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

JAN 16 2001

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Label Amendment of ReJeX-iT® TP-40 (EPA Reg. No. 58035-7), containing 40% Methyl Anthranilate as its Active Ingredient (Chemical No.128725). Review of Efficacy and Water Residue Studies. DP Barcode D270616; Case No. 004321; S587244; MRIDs 450886-01 and -02; 452102-01 and -02; 452297-01; and 452375-01.

FROM: Russell S. Jones, Ph.D., Biologist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

THRU: Freshteh Toghrol, Ph.D., Senior Scientist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

TO: Rosemary Biancardi, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

ACTION REQUESTED

On behalf of Becker-Underwood, Inc. C. B. Rice requested an amendment to the product label for ReJeX-iT® TP-40 (EPA Reg. No. 58035-7), containing 40% methyl anthranilate (MA, or methyl 2-aminobenzoate) as its active ingredient, to expand its use sites to include (i) trees and shrubs; (ii) airports; and (iii) urban and suburban turf environments sites for the purpose of repelling birds (see letter from C. B. Rice to Driss Benmhend, dated 4/11/2000). In support of this label amendment, the registrant submitted three efficacy studies (MRIDs 450886-01, -02, and 452375-01) that pertained to fogging applications of the end-use product at commercial and residential sites. In a later submission (see letter from C. B. Rice to D. Benmhend, dated 9/15/2000) the registrant requested additional amendment to the product label to permit fogging applications over and/or adjacent to fish-bearing bodies of water (lakes and ponds and harbors and boat docks. In support of the second amendment request, the registrant submitted water residue studies (MRIDs 452102-01, -02, and 452297-01). Also submitted was a CSF dated 1/13/2000, and a proposed label.

RECOMMENDATIONS AND CONCLUSIONS

1. The submitted data support the proposed label amendments for ReJeX-iT® TP-40 (EPA Reg. No. 58035-7).

2. The product performance (efficacy) data is acceptable. No additional data are required.

3. The data pertaining to methyl anthranilate residues in water following fogging applications over fish-bearing waters (ponds) is acceptable. No additional data are required.

4. Methyl anthranilate is exempt from the requirements of a tolerance when used on blueberry, cherry, and grape (40 CFR §180.1143).

STUDY SUMMARIES

Product Performance (Efficacy); MRIDs 450886-01 and -02; and 452375-01

Three studies, conducted at three different geographic locations were submitted by the registrant. In the first study (MRID 452375-01), the end-use product is apparently effective in repelling pigeons (*Columbia livia*) and English sparrows (*Passer domesticus*) from a parking garage at fog application rates of 0.9-<4 gal/hr. Removal of nest building materials and filling of holes wherein new nests could potentially be built (exclusion) coupled with the fog applications was highly effective in reducing pigeon and English sparrow populations in the treated structure. The duration of the treatment effects could not be determined based on the submitted data. Furthermore the separate effects of nest removal/exclusion activities vs. fogging could not be determined. BPB disagrees with the study author's conclusion that sanitation/exclusion did not substantially enhance the effects of fogging in deterring birds from the test site. BPB agrees with the conclusion that sanitation/exclusion coupled with fogging with the end-use product will result in long-term bird deterrence. In the second study (MRID 450886-01), multiple fogging applications with the end-use product at 4/ gal/hr for 2.5 hours demonstrated that the product will repel birds from roosts around an apartment complex. Bird populations were reduced up to 94% following the third of four fog applications. The duration of repellency after the fourth of four applications was reported by the study authors to be several weeks, although the degree of repellency was not reported. In the third study (MRID 4508806-02), the end-use product, the product can repel Canada geese, but only with daily applications. Due to the small target population size, the degree of repellency could not be determined. Daily applications were necessary to prevent geese from returning.

