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

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 Studies (Submission No. S546089; Case No. 004321), MRID Nos. 445843-01, -02, and -03; DP Barcode D247853.

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

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

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

ACTION REQUESTED

R J Advantage, Inc. requests 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 permit a fogging application use around electrical equipment. In support of this label amendment, the registrant has submitted three efficacy studies (MRIDs 445843-01, -02, and -03) and a proposed label.

RECOMMENDATIONS AND CONCLUSIONS

1. The submitted efficacy studies are acceptable. No additional data are required.
2. BPB approves the label amendment for ReJeX-iT® TP-40 (EPA Reg. No. 58035-7) to permit fogging application use around electrical equipment. BPB also supports fogging application of the end-use product around buildings and other structures that are not in/on or adjacent to natural bodies of water.

3. A revised label must be submitted. The label must be revised as follows (see Label Review below for details):
 - a. In lieu of a study showing that the end-use product is non-toxic to aquatic invertebrates, the following statement must be placed under the "Precautionary Statements" subheading: **"This pesticide is toxic to aquatic invertebrates."** Unless the data requirement is satisfied, applications of the product at, on or adjacent to lakes, ponds, fisheries, other bodies of waters, harbors, and docks are not permitted and must be removed from the label;
 - b. In lieu of a study, or other information showing that the end-use product is non-toxic to non-target vegetation, the following statement must be placed under the "Fogging, Use Restrictions" subheading: **Do not apply this product in areas where plant toxicity is likely to occur.** The registrant may also suggest may also suggest its own phytotoxicity mitigation statement; and
 - c. The precautionary statement **"CAUTION"** should also be placed above the **"Hazards to Humans & Domestic Animals"** subheading in the **Precautionary Statements** box.
4. All other issues addressed in the letters from R. D. Sjoblad to C. B. Rice (dated 7/16/98 and 9/4/98) remain outstanding.

STUDY SUMMARIES

Ecotoxicity/Non-target Organisms

The registrant did not submit any new ecotoxicity/non-target organism data. A previous review of ecotoxicity data (Memorandum from A. F. Maciorowski to R. Forrest, dated 3/21/96) indicated that the TGA1 (methyl anthranilate; >99% purity) was only slightly toxic to rainbow trout and bluegill sunfish ($LC_{50} = 25.4$ ppm and 42.56 ppm, respectively), non-toxic to bobwhite quail ($LD_{50} > 2220$ mg/kg), and non-toxic to honeybees ($LD_{50} > 25.0$ μ g/bee). A review of fish toxicity data also showed that the end-use product end use product was non-toxic to catfish in aquaculture systems that do not extend into natural waters (Memorandum from R. S. Jones to R. Kumar, dated 3/3/98); however, the active ingredient has been reported to have toxicity towards algae and aquatic organisms. Fog applications have the potential for drift of the product onto open bodies of water, wetlands, and other aquatic areas that are adjacent to the treatment sites (see Label Review below).

Efficacy

Three studies, conducted at three different geographic locations and at three different times of year, were submitted by the registrant. In the first study (MRID 44584301), 1 gallon of end-use product was applied as a fog around an electrical transformer substation in Puerto Rico. Roosting grackles (*Quiscalus quiscula*) were immediately repelled from the treated area and repellent activity against the grackles continued for at least 4 weeks posttreatment. In a second study at an oil refinery in Illinois (MRID 44584302), fog application of the end-use product (3 to 6 gallons each day for four consecutive days) was immediately effective in repelling roosting starlings (*Sturnus vulgaris*) from treated structures. Birds were observed to evacuate the treated area upon contact with the fog and repellency against starlings continued for at least nine days after the initial application. In the third study (MRID 44584303), fog applications of end-use product (≤ 34 L/hour; total not specified) at a NASA site in OH was approximately 80% effective in repelling starlings and almost 100% effective in repelling Canada geese from utility lines and fences along roadsides. Similar to the studies above, starlings and geese were immediately repelled upon contact with the fog. The posttreatment duration of repellent activity in the third study was not assessed by the study authors. Classification: Acceptable; no additional data are required

LABEL REVIEW

Under the subheading "Fogging, Use Restrictions," the proposed label indicates that the product may be used:

"...to repel nuisance birds from "...6) lakes, ponds, fisheries, or other bodies of water;" and "7) harbors and boat docks;"

This portion of the label use restrictions somewhat contradicts the environmental hazards statement "... **do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark.**" that is on the front of the proposed label.

