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

OFFICE OF PREVENTION, PESTICIDE AND TOXIC SUBSTANCES

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

Date: June 9, 2008

SUBJECT: Etofenprox: Occupational and Residential Exposure/Risk Assessment for Proposed Section 3 Uses on Rice and as ULV Mosquito Adulticide.

PC Code: 128965
Decision No.: 379311 and 382155

Petition No.: NA
Risk Assessment Type: Single chemical aggregate
TXR No.: NA
MRID No.: 471956-16

DP Barcode: D342643
Registration No.: 2724-TOR – RF2056 OL and 33657-GO – TREBON 3G
Regulatory Action: Section 3
Case No.: NA
CAS No.: 080844-07-1

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Introduction

Two new Section 3 uses of etofenprox have been requested. Mitsui Chemicals Inc. has requested the "first food" use of etofenprox on rice. Wellmark International has requested the use of etofenprox as a mosquito adulticide, including in wide-area mosquito abatement programs. This document contains HED's occupational and residential exposure/risk assessments for these proposed new uses. An aggregate human health risk assessment for these uses is presented in a separate HED memorandum. It is noted that Wellmark submitted an assessment, "Occupational and Residential Exposure and Risk Assessment for Mosquito Abatement Product Containing Etofenprox" MRID#:471956-16, dated 06/12/07. HED reviewed and considered the approach and conclusions of MRID#:471956-16 for inclusion in its own assessment, where appropriate (i.e., where agreement exists between the two).

Received in RRC
6/10/2008
CW

Executive Summary

General Information

Etofenprox is a synthetic pyrethroid-like substance. Its mode of action against insects is very similar to that of pyrethroids, and its main action site is the neuronal axon. However, its toxicity and its chemical structure are somewhat different from that of a pyrethroid. It differs in structure from pyrethroids in that it lacks a carbonyl group. Etofenprox contains an ether moiety; pyrethroids contain ester moieties.

Etofenprox (2-[ethoxyphenyl]-2-methylpropyl-3-phenoxy benzyl ether) is currently registered for residential nonfood uses to control a variety of crawling and flying insect pests. It is used for outdoor (yard/patio) and indoor foggers, and crack and crevice/spot treatment, as well as dog and cat spot-on flea treatment. Also, a Section 18 use on rice had been approved for the State of Louisiana.

The currently requested Section 3 uses are for: TREBON 3G (etofenprox 3.0% granular formulation) to be applied on rice fields at a maximum rate of 0.27 pounds of active ingredient (ai) per acre immediately after flooding the rice fields, and for RF2056 OL (etofenprox 20% liquid formulation) to be applied at ultra low volume (ULV) by aerial and ground equipment at a maximum rate of 0.0070 pounds ai per acre to control adult mosquitoes, midges and Black flies.

Toxicology/Hazard Assessment

The toxicology database for etofenprox is essentially complete. The data are sufficient for endpoint selection for exposure/risk assessment scenarios and for evaluation of the requirements under the Food Quality Protection Act (FQPA).

Etofenprox has low acute toxicity via the oral, dermal, and inhalation routes. It is not an acute eye or skin irritant and is not a dermal sensitizer, however, etofenprox does cause skin irritation after repeated exposure. The major target organs of etofenprox are the liver, thyroid, kidney, and hematopoietic system.

On Jan. 30, 2001, the Hazard Identification Assessment Review Committee (HIARC) reviewed the toxicology database and selected Reference Doses (RfD) and the toxicological endpoints for etofenprox risk assessments. The potential for increased susceptibility of infants and children from exposure to etofenprox was also evaluated by the HIARC, as required by the Food Quality Protection Act of 1996.

On February 28, 2006 the RAB3 Toxicology Team re-examined the endpoints and FQPA considerations regarding increased susceptibility of infants and children, in light of newly submitted studies on neurotoxicity and current divisional policies. Evidence of quantitative and qualitative susceptibility of offspring was not observed, and therefore, the FQPA 10x safety factor was reduced to 1x. An acute dietary endpoint was not identified. A chronic dietary toxicity endpoint NOAEL of 3.7 mg/kg/day is based on effects on the liver and thyroid in a

combined chronic toxicity/carcinogenicity study in the rat. With an uncertainty factor of 100, the chronic reference dose is 0.037 mg/kg/day. No dermal toxicity endpoint was identified due to the lack of any biologically significant systemic effect at the limit dose in a 28-day dermal toxicity study in the rat. Individual toxicity endpoint NOAELs were identified for short-term and intermediate-term incidental oral exposures. Long-term incidental oral exposures are not anticipated. For inhalation toxicity, a single endpoint NOAEL was identified for all exposure durations from a 13-week inhalation toxicity study in the rat. Etofenprox was classified as "Not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis," and, therefore, no quantitative cancer risk assessment is required.