Magnitude of the Residues in Water (Non-guideline Study): MRIDs 452102-01 and -02; and 452297-01

Three reports describe a single study conducted to determine the maximum methyl anthranilate (MA) residues that would be found in pond water immediately after fogging of ponds with Rejex-it® TP-40. The information contained in MRID 452297-01 describes he details of the experimental protocol; MRID 452102-01 summarizes the results of the experiment, and MRID 452102-02 provides details of the analytical methods used to analyze the water samples (conducted by Case Consulting Laboratories, Whippany, NJ). No DER was written for MRID 452102-02, but the information is summarized in the Magnitude of the Residues DER. Two different types of foggers [thermal and ultra low volume (UV]) were used to apply the end-use product over fish-bearing waters (ponds) to determine to what extent methyl anthranilate (MA) residues would accumulate in water. MA content of water samples generally decreased with product application rate and distance from the fogger. Using the Golden Eagle thermal fogger and rates varying from 180 to 1800 g of end-use product, MA concentrations ranged from <0.016 ppm at 150 feet from the fogger to 0.256-1.623 ppm at 10 feet from the fogger (Table 1). Using the Hurricane ULV fogger and rates varying from 36 to 360 g of end-use product, MA concentrations in pond water ranged from <0.016 ppm at 150 feet from the fogger to 0.256-1.623 ppm at 10 feet from the fogger.

LABEL REVIEW

The following ecotoxicity data were cited by the registrant (in MRID 452102-01, p. 9) and listed in the table below:

Species	Static	Flow-Through
Bluegill Sunfish	LC_{50} = 9.12 mg/L (MRIDs 426998-02, -03, 427182-02, & 429669-01)	LC_{50} = 9.12 mg/L (MRIDs 426998-02, -03, 427182-02, & 429669-01)
Channel Catfish	LC_{50} = 16.23 mg/L (MRIDs 426998-02, -03, 427182-02, & 429669-01)	
Rainbow Trout	LC_{50} = 22.91 mg/L (MRIDs 426998-02, -03, 427182-02, & 429669-01)	LC_{50} = 25.4 mg/L (MRIDs 436107-03)
Atlantic Salmon	LC_{50} = 32.25 mg/L (MRIDs 426998-02, -03, 427182-02, & 429669-01)	
Daphnia	LC_{50} = 29.1 mg/L (MRIDs 427182-03 & 429951-01)	

Based on these data, the environmental hazards statement should be changed from "This pesticide is slightly toxic to aquatic invertebrates" to "This pesticide is slightly toxic to fish and aquatic invertebrates."

cc: F. Toghrol, R. S. Jones, R. Biancardi: BPPD Subject File
R. S. Jones: F.T. CM2, 703/308-5071: 1/16/2001

DATA EVALUATION REPORT

Reviewed by: Russell S. Jones, Ph.D. BPPD
Secondary Reviewer: Freshteh Toghrol, Ph.D. BPPD

STUDY TYPES:	Product Performance (Efficacy) Studies; Subdivision M *Guideline 96-6*
DP BARCODE:	270616
CASE NO:	004321
SUBMISSION NO.:	S587244
CASWELL NO.:	None
MRID Nos.	450886-01, -02, and 452375-01
NAME; TEST MATERIAL:	ReJeX-iT TP-40 (containing 40% methyl anthranilate as its active ingredient)
CHEMICAL NO.:	128725
SPONSOR:	Becker-Underwood, Inc., 801 Dayton Avenue, Ames, IA 50010
STUDY NO.:	None
TITLE OF REPORTS:	*Fogging of ReJex-It® TP-40, Apartment Property in* Wheaton, MD (MRID 450886-01); Fogging of ReJex-It® TP-40, Corporate Office Park, Fort Wayne, IN (MRID 450886-02) Fogging of ReJex-It® TP-40, Parking Garage in Fort Wayne, IN (MRID 452375-01).
AUTHOR:	Peter F. Vogt, Ph.D. and Kim Lewis (MRID 450886-01); Peter F. Vogt, Ph.D. and Jeffrey Ling (MRIDs 450886-01 and 452375-01)
DATE OF REPORTS:	30 March 2000
QUALITY ASSURANCE:	The studies were not performed under Good Laboratory Practice Standards because the studies consisted of field trials with animals.

Non-compliance Statements were signed by the submitter/sponsor and/or the study director.

