

US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (75-767) WASHINGTON, DC 20460 NOTICE OF PESTICIDE: <input type="checkbox"/> REGISTRATION <input checked="" type="checkbox"/> REREGISTRATION <i>(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</i>	EPA REGISTRATION NO. 53219-6	DATE OF ISSUANCE SEP 28 1995
	TERM OF ISSUANCE	
	NAME OF PESTICIDE PRODUCT M-Pede® Insecticide	

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Timothy P. Debus
 Mycogen Corporation
 4980 Carroll Canyon Road
 San Diego, CA 92121

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

Based on your response to the Reregistration Eligibility Document, the product listed above is reregistered provided that you make the following changes to your label:

1) The signal word for this product is "DANGER" based on the results of the primary eye irritation study.

2) The precautionary statements must state:

"Corrosive. Causes irreversible eye damage and skin irritation. Harmful if inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist or vapor. Wear goggles or safety glasses. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse."

3) The statements of practical treatment must state:

If in eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.
If on skin: Wash with plenty of soap and water. Get medical attention.
If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention."

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ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL: *[Signature]* DATE: _____

The following background information is provided to describe how the Agency determined that the signal word should be "Danger" for this product.

You cited a complete series of acute toxicity studies to support "M-Pede Insecticide" (EPA Reg. No. 53219-6) in response to the Soap Salts RED. The acute oral toxicity, acute dermal toxicity, primary eye irritation and dermal sensitization studies were conducted using Safer Insecticidal Soap Concentrate (EPA Reg. No. 42697-1). Both of these products were placed in Soap Salts RED batch #3. However, you chose to cite an acute inhalation toxicity study and an additional primary eye irritation study conducted using "M-Pede" (EPA Reg. No. 53219-6). This additional primary eye irritation study was assigned toxicity category I.

You then submitted an addendum to the study rebutting the toxicity category I classification. The following references were cited but not submitted:

- a. Chambers, W.A. et al., 1993. Scoring for Eye Irritation Tests. Food Chem. Toxic. 31:111-115.
- b. Gupta, K.C. et al., 1993. An Eye Irritation Test Protocol and an Evaluation and Classification System. Food Chem. Toxic. 31:117-121.
- c. Springer, J.A., et al., 1993. Number of Animals for Sequential Testing. Food Chem. Toxic. 31:105-109.

The Gupta, et al. article states: "The material is classified as a severe irritant when the rabbit in the one-animal test or two or more rabbits in the standard test have responses of corneal opacity of 3 or above and iritis of 2 at 24, 48, or 72 hours, or positive responses on day 7 after instillation."

In a letter to the Agency, you stated that this product should be placed into toxicity category II instead of category I for the following reasons:

Mycogen Rebuttal:

- "1. Only 1 rabbit out of a total of 9 rabbits tested had opacities that did not reverse within 21 days.
- 2. Only 1 rabbit had a corneal opacity score greater than 1; this is the same rabbit discussed in (1) above.
- 3. Extending the conclusions of the Springer et al. paper to situations such as this, in which only one rabbit is affected in a much more severe manner than the other rabbits on test, the finding in this rabbit can be considered a "false positive" as far as a Toxicity Category I classification is concerned.
- 4. M-Pede is not corrosive and therefore should be classified separately and labeled differently than a corrosive material."

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EPA Response:

1. The addendum stated that only 1 of 9 animals tested displayed corneal opacity on day 21. The Agency scores "washed" and "unwashed eye separately, because of different exposure times. Therefore, it would be 1/6 and 0/3 with opacity at day 21. The product is placed into toxicity category I because of corrosiveness (irreversible destruction of ocular tissue) or corneal involvement persisting for more than 21 days.

2. The registrant has not demonstrated that the test material is not corrosive. In fact, in a primary dermal irritation study (MRID no. 429364-01) of M-Pede, the Agency evaluated the data and placed it into toxicity category I (Corrosive).

3. The seven published papers by Gupta, Springer, Chambers and others in the Journal of Food and Chemical Toxicology (Vol. 31, #2, Feb. 1993) are technical proposals and not formal statements of policy made on the behalf of EPA or other federal regulatory agencies. For opacity at 21 days, it is our policy to place the product into toxicity category I.

4. One animal's exhibition of opacity that is not consistent with the other animals in a study does not invalidate the animal's response.