Non-Dietary Non-Occupational (Residential) Exposure & Risk

Residential exposure to etofenprox may occur from the proposed Section 3 mosquitocide use. Only postapplication exposure is possible because the etofenprox mosquito adulticide (RF2056 OL) label specifically restricts this use to certain authorized personnel (does not include residential applicators). The relevant routes of exposure for which toxicity endpoints have been identified are inhalation (adult and children) and incidental oral (hand-to-mouth) exposure from contact with turf where etofenprox residues from aerial and ground-based fogging applications have settled. These potential exposures and consequent risks have been assessed. The level of concern (LOC) is for MOEs ≤ 100. Adult and toddler MOEs from bystander inhalation are all $\geq$ 100, and therefore, not of concern to HED.

Occupational Exposure and Risk for Proposed Use on Rice

Because dermal toxicity endpoints were not identified for etofenprox, only short- and intermediate-term inhalation exposures were assessed for occupational handlers mixing, loading, and applying etofenprox to rice fields. For all mixers, loaders, and applicators, the MOEs for short- and intermediate-term inhalation exposures do not exceed HED's level of concern, i.e. all MOEs $\geq$100.

This proposed Section 3 use on rice involves foliar applications; therefore, there is a potential for short- and intermediate-term dermal exposure to workers entering etofenprox-treated areas to perform a variety of agricultural/occupational tasks, including scouting. However, because no dermal toxicity endpoint was identified for etofenprox and postapplication inhalation exposure is considered to be negligible, no occupational postapplication exposure/risk assessment is required. An interim restricted entry interval (REI) of 12 hours applies under the Worker Protection Standard (WPS) for pesticides, including etofenprox, that have acute toxicity categories of III and IV.

Occupational Exposure and Risk for Proposed Use as Mosquito Adulticide

The proposed new mosquitocide end-use product is labeled, RF2056 OL (etofenprox 20% liquid formulation) and is to be applied at ultra low volume by aerial and ground equipment at a maximum rate of 0.0070 pounds ai per acre to control adult mosquitoes, midges and Black flies. Because dermal toxicity endpoints were not identified for etofenprox, only short- and

intermediate-term inhalation exposures were assessed for occupational handlers mixing, loading, and applying etofenprox for aerial ULV and ground fogger mosquitocide use. For all handlers, the MOEs for short- and intermediate-term inhalation exposures do not exceed HED's level of concern, i.e. all MOEs ≥100. Occupational postapplication exposure is not expected.

Human Studies

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies have been determined to require a review of their ethical conduct, and some are also subject to review by the Human Studies Review Board. The studies used in this assessment have received appropriate review.

Hazard Identification and Endpoint Selection

Etofenprox has low acute toxicity via the oral, dermal, and inhalation routes. It is not an acute eye or skin irritant and is not a dermal sensitizer, however, etofenprox does cause skin irritation after repeated exposure. The major target organs of etofenprox are the liver, thyroid, kidney, and hematopoietic system. The acute toxicity of etofenprox technical is shown in the Table 1.

Table 1. Acute toxicity of etofenprox technical

Guideline #	Study Type	MRIDs #	Results	Toxicity Category
870.1000	Acute Oral - Dog	40449724	LD_{50} = > 5000 mg/kg	IV
870.1200	Acute Dermal- Rabbit	40237710	LD_{50} = > 2100 mg/kg	III
870.1300	Acute Inhalation - Rat	40237705	LC_{50} = > 5.9 mg/L	IV
870.2400	Primary Eye Irritation - Rabbit	40237706	PIS for Conjunctival redness/edema at 24 hrs < 0.8; at 72 hrs = 0; reversible	IV
870.2500	Primary Dermal Irritation - Rabbit	40237707	PIS = 0.1 to 0.5, minimal irritation	IV
870.2600	Dermal Sensitization - Guinea Pig	40237708	Negative	NA

On April 3, 2001, the HED Hazard Identification and Assessment Review Committee (HIARC) evaluated the etofenprox toxicology database and selected the doses and toxicological endpoints for dietary and occupational exposure/risk assessments. The appropriateness of the endpoints selected were re-examined by RAB3 on February 28, 2006 and again on April 30, 2008 in light of new policies, newly submitted studies and proposed new uses. The doses and toxicological endpoints selected for various exposure scenarios for etofenprox are summarized in Table 2.

