

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

SEP 27, 2001

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Hawaii Department of Agriculture
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Attention: Mr. Robert A. Boesch (shennanp@hgea.org)
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File Symbol: 01-HI-03
Expiration: SEP 27 2002
Report Due: MAR 30 2003

The Environmental Protection Agency hereby grants a specific exemption under the provisions of section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to the Hawaii Department of Agriculture for the use of caffeine (1,3,7-trimethylxanthine) on floriculture and nursery crops, outdoor ornamental plants in residential areas, parks, hotels and resorts, and forest habitats to control coqui (*Eleutherodactylus coqui*) and greenhouse (*E. planirostris*) frogs. This specific exemption is subject to the conditions and restrictions set forth in your application except as superceded by this document, as follows:

1. The Hawaii Department of Agriculture is responsible for ensuring that all provisions of this specific exemption are met. It is also responsible for providing information in accordance with 40 Code of Federal Regulations (CFR) 166.32. Accordingly, a report summarizing the results of this program must be submitted to EPA Headquarters and the EPA Region 9 office no later than six months from the date of issuance or prior to requesting another specific exemption for this use.

2. Caffeine is an unregistered chemical. There are no end use products registered containing caffeine. The State of Hawaii proposes use of a soluble powder containing 99-100% caffeine supplied by EastWest United Group, Inc. The Hawaii Department of Agriculture submitted a proposed product label for use under this emergency exemption. The following revisions must be made to the label prior to use of this product under this emergency exemption:

- There must be a "Restricted Use Pesticide" statement at the top of the main panel of the label that reads:

"Restricted Use Pesticide

Due to High Acute Toxicity and Potential Hazard to Applicators

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."

- The proposed label lacks an ingredient statement. Such a statement is required and should appear on the front of the label. The ingredient statement should read:

Active ingredient
Caffeine 99 %
Inert Ingredient..... 1 %

Total 100 %

- A signal word must be put on the front of the label which must read:

WARNING (AVISO).

- The directions for use must include the following statement:

“AGRICULTURAL USE REQUIREMENTS:

DIRECTIONS FOR USE:

For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear: coveralls over long-sleeved shirt and long pants, socks and chemical resistant footwear, goggles or face shield, and waterproof gloves.”

- Based on the toxicity and pharmacological effects of caffeine as reported in the literature, labeling must indicate that the following groups, in particular, should not be exposed to either the spray or its residues:
 - pregnant women,
 - toddlers and infants under the age of 2,
 - children taking medications for asthma or attention-deficit disorder,
 - individuals with a history of heart disease, high blood pressure, or circulatory problems.
- Taking into consideration the unknown persistence of residues, the pharmacological effects of caffeine, and the groups of individuals at risk, the following modifications must be made regarding Sites of Application:
 - Applications to turf or lawns are prohibited.
 - Caffeine may be applied to floriculture and nursery crops, outdoor ornamental plants in residential areas, parks, hotels and resorts, and forest habitats.

- The proposed labeling is somewhat confusing in that it appears to direct the use of eye protection (goggles, face shield or full face respirator) and the use of respiratory protection in the form of an approved dust-mist respirator. If an approved full face respirator is used, a dust-mist respirator cannot be used. The use of a dust-mist respirator may be combined with the use of goggles or a face shield. Therefore, the Personal Protective Equipment (PPE) section should be revised to read:

“Applicators and other handlers must use the following PPE:

Coveralls over long-sleeved shirt and long pants, chemical resistant footwear plus socks, waterproof gloves, protective eyewear (goggles or face shield) and a dust-mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a full-face respirator “

- The PRECAUTIONARY STATEMENTS must be revised to read:

“May be fatal if swallowed or inhaled. Causes substantial but temporary eye injury or skin irritation. Harmful if absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe dust. For handling activities, use dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21 C), or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear coveralls worn over long-sleeved shirt and long pants, socks and chemical resistant footwear, goggles or face shield and waterproof gloves. For Cleaning Equipment: Add a chemical resistant apron.”

- The First Aid section must read:

“IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: 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: Move person to fresh air. If person is not breathing, call 911 or 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: 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 eye. Call poison control center or doctor for treatment advice.”

- A statement must be added to the label that reads:

“NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.”

Additionally, the following statements are suggested types of information that may be included in the Note to Physician, if applicable:

- technical information on symptomatology;
 - use of supportive treatments to maintain life functions;
 - medicine that will counteract the specific physiological effects of the pesticide;
 - company telephone number to specific medical personnel who can provide specialized medical advice.
- A “USER SAFETY RECOMMENDATIONS” section must be added to the label that reads:

“Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.”

