

iv. Percent Acute RfD consumed is 0.04%

4. *Short-term aggregate exposure and risk including pet use for children 1 to 6-years old*—i. Dietary exposure estimate including water is 0.001296 mg/kg bwt/day.

ii. Predicted hand to mouth transfer is 0.0341 mg/kg bwt/day.

iii. Total exposure equals 0.035 mg/kg bwt/day.

iv. Percent Acute RfD consumed is 0.23%.

#### D. Cumulative Effects

The potential for cumulative effects of thiamethoxam and other substances that have a common mechanism of toxicity has also been considered.

Thiamethoxam belongs to a new pesticide chemical class known as the neonicotinoids. There is no reliable information to indicate that toxic effects produced by thiamethoxam would be cumulative with those of any other chemical including another pesticide. Therefore, Novartis believes it is appropriate to consider only the potential risks of thiamethoxam in an aggregate risk assessment.

#### E. Safety Determination

1. *U. S. population.* Using the chronic exposure assumptions and the proposed RfD described above, the aggregate exposure (including drinking water) to thiamethoxam to the U. S. population (48 States, all seasons) was calculated to be 4.5% of the RfD of 0.013 mg/kg bwt/day. Therefore, Novartis concludes that there is reasonable certainty that no harm will result from aggregate chronic exposure to thiamethoxam residues.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of thiamethoxam, data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat have been considered.

In teratology studies, delayed fetal development was apparent only at maternally toxic doses of thiamethoxam in rats and rabbits. In rabbits, 150 mg/kg/day was clearly toxic to does, causing death, weight loss, reduced food consumption and perineal or vaginal discharge. Developmental toxicity occurred secondary to maternal toxicity and consisted of reduced fetal bwts and an increase in minor skeletal anomalies or variations. Maternal toxicity was also noted at 50 mg/kg/day, consisting of reduced bwts and food consumption and total resorptions in one female. There was no indication of developmental toxicity at 50 mg/kg/day. The NOAEL for maternal toxicity was 15 mg/kg/day and for developmental

toxicity was 50 mg/kg/day in rabbits. In rats, 200 and 750 mg/kg/day caused maternal toxicity, but developmental toxicity secondary to maternal toxicity was observed only at 750 mg/kg/day. The NOAEL for maternal toxicity was 30 mg/kg/day and for developmental toxicity was 200 mg/kg/day.

In a rat multigeneration study, parental toxic effects were noted at 2,500 ppm (250 mg/kg/day) and 1,000 ppm (100 mg/kg/day). Offspring bwts were reduced in males and females at 2,500 ppm (250 mg/kg/day) and in females (F1 only) at 1,000 ppm (100 mg/kg/day). The NOAEL for systemic toxicity in adult males was 30 ppm (approximately 3 mg/kg/day, range = 1.3 - 4.3 mg/kg/day) and in adult females was 1,000 ppm (approximately 100 mg/kg/day, range = 59.3 - 219.6 mg/kg/day). The NOAEL for toxicity to offspring was 30 ppm (approximately 3 mg/kg/day, range = 1.3 - 6.4 mg/kg/day). These studies show no evidence that developing offspring are more sensitive to than adults to the effects of thiamethoxam.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological requirements, the database for thiamethoxam relative to pre- and post-natal effects for children is complete. Further, for thiamethoxam, the developmental studies showed no increased sensitivity in fetuses as compared to maternal animals following in utero exposures in rats and rabbits, and no increased sensitivity in pups as compared to the adults in the multi-generation reproductive toxicity study. Therefore, it is concluded that an additional uncertainty factor is not warranted to protect the health of infants and children and that an RfD of 0.013 mg/kg/day is appropriate for assessing aggregate risk to infants and children of thiamethoxam.

Assuming tolerance level residues and adjusting for the percent of crops treated, only 7.0% of the thiamethoxam chronic RfD is utilized in the population subgroup all infant (> 1-year old). Therefore, based on the completeness and reliability of the toxicity database, Novartis concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to thiamethoxam residues.

#### F. International Tolerances

There are no Codex maximum residue levels (MRLs) established for residues of thiamethoxam on fruiting vegetables,

tomato paste, head and stem brassica vegetables, leafy brassica greens, cucurbit vegetables, leafy vegetables, tuberous and corm vegetables, barley grain, barley hay, barley straw, cottonseed, cotton gin by-products, pome fruit, wheat grain, wheat forage, wheat straw, wheat hay, sorghum grain, sorghum forage, sorghum fodder, or milk. (Dani Daniel)

[FR Doc. 99-11169 Filed 5-4-99; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-181069; FRL 6078-7]

### Emamectin Benzoate, Receipt of Application for Emergency Exemptions; Solicitation of Public Comment

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA has received a specific exemption request from the Oklahoma Department of Agriculture (hereafter referred to as the "Applicant") to use the insecticide emamectin benzoate (CAS 137512-74-4) to treat up to 150,000 acres of cotton to control the beet armyworm. Emamectin benzoate is an unregistered material, and its proposed use is thus use of a "new" chemical. Therefore, in accordance with 40 CFR 166.24, EPA is soliciting public comment before making the decision whether or not to grant the exemption.