Table 2 Summary of Toxicological Doses and Endpoints for Etofenprox				
Exposure Scenario	Point of Departure	Uncertainty/ FQPA Safety Factor	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (females 13-49 years of age)	NA	NA	N/A	No acute dietary endpoint was selected
Acute Dietary (General population including infants and children)				
Chronic Dietary (All populations)	NOAEL = 3.7 mg/kg/day Chronic RfD = 0.037 mg/kg/day	FQPA = 1x UF_A = 10x UF_H = 10x	cRfD = 0.037 mg/kg/day cPAD = 0.037 mg/kg/day	Combined Chronic Toxicity /Carcinogenicity Study in Rat (MRID No. 40449707) LOAEL = 25.5 mg/kg/day based on increased thyroid weights. Related to increased liver weights and histopathology changes in liver and thyroid that occurred at the higher dose.
Incidental Oral Short-Term (1 - 30 days)	NOAEL = 20 mg/kg/day	FQPA = 1x UF_A = 10x UF_H = 10x	LOC for MOE ≤100	Subchronic Oral Toxicity in Rat (MRID No. 40449703) LOAEL = 120 mg/kg/day based on decreased body weight gain, increased liver and thyroid weights with corresponding histopathology, changes in hematology and clinical chemistry.
Incidental Oral Intermediate-Term (1 - 6 months)	NOAEL = 20 mg/kg/day	FQPA = 1x UF_A = 10x UF_H = 10x	LOC for MOE ≤ 100	Subchronic Oral Toxicity in Rat (MRID No. 40449703) LOAEL = 120 mg/kg/day based on decreased body weight gain, increased liver and thyroid weights with corresponding histopathology, changes in hematology and clinical chemistry.
Dermal (All durations)	NA	NA	NA	No systemic toxicity was identified in the dermal 28-day study; Highest Dose Tested was 1000 mg/kg/day.
Inhalation (All durations)	NOAEL = 10.6 mg/kg/day	FQPA = 1x UF_A = 10x UF_H = 10x	LOC for MOE ≤ 100	13-Week Inhalation Toxicity in Rat (MRID No. 40449705) LOAEL = 52.3 mg/kg/day based on organ weight changes and histopathological changes in liver, adrenals and thyroid.
Cancer (oral, dermal, inhalation)	**Classification: "Not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis."**			

UF = uncertainty factor, FQPA SF = Any additional safety factor retained due to concerns unique to the FQPA, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population

adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

Occupational Exposure & Risk

Occupational exposure and risk may result from the proposed etofenprox use on rice and as a public health mosquitocide. These exposures and risks are discussed separately below for the two proposed uses.

Handler Exposure & Risk from Use on Rice

The potential exposures and associated risks for handlers mixing, loading and applying etofenprox to rice were based on the proposed Section 3 label. The proposed maximum use rate for the etofenprox granular formulation (TREBON 3G) is 0.27 lb ai per acre per application, with a pre-harvest interval (PHI) of 60 days. Applications are to be made using aerial application equipment.

Short- and intermediate-term dermal and inhalation exposures are anticipated for occupational handlers mixing, loading, and applying etofenprox to rice fields. A dermal toxicity endpoint was not identified for etofenprox. Only inhalation exposures are assessed. Because etofenprox-specific exposure data were not submitted, handler scenarios were assessed using surrogate PHED unit exposure data (version 1.1, 1998). Table 3 below presents the risks to occupational handlers. **For all mixers, loaders, and applicators, the MOEs for short- and intermediate-term exposures range from 1300 to 53,000, and therefore, do not exceed HED's level of concern (MOEs ≥100).**

Table 3. Occupational Handler Exposure & Risk Estimates for Etofenprox Section 3 Use on Rice to Control Rice Water Weevil

Short- & Intermediate-Term Exposure	Unit Exposure[1] (mg/lb ai handled)	Application Rate[2] (lb ai/Acre)	Units Treated[3] (Acres/Day)	Average Daily Dose[4] (mg/kg/day)	Short- and Intermediate-term MOE[5]
Mixer/Loader - Granular - Open Loading (for Aerial)					
Inhalation	0.0017	0.27	1200	0.0079	1300
Applicator - Granular - Aerial					
Inhalation	0.0013	0.27	1200	0.0060	1800
Flagger - Granular - Aerial					
Inhalation	0.00015	0.27	350	0.00020	53,000

[1] Unit Exposure = mg a.i./lb a.i. handled from the Pesticide Handler Exposure Database (PHED), Version 1.1, August 1998.
[2] Maximum Application Rate.
[3] Units Treated taken from Science Advisory Council for Exposure, Standard Operating Procedure 9.1, Standard Values for Daily Acres Treated in Agriculture, Rev. 25 SEP 2001.
[4] Average Daily Dose (ADD) = Unit Exposure * Application Rate * Units Treated * Absorption Factor (inhalation 100%) ÷ Body Weight (70 kg).
[5] Margin Of Exposure (MOE) = NOAEL (mg/kg/day) ÷ ADD (mg/kg/day); where the NOAEL = 10.6 mg/kg/day for all durations of inhalation exposure.

Postapplication Exposure & Risk from Use on Rice

This proposed Section 3 use on rice involves foliar applications; therefore, there is a potential for short- and intermediate-term dermal exposure to workers entering etofenprox-treated areas to perform a variety of agricultural/occupational tasks. However, because a dermal toxicity endpoint was not identified for etofenprox, and inhalation exposure is expected to be negligible for postapplication scenarios, a **postapplication risk assessment is not required.**

Handler Exposure & Risk from Use as Mosquito Adulticide

Etofenprox has been requested for public health mosquitocide uses; to be applied by PCOs only, using ULV aerial applications, ULV backpack applications, truck-mounted thermal ground foggers or handheld thermal foggers. The potential exposures and associated risks for handlers mixing, loading and applying etofenprox as a mosquito adulticide are based on the proposed Section 3 label for RF2056 OL (etofenprox 20% liquid formulation). Regardless of equipment, the maximum application rate is 0.007 lb ai/acre. Application is not to be made to the same site more than once in three days, and no more than 2 times to a single site in any week. A maximum of 25 applications is allowed per year.

