



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND  
TOXIC SUBSTANCES

Fax On Demand  
Item Number

January, 8 2001

**PESTICIDE REGISTRATION (PR) NOTICE 2001-2**

**NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND  
REGISTRANTS OF PESTICIDE PRODUCTS**

**ATTENTION:** Persons Responsible for the Registration and Reregistration of Pesticides

**SUBJECT:** Acute Toxicity Data Requirements For Granular Pesticide Products, Including Those With Granular Fertilizers in the Product.

This PR Notice announces guidance intended to streamline the acute toxicity review and classification process for certain granular pesticide products, including those products that contain granular fertilizers. Based on OPP's extensive experience with granular pesticide products, the Agency believes that an effective precautionary labeling policy can be implemented without testing of each individual product. Please refer to Section IV on how OPP will implement this guidance. This guidance is supported by a large toxicology data base and involves the application of sound scientific principles. This guidance should achieve the following objectives: (1) significantly reduce the number of animals subject to testing; (2) reduce the use of Agency resources while maintaining protection of the public health and environment; and (3) decrease the time required to register qualifying granular pesticide products. This notice is effective immediately, but comments will be accepted for 30 days, after which the Agency may revise the notice.

**I. Background**

FIFRA and Agency regulations require that each pesticide product bear on the label danger, warning or caution statements. The signal word and precautionary statements are based on the acute toxicity category of the pesticide, which is designed to protect the public health. This labeling informs pesticide users/workers of the acute health hazards from exposure to the pesticides and what precautions should be taken to mitigate adverse effects. To

determine the appropriate human hazard signal word and label instructions the Agency evaluates six acute toxicological studies: acute oral toxicity (870.1100), acute dermal toxicity (870.1200), acute inhalation toxicity (870.1300), eye irritation (870.2400), dermal irritation (870.2500) and dermal sensitization (870.2600). The Series 870 numbers are the new guideline numbers which previously appeared in 40 CFR 158.340 as guidelines § 81-1 through § 81-6.

Pesticide products are generally composed of the active ingredient(s) and inert ingredient(s). This notice refers to those granular pesticide products that are composed of a registered source product at less than 10% active ingredient, one or more clearly recognized innocuous (List 4) inert carrier(s) and/or a fertilizer component(s) at greater than 90% and a sticker/binder (5% of the formulation). Innocuous inerts (List 4) are carriers that are considered to be chemically inactive based on available information and experience. Inerts in this category include corncobs, clay, limestone, sand or food, etc.

This policy only applies to granular pesticide products and granular fertilizer pesticide products. The Agency will not extrapolate for other products, because; 1) the LD<sub>50</sub> is imprecise (dilution does not always equal reduced toxicity); 2) a complete dose response curve, required at a minimum, is rarely available; and 3) the Agency does not have a database that indicates that dilution always means reduced toxicity.

## **II. Products Affected By the Guidance**

### **A. Granular Pesticide Products**

For purposes of this guidance, the Agency defines granular pesticide products to include those products composed of less than 10% of a registered active ingredient(s), greater than 90% of List 4 inert carrier(s) (corn cobs, clay, limestone, sand, food) and a minimal amount of sticker/binder (5% or less of the formulation).

If the acute toxicity profile of the registered source product(s) is in Category III or IV for all endpoints, then the proposed pesticide product may use the acute toxicity profile of the registered source product.

In addition, for systemic toxicity (i.e. acute oral, dermal and inhalation) endpoints, it is acceptable to extrapolate Category III data down to Category IV. This extrapolation for acute systemic toxicity is based on dilution. The assumption is that the innocuous inert does not contribute to the toxicity, and thus acts as a diluent. If an extrapolated dose is borderline between two toxicity categories, the Agency will label with the more restrictive toxicity category.

If the primary eye and dermal irritation effects are classified in Category III and/or IV, the categories of the source registered product may be used for the proposed pesticide product

and the toxicity profile will be complete.

**EXAMPLE 1:**

Source Product Study	Toxicity Category	Toxicity Category for Granular Product
Acute oral LD50	III	IV
Acute dermal LD50	III	IV
Acute inhalation LD50	III	IV
Primary Eye Irritation	III	III
Primary Skin Irritation	III	III
Skin Sensitization	Non-sensitizer	Non-sensitizer

If the acute LD<sub>50</sub>, dermal LD<sub>50</sub>, Inhalation LD<sub>50</sub>, primary dermal and/or eye irritation effects for the registered product(s) are classified in Category I and/or II, then the Agency will not accept calculations that bridge down from these categories and additional data would be required for the proposed pesticide product. Either these studies would need to be submitted, or the registrant would need to cite data on a substantially similar product.