Furthermore, bodies of waters (i.e. natural waters that include lakes, ponds, fisheries, rivers, streams, wetlands, and any other aquatic site) and by extension, structures that are adjacent to, or located in or on bodies of water, are not use sites that are currently permitted by the Agency for this product. It is likely that the end-use product will be introduced into bodies of water as a result of drift from fogging operations that are at or near bodies of water. In a letter from R. D. Sjoblad to C. B. Rice (dated 7/16/98) it was stated that "... a label use pattern that includes all bodies of water..." was not supported by any of the submitted toxicity data. In the same letter it was further stated that the use of methyl anthranilate would not be supported unless additional ecological effects testing

data was submitted. These ecological effects data requirements are included the following Subdivision M Guidelines: 154-9, Freshwater Aquatic Invertebrate Acute Bioassay; 154-10, Non-target Plant; and 154-11, Non-target Insect Testing.

Since the Agency has concerns regarding the potential toxicity of the end-use product to aquatic invertebrates, the data requirements for a freshwater aquatic invertebrate study (154-9) remain outstanding. In lieu of a freshwater aquatic invertebrate study, the registrant may place the following precautionary statement on the product label:

"This pesticide is toxic to aquatic invertebrates"

Unless the above data requirement is satisfied, applications of the product at, on, or adjacent to lakes, ponds, fisheries, other bodies of water, harbors, and docks are not permitted and should be removed from the label.

Under the subheading "**Fogging, Use Restrictions,**" the proposed label states that

"Before treating roosts or trees or shrubbery, test the product on a few leaves to determine whether treatment might harm the plants."

This statement suggests that the product has the potential to cause phytotoxicity, but no mitigation statement was included to inform the applicator of the actions that need to be taken if leaf testing showed that the "treatment might harm the plants." If available, the registrant should submit any data showing whether the end-use product is toxic to vegetation following a fog application. In lieu of this data submission, the registrant should suggest a phytotoxicity mitigation statement for the label, or use the following statement suggested by BPB:

"Do not apply product in areas where plant toxicity is likely to occur."

If the above requirements are satisfied, a non-target plant study (154-10) will not be required.

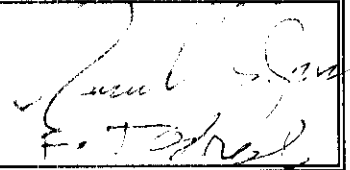
Additionally, our records show that a honeybee toxicity study had been conducted (Memorandum from A. F. Maciorowski to R. Forrest, dated 3/21/96) and that the product was relatively non-toxic to honeybees ($LD_{50} = 25 \mu\text{g}/\text{bee}$). Since the product is relatively non-toxic to honeybees, a non-target insect study (154-11) will not be required.

The precautionary statement "**CAUTION**" should also be placed above the "**Hazards to Humans & Domestic Animals**" subheading in the **Precautionary Statements** box.

cc: F. Toghrol, R. S. Jones, J. Loranger, BPPD Subject File
R. S. Jones: F.T. CM2, 703/308-5071: 10/1/98

DATA EVALUATION REPORT

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



STUDY TYPES: Efficacy Studies (Subdivision M Guideline 96-9)

CHEMICAL NO.: 128725

CASE NO: 004321

SUBMISSION NO.: S546089

CASWELL NO.: None

MRID Nos.: 445843-01, -02, -03

NAME; TEST MATERIAL: ReJeX-iT TP-40 (containing 40% methyl anthranilate as its active ingredient)

SPONSOR: R J Advantage, Inc., 501 Murray Road, Cincinnati, OH 45217

STUDY NO.: None

TESTING SITES: Electrical Transformer Station of Autoridad de Energia de Puerto Rico, Fajardo, PR (MRID 44584301); Shell Oil Refinery, Wood River, IL (MRID 44584302); and .

