

8033-20

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



OFFICE OF
PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

February 12, 2010

John J. Wrubel
Nisso America, Inc.
45 Broadway, Suite 2120
New York, NY 10006

Dear Mr. Wrubel:

Subject: Amended labeling to add clover and greenhouse-grown tomatoes
Acetamiprid Technical
EPA Registration No. 8033-20
EPA Decision No. 408292
Your submission dated March 5, 2009; resubmission dated February 9, 2010

The proposed labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable with the following comments:

- On page 3, under the Storage and Disposal section, reorder the statements under the Container Disposal paragraph as follows: "Non-refillable container. Do not reuse or refill this container. Completely empty container into manufacturing equipment. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Offer for recycling if available."
- On page 3, under the Conditions paragraph, add a space between the words "must" and "be."
- Please add a U.S. address to the label.

A stamped copy of the label is enclosed for your records. Please submit two copies of your final printed labeling before you release the product for shipment. Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label or durably marked on the container itself. (This information can be added by non-notification/PR Notice 98-10). Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e).

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As a condition of registration, you must **submit the following within 18 months** from the date of this letter:

- Two clover field trials reflecting the same use pattern utilized in the submitted studies.
- Analytical standards for the IM-2-1 and IM-2-1-amide metabolites. Send the reference standards to the Analytical Chemistry Lab, to the attention of Theresa Cole, at the following address:

United States Environmental Protection Agency
National Pesticides Standards Repository
Analytical Chemistry Branch, Office of Pesticide Programs
Fort George G. Meade, MD 20755-5350
(Note that the mail will be returned if the extended zip code is not used)

- A study on photodegradation on soil (OPPTS Guideline 835.2410). The currently available study is not scientifically sound and does not satisfy Subdivision N Guideline data requirements for photodegradation in soil.
- Anaerobic soil metabolism studies (OPPTS Guideline 835.4200). No study has been submitted to date.
- A terrestrial field dissipation study (OPPTS Guideline 835.6100) to be conducted domestically and at the maximum label rate. The submitted studies are each considered to be supplemental.
- A study on acute effects (oral toxicity) to passerines (OPPTS Guideline 850.2100), a requirement recently added to the 40 CFR Part 158 (October 2007). Given that acetamiprid may pose a risk to avian species based on the available data, the submission of these data may affect the risk assessment, since passerines may be more sensitive than upland game or waterfowl species.

In addition, please note that the available avian reproduction study (OPPTS Guideline 850.2300) with mallard duck did not establish a definitive no-observed-adverse-effect concentration (NOAEC), an endpoint necessary to evaluate chronic risk to avian species. Without this endpoint, the Agency has to assume that acetamiprid use poses a chronic risk to birds, as well as reptiles and terrestrial-phase amphibians. The lack of these data will limit the flexibility the Agency and registrants have in coming into compliance with the Endangered Species Act in future assessments and could result in use restrictions for acetamiprid use that are unnecessarily severe.

Finally, please note that while acute oral and contact toxicity studies to individual adult honeybees are available, there are uncertainties regarding the toxicity to larvae and chronic toxicity at both the individual bee and colony level. It is not known if acetamiprid be stored in the hive (honey or bee bread). While several semi-field studies are available, no data are available regarding potential effects of acetamiprid on over-wintering success or whether colonies appear more susceptible to disease.

As a reminder, please note that the immunotoxicity study (OPPTS Guideline 870.7800) requested on January 14, 2009 is due July 14, 2010. This study is required under the new 40 CFR Part 158 data requirements.

If you have any questions, please contact Julie Chao by phone at: (703) 308-8735, or by email at: chao.julie@epa.gov.

Regards,



for Venus Eagle, PM01
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

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ACCEPTED
With COMMENTS
In EPA Letter Dated:
FEB 12 2010

DRAFT February 9, 2010

ACETAMIPRID Technical
For Manufacturing Use Only
Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No: 8033-20

ACTIVE INGREDIENT:
Acetamiprid, (E)-N¹-[(6-chloro-3-pyridyl)methyl]-N²-cyano-N¹-methylacetamidine 99.5% by wt.
INERT INGREDIENTS 0.5% by wt.

EPA Reg. No. 8033-20 EPA Est. No. _____

**KEEP OUT OF REACH OF CHILDREN
WARNING**

For MEDICAL and TRANSPORTATION Emergencies ONLY Call CHEMTREC at 1-800-424-9300
FIRST AID

IF SWALLOWED:	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything by mouth to an unconscious person.
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 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 mouth-to-mouth if possible. • Call a poison control center or doctor for further 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. • Call a poison control center or doctor for treatment advice.
For MEDICAL Emergencies Call CHEMTREC at 1-800-424-9300	
Have the product container or label with you when calling a poison center or doctor or going for treatment.	
NOTE TO PHYSICIAN: There is no specific antidote. All treatments should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred.	

PRECAUTIONARY STATEMENTS

**HAZARD TO HUMANS AND DOMESTIC ANIMALS
WARNING**

May be fatal if swallowed, absorbed through the skin, or inhaled. Causes eye injury. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Wear protective clothing and rubber gloves. Remove contaminated clothing and wash clothing before reuse. Do not breathe dust. Wear a mask or pesticide respirator jointly approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health.

SYMPTOMS OF POISONING: In severe cases of overexposure by oral ingestion, lethargy, muscle tremors, and in extreme cases, possibly convulsions, may occur.

ENVIRONMENTAL HAZARDS

This product is toxic to bees, birds, fish, and aquatic invertebrates. 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. Read entire label before using this product.

Only for formulation into an insecticide for (1) the following uses: Cotton, Leafy Vegetables (Group 4), Tuberous and Corm Vegetables (Group 1C), Cole Crops (Group 5), Fruiting Vegetables (Group 8) including Greenhouse-grown Tomatoes, Cucurbit Vegetables (Group 9), Citrus Fruits (Group 10), Pome Fruits (Group 11), Stone Fruits (Group 12), Tree Nuts (including Pistachios) (Group 14), Tobacco, Edible-Podded Legumes (Group 6A), Succulent Shelled Peas and Beans (Group 6B), Bulb Vegetables (Group 3-07), Caneberries (Group 13-07A), Bushberries (Group 13-07B), Small Climbing Vine Fruit except fuzzy kiwifruit (Group 13-07F), Low Growing Berries (Group 13-07G), Clover (*Trifolium spp.*) Grown for Seed, Ornamentals and Flowering Plants (grown outdoors and in greenhouses, shadehouses, and lathhouses), Outdoor and Indoor Insect Control when Formulated as a Bait for Ants and Roaches, Termite Control (only when in combination with bifenthrin), Outdoor (perimeter only) General Household Pest Control, (2) Uses for which US EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) Uses for experimental purposes that are in compliance with US EPA requirements.

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STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

In case of spill, clean up spillage using shovels and avoiding skin contact. Carefully scoop up loose material and place it in appropriate containers so as to avoid dust generation. Ensure adequate decontamination of tools and equipment following cleanup.

CONTAINER DISPOSAL

Completely empty container into manufacturing equipment. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles.

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability

CONDITIONS: 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 Nippon Soda Co., Ltd. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent allowable by applicable laws Nippon Soda Co., Ltd. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Nippon Soda Co., Ltd. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent allowable by applicable laws Nippon Soda Co., Ltd. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent allowable by applicable laws the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid, or at Nippon Soda Co., Ltd.'s election, the replacement of product.

Nippon Soda Co., Ltd.
2-1, 2-Chome Ohtemachi
Chiyoda-ku, Tokyo 100-8165 Japan

Net Contents: _____ Batch No. _____