Short- and intermediate-term dermal and inhalation exposures are anticipated for occupational handlers mixing, loading, and applying etofenprox at low volume by aerial and ground equipment. . A dermal toxicity endpoint was not identified for etofenprox. Only inhalation exposures are assessed. Because etofenprox-specific exposure data were not submitted, most handler scenarios were assessed using surrogate PHED unit exposure data (version 1.1, 1998). Where PHED does not contain data for the specific proposed equipment/application method, PHED data for a similar formulation/equipment scenario are used. This is the case for the truck-mounted mosquitocide fogger scenario. No equipment-specific PHED data exist for such an application, so the PHED data for an airblast sprayer were used as a reasonable approximation of the handler exposure resulting from the fogger use. Also, the surrogate data for the proposed etofenprox handheld thermal fogger, is taken from the study of a pulse-fogger used in a greenhouse (Nigg, et.al., 1987). While the Nigg study has poor data quality (only 3 valid replicates), its results have been used in some previous assessments because it provides the only useable data set upon which to specifically evaluate a handheld fogger.

Table 4 below presents the risks to occupational handlers. **For all mixers, loaders, and applicators, the MOEs for short- and intermediate-term exposures are all ≥100 and therefore, do not cause concern to HED.**

Table 4. Occupational Handler Exposure & Risk Estimates for Etofenprox Section 3 Use as Mosquitocide					
Short- & Intermediate-Term Exposure	**Unit Exposure[1]** (mg/lb ai handled)	**Application Rate[2]** (lb ai/Acre)	**Units Treated[3]** (Acres/Day)	**Average Daily Dose[4]** (mg/kg/day)	**Short- and Intermediate-term MOE[5]**
Mixer/Loader – Liquids (ULV) Open Loading for Aerial Application					
Inhalation	0.0012	0.007	7500	0.0009	12,000
Mixer/Loader – Liquids (ULV) Open Loading for Truck-Mounted Ground Fogging					
Inhalation	0.0012	0.007	3000	0.00036	29,000
Applicator – Aerial Liquids (ULV)					
Inhalation	0.000068	0.007	7500	0.000051	200,000
Applicator – Truck-Mounted Ground-Fogger (Airblast used as Surrogate)					
Inhalation	0.0045	0.007	3000	0.0014	7600
Mixer/Loader/Applicator – Handheld Fogger					
Inhalation	0.19	0.007	5	0.000095	110,000
Flagger – Aerial Liquids (ULV)					
Inhalation	0.00035	0.007	350	0.000012	870,000

[1] Unit Exposure = mg ai/lb ai handled from the Pesticide Handler Exposure Database (PHED), Version 1.1, August 1998, except for handheld fogger based on Nigg et.al., 1987.
[2] Maximum Application Rate.
[3] Units Treated taken from Science Advisory Council for Exposure, Standard Operating Procedure 9.1, Standard Values for Daily Acres Treated in Agriculture, Rev. 25 SEP 2001.
[4] Average Daily Dose (ADD) = Unit Exposure * Application Rate * Units Treated * Absorption Factor (inhalation 100%) ÷ Body Weight (70 kg).
[5] Margin Of Exposure (MOE) = NOAEL (mg/kg/day) ÷ ADD (mg/kg/day); where the NOAEL = 10.6 mg/kg/day for all durations of inhalation exposure.

Postapplication Exposure and Risk from Use as Mosquito Adulticide

Occupational postapplication activities are not expected with mosquito adulticide applications and therefore, no assessment is required.

Residential (Non-Occupational) Exposure and Risk

Both of the Section 3 applications (rice and mosquitocide) subject to this assessment are to be made by professional (agricultural or commercial) personnel (i.e., not residential). Therefore, **a residential handler exposure assessment is not required.**

HED has determined that **there are potential postapplication exposures** to adults and children from the ultra low volume (ULV) aerial and ground-based fogger applications for public health mosquito control uses in the vicinity of residential dwellings.

The assessment has been developed as conservative model that encompasses potential exposures received in residential and recreational areas (e.g., school playgrounds, parks, athletic fields). The scenarios likely to result in postapplication exposures are as follows:

* Dermal exposure from contact with residues deposited on turf at residential, park, and school sites (adult and toddler);
* Incidental nondietary ingestion of residues deposited on turf at residential, park, and school sites from hand-to-mouth transfer (toddler);
* Incidental nondietary ingestion of residues deposited on turf at residential, park, and school sites from object-to-mouth transfer (toddler);
* Incidental ingestion of soil from treated areas (toddler); and
* Inhalation (adult and toddler).

Chemical-specific exposure data for mosquito uses have not been submitted by the registrant. Therefore, the equations and assumptions used for each of the scenarios were taken from the Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments guidance. Interim changes to these SOPs have been adopted by the HED Exposure Science Advisory Council regarding standard values for turf transferrable residues and hand-to-mouth activities and are included in this assessment. The *AgDRIFT* model was used to assess air concentrations and deposition to residential turf after aerial ULV mosquitocide applications.