TITLE OF REPORTS: Fogging of ReJeX-iT® TP-40 at an Electrical Transformer Station in Puerto Rico (MRID 44584301); Fogging of ReJeX-iT® TP-40 at the Shell Oil Refinery in Wood River, IL (MRID 44584302); and Methyl Anthranilate Aerosols As a Dispersal Technique for Swallows (MRID 44584303).

AUTHOR: Dr. Peter F. Vogt, Study Director, RJ Advantage, Inc. (MRIDs 445843-01 and -02); R. Dolbeer (MRID 445843-03).

DATE OF REPORTS: May 14, 1998 (MRIDs 445843-01 and -02) and June 18, 1998 (MRID 445843-03).

QUALITY ASSURANCE: The studies were not performed under Good Laboratory Practice Standards. Non-compliance Statements were signed by the submitter/sponsor and/or the study director.

STUDY SUMMARIES: Three studies, conducted at three different geographic locations and at three different times of year, were submitted by the registrant. In the first study (MRID 44584301), 1 gallon of end-use product was applied as a fog around an electrical transformer substation in Puerto Rico. Roosting grackles (*Quiscalus quiscula*) were immediately repelled from the treated area and repellent activity against the grackles continued for up to 4 weeks posttreatment. In a second study at an oil refinery in Illinois (MRID 44584302), fog application of the end-use product (3 to 6 gallons each day for four consecutive days) was immediately effective in repelling roosting starlings (*Sturnus vulgaris*) from treated structures. Birds were observed to evacuate the treated area upon contact with the fog and repellency against starlings continued for at least nine days after the initial application. In the third study (MRID 44584303), fog applications of end-use product [≤ 34 L/hour (approximately 9 gallons/hour)]; total not specified) at a NASA site in OH was approximately 80% effective in repelling starlings and almost 100% effective in repelling Canada geese from utility lines and fences along roadsides. Similar to the studies above, starlings and geese were immediately repelled upon contact with the fog. The posttreatment duration of repellent activity in the third study was not assessed by the study authors.

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

I. Study 1. Fogging of ReJex-iT® TP-40 at an Electrical Transformer Station in Puerto Rico (MRID 44584301)

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:	8 gallons/hour
Total Volume Used:	Approximately 1 gallon
Application Time:	6:00-6:30 pm (4 November 1997).

Test Site: Electrical transformer station of "Autoridad de Energia de Puerto Rico", Fajardo, PR. The test site was approximately one acre in area and contained structures that were approximately 25-30 feet in height.

Environmental: At the time of application, the weather was cloudy with no rain in the test area.

Target Species: Grackles (*Quiscalutus quiscula*)

B. OBSERVATIONS

Approximately one hour before application of the test substance, the first birds [Grackles (*Quiscalutus quiscula*)] arrived at the test site. More birds continued to arrive up to 6:00 pm, when approximately 900-1000 birds had settled on the steel beams and transformers of the station. Thirty minutes prior to application (5:30 pm), the fogger was started for approximately five minutes without any fog application occurring; the birds were observed to be undisturbed by the noise of the machine. At 6:00 pm, fogging application was begun at ground level directly at the transformer station. When contacted by the fog, birds immediately flew off downwind for an unspecified distance before landing. When the fog overtook these birds, they flew away from the landing area. The fogging continued intermittently until 6:30 pm with approximately one gallon of end-use product used. At the end of the fogging period, only five birds remained in the test area. By 7:00 pm the same day, no birds were visible in the test area. The following day (5 November 1997), observers arrived at the test site at 4:30 pm. The weather was clear and cloudless. At 5:09 pm, a few (number unspecified) birds arrived at the test site but immediately flew away. A second group (number unspecified) arrived at 5:12 pm, but flew away in <1 minute. A third group (number unspecified) approached at 5:27 pm, flew to the far end of the test site, and flew away in less than one minute. Several groups of birds approached the test site at 5:36 pm but flew off through the station without landing. At 5:45 pm to 6:00 pm (the end of the observation period), no birds were visible in the test site. The study director subsequently reported that personnel at the substation did not see any birds "...settling in the transformer station..." during a four week period following the fogging application.