Another argument that you gave to decrease the toxicity category for this study was that a primary eye irritation study with similar results (accession number 00260353) was previously graded toxicity category II by the Agency and the California Department of Pesticide Regulation. This issue was recently discussed at an internal Peer Review meeting which included toxicologists from the Health Effects Division and Precautionary Review Section. They determined that this product qualifies for a toxicity category I for primary eye irritation because the product induced corneal opacity in one of the six test animals that was still present on day 21. The primary eye irritation categories are based on valid data and we feel that we must base the products labeling on this data until given a substantial reason to do otherwise.

We would like to note that the intent of batching is that all products within a batch might cite or submit the same set of data in order to reduce the amount of work to be done by industry and the Agency. However, if registrants choose to cite separate studies, there is a possibility for batch products to have conflicting study results. The formulations of products within a batch tend to be very similar; however, these formulations are not usually identical. Batching is not exact enough to negate variations in product formulas that may account for differences in the outcome of acute toxicity studies. In these situations, it is the Agency's responsibility to assess precautionary labeling based on data gathered on that product itself, rather than studies submitted to support the batch or another product within the batch.

CONCURRENCES

SYMBOL							
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We are not sure why additional studies were conducted when there were already studies cited for the batch. We speculate that you were unhappy with the toxicity category II rating assigned to 42697-1 and felt that if you had new studies conducted, you could obtain lower toxicity categories for 53219-6. However, studies conducted on 53219-6 did not turn out to provide a lower toxicity category for eye irritation.

This action is taken under the authority of section 4(g)(2)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.

The Agency may bring misbranding action under section 12(a)(1)(E) of FIFRA or may cancel or suspend the registration of your product under section 6 if you distribute or sell products not bearing revised labeling after 45 days from the receipt of this letter. Because of the time frame set forth above, registrants may sticker over the current label with the new signal word and precautionary labeling specified in this letter without receiving prior approval of amended labeling. However, registrants must also submit amended labeling to Product Manager 14, Registration Division (7505C) for Agency approval within 30 days of their receipt of this letter.

You are also required to correct the labeling of products under your custody and control (i.e., warehouses, etc...). You are not required to sticker over stocks in the channels of trade.

Submit one copy of the final printed label before releasing the product for shipment with the revised labeling. A copy of the stamped label is enclosed. If you have any questions about this letter, please contact Beth Edwards at (703) 305-5400 or (703) 305-6600.

Sincerely yours,



Robert A. Forrest
Product Manager (14)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

M-PEDE®

INSECTICIDE

FOR COMMERCIAL USE

ACTIVE INGREDIENT

Potassium salts of fatty acids.....49%

INERT INGREDIENTS.....51%

TOTAL.....100%

KEEP OUT OF REACH OF CHILDREN

WARNING

See side and back panels for additional precautionary statements

EPA Registration No. 53219-6

Net Contents: 2½ gallons

EPA Establishment No. 907-TN-01 4091-CA-01 4091-TN-03

M-Pede is a registered trademark of Mycogen Corporation.

ACCEPTED
with COMMENTS
in EPA Letter Dated

SEP 28 1995



Mycogen Corporation
4980 Carroll Canyon Road
San Diego, California 92121
(800-745-7476)

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this pesticide is registered under EPA Reg. No.

53219-6

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label before using this product.

GENERAL INFORMATION

This product controls adelgids, aphids, earwigs, lace bugs, leafhoppers, mealybugs, plant bugs, psyllids, sawfly larvae, scales, spider mites, tent caterpillars, thrips, whitefly and woolly aphids on vegetables, fruits, tree nuts, shrubs, trees, foliage plants and flowers.

This product can be applied up to harvest.

This product also provides curative control of powdery mildew on grapes and roses.

PRECAUTIONARY STATEMENTS

WARNING

Hazards to Humans and Domestic Animals: Causes skin irritation. Causes substantial but temporary eye injury. Do not get in eyes, on skin or on clothing. Wear goggles or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

First Aid: If in eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes.

If on skin: Wash with plenty of soap and water. Get medical attention.

If swallowed: Drink promptly a large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol.

Environmental Hazards: This product may be hazardous to aquatic invertebrates. Do not apply directly to water, areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of water.

Physical or Chemical Hazards: Flammable. Keep away from heat or open flame.

