

surfacewater will rapidly bind to soil particles and remain with sediment where it is quickly degraded; and therefore, not contribute to potential dietary exposure from drinking water. The estimated environmental concentration (EEC) values for spirodiclofen and the enol metabolite were calculated using the tier I screening concentration in ground water (SCI-GROW), screening model for ground water estimates, and the tier II PRZM/EXAMS, models with index reservoir (IR) and percent crop area (PCA) factor for surface water estimates. The potential EEC levels were determined for the maximum usage intensity for each crop. The acute and chronic percent of population adjusted dose (%PAD) values associated with drinking water exposure were calculated based on a NOAEL of 100 mg/kg/day for acute exposure and 1.38 mg/kg/day for chronic exposure. The uncertainty factor (UF) considered in the analysis was 100X, and an additional Food Quality Protection Act (FQPA) safety factor of 3X was used both for acute and chronic calculations. The SCI-GROW estimated maximum ground water EEC level for spirodiclofen and enol combined was 0.003 ppb, suggesting that the compounds have a low potential to leach and contaminate the ground water under normal use. The highest estimate of the total acute concentration in surface water for spirodiclofen and enol combined was 6.04 parts per billion (ppb). The highest estimate of the total chronic concentration in surface water for spirodiclofen and enol combined was 0.67 ppb. The maximum %PAD calculated, 1.46%, was for infant/children chronic exposure. The low %PAD indicates that the human health risk associated with the presence of spirodiclofen and/or its enol metabolite in drinking water is minimal.

2. *Non-dietary exposure.* There are no indoor residential, indoor commercial or outdoor residential uses for spirodiclofen. Exposure and risk assessments were prepared for both mixer/loader-applicators and reentry workers during use of spirodiclofen on citrus, tree nuts and pome/stone fruit. Worker margins of exposure (MOE) estimates were conservatively based on a NOAEL of 1.38 mg/kg/day, maximum label rates, and a dermal absorption value of 2.3%. An occupational exposure uncertainty factor of 100 was used in the assessment. Margins of exposure total ranged from 360 to 69,000, indicating that the use of spirodiclofen poses no significant risk to workers who mix, load and apply this

product, or to those who reenter treated areas to perform post-application activities. These data support the use of a single layer of clothing for mixer/loaders and applicators, and gloves for mixer/loaders, and a 12-hour REI for reentry workers.

D. Cumulative Effects

Spirodiclofen represents a new class of chemistry, ketoenols. Bayer will submit information, if necessary, for EPA to consider concerning potential cumulative effects of spirodiclofen consistent with the schedule established by EPA at 62 **Federal Register** 42020 (Aug. 4, 1997) and other EPA publications pursuant to the Food Quality Protection Act.

E. Safety Determination

1. *U.S. population.* Based on the exposure assessments described above and on the completeness and reliability of the toxicity data, it can be concluded that total aggregate exposure to spirodiclofen from all label uses will utilize less than 5% of the RfD for chronic dietary exposures and that margins of exposure in excess of 360 exist for aggregate exposure to spirodiclofen for non-occupational exposure. EPA generally has no concerns for exposures below 100% of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. Margins of exposure of 100 or more (300 for infants and children) also, indicate an adequate degree of safety. Thus, it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to spirodiclofen residues.

2. *Infants and children.* In assessing the potential for increased sensitivity of infants and children, data from developmental studies in both rat and rabbit and a 2-generation reproduction study in the rat can be considered. The developmental toxicity studies evaluate any potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates any effects from exposure to the pesticide on the reproductive capability of mating animals through two generations, as well as any observed systemic toxicity. None of these studies conducted with spirodiclofen indicated developmental or reproductive effects. The toxicology data which support these uses of spirodiclofen include the following: An oral developmental toxicity study in rat that did not reveal any evidence of teratogenic potential. Maternal and

developmental NOAELs were 1,000 mg/kg bwt/day. An oral developmental toxicity study in rabbits demonstrated a maternal NOAEL of 100 mg/kg bwt/day and did not reveal any teratogenic potential. A two-generation study in rats, with a parental toxicity NOAEL of 5.2 mg/kg bwt/day, did not reveal evidence of a primary reproductive toxicity potential. The reproductive NOAEL was 26.2 mg/kg bwt/day based on various clinical and histopathological findings at higher dose levels. FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children. The additional safety factor may be used when prenatal and postnatal threshold effects were observed in studies or to account for incompleteness of the toxicity database. Based on the toxicological data requirements, the data relative to prenatal and postnatal effects in children is complete. No indication of increased susceptibility of younger animals was observed in any of the above studies. For the population with the highest exposure, non-nursing infants <1 year old, the acute dietary exposure at the 95th percentile was 2.3% of the aPAD, equivalent to an MOE of 13,167. For the population described as children 1–6 years old, the exposure was 1.2% of the aPAD, equivalent to an MOE of 25,638. Acute exposure of the overall U.S. population was equivalent to 0.45% of the aPAD. For the chronic dietary analysis, the most highly exposed population subgroup was children 1–6 years old, with an exposure equal to 1.9% of the cPAD. Chronic exposure for the overall U.S. population equated to 0.6% of the cPAD.

F. International Tolerances

Codex maximum residue levels MRLs are not yet established for spirodiclofen. [FR Doc. E4–270 Filed 2–17–04; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0026; FRL–7344–4]

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 pesticide applicant. An EUP permits use of a pesticide for experimental or research purposes only

in accordance with the limitations in the permit.

FOR FURTHER INFORMATION CONTACT:

Andrew Bryceland, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6928; e-mail address: bryceland.andrew@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this action, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2004-0026. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically.

Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

II. EUP

EPA has issued the following EUP:
75437-EUP-2. Issuance. Great Lakes Fishery Commission (GLFC), 2100 Commonwealth Blvd., Suite 100, Ann Arbor, MI 48105. This EUP allows the use of 0.220 pounds of the male sea lamprey sex pheromone 3-ketopetromyzonol sulfate on 33 acres of river water to evaluate the control of sea lamprey. The program is authorized only in the State of Michigan. The EUP is effective from April 1, 2004 to October 31, 2004.

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

List of Subjects

Environmental protection,
Experimental use permits.

Dated: February 5, 2004.

Sheryl K. Reilly,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. E4-304 Filed 2-17-04; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0027; FRL-7344-3]

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 pesticide applicant. An EUP permits use of a pesticide for experimental or research purposes only in accordance with the limitations in the permit.

FOR FURTHER INFORMATION CONTACT:

Andrew Bryceland, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6928; e-mail address: bryceland.andrew@epa.gov.

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B. How Can I Get Copies of this Document and Other Related Information?

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