The following general assumptions were made for all scenarios:

* Postapplication was assessed on the same day the pesticide is applied because it was assumed that the homeowner could be exposed to turfgrass immediately after application. Therefore, postapplication exposures were based on day 0.

* Adults were assumed to weigh 70 kg. Toddlers (3 years old), used to represent the 1 to 6 year old age group, were assumed to weigh 15 kg.

* The maximum labeled application rate (ULV) for aerial mosquito control is 0.007 lb ai/acre. The maximum labeled application rate (ULV) for ground-based fogger mosquito control also is 0.007 lb ai/acre.

While the maximum application rate is the same for aerial and ground mosquitocide applications (i.e., 0.007 lb ai/acre), methods for estimating potential postapplication exposure from these uses are different.

Postapplication Inhalation Exposure and Risk from Mosquito Adulticide Applications

To calculate airborne concentrations from aerial ULV applications, HED used *AgDRIFT* (V 1.03 -- June 1997), a model developed through the efforts of the *Spray Drift Task Force (SDTF).* The SDTF is a coalition of 38 pesticide registrants whose primary objectives were to develop a comprehensive database of off-target drift information in support of pesticide registrations and an appropriate model system. This model was selected by the consensus of several experts in the spray drift area because it represents the current state-of-the-art. HED discussed the issue of model selection with several experts in the spray drift community prior to selecting *AgDRIFT* (e.g., Sandra L. Bird, U.S. EPA; Steven G. Perry, U.S. EPA; Milton E. Teske, Continuum Dynamics; Pat Skyler, U.S. Forest Service;

Arnet Jones, U.S. EPA; and Harold Thistle, U.S. Forest Service). HED considered using the *USDA Forest Service Cramer-Barry-Grim Model* (commonly referred to as *FSCBG*). *FSCBG* was developed through support from the U.S. Forest Service, in cooperation with the U.S. Army, and has been in existence for over 20 years. Development of *FSCBG* was actually completed by Continuum Dynamics, Inc. located in Princeton, New Jersey under the technical direction of Milton E. Teske. However, it was decided that *AgDRIFT* should be used because it is based on essentially the same algorithms as *FSCBG* (personal communication with Milton E. Teske of Continuum Dynamics), it has undergone extensive validation by the *SDTF*, and it is very user-friendly compared to *FSCBG*.

AgDRIFT is a *Microsoft Windows*-based personal computer program, provided to the U.S. Environmental Protection Agency's Office of Pesticide Programs through the Cooperative Research and Development Agreement (CRADA) between EPA's Office of Research and Development and the *SDTF*. *AgDRIFT* predicts the motion of spray material released from aircraft, including the mean position of the material and the position variance about the mean as a result of turbulent fluctuations. *AgDRIFT* includes extensive validation based on 180 separate aerial treatments performed during field trials in 1992 and 1993 by the SDTF.

AgDRIFT is capable of producing a variety of useful outputs. The key for HED in this assessment was to determine from the model what amount of the application volume remained aloft and what amount of the resulting droplets deposited on the surfaces in the treatment area as well as downwind from the treatment area. The model allows for the estimation of air concentrations in the breathing zones of adults and toddlers, as well as residues depositing on turf for use in calculating the risks to individuals residing in areas being treated by aerial application of etofenprox. The *AgDRIFT* model input parameters used for the public health mosquito control risk assessment appear in Table 5. The input parameters below and air concentration estimates from *AgDRIFT* that follow were provided by Greg Orrick, OPP Environmental Fate and Effects Division (email 04/29/08).

Table 5. Input parameters to AgDRIFT for etofenprox aerial applications.

Parameter	Value	GUI Section	Reference
Aircraft Features			
Tier	Tier III Aerial	(Toolbar)	Default
Aircraft name	Air Tractor AT-401	Aircraft/Aircraft	Default
Aircraft type	Fixed wing	Aircraft/Aircraft	Default
Wing semispan	24.5 ft	Aircraft/Aircraft	Default
Aircraft weight	6000 lbs	Aircraft/Aircraft	Default
Propeller rpm	2000	Aircraft/Aircraft	Default
Propeller radius	4.5 ft	Aircraft/Aircraft	Default
Planform area	294 ft^2	Aircraft/Aircraft	Default
Engines	1	Aircraft/Aircraft	Default
Engine vertical	-1.2 ft	Aircraft/Aircraft	Default
Engine forward	11.9 ft	Aircraft/Aircraft	Default
Wing vertical	1.51 ft	Aircraft/Aircraft	Default
Vortex decay rate	1.25 mph	Advanced settings	Default
Aircraft drag	0.1	Advanced settings	Default