For emergency medical information, call toll free 1-800-228-5635

MIXING AND APPLICATION

For best results, use freshly mixed solution with soft water. If water has a high mineral content, check for compatibility. If needed, soften water with an approved softening agent before adding this product. A defoaming agent may be needed for use in sprayers equipped with an agitator.

Do not use on new transplants, unrooted cuttings or plants stressed by drought. Avoid application when leaf temperature exceeds 90°F.

When combined with other pesticides:

This product may be combined with other pesticides to broaden the target spectrum. Such use must conform to use precautions and directions for use of both products. This product should be tank mixed at a rate of 1 to 2 parts product per 100 parts of spray solution containing the companion pesticide.

Recommended Rates:

INSECTICIDAL USE

VEGETABLES, HERBS AND SPICES

Root and tuber vegetables	Insects and Mites: For control of whiteflies, aphids, leafhoppers, plant bugs, spider mites and thrips on the crops listed at left Rate: Mix 1 part product per 50 parts water or 2 ½ oz. product per gallon water. Comments: Apply this product when insects or mites first appear, or when damage first occurs. Spray to wet all infested plant surfaces. Repeat at weekly to biweekly intervals. Rotate sprays or rinse foliage to avoid more than three consecutive sprays. Use up to day of harvest. Use includes crops grown in greenhouses and outdoors.
Bulb vegetables	
Leafy vegetables	
Brassica (cole) vegetables	
Legume vegetables	
Fruiting vegetables	
Cucurbit vegetables	
Asparagus	
Herbs and spices	

OTHER CROPS

<p>Cotton</p>	<p>Insects and Mites: For control of whiteflies, aphids, leafhoppers, plant bugs, spider mites and thrips.</p> <p>Rate: In concentrate applications use up to 2 quarts M-Pede per acre alone or in tank mix.</p> <p>Use between 3 to 20 gallons of water per acre.</p> <p>Comments: Apply this product when insects or mites first appear, or when damage first occurs. Spray to wet all infested plant surfaces. Repeat at weekly to biweekly intervals. Rotate sprays or rinse foliage to avoid more than three consecutive sprays. Use up to day of harvest.</p>
<p>Tobacco Hops Peanuts Wheat Coffee Alfalfa Canola Artichokes Watercress Bananas Pineapple</p>	<p>Insects and Mites: For control of whiteflies, aphids, scales, leafhoppers, plant bugs, spider mites and thrips on the crops listed at left.</p> <p>Rate: Mix 1 part product per 50 parts water or 2 ½ oz. product per gallon water.</p> <p>Comments: Apply this product when insects or mites first appear, or when damage first occurs. Spray to wet all infested plant surfaces. Repeat at weekly to biweekly intervals. Rotate sprays or rinse foliage to avoid more than three consecutive sprays. Use up to day of harvest. Use includes crops grown in greenhouses and outdoors.</p>

FRUIT AND NUT CROPS

<p>Citrus Pome fruits Stone fruits Small fruits and berries Tree nuts</p>	<p>Insects and Mites: For control of whiteflies, aphids, scale crawlers, pear psylla, pear slug (sawfly larvae), leafhoppers, and spider mites on the crops listed at left.</p> <p>Rate: Mix 1 part product per 50 parts water or 2 ½ oz. product per gallon water.</p> <p>Comments: Apply this product when insects first appear. Apply to achieve thorough coverage of infested foliage and/or branches. Repeat at weekly intervals as needed. Avoid spraying when the blossoms are present. Use up to day of harvest.</p>
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NOTE: If sooty mold is present on citrus, some marking of fruit may occur. Some marking of fruit may occur in some pome fruit varieties.

ORNAMENTAL LANDSCAPE TREES AND SHRUBS

Insect	Rate	Comments
adelgids, psyllids, scales	1 part product per 50 parts water, or 2½ oz. product per gallon of water	Spray to wet bark surface
spider mites	1 part product per 50 parts water, or 2½ oz. product per gallon of water	Wet underside of leaves and needle sheaths.
tent caterpillars	1 part product per 30 parts water, or 4 oz. product per gallon of water	Spray directly on young larvae when congregated on outside of tent.
balsam woolly aphid	1 part product per 80 parts water, or 1½ oz. product per gallon of water	Spray trees thoroughly when crawlers are abundant in early spring and/or fall. Make a second application after 10 days.
spruce woolly aphid	1 part product per 25 parts water, or 5 oz. product per gallon of water	Spray spruce in fall or spring when females begin egg laying.
conifer and pine needle scale	1 part product per 40 parts water, or 3 oz. product per gallon of water	When insects first appear, spray to thoroughly wet foliage.