C. CONCLUSIONS

When applied as a fog, the end-use product is apparently 100% effective in repelling grackles (*Quiscalutus quiscula*) from an electrical transformer station for a period of approximately four weeks.

D. STUDY DEFICIENCIES

Minor: No raw data was submitted and the study director relied on observations of personnel not directly involved in the study during the four weeks following application

of the product. Temperature, humidity, and precipitation during application and during the observation period were not reported.

II. Study 2. Fogging of ReJeX-iT® TP-40 at the Shell Oil Refinery in Wood River, Illinois (MRID 44584302)

A. MATERIALS AND METHODS

Test Substance: ReJeX-iT® TP-40 (containing 40% methyl anthranilate as its active ingredient).

Fog Applicator: 2 Curtis Dyna-Fog Model "Golden Eagle"

Application Rate: 2 to 4 gallons/hour/fogger

Total Volume Used: 3 to 6 gallons

Application Time: 6:00-9:00 pm (28-31 January 1998).

Test Sites: Shell Oil Refinery, Wood River, IL: (i) Catalytic Cracker, Unit 1 (CCU-1); (ii) CCU-2; (iii) Distillation Unit 1 (DU-1); and DU-2. The refinery covers 41 acres and contains open structures and pipes, catwalks, and towers that provide shelter for roosting birds. The constant heat generated by refinery operations draws starlings to the plant as their preferred winter roost. Several days (number unspecified), approximately 300,000 birds were estimated to be at the entire plant site. The selected target sites (see above), collectively covering an area of 6.1 acres, had various structures up to 480 feet in height. There were approximately 100,000 starlings in the selected sites, and the target height for fogging was 80 feet.

Environmental: Temperature: 55-60°F, day; low 30's, night. A light wind was reported at night.

Target Species: Starlings (*Sturnus vulgaris*)

B. OBSERVATIONS

On day 1 (28 January 1998) the first starlings arrived at 5:00 pm, with larger and larger flocks arriving as dusk approached; at 6:00 pm, the majority of birds had arrived and settled in on the structures of the test sites. Fogging was begun with two foggers at the top of CCU-1 at 4 gallons/hour/fogger (total 8 gallons/hour). It was observed that the birds were not disturbed by the noise of the foggers, but upon contact with the fog, the birds immediately took off and flew away to search for new roosting areas. Fogging continued on the top of CCU-2, and then was continued at ground level at DU-1 and DU-2. As the fog moved through the structures of the test site, birds left their roosts with loud noises; birds not directly affected by the fog, but in the general area, also left their roosts as part of their flock behavior. Approximately 95% of the birds were repelled from

the roosting sites. Fogging occurred intermittently between 6:00 and 9:00 pm, with a total application of 6 gallons of product. Winds limited effectiveness of the fog at higher (unspecified) levels. On day 2 (29 January 1998), fogging was begun at the same time as the previous day beginning with DU-1, DU-2, and on to CCU-1 and CCU-2. To apply the fog at higher elevations, a lift vehicle was used at DU-1 and DU-2. With updrafts and light winds, birds were repelled up to 100-feet high on columns within the test sites. Total product applied was 3 gallons. On day 3 (30 January 1998), starling returned later than usual and in smaller (unspecified) numbers. Overcrowding and competition was observed on the uppermost levels of structures that had not been fogged with the product. Bird numbers were estimated to be approximately 20% of the previous day, and birds responded with commotion and flight at the beginning of fogging. All birds were repelled at the slightest contact with the fog. Total product application was 3 gallons. On day 4 (31 January 1998), approximately 10% of the birds returned to the target areas, and these appeared to be in disarray with competition for roosting sites that had not been reached by previous fog applications. Total product application was 3 gallons. On day 9, (5 February 1998), it was observed that starling competition for high, untreated sites continued; with weaker birds being driven down to lower areas. Large groups of birds roosted on pipes, "just out of range" of the treated areas, where they had not roosted previously. All treated areas had a very low number (unspecified) of birds.

C. CONCLUSIONS

The end-use product is >90% effective in repelling starlings (*Sturnus vulgaris*) from treated oil refinery structures following four consecutive daily applications at 3 to 6 gallons as a fog. Repellency is immediate and occurs upon first contact of the birds with the fogged end-use product. Based on the data, repellency continues undiminished for at least 9 days following the initial application.