STUDY SUMMARIES: Three studies, conducted at three different geographic locations were submitted by the registrant. In the first study (MRID 452375-01), the end-use product is apparently effective in repelling pigeons (*Columbia livia*) and English sparrows (*Passer domesticus*) from a parking garage at fog application rates of 0.9-<4 gal/hr. Removal of nest building materials and filling of holes wherein new nests could potentially be built (exclusion) coupled with the fog applications was highly effective in reducing pigeon and English sparrow populations in the treated structure. The duration of the treatment effects could not be determined based on the submitted data. Furthermore the separate effects of nest removal/exclusion activities vs. fogging could not be determined. BPB disagrees with the study author's conclusion that sanitation/exclusion did not substantially enhance the effects of fogging in deterring birds from the test site. BPB agrees with the conclusion that sanitation/exclusion coupled with fogging with the end-use product will result in long-term bird deterrence. In the second study (MRID 450886-01), multiple fogging applications with the end-use product at 4/ gal/hr for 2.5 hours demonstrated that the product will repel birds from roosts around an apartment complex. Bird populations were reduced up to 94% following the third of four fog applications. The duration of repellency after the fourth of four applications was reported by the study authors to be several weeks, although the degree of repellency was not reported. In the third study (MRID 4508806-02), the end-use product, the product can repel Canada geese, but only with daily applications. Due to the small target population size, the degree of repellency could not be determined. Daily applications were necessary to prevent geese from returning.

CLASSIFICATION: Acceptable; no additional efficacy data are required for fogging applications.

I. Study 1. Fogging of ReJex-It® TP-40. Parking Garage in Fort Wayne, IN (MRID 4452375-01)

A. MATERIALS AND METHODS

Test Substance: ReJeX-iT® TP-40 (containing 40% methyl anthranilate as its active ingredient).
Fog Applicator: Curtis Dyna-Fog Model "Blackhawk"

Application Rate:	<4 gallons/hour
Total Volume Used:	Approximately 2 gallons
Application Date:	24-26 March 2000
Test Site:	Carew Medical Center, Fort Wayne, IN; three-level parking garage, approx. 3 million cubic feet in volume containing 100+ sparrows and 30+ pigeons; all showed nesting activities.
Environmental:	Not reported
Target Species:	Pigeons (*Columbia livia*) and English sparrows (*Passer domesticus*)

B. RESULTS

Day 1: Fog applied at 6:00 pm. All birds immediately evacuated the area and only the pigeons attempted to return before fog dissipated. Wherever fog remained, pigeons altered flight paths and exited the fog immediately.

Day 2: Nest materials were manually removed from perches and target holes were filled with expandable foam for permanent exclusion. Fogging then conducted at 12:30, 4:00 and 7:00 pm with lowest application rate permitted by the fogger (0.9 gal/hour). Birds immediately evacuated the fogged area and stayed away longer (time not specified) after each fogging; pigeons were observed on adjacent rooftops.

Day 3: Removal of nest material and "hole-filling" activities were completed and fogging was conducted at 12:30, 4:30, and 6:45 pm. Pigeons did not return to the fogged areas before the last two foggings and only a few (number unspecified) sparrows were observed.

C. CONCLUSIONS

When applied as a fog, the end-use product is apparently effective in repelling pigeons (*Columbia livia*) and English sparrows (*Passer domesticus*) from a parking garage. Removal of nest building materials and filling of holes wherein new nests could potentially be built (exclusion) coupled with the fog applications are highly effective in reducing pigeon and English sparrow populations in the treated structure. The duration of the treatment effects could not be determined based on the submitted data.

D. STUDY DEFICIENCIES

No raw data were submitted. Temperature, humidity, and other environmental factors during application and during the observation period were not reported. Removal of nest materials (sanitation) and filling of holes (exclusion) where new nests could be built (on Day 2) compromised the experiment. The experiment was not designed to assess the effects of sanitation/exclusion on deterring birds from returning to the test site relative to fogging with the end-use product. BPB disagrees with the study author's conclusion that sanitation/exclusion did not substantially enhance the effects of fogging in deterring birds

from the test site. BPB agrees with the conclusion that sanitation/exclusion coupled with fogging with the end-use product will result in long-term bird deterrence.

