98 at the 95<sup>th</sup> percentile of exposure. For the total U.S. population the 95<sup>th</sup> percentile of exposure results in an MOE of 373. This analysis included all commodities, including water, at theoretical “worst case” levels resulting in an extreme over estimation of acute risk from dietary exposure to potential endothall residues. This analysis has not included estimates of anticipated residues, percent of crop treated, or the likelihood of residues in water accounting for endothall’s use pattern, movement and degradation. Additionally, processing effects on

residue levels have not been considered. Despite all of the worst case assumptions, the dietary exposure analysis for the U.S. population, and all population subgroups except all infants and non-nursing infants <1-year results in acceptable MOE, i.e., >100. The MOE for all infants and non-nursing infants <1-year were 99 and 98, respectively. Clearly these MOEs in this worst case assessment would exceed 100 if adjustments described above were applied.

2. *Infants and children.* The exposure to infants and children has been calculated in both the acute and chronic dietary assessments. In all cases and all age groups of infants and children, the margins of exposure are sufficient to protect the health of infants and children.

#### *F. International Tolerances*

No international tolerances have been established for endothall.

[FR Doc. 01–3092 Filed 2–6–01; 8:45 am]

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### ENVIRONMENTAL PROTECTION AGENCY

[OPP–00697; FRL–6765–5]

#### Acute Toxicity Data Requirements For Granular Pesticide Products, Including those with Granular Fertilizers in the Product; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

**SUMMARY:** EPA is announcing the availability of guidance which intends to streamline the acute toxicity review and classification process for certain granular pesticide products, including those products that contain granular fertilizers. The policies should achieve the following objectives: Significantly reduce the number of animals subject to testing; reduce the use of Agency resources while maintaining protection of the public health and environment, and decrease the time required to register qualifying granular pesticide products. Pesticide Registration (PR) Notice 2001–2 is effective now, but comments will be accepted for 30 days, after which the Agency may revise the notice.

**DATES:** Comments, identified by docket control number OPP–00697, must be received on or before March 9, 2001.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as

provided in Unit I. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–00697 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: John Redden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–1969; fax number: (703) 308–9382; e-mail address: [redden.john@epa.gov](mailto:redden.john@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. General Information**

###### *A. Does this Action Apply to Me?*

This action is directed to the public in general. This action may, however, be of interest to those persons who are required to conduct testing of chemical substances under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. 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 Get Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document and the PR Notice from the Office of Pesticide Programs’ Home Page at <http://www.epa.gov/pesticides/>. You can also go directly to the listings from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select “Laws and Regulations,” “Regulations and Proposed Rules,” and then look up the entry for this document under the “**Federal Register**—Environmental Documents.” You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *Fax-on-demand.* You may request a faxed copy of the PR Notice titled, “Acute Toxicity Data Requirements For Granular Pesticide Products, Including those with Granular Fertilizers in the Product,” by using a faxphone to call (202) 401–0527 and selecting item 6136. You may also follow the automated menu.

3. *In person.* The Agency has established an official record for this action under docket control number OPP–00697. The official record consists of the documents specifically referenced

in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

#### *C. How and to Whom Do I Submit Comments?*

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-00697 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov), or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP-00697. Electronic comments may

also be filed online at many Federal Depository Libraries.

#### *D. How Should I Handle CBI that I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this notice.
8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## **II. Background**

#### *A. What Guidance Does This PR Notice Provide?*

This Pesticide Registration (PR) Notice provides a policy intended to streamline the acute toxicity review and classification process for certain granular pesticide products, including those products that contain granular

fertilizers. The policies should achieve the following objectives: Significantly reduce the number of animals subject to testing; reduce the use of Agency resources while maintaining protection of the public health and environment, and decrease the time required to register qualifying granular pesticide products. This guidance is supported by a large toxicology data base and involves the application of sound scientific principles. This notice is effective immediately, but comments will be accepted for 30 days, after which the Agency may revise the notice.

#### *B. PR Notices are Guidance Documents*

The PR Notice discussed in this notice provides guidance to EPA personnel and decision makers and to pesticide registrants. This notice is not binding on either EPA or pesticide registrants, and EPA may depart from the guidance where circumstances warrant and without prior notice. Likewise, pesticide registrants may assert that the guidance is not appropriate generally or not applicable to a specific pesticide or situation.

#### **List of Subjects**

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

Dated: January 22, 2001.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

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## **ENVIRONMENTAL PROTECTION AGENCY**

[OPPTS-51961; FRL-6763-9]

### **Certain New Chemicals; Receipt and Status Information**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory) to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish a notice of receipt of a premanufacture notice (PMN) or an application for a test marketing exemption (TME), and to publish