Table 5. Input parameters to AgDRIFT for etofenprox aerial applications.			
Parameter	**Value**	**GUI Section**	**Reference**
coefficient			
Propeller efficiency	0.8	Advanced settings	Default
Nozzle Array			
Boom vertical	-1.15 ft	Aircraft/Aircraft	Default
Boom forward	-0.8333 ft	Aircraft/Aircraft	Default
Number of nozzles	42	Aircraft/Nozzles	Default
Nozzle extent	65% (regular distribution)	Aircraft/Nozzles	Default
Droplet Size Distribution			
Droplet size distribution	Aerosol to Very Fine	Aircraft/Nozzles/Nozzle drop size distribution	User defined, based on the proposed label
or			
Distribution type	Parametric	Aircraft/Nozzles/Nozzle drop size distribution	User defined, based on the proposed label
$D_{V0.5}$	47.79 µm	Aircraft/Nozzles/Nozzle drop size distribution	User defined, based on the proposed label
Relative span	1.62	Aircraft/Nozzles/Nozzle drop size distribution	User defined, based on the proposed label
Aircraft Operation			
Typical flight speed	120 mph	Aircraft/Aircraft	Default
Release height	100 ft	Aircraft	User defined, based on the proposed label
Flight lines	20	Aircraft	Default
Swath width	60 ft	Swath	Default
Swath displacement	0 ft	Swath	Default
Spray Material			
Spray material	Oil	Spray material	User defined, based on the proposed label
Specific gravity, carrier	0.891	Spray material	User defined, based on product chemistry
Specific gravity, nonvolatile	0.891	Spray material	User defined, based on product chemistry
Evaporation rate	2.49 um^2/°C/sec	Spray material	User defined, minimum value allowed by model
Nonvolatile rate	0.375 lbs/A	Spray material	User defined, based on spray volume rate
Active rate	0.0070 lbs a.i./A	Spray material	User defined, based on the proposed label
Spray volume rate	0.050 gal/A	Spray material	User defined, minimum value allowed by model
Environmental Features			
Wind speed	2 mph	Meteorology	User defined, based on the proposed label
Wind speed measurement height	6.56 ft	Advanced settings	Default

Table 5. Input parameters to AgDRIFT for etofenprox aerial applications.			
Parameter	**Value**	**GUI Section**	**Reference**
Wind direction	-90°	Meteorology	Default
Relative humidity	90%	Meteorology	User defined; typical of mosquito habitat
Temperature	85°F	Meteorology	User defined; typical of mosquito habitat
Ambient pressure	29.91 in Hg	Advanced settings	Default
Surface roughness	0.0246 ft	Terrain	Default
Computational Settings			
Flux plane location	0 ft	Transport	Default
Maximum computational time	600 sec	Advance settings	Default
Maximum downwind distance	2608.24 ft	Advance settings	Default

While estimates of air concentration from aerial applications were produced from *AgDRIFT,* the approach for estimating air concentrations from truck-fogger applications is based on the one described in the Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessment for inhalation exposure to outdoor residential short-term pest control. The major difference is that the SOPs begin by assuming the use of a commercial fogger product that has a known volume. In the scenario below, the beginning assumption is that the full application rates for a ground-based fogger truck (with a dilution factor of 1 to 100) is available in the breathing zone of the residential bystander, thus turning an application rate expressed as lbs. ai/ft^2, into a concentration expressed in a per cubic meter (m^3) basis. Below are some of the data and assumptions used in the inhalation exposure assessment, followed by the stepwise process, including assumptions and calculations used for estimating residential bystander inhalation exposure from aerial ULV and truck fogger mosquito control applications.

* *Aerial and Ground ULV* application rate is 0.007 lb ai/acre.
* Dilution of airborne concentration of 1 to 100 (i.e., 0.01) of product released is available for exposure from truck fogger application.
* Adult breathing rate = 0.5 m^3/hour (sedentary activity), and weight is 70 kg.
* Toddler breathing rate = 0.4 m^3/hour (sedentary activity), and weight is 15 kg.
* Exposure time is 20 minutes (0.33 hours). [Note: For the ground-based fogger, the twenty-minute exposure period is based on the conservative assumption that an individual is walking along side a ground-based fogger for 20 minutes with the full application rate only diluted by HED's standard outdoor 1 to 100 dilution factor, with no further dilution. For aerial application, it is conservatively assumed that an individual is standing in the highest concentration of the drift profile for twenty minutes, as it moves by, without taking into account the decrease in air concentration of the drift profile over that time period. This represents an individual in their yard taking twenty minutes to remove themselves to the indoors.]

* Adult and Toddler short-/intermediate-term inhalation NOAEL = 10.6 mg/kg/day. (LOC = 100).

Only short-term postapplication inhalation exposure is expected following public health mosquito control applications due to the intermittent use pattern.

Aerial ULV (100 ft. release height):

Adult Exposure

* Airborne concentration estimate at approx. 6 ft. from ground = 0.000949 mg/m^3

* $Dose_{adult}$ = (concentration) x (breathing $rate_{adult}$) x (exposure duration)) BW_{adult} = (0.000949 mg/m^3) x (0.5 m^3/hour) x (0.33 hours/day)) 70 kg = 0.0000022 mg/kg/day

* Short-term $Risk_{adult}$ = MOE = $NOAEL_{inhal.}/Dose_{adult}$
MOE = (10.6 mg/kg/day)/(0.0000022 mg/kg/day) = **4.8E+6**

Toddler Exposure

* Airborne concentration estimate at approx. 3 ft from ground = 0.000898 mg/m^3

* $Dose_{toddler}$ = (concentration) x (breathing $rate_{toddler}$) x (exposure duration)) $BW_{toddler}$ = (0.000898 mg/m^3) x (0.4 m^3/hour) x (0.33 hours/day)) 15 kg = 0.0000079 mg/kg/day

* Short-term $Risk_{toddler}$ = **MOE** = (10.6 mg/kg/day)/(0.0000079 mg/kg/day) = **1.3E+6.**

Both adult and toddler risk estimates for inhalation exposure do not concern HED.