NOTE: Do not apply to horse chestnut, Japanese maple or mountain ash. Do not apply to evergreens during drought or when tender new foliage is present.

FLOWERS AND BEDDING

For control of adelgids, aphids, earwigs, lace bugs, leafhoppers, mealybugs, plant bugs, psyllids, scales, spider mites, thrips and whiteflies on plants listed below.

Crop	Rate	Comments
ornamentals grown outdoors or in greenhouses	1 part product per 50 parts water, or 2½ oz. product per gallon of water	Apply when insects first appear. Thoroughly wet all infested plant surfaces. Repeat weekly as needed. For earwigs, spray directly on insects after disturbing their hiding place.
indoor plants	1 part product per 50 parts water, or 2½ oz. product per gallon of water	Thoroughly wet all surfaces of infested foliage and branches. For aphids, examine plants after two days and spray again if needed. For other pests, spray weekly as needed. For blossom thrips on African violets, spray to contact thrips on blooms.

NOTE: Rotate sprays or rinse foliage to avoid more than 3 consecutive sprays. Do not use on bleeding heart, gardenia, jade plant, lantana or sweetpeas or Crown of Thorns. Test other euphorbia for phytotoxicity before full scale application. Test first on azaleas, begonias, camellias, fuchsias, impatiens, delicate ferns, ornamental ivies, palms or succulents. If wilting occurs within a few hours, rinse with clean water spray.

TURF

Turf	<p>Insects: For control of mole crickets, chinch bugs, sod webworms, fleas, grubs</p> <p>Rate: Mix 1 part product per 50 parts water or 2 ½ oz. product per gallon water.</p> <p>Comments: Apply in a total water volume of 100 gpa. For best results, an irrigation equal to 600 gal. per 1000 sq. ft. should be applied immediately following treatment.</p>
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FUNGICIDAL USE

This product provides curative control of powdery mildew on plants listed below.

Crop	Rate	Comments
Grapes	Mix 1 to 2 parts product per 100 parts water. Application of 100 to 150 gallons of water per acre normally provides adequate coverage. Use the higher rates and higher volumes when powdery mildew pressure is high.	Best results are obtained by initiating applications at bud break. To be effective, this product must come into direct contact with the powdery mildew fungus. Complete coverage of upper and lower leaf surfaces as well as grape clusters is essential. Apply every 7 to 14 days, or as needed. This product may alter the waxy bloom and/or cause marking on the surface of grapes that can affect the quality rating of table grapes at harvest.
Roses	Mix 1 to 2 parts product per 100 parts water. Use the higher rates if powdery mildew infections become heavy.	Begin application at first appearance of disease. To be effective, this product must come into direct contact with the powdery mildew fungus. Complete coverage of upper and lower leaf surfaces as well as canes is essential. Apply every 7 days, or as needed. Rotate sprays or rinse foliage with water to avoid more than 3 consecutive sprays.

Note: Do not combine with sulfur or apply within 3 days of a sulfur application. Foliage burn may occur if applied when temperatures exceed 90°F. Do not apply to Calmeria or Italia varieties of table grapes. Do not tank mix with gibberellic acid.

STORAGE AND DISPOSAL

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

STORAGE: Keep container tightly sealed when not in use. Store only in original container, in a dry place, inaccessible to children and pets.

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: Do not reuse empty container. Triple rinse, then offer for recycling or reconditioning, or puncture and dispose of in sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

LIMIT OF WARRANTY AND LIABILITY

This product conforms to the description on this label and is reasonably fit for the purposes set forth on this label when used according to the label directions and under the specified label conditions. THE MANUFACTURER DISCLAIMS ANY AND ALL OTHER EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PARTICULAR PURPOSE. Buyer and all users assume all risks and responsibility for loss or damage if this product is used, stored, handled or applied under any condition not reasonably foreseeable or beyond the manufacturer's control, or not as explicitly set forth in this label. THE LIMIT OF THE MANUFACTURER'S LIABILITY SHALL BE THE PURCHASEPRICE FOR THE QUANTITY INVCLVED IN NO EVENT SHALL THE MANUFACTURER BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES.