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

JAN 4 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Naled - Section 18 Request by USDA for Control of Oriental Fruit Fly (Dacus spp.) in California
EPA ID No. 90-DA-25

Caswell No.: 586
TB Proj.: 0-0199
RD Record: 254,430

FROM: Irving Mauer, Ph.D., Geneticist
Toxicology Branch I - Insecticide, Rodenticide Support
Health Effects Division (H7509C)
12-19-89

TO: Susan Stanton, PM 41
Registration Division (H7505C)

THRU: Karl P. Baetcke, Ph.D., Chief
12/19/89
Toxicology Branch I - Insecticide, Rodenticide Support
Health Effects Division (H7509C)

Requestor: USDA (APHIS), Hyattsville, Maryland

Action Requested (535)

Review proposed quarantine exemption (FIFRA section 18) for use of naled to control oriental fruit flies (Dacus dorsalis, Hendel) statewide in California as possible hazard to applicators.

Toxicology Branch Recommendations

Toxicology Branch (TB) has no objection on toxicological grounds to granting this quarantine exemption under the conditions as stated in the request, since no additional adverse

effects to humans, domestic animals/pets, or the environment are anticipated.

Detailed Background

Under cover letter of October 17, 1989 (and followup of November 9, 1989), USDA (APHIS) is requesting a quarantine exemption under 40 CFR 166.20 Subpart B for the use of a combined formulation consisting of the insecticide naled (as Ortho Dibrom 14 Concentrate, EPA Registration No. 239-1721-AA) and the insect attractant methyl eugenol (as Dorsalure ME) under the following conditions:

1. Lure baits are prepared consisting of either 1.75 oz naled per 12.7 oz methyl eugenol, or 1.75 oz naled per 11.7 oz methyl eugenol, both added to Min-U-Gel to obtain the desired consistency (minimizing potential inhalation hazard).

2. Approximately 6 sq in of this lure-bait formulation is applied by registered Federal, State, or county agricultural personnel at each of 600 bait stations per square mile, if necessary every 2 to 4 weeks until infestation is eradicated (as determined by periodic fly counts).

3. The lure baits are applied by handheld spray ("spot application") to tree trunks, utility poles, or other inanimate objects, out of the normal reach of children and pets. Residents within a treatment area (as defined by fly finds) are to be notified prior to application.

4. All (other) applicable directions, restrictions, and precautions on EPA-registered label(s) are to be followed.

5. Food residues from this use are not anticipated, since this material is not to be applied to raw agricultural commodities.

6. Exposure to mixers should be limited by appropriate safety equipment and proper ventilation, and applicators are encouraged to wear long-sleeved shirts, brimmed hats, and gloves either impervious to pesticide absorption or discardible (frequent changes).

Accompanying the current request for continuance of the quarantine exemption, USDA submitted a copy of a published article involving methyl eugenol in mouse oncongenicity studies,* plus a study recently concluded of air levels for both actives measured during last year's fruit fly eradication program in California.**

TB Conclusions

TB has no objections to granting this continuing quarantine exemption based upon the following:

1. Previous authorizations of emergency-specific exemptions for similar naled-methyl eugenol-Min-U-Gel formulations and comparable site-specific methods of application for oriental fruit fly infestations since 1980 (80-DA-13, 14 et seq., e.g.: see Memorandum: Mauer to Stubbs, January 15, 1981), most recently 87-DA-43 (-07) which is about to expire December 16, 1989 (see Memorandum Mauer to Stubbs, December 31, 1986).

2. Applications of the formulation will continue to be made by or under the supervision of trained peticide applicators, and authorized by the State of California and county agricultural commissioners prior to this use.

3. Existing toxicity data will support the current requested emergency-specific exemption (Naled Registration Standard, December 21, 1982, and subsequent satisfaction of Data Call-In Notice

4. The declared (by APHIS) absence of maximally tive pesticide alternatives (such as combinations attractants with malathion), compared to the er effectiveness of the naled-methyl-eugenol-Mi l formulation found in past eradication progra

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*Miller et al. (1983) Structure-Activity Studies of Carcinogenicities in the Mouse and Rat of Some Na d Occurring and Synthetic Alkenylbenzene Derivative to Safrole and Estragole. Cancer Res. 43: 1124-

**The Environmental Monitoring of Methyl Eugenol, Dichlorvos During a Pest Trapping and Eradicatic hed by B. Turner, N. Miller, D. Tran, and S. Powell ure study from the California Department of Food an (CDFA), dated October 1989).

5. The publication reporting an increased incidence of "hepatomas" (twice control) in weanling male mice following ip injection of methyl eugenol at a single dosage level is unconfirmed and considered inadequate according to our evaluation (data review) procedures; additionally, no data were included on treatments or results in female mice, nor in rats. Methyl eugenol is in the preliminary stage of evaluation for oncogenicity by the NTP; it is to be administered by oral gavage to rats and mice of both sexes according to the standard protocol for this type of bioassay.

   There is no evidence for oncogenicity of naled administered up to MTD levels in either rats or mice.

6. The unpublished environmental monitoring study submitted by CDFA recorded negligible to undetectable quantities of the product's active ingredients in ambient air samples 1 to 4 days after application. Levels of exposure to methyl eugenol (maximally 1050 ng/m^3, or approximately 0.145 ppm) during the 1988 eradication program were cited as much lower than amounts currently allowed as food additives (see ff*), while the published TLV for DDVP (1 mg/m^3, according to the ACGIH, 1987) was more than four orders of magnitude higher than the highest concentration found in air samples (=30 ng/m^3, or roughly 0.003 ppm). Naled per se (parent compound of DDVP) was not detected in any of these air monitoring programs.

   Residues of both methyl eugenol (up to 210 ppb) and DDVP (0.73 to 1.20 ppb) were found in fruit collected from two of the four trap sites, but these two "positive" traps had been freshly rebaited the morning of fruit collection; neither substance was detectable in fruit from the remaining sites left undisturbed for 4 weeks. Methyl eugenol occurs naturally in several fruit species including citrus; CDFA plans to conduct a more comprehensive monitoring program in 1990 to test for the presence of both actives (ME + DDVP) in other common fruit trees used in its trapping programs.

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* 2 to 52 ppm, according to L. Nelson of the CDFA (MEMO to R. Magee, 1989), citing 21 CFR 72.515