D. STUDY DEFICIENCIES

Minor: No raw data were submitted.

III. Study 3. Methyl Anthranilate Aerosols as a Dispersal Technique for Swallows. (MRID 44584303)

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:	≤34 L/hour
Total Volume Used:	Not specified

- Application Time: Four days during August-September 1996
- Test Site: NASA Plum Brook Station (PBS); a 2200-ha area in Erie County, OH. The habitat consists of grasslands, wooded grasslands, and mixed hardwood forests. Roads with adjacent utility poles criss-cross the facility and provide roosting habitat.
- Environmental: Not specified
- Target Species: Tree swallow (*Tachycineta bicolor*) primarily, and occasionally, rough-winged swallows (*Stelgidopteryx serripennis*). Data were also collected on five flocks of Canada geese (*Branta canadensis*).
- Treatment Protocol: After one day of preliminary observations, the following method was devised to apply the end-use product. Two people drove in a pick-up truck along PBS roads. When a flock of swallows was observed on utility pole wires or a fence within 20 meters of the road, the vehicle was stopped approximately 100 meters from the flock. The number and species of swallows was determined by binoculars and one of four treatments was selected: (i) approach flock at 5 km/hour with one person in the bed of the truck with the fogger motor running, but no fog released; (ii) same as (i), except fogger was activated and releasing fog; (iii) same as (i), except one person approached flock on foot with fogger; and (iv) same as (iii), except fogger was activated and releasing fog. Flocks were always approached when they were downwind of the fogger. The same methodology was used for flocks of Canada geese within 20 meters of the road. For statistical analysis, walking and driving treatments were combined because of the limited sampling size. A t-test was used to compare pre- and posttreatment means. Data were collected for 15 blocks of swallows and five blocks of Canada geese.

B. OBSERVATIONS

In the fogging treatments, the fog remained highly visible until dissipating after drifting approximately 50-75 meters from the fogger. Fogging with the end-use product (with both the truck-mounted fogger and on foot) significantly ($P = 0.03$) reduced the numbers of swallows perched on wires and fences by a mean of 80% compared to pretreatment numbers. There was a 20% mean increase in swallow numbers when the fogger was on, but not activated (i.e. not dispensing fog). The posttreatment duration of repellency was not recorded.

Fogging also immediately repelled Canada geese from three sites where they were grazing; almost 100% of the geese were repelled from the treated sites. When the fogger

was on, but not activated (at two sites), there was no change in goose numbers, although they stopped grazing and exhibited alert (“heads up”) responses. The sample size precluded a statistical analysis of the goose data. As with the swallow applications, the duration posttreatment repellency was not recorded.

The study authors also described several difficulties in conducting the study which limited sampling size. These difficulties included fogger mechanical difficulties, variation in winds causing a misdirection of the fog, and an inability to conduct more than 4 days of testing because of limited resources. Despite these difficulties, the data indicate that a fog application of the end-use product is effective in repelling swallows and geese from utility lines and fences along roadsides. The study authors referenced other studies (but did not cite any data) that demonstrate that the end-use product has repellent activity against gulls and waterfowl (Dolbeer et al., 1995, Proc. East. Wildl. Damage Control Conf. 5:112-116; and Belant et al., 1995, Crop. Prot. 14:171-175). It is not known if these references describe fogging applications.

C. CONCLUSIONS

When applied as a fog, the end-use product is approximately 80% effective in repelling starlings and almost 100% effective in repelling Canada geese from utility lines and fences along roadsides. Since posttreatment observations were not conducted, the duration of repellency following product application could not be assessed for this experiment.

D. STUDY DEFICIENCIES

Minor: No raw data were submitted; temperature, humidity, and precipitation during application and during the observation period were not reported; and no posttreatment observations were conducted to determine the duration of repellency at the treated sites.



13544



R136594

Chemical: Benzoic acid, 2-amino-, methyl ester

PC Code:
128725

HED File Code: 41600 BPPD Other

Memo Date: 10/1/1998

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Accession #: 000-00-9001

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