ULV Truck-fogger

* Application rate of 0.007 lb ai/acre x 1 acre/43,560 ft^2 = 0.00000016 lbs ai/ft^2 = 0.0000017 lb ai/m^2

* Expressed as an airborne concentration = 0.0000017 lbs ai/m^3, and 0.0000017 lbs ai/m^3 x 454,000 mg/lb = 0.77 mg/m^3
* Application concentration (0.77 mg/m^3) x dilution factor (0.01) = 0.0077 mg/m^3

Adult Exposure

* $Dose_{adult}$ = (concentration) x (breathing $rate_{adult}$) x (exposure duration)) BW_{adult} = (0.0077 mg/m^3) x (0.5 m^3/hour) x (0.33 hours/day)/70 kg = 0.000018 mg/kg/day

* Short-term $Risk_{adult}$ = MOE = $NOAEL_{inhal.}/Dose_{adult}$
MOE = (10.6 mg/kg/day)/(0.000018 mg/kg/day) = **590,000**

Toddler Exposure

* $Dose_{toddler}$ = (concentration) x (breathing $rate_{toddler}$) x (exposure duration)) $BW_{toddler}$ = (0.0077 mg/m^3) x (0.4 m^3/hour) x (0.33 hours/day)/15 kg = 0.000068 mg/kg/day

* Short-term $Risk_{toddler}$ = **MOE** = (10.6 mg/kg/day)/(0.000068 mg/kg/day) = **160,000**

Both adult and toddler risk estimates for inhalation exposure do not exceed HED's level of concern.

Incidental Oral Exposure/Risk from Public Health Mosquito Control

A dermal toxicity endpoint was not identified for etofenprox and therefore, a dermal postapplication exposure and risk assessment was not performed. However, in addition to the potential inhalation risk described above, toddlers may be exposed by incidental ingestion from contact with residues on turf upon which residues deposited from aerial and ground-based public health mosquitocide applications.

The following general assumptions were made for incidental oral scenarios:

* Toddler activities on turf are expected to occur for a 2-hour period.
* For short-term contact, 20 hand-to-mouth events are expected to occur per hour; for intermediate-term, 9.5 events per hour.
* Twenty (20) cm^2 of hand surface area is expected to contact the mouth on each event.
* Fifty percent (50%) of the residues are expected to be removed from the hand by saliva.
* Deposition on turf from aerial ULV application was estimated by use of the *AgDRIFT* model, and provided by Greg Orrick, OPP Environmental Fate and Effects Division.
* Deposition on turf from ground-based foggers was estimated as the full application rate without a dilution factor.
* Twenty percent (20%) of the deposited residues are expected to be available for object-to-mouth transfer.
* Residues from a 25 cm^2 area are expected to be contacted for object-to-mouth transfer.

Results of the assessment for residential postapplication incidental oral exposure and risk are presented in Table 6, along with the formulae used (see footnotes).

Table 6: Short- and Intermediate-Term Incidental Oral Postapplication Risks from Public Health Mosquito Control

Scenario	Crop or Target	Receptor	Deposition Per Treatment[a] (ug ai/ cm^2)	TTR (ug/cm^2)[b]	Grt (ug/cm^2)[c]	Srt (ug/g)[d]	Exposure Time (ET) (hrs/day)	Surface Area (SA) (cm^2/ event)	Freq. (FQ) (events/ hr)	IgR (cm^2/day) or (mg/day)[e]	ADD (mg/kg/day)[f]	MOE[g]
Hand-to-Mouth	Turf (air ULV)	Toddler	0.0386	0.0019	-	-	2	20	20	-	0.00005	400,000
	Turf (grnd ULV)		0.078	0.0039							0.0001	200,000
Object-to-mouth Turfgrass	Turf (air ULV)	Toddler	0.0386	-	0.0077	-	-	-	-	25	0.000013	150,000
	Turf (grnd ULV)		0.078		0.016						0.000027	740,000
Incidental soil ingestion	Turf (air ULV)	Toddler	0.0386	-	-	0.025	-	-	-	100	0.00000017	1.2E+8
	Turf (grnd ULV)		0.078			0.052					0.00000035	5.7E+7

a Deposition: Air ULV = estimate from *AgDRIFT* ; Ground ULV = application rate (0.007 lb ai/A)/(43,560 ft^2. per A) * (4.54E+8 ug/lb) * (1.08E-3 ft^2/cm^2)

b Turf transferrable residue (ug/cm^2) = fraction ai retained on foliage (5% for hand-to-mouth) * deposition [(0.0386 ug ai/cm^2 for air ULV), and (0.078 ug ai/cm^2 for ground ULV)].