**DATES:** Comments must be received on or before May 20, 1999.

**ADDRESSES:** Three copies of written comments, bearing the identification notation "OPP-181069," should be submitted by mail to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Follow the instructions under SUPPLEMENTARY INFORMATION. No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as CBI.

Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be provided by the submitter for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. The docket is available for public inspection at the Virginia address given above, 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** By mail: Andrea Beard, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. Office location, telephone number and e-mail address: Rm. 271, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, (703-308-9356); e-mail: beard.andrea@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), the Administrator may, at her discretion, exempt a state agency from any registration provision of FIFRA if she determines that emergency conditions exist which require such exemption. The Applicant has requested the Administrator to issue a specific exemption for the use of emamectin benzoate on cotton to control beet armyworm. Information in accordance with 40 CFR part 166 was submitted as part of this request.

According to the Applicant, the beet armyworm (BAW) has been a sporadic pest of cotton the past four years, and has caused major economic losses throughout the cotton growing areas. BAW populations were present in especially large numbers over the last growing season. Key outbreak factors are mild winters; late planting; delayed crop maturity; heavy early season organophosphate and pyrethroid use; prolonged hot, dry weather; presence of the BAW early in the season; and weather conditions that support migration of the adult moths. Much of the acreage in question is in the boll weevil eradication program, which requires insecticides that are harsh on natural enemies of the BAW to be used early in the season. The applicant states that this, in combination with lingering drought conditions and a mild winter are expected to result in high BAW populations for the upcoming season. Available insecticides are either ineffective, do not fit into the boll weevil eradication program, or are not expected to be available in sufficient quantities to treat all affected acreage.

Under the proposed exemption, emamectin benzoate may be applied at a rate of 0.0075 – 0.01 lb., active ingredient (a.i.) (6 – 8 oz. product) per acre, with up to 3 applications during the growing season, using ground or aerial equipment. If all acres are treated at the maximum rate, this could potentially result in a total use of 4,500 lb., a.i., or 28,125 gal. of product.

This notice does not constitute a decision by EPA on the application itself. The regulations governing section 18 require publication of a notice of receipt in the **Federal Register** for an application for a specific exemption proposing the use of a new (unregistered) chemical. Such notice provides for opportunity for public comment on the application.

The official record for this notice, as well as the public version, has been established under docket number (OPP-181069) including comments and data submitted electronically as described below. A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at: opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket number (OPP-181069). Electronic comments on this notice may be filed online at many Federal Depository Libraries.

The Agency, accordingly, will review and consider all comments received during the comment period in determining whether to issue the emergency exemption requested by the Oklahoma Department of Agriculture.

#### List of Subjects

Environmental protection, pesticides and pests, emergency exemptions.

Dated: April 23, 1999.

#### Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 99-11170 Filed 5-4-99; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-50858; FRL-6078-2]

### Issuance of an Experimental Use Permit

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA has granted an experimental use permit (EUP) to the following applicant. The permit is in accordance with, and subject to, the provisions of 40 CFR part 172, which defines EPA procedures with respect to the use of pesticides for experimental use purposes.

**FOR FURTHER INFORMATION CONTACT:** By mail: Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 1921 Jefferson Davis Highway, Rm. 910W16, CM #2, Arlington, VA, 703-308-8715, e-mail: mendelsohn.mike@epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA has issued the following EUP:

68467-EUP-2. Issuance. Mycogen Plant Sciences, Mycogen Corporation, 5501 Oberlin Drive, San Diego, CA 92121. This experimental use permit allows the use of 4 grams of the insecticidal *Bacillus thuringiensis* Cry1F protein in seeds shipped containing the plant-pesticide (*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHI8999) in corn plants) on 134 acres of corn to evaluate the control of various insect pests including European corn borer. The program is authorized only in the States of Hawaii, Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Puerto Rico, South Dakota, Tennessee, Texas, and Wisconsin. The experimental use permit is effective from April 15, 1999 to March 31, 2000. This permit is issued with the limitation that all treated crops will be destroyed or used for research purposes only.

Persons wishing to review this EUP are referred to the designated contact person. Inquires concerning this permit should be directed to the person cited above. It is suggested that interested persons call before visiting the EPA office, so that the appropriate file may be made available for inspection purposes from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

**Authority:** 7 U.S.C. 136.