The deficiencies described above do not affect the overall conclusion that the end-use product will repel pigeons and sparrows. The duration of repellency is unknown and was not measured.

II. Study 2. Fogging of ReJeX-iT® TP-40. Apartment Property in Wheaton, MD (MRID 450886-01)

A. MATERIALS AND METHODS

Test Substance:	ReJeX-iT® TP-40 (containing 40% methyl anthranilate as its active ingredient).
Fog Applicator:	Curtis Dyna-Fog Model "Golden Eagle"
Application Rate:	4 gallons/hour/fogger
Total Volume Used:	4 gallons
Application Time:	14-23 July 1998
Test Sites:	70 Ornamental Bradford pear trees approx. 26 feet in height throughout apartment complex property.
Environmental:	Not reported
Target Species:	Grackels (*Quiscalus quiscula*)

B. RESULTS

Day 1: Bird population counted at 10,000. Fogging initiated at 7:30 pm for 2.5 hours, completely covering the test area and exposing birds as much as possible.

Day 2: Bird counts showed that 6000 birds had returned to the area. Area was re-fogged as described above.

Day 4: Day 3 skipped due to bad weather. Bird counts showed that 2500 birds had returned to the area. Area was re-fogged as described above.

Day 7: Days 5 and 6 skipped . Bird counts showed that 600 birds had returned to the area. Area was re-fogged as described above.

Observations conducted several weeks after the last fogging showed that no significant numbers of birds (number unspecified) had returned to the area.

C. CONCLUSIONS

Multiple fogging applications with the end-use product at 4/ gal/hr for 2.5 hours demonstrated that the product will repel birds from roosts (Bradford pear trees) around an

apartment complex. Bird populations were reduced up to 94% following the third of four fog applications. The duration of repellency after the fourth of four applications was reported by the study authors to be several weeks, although the degree of repellency was not reported. No raw data were submitted in support of the reported results.

D. STUDY DEFICIENCIES

No raw data were submitted. Temperature, humidity, and other environmental factors during application and during the observation period were not reported. The degree of repellency following the final application is unknown but is evidently >94%; the duration of repellency was reported as "several weeks" after the fourth of four applications (each 4 gal/hr for 2.5 hrs). The deficiencies described above do not affect the overall conclusion that multiple applications (up to four) of the end-use product will repel grackels from treated areas for up to "several weeks."

III. Study 3. Fogging of ReJeX-iT® TP-40. Corporate Office Park, Fort Wayne, IN (MRID 450886-02)

A. MATERIALS AND METHODS

Test Substance:	ReJeX-iT® TP-40 (containing 40% methyl anthranilate as its active ingredient).
Fog Applicator:	Curtis Dyna-Fog Model "Golden Eagle"
Application Rate:	4 gallons/hour/fogger
Total Volume Used:	11 gallons
Application Time:	17-22 March 2000
Test Site:	A 24 acre site with a 2.5 acre lake used as a breeding site for non-migratory geese
Environmental:	Not specified
Target Species:	Canada geese (*Branta canadensis*).

B. RESULTS

Day 1: Windy conditions made fogging difficult. Fogging was initiated at 6:00 pm; a resident breeding pair and three non-breeding juveniles were exposed and flew away from the water.

Day 2: An unspecified number of geese were present on the water at midmorning and were fogged. All birds left the lake. An afternoon application had the same results. In the evening, 12 birds were observed on the lake; after two fog applications, the birds evacuated and did not return.

Day 3: A breeding pair was observed o th lake in the afternoon, but left the lake after fogging.

Day 4: Evening fogging needed to drive away breeding pair and the birds left the property after several (unspecified number) foggings.

Day 5: Two pairs of geese were found onsite. After fogging, one pair left and the other flew to the roof of a nearby building. Evening fogging prevented the two groups of visiting geese from landing and they left the site.

C. CONCLUSIONS

When applied as a fog, the end-use product, the product can repel Canada geese, but only with daily applications. Due to the small target population size, the degree of repellency could not be determined.

D. STUDY DEFICIENCIES

No raw data were submitted. Temperature, humidity, and other environmental factors during application and during the observation period were not reported. The degree and duration of repellency following the final application to geese is unknown, although daily applications were necessary to prevent geese from returning. The deficiencies described above do not affect the overall conclusion that multiple applications of the end-use product will repel geese from treated areas, though daily applications are necessary.

DATA EVALUATION REPORT

Reviewed by: Russell S. Jones, Ph.D. BPPD
Secondary Reviewer: Freshteh Toghrol, Ph.D. BPPD

STUDY TYPES:	Magnitude of the Residue in Water Studies; Non-Guideline
DP BARCODE:	270616
CASE NO:	004321
SUBMISSION NO.:	S587244
CASWELL NO.:	None
MRID Nos.:	452102-01, -02, and 452297-01
NAME; TEST MATERIAL:	ReJeX-iT TP-40 (containing 40% methyl anthranilate as its active ingredient)
CHEMICAL NO.:	128725
SPONSOR:	Becker-Underwood, Inc., 801 Dayton Avenue, Ames, IA 50010
TESTING LABORATORY:	Case Consulting Laboratory
STUDY NO.:	Project RJ 3.12 (MRID 452102-01)
TITLE OF REPORTS:	Residue of MA in Water after Fogging with Rejex-it® TP-40 (MRID 452102-01); Methyl Anthranilate - Magnitude of the Residue in Water after Fogging (452102-02); and Collection of Water Samples for Residue Analysis from Ponds Treated by Fogging with Bird-Repellent Formulation, Rejex-it® TP-40 (MRID 452297-01). **NOTE: All three reports describe different parts of the same study; MRID 452102-01 is a summary.**
AUTHOR:	Peter F. Vogt (MRID 452102-01); Charles V. Willis (MRID 452102-02); and Richard A. Dolbeer and Jonathan D. Cepek (MRID 452297-01).
DATE OF REPORTS:	June- August 2000

QUALITY ASSURANCE: The study described in MRIDs 452102-01 and 452297-01 were not performed under Good Laboratory Practice Standards because the study consisted of a field trial. Non-compliance Statements were signed by the submitter/sponsor and/or the study director. The analytical procedures conducted by Case Consulting Laboratories (CCL) in MRID 452102-02 were conducted under GLP standards; a compliance statement was signed by the study director and the sponsor/submitter.

STUDY SUMMARIES: Two different types of foggers [thermal and ultra low volume (UV]) were used to apply the end-use product over fish-bearing waters (ponds) to determine to what extent methyl anthranilate (MA) residues would accumulate in water. MA content of water samples generally decreased with product application rate and distance from the fogger. Using the Golden Eagle thermal fogger and rates varying from 180 to 1800 g of end-use product, MA concentrations ranged from <0.016 ppm at 150 feet from the fogger to 0.256-1.623 ppm at 10 feet from the fogger (Table 1). Using the Hurricane ULV fogger and rates varying from 36 to 360 g of end-use product, MA concentrations in pond water ranged from <0.016 ppm at 150 feet from the fogger to 0.256-1.623 ppm at 10 feet from the fogger.

Three reports describe a single study conducted to determine the maximum methyl anthranilate (MA) residues that would be found in pond water immediately after fogging of ponds with Rejex-it® TP-40. The information contained in MRID 452297-01 describes he details of the experimental protocol; MRID 452102-01 summarizes the results of the experiment, and MRID 452102-02 provides details of the analytical methods used to analyze the water samples (conducted by Case Consulting Laboratories, Whippany, NJ). No DER was written for MRID 452102-02. However, water samples were analyzed for MA by liquid chromatography using a Luna C18 column and an isocratic mobile phase of acetonitrile:water (70:30, v:v). The limit of quantitation was 0.016 mg/L. Sample chromatograms were included with the submission.

I. Magnitude of Methyl Anthranilate Residues in Water after Fogging (MRIDs 452102-01, -02, and 452297-01)

A. MATERIALS AND METHODS

Test Substance: ReJeX-iT® TP-40 (containing 40% methyl anthranilate as its active ingredient).
Fog Applicator: Curtis Dyna-Fog Models "Golden Eagle" and "Hurricane" (an ultra low volume or ULV fogger).