- Treatments to any site including outdoor ornamental plants in residential areas, parks, hotels and resorts can not be accessible to the general public and must be sealed off and restricted for at least 24 hours following spraying. Therefore the re-entry statements must be revised to read:

“Treated areas are not to be entered for at least 24 hours following spraying.”

3. Caffeine may be applied at 100 - 200 pounds of caffeine in 1200 gallons of water per acre. Six applications per acre per year may be made at the maximum application rate. If a lower rate is used more applications may be made but shall not exceed a maximum of 1200 pounds of caffeine per acre per year.
4. Applications can be made with ground equipment only. Aerial applications or by chemigation is prohibited.
5. A total of 2000 acres may be treated throughout Hawaii.
6. Applications must be made by or under the direct supervision of a certified applicator. Treatments to any site including outdoor ornamental plants in residential areas, parks, hotels and resorts can not be accessible to the general public and must be sealed off and restricted for at least 24 hours following spraying. A 24 hour re-entry period is required for all areas treated.
7. Applications made in accordance with the above provisions are not expected to result in residues of caffeine in or on food crops. Therefore, no time-limited tolerances will be established to support this emergency exemption.
8. There-is great uncertainty regarding the risks to non-target organisms resulting from the application of caffeine to control coqui and greenhouse frogs. The only toxicity information submitted by the State is for acute lethality and chronic toxicity in mammals. Based on this information, applications could present considerable acute and chronic risk to directly and indirectly exposed mammals. Very limited toxicity information is available for an assessment of the risk caffeine may present in the terrestrial environment. No acute or chronic toxicity data were presented for aquatic organisms, aquatic and terrestrial plants, birds, and terrestrial invertebrates, nor were any found in the scientific literature. This does not allow a full assessment of risk for those organisms. Some ad-hoc observations were presented that indicate caffeine is lethal to terrestrial invertebrates (snails). Considering caffeine toxicity to mammals and amphibians, it is likely to affect other terrestrial organisms as well. In addition, although caffeine has a short aquatic half-life, it is unclear if significant risk is present for aquatic organisms since no aquatic toxicity information was presented.

Two major areas of uncertainty regarding caffeine use need to be addressed. First is the potential effect caffeine may have on non-target organisms. Since very little information exists regarding caffeine hazard to non-mammalian

species, systematic monitoring studies for affected non-target organisms, including insects, birds, mammals, reptiles, and amphibians, need to be conducted in and around areas of caffeine use. Effects on behavior and survival should both be noted. Accurate data, including the number and species of effected organisms, should be recorded. Dead and moribund organisms found near areas of caffeine use should be collected, placed into individual chemically clean containers, labeled, frozen, and shipped to a qualified analytical laboratory where whole body caffeine residues can be determined.

The second area of uncertainty is the effectiveness with which caffeine will address the purpose for which it is used. Systematic studies to determine efficacy should be conducted in concert with studies of non-target organism impacts. These studies should address pre and post application frog densities at application sites taking into account time-dependent population density recovery. They should also address the control program's ability to prevent frog population emigration.

This information must be submitted if an emergency exemption request for use of caffeine under FIFRA Section 18 is submitted to the Agency in the future. The state may contact Dr. Tim Bargar at (703) 605-1531 if there are specific questions about the requirements of the monitoring program or efficacy studies.

9. The United States Department of Interior, Fish and Wildlife Service, Pacific Islands Ecoregion sent a letter, dated June 20, 2001, to the Hawaii Department of Agriculture indicating that the endangered Hawaiian hoary bat (*Lasiurus cinereus semotus*) may be present at application sites, such as Lava Tree and Kalopa State Parks on the island of Hawaii, but the application method is not likely to expose bats to caffeine. However, since non-target mortality to snails and slugs was noted the proposed label specifically excludes application 'in habitats of the endangered Oahu Tree Snails' (*Achatinella* spp.). Additionally, if application of caffeine is proposed, for any habitats containing threatened and endangered plants, invertebrates, or any species proposed for listing, the Hawaii State Department of Agriculture must contact the United States Department of Interior, Fish and Wildlife Service, Pacific Islands Ecoregion prior to treatment.

10. The EPA Headquarters and Regional office shall be immediately informed of any adverse effects or misuse resulting from the use of this pesticide in connection with this exemption.

11. This specific exemption will expire one year from the date of issuance.

Any future correspondence in connection with this exemption should refer to file symbol OI-HI-03. If you have any further questions regarding this issue, please do not hesitate to contact Barbara Madden, of my staff, at (703) 305-6463 or by e-mail at [Madden.Barbara@epa.gov](mailto:Barbara@epa.gov).

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