**EXAMPLE 2:**

Source Product Study	Toxicity Category	Toxicity Category for Granular Product
Acute oral LD50	II	II
Acute dermal LD50	II	II
Acute inhalation LD50	I	I
Primary Eye Irritation	III	III
Primary Skin Irritation	III	III
Skin Sensitization	Non-sensitizer	Non-sensitizer

For dermal sensitization, if a granular product contains any ingredient which is a known sensitizer, the formulated product would be labeled as a sensitizer. If the product is not a dermal sensitizer, and there are no known dermal sensitizers in the product, a dermal sensitization study may be waived and the product will not require sensitization labeling. If dermal sensitization data on a substantially similar product indicates no dermal sensitization at low concentrations, these data may be cited in support of the product. This determination will be made with data on the active ingredient or information provided by the registrant on an inert (e.g., Material Safety Data Sheet - MSDS). If the registrant knows there is a sensitizing component and can justify the finding, the Agency will not require testing.

**B. Granular Fertilizer Pesticide Products**

For purposes of this guidance, EPA defines granular fertilizer pesticide products to include those products composed of less than 10% of a registered active ingredient(s), greater than 90% granular fertilizer components plus clearly recognized innocuous (List 4) inert

carrier(s), and a minimal amount of sticker/binder (5% or less of the formulation).

The fertilizer components of these products are considered analogous to the innocuous inert described above with the exception of eye irritation. In some cases, fertilizer products are more irritating to the eye than the comparable non-fertilizer granular products. Therefore, the primary eye irritation results may not be bridged under this guidance. A separate eye irritation study is expected to be performed with the pesticide/fertilizer formulation containing the highest free level of nitrogen. If, at some point, the nitrogen content of the fertilizer component is increased above the tested level, a new primary eye irritation study will be required.

### **III. Exclusions To This PR**

Rodenticide baits are not included in this policy. In the Agency's experience, rodenticide baits are often more toxic than would be predicted using the bridging methods outlined above. In general, the Agency will continue to allow similar baits to use one set of data for purposes of precautionary labeling.

### **IV. What Registrants And Applicants Should Do**

The registrant should submit the following information with the application: (1) request in writing that the Agency apply this guidance to their product; (2) the acute toxicity profile (with corresponding MRID Numbers) for the registered product(s); and (3) the current label for the registered product(s). The Agency will use this information to determine an acute toxicity profile for the product.

### **VI. Non-Binding Statement**

This PR Notice provides guidance to EPA and to pesticide registrants. This notice is not binding on either EPA or pesticide registrants, and EPA may depart from the guidance provided in individual circumstances. Likewise, pesticide registrants may assert that the guidance is not appropriate for a specific pesticide or situation.

### **VI. Additional Information**

You may contact:     John Redden  
                                 Registration Division (7505C), USEPA  
                                 401 M Street, SW  
                                 Washington, DC 20460  
                                 (703) 305-1969  
                                 [redden.john@epa.gov](mailto:redden.john@epa.gov)

James J. Jones, Director  
Registration Division

FILE NAME: pnshell.wpd (11/1/2000)

**ENVIRONMENTAL PROTECTION AGENCY**

**[OPP-00XXX; FRL-XXXX-X]**

*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.

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**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: (1) significantly reduce the number of animals subject to testing; (2) reduce the use of Agency resources while maintaining protection of the public health and environment; and (3) 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:** 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. Comments, identified by docket control number OPP-XXXXX, must be received on or before *30 days after date of publication in the Federal Register*].

**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-XXXXX in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** *John Redden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 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 or may be 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 certain other related documents that might be available electronically, 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) XXX-XXXX and selecting item XXXX. You may also follow the automated menu.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-XXXXXX. 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-XXXXXX 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, 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-XXXXXX. 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: (1) significantly reduce the number of animals subject to testing; (2) reduce the use of Agency resources while maintaining protection of the public health and environment; and (3) 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.*

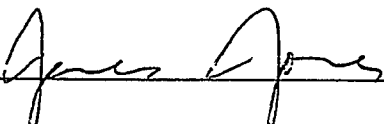
### B. PR Notices are Guidance Documents

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, *granular pesticide products, granular fertilizers, Precautionary Labeling.*

Dated: 1/8/01

  
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 James J. Jones, Director  
 Registration Division (7505C)

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]  
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