Application Rate:	<0.2-0.6 gallons/hour (two ponds); 3 gallons/hour (two ponds); each fogger was elevated approx. 2 feet above the ground at the edge of a pond on the upwind side. Foggers were activated for 5 or 10 minutes
Application Date:	27 June 2000; 10:00-15:00 hours
Test Site:	Four ponds within the NASA Plum Brook Station in Erie County, OH. All ponds contained frogs and aquatic insects; two ponds contained fish. Ponds ranged from 0.3-1.5 acres in area and were 4-8 feet deep.
Sampling:	Water samples were collected at 1-10 minutes after initiation of fogging at distances ranging from 5-150 feet from the fogger nozzle. Each sample was 40 mL and collected at 0-1 inch below the surface of the pond. Samples were placed on ice in a cooler prior to overnight shipping to the analytical laboratory.
Other observations:	At 2 days posttreatment, visual observations were made at the edges of the pond to check for dead or sick frogs, fish, insects, or other wildlife.
Environmental:	Air temperature: 79-86°F; water temperature: 71-76°F; RH%: 60-73%; wind: 5-10 mph.

B. RESULTS

Regardless of the fogger used, MA content of water samples generally decreased with application rate and distance from the fogger (see tables below). There was no replication with treatment distance and rate and, therefore, the data could not be statistically analyzed. Sample variability could not be assessed. Using the Golden Eagle thermal fogger and rates varying from 180 to 1800 g of end-use product, MA concentrations ranged from <0.016 ppm at 150 feet from the fogger to 0.256-1.623 ppm at 10 feet from the fogger (Table 1). Using the Hurricane ULV fogger and rates varying from 36 to 360 g of end-use product, MA concentrations in pond water ranged from <0.016 ppm at 150 feet from the fogger to 0.256-1.623 ppm at 10 feet from the fogger (Table 2).

The registrant also listed fish and aquatic invertebrate (daphnid) toxicity data (previously submitted in MRIDs 426998-02, -03, 427182-01, 429669-01, 429951-01, and 436107-02; collected in Table 3, MRID 452102-01). These data demonstrated that concentrations of MA in water samples should not exceed toxic levels for daphnids (static LC_{50} = 29.1 mg/L) and fish (static LC_{50} = 9.12-32.5 mg/L; flow-through LC_{50} = 25.4-42.56 mg/L). BPB notes that one sample had an MA content of 60.747 mg/L (see Table 2: ULV fogger; 36 g TP-40 rate; 5 ft from fogger). This value may be an anomaly since no other measured value is at that magnitude. Furthermore, since MA levels decline rapidly with distance from the fogger, any potential toxic effects would be localized and MA would be rapidly diluted and/or dissipated once fog application of the end-use product has ended.

Table 1. Methyl anthranilate content of water samples collected from ponds fogged with the thermal fogger "Golden Eagle" (MRID 452102-01, p. 7).

Rate (g product)	Distance from Fogger	ppm MA
180	10	0.256
	30	<0.016
	100	Not detected (ND)
	150	<0.016
900	10	1.623
	20	1.609
	30	0.310
	50	0.235
	100	0.950
	111	0.200
	150	<0.016
1800	10	1.591
	30	0.688
	100	0.140
	150	<0.016

Table 2. Methyl anthranilate content of water samples collected from ponds fogged with the ULV fogger "Hurricane" (MRID 452102-01, p. 8).

Rate (g product)	Distance from Fogger	ppm MA
36	5	60.47
	20	0.700
	130	<0.016
60	15	5.968
	117	0.088
80	5	8.066
	20	9.949
	130	0.098
360	5	0.167
	20	7.975
	130	0.241

C. CONCLUSIONS

Based on the data, it is unlikely that application of the end-use product will result in toxic effects to fish and aquatic invertebrates when the product is used according to label directions.

D. DEFICIENCIES

The study was inadequately replicated which, therefore, precluded statistical analysis and assessment of sample variability.

13544

R136592

Chemical:	**Benzoic acid, 2-amino-, methyl ester**
	PC Code:
	128725
HED File Code:	**41600 BPPD Other**
Memo Date:	**1/16/2001**
File ID:	**DPD270616**
Accession #:	**000-00-9001**

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