c *Grass residue (ug/cm^2) = fraction ai retained on foliage (20% for object-to-mouth) * deposition* [(0.0386 ug ai/cm^2 for air ULV), and (0.078 ug ai/cm^2 for ground ULV)].

d Soil residue (ug/g) = deposition [(0.0386 ug ai/cm^2 for air ULV), and (0.078 ug ai/cm^2 for ground ULV)] * 1/cm * 0.67 cm^3/g soil.

e Ingestion rate: cm^2/day for object-to-mouth, and mg/day for incidental soil ingestion.

f Average daily dose (ADD) (mg/kg/day)
Hand-to-mouth: = [TTR (ug/cm^2) * SA (cm^2/event) * FQ (events/hr) * mg/1,000 ug * Saliva extraction (50%) * ET (hrs/day)] / [BW (15 kg toddler)];
Object-to-mouth: = [GRt (ug/cm^2) * IgR (cm^2/day) * mg/1000 ug] / [BW (15 kg toddler)]; and
Incidental soil ingestion: = [SRt (ug/g) * IgR (mg/day) * g/1,000,000 ug] / [BW (15 kg toddler)].

g MOE = NOAEL/ADD, where Short- and Intermediate-term NOAEL (toddler incidental oral) = 20 mg/kg/day, with an LOC of 100.

3.2.1 Summary of Non-occupational Postapplication Risks, Data Gaps, and Confidence in Exposure and Risk Estimates

The assessment of residential inhalation and incidental oral exposures following the public health use of etofenprox to control mosquitos **resulted in all MOEs of >100, and therefore, does not cause concern for HED.** While these estimates do not include any build-up of sequential applications (up to 2 times to a single site in any week, with a maximum of 25 applications is allowed per year), the estimated risks are based on conservative assumptions regarding the circumstances of exposure:

* Maximum label rates were used;
* For truck-foggers, individuals were assumed to be standing for 20 minutes in an air concentration that is based on the entire application rate (with a dilution factor of 1 to 100);
* No dissipation (breakdown) of etofenprox in the breathing zone concentration or in turf residues was included.

3.3 Combined Non-occupational Exposures and Risks

Under the Food Quality Protection Act (FQPA), various exposure scenarios that could result in multiple non-occupational exposures to a particular pesticide must be aggregated. A realistic exposure assessment under this FQPA requirement would aggregate exposure only from activities that would reasonably be expected to occur on the same day. An assessment for etofenprox that aggregates dietary, non-dietary (i.e., residential) and drinking water sources of exposure is addressed in a separate HED human health assessment document. In order to develop the non-dietary or residential exposure component to this aggregate risk, an assessment is made of the combined exposures of all relevant routes for all activities that could reasonably occur on the same day.

Table 7 below presents the combined inhalation and incidental oral risk estimates for toddlers from postapplication exposure following public health mosquito treatment. Risks are calculated using the Total MOE approach because, while inhalation and incidental oral endpoint effects are the same, they occur at different dose levels. Calculated total MOEs of greater than or equal to 100 do not cause concern to HED. There are no concurrent adult exposures to aggregate.

From Table 7 below, it can be seen that **combined short- and intermediate-term risks to toddlers, from all routes of exposure following both ground and aerial etofenprox public health mosquito control treatments, do not exceed HED's level of concern.**

It is important to note that the conservative assumptions listed for the individual routes of exposure are combined here, leading to an upper-range to upper-bound estimate of combined risks. An example of the conservative nature of the estimate of combined exposures following truck-fogger application is the fact that the inhalation exposure (based on the full maximum application rate with a dilution factor of 1 to 100) is combined with the dermal and/or incidental ingestion exposure from residues depositing on the turf (based on an estimated deposition rate based on the full application rate). This approach may result in double-counting some of the residue levels estimated for ground-based etofenprox applications.

Table 7: Combined Toddler Inhalation and Incidental Oral Risks from Public Health Mosquito Control

Scenario	Inhalation Daily Dose (mg/kg/day)	Inhal. MOE[1]	Combined Incid. Oral Dose[2] (mg/kg/day)	Incid. Oral MOE[2]	Total MOE[3]
(1) Postapplication following **Ground ULV** application	0.0000079	1.3E+6	0.000063	300,000	240,000
(2) Postapplication following **Aerial ULV** application	0.000068	160,000	0.00013	150,000	77,000

1. MOE = NOAEL/ADD, where

NOAEL (toddler inhalation) = 10.6 mg/kg/day, with an LOC of 100.
NOAEL (toddler incidental oral) = 20 mg/kg/day, with an LOC of 100.

2. Combined Incidental oral dose = combined dose from hand-to-mouth, object-to-mouth, and soil ingestion.
3. Total MOEs = $1/[\ (1/MOE_{inhal}) + (1/MOE_{incid\ oral})]$. MOEs greater than or equal to 100 for for toddlers, are not of concern to HED.

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R159749

Chemical Name: **Ethofenprox**

PC Code: **128965**
HED File Code: **12000 Exposure Reviews**
Memo Date: **6/9/2008**
File ID: **00000000**
Accession #: **000-00-0125**

HED Records Reference Center
6/11/2008