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

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **Section 18: ID# 96CA0019.** Emergency Exemption for Use of Provado 1.6F (Imidacloprid) on Spinach in California

Tox. Chem. No.:	497E
PC No.:	129099
Barcode No.:	D222378
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I. CONCLUSIONS

The toxicology data support the issuance of a Section 18 emergency exemption by the State of California for the temporary use of imidacloprid (Provado 1.6F) to control green peach aphids on spinach. The short term margins of exposure (MOEs) for farm workers are substanially greater than 100. Imidacloprid is a "Group E" carcinogen, so there is no cancer risk associated with exposure to this chemical.

For acute dietary exposure, a toxicological NOEL of 24 mg/kg/day based on the increased resorptions and abortions in the rabbit developmental study should be used.

Toxicology Branch I has no objection to the issuance of this exemption.

II. ACTION REQUESTED

In a letter dated January 18, 1996, the California Department of Pesticide Regulation requested an emergency exemption under Section 18 for the use of imidacloprid to control green peach aphids. This is the first request made by California for this use.

Provado 1.6F (Miles, Inc.) is the formulation for the active ingredient. The pesticide will be used up to seven days of harvest to approximately 460 acres of unharvested crop. The rate of application will be 18.75 fl. oz. of Provado 1.6F per acre (0.75 oz of ai) by ground or air.

III. TOXICOLOGY BRANCH I COMMENTS

The toxicology data base for imidacloprid is sufficient to support the proposed Section 18 exemption.

IV. RISK/EXPOSURE ASSESSMENT

This action was submitted to OREB (Occupational and Residential Exposure Branch) for determination of exposure estimates (see attached memo from G. Tompkins to W. Dykstra, dated 2-14-96). Therefore, the OREB daily exposure estimates and the 21 day dermal study in rabbits which has a systemic NOEL of 1000 mg/kg/day (HDT) were used to calculate short term MOEs. Cancer risk is not quantitated, since imidacloprid is a group E carcinogen.

Formula used in calculations:

Short term MOE = NOEL (1000 mg/kg BW/d) ÷ Exposure (mg/kg BW/d)

OPERATION*	EXPOSURE (mg/kg/d)	SHORT TERM MOE
Mixer/Loader, ground	0.002389	418,585
Applicator, ground	0.001442	693,481
Mixer/Loader, aerial	.002389	418,585
Applicator, aerial	0.001442	693,481

* Minimum clothing requirements for Applicators are long pants, long-sleeved shirt, and chemical resistant gloves; Mixer/Loader exposure is based on wearing long pants, long sleeves, and gloves (Worker Protection Standard for Agricultural Pesticides).

V. SPECIAL TOXICOLOGY ISSUES AND PROBLEMS

1. Labelling. The labelling precautionary statements for Provado 1.6F are governed by toxicity studies on the active ingredient.

2. Carcinogenicity. There is no cancer risk associated with exposure to this chemical, because the HED RfD Review Committee has determined that the test compound is a "Group E" carcinogen.

3. RfD. The RfD/Quality Assurance Peer Review Committee met on April 22, 1993 to assess the reference dose for this chemical. The Committee recommended that an RfD of 0.057 mg/kg/day should be established, based upon a NOEL of 5.7 mg/kg/d in a chronic toxicity study in rats. An uncertainty factor of 100 was used to account for interspecies extrapolation and intraspecies variability.

4. Non-carcinogenic risk assessment. In a chronic/oncogenicity study, male rats exhibited increased thyroid lesions at 16.9 mg/kg/day and above, and females at 73 mg/kg/day. In a developmental study in rabbits, 72 mg/kg/d of technical imidacloprid (administered on days 6-19 of gestation) increased the number of resorptions and abortions in the dams, and increased skeletal abnormalities and decreased body weight in the pups.

5. Mutagenicity/genetic toxicity comments. Most of the genotoxicity studies for imidacloprid were negative, although an in vitro chromosome aberration study (human lymphocytes) was positive at cytotoxic concentrations, and an in vitro sister chromatid exchange mutagenicity study (CHO cells) was positive at cytotoxic doses.

6. Dermal Penetration. There are no available dermal penetration data for imidacloprid. However, a 21 day dermal toxicity study in rabbits has a systemic NOEL of 1000 mg/kg/day (HDT).