IRB BRANCH REVIEW - TSS

Record Number(s)

D198495

IN 1/24/94 OUT 3/10/94

EFFICACY

FILE OR REG. NO. 58035-0

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 11/5/93, 12/28/93, 1/11/94, etc.

DATE OF SUBMISSION 10/27/93 and others

DATE SUBMISSION ACCEPTED 1/24/94

TYPE PRODUCTS(S): I, D, H, F, N, R, S

DATA ACCESSION NO(S). 430450-03

PRODUCT MGR. NO. 14

PRODUCT NAME(S) ReJeX-iT AG-36

COMPANY NAME PMC Specialties Group, Inc.

SUBMISSION PURPOSE Support claims and getproduct registered

CHEMICAL & FORMULATION 14.5% Methyl anthranilate liquid (or semi-liquid)

Efficacy Review: ReJeX-iT AG-36, 58035-O
PMC Specialties Group
Division of PMC, Inc.
Cincinnati, OH 45217

200.0 INTRODUCTION

200.1 Uses

A 14.5% (encapsulated) Methyl Anthranilate liquid formulation proposed for Federal registration to repel

> "birds such as Canada geese from golf courses and other turf areas."

200.2 Background Information

The materials routed for review appear to be part of the initial application for registration of this product. PMC has applied for Federal registration of at least three other Methyl Anthranilate (MA) formulations (see joint efficacy review of 5/24/93 for 58035-A, 58035-T, and 58035-I).

MA is a material which occurs in Concord grapes, fruits which birds are claimed not to feed upon to any great extent. Based upon such claims, it has been reasoned that by placing MA on other fruits, in bodies of water, and on land areas, the amount of attention which these things receive from birds can be reduced significantly.

In the cover letter, dated 10/27/93, Peter Vogt of PMC makes a number of statements attesting to the alleged safety of the product and a number of misstatements regarding the current registration status of possible alternatives to the use of MA. He summarizes one paragraph by stating

> "ReJeX-iT products are therefore filling a recognized need for a safe but effective avian control agent."

Considering the content of this letter, I feel that we must tell PMC in no uncertain terms that they may not make safety claims, comparative safety claims, or any other false or misleading statements on their MA labels or in their promotional materials. Such statements render products "misbranded" under FIFRA and do not help the general public or pesticide users in any way.

In addition to Vogt's cover letter, the package routed for my review included a Confidential Statement of Formula (CSF), a partially completed EPA "DATA REFERENCE SHEET" form, an efficacy report, a specification sheet, and a "TECHNICAL

BULLETIN # BA-4811" -- a PMC document cluttered with specifications, sales information, and descriptive text which bears at its top center the words (in quotes)

"'FOR EXPERIMENTAL USE ONLY'"

A proposed label received by EPA on 12/28/93 also was routed for my review.

201.0 DATA SUMMARY

In addition to MA, the CSF also reports that the product contains [redacted] as an "Inert Ingredient." This [redacted]

The full citation for the efficacy study routed for my review is presented below.

1. Cummings, J.L., Pochop, P.A., Davis, J.E., Jr., and Krupa, H.W. (1993) Evaluation of ReJeX-iT AG-36 as a Canada goose grazing repellent. Manuscript (submitted to or to be published by The Journal of Wildlife Management). Denver Wildlife Research Center, Animal Damage Control Program (ADC), Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, Denver, CO, 15 pp.

MRID # 430450-03

This report describes the results of trials performed with captive birds collected from the free-ranging Canada goose population which resides, at least seasonally, in the vicinity of a pond in the northwest corner of the Denver Wildlife Research Center (DWRC). Birds were cannon-netted and held in 8m X 4m X 2m outdoor pens for 4 weeks prior to the start of the study itself. Primary feathers were clipped so that the birds could not fly away.

For the test itself, a 40m X 120m enclosure was used. This area was subdivided by 2m-high woven-wire fencing into six 20m X 40m "units." Within each unit, two 14m square "plots" of Kentucky blue grass (Poa pratensis) were established. The blue grass was to be the sole source of food for the geese. The plots were separated from one another and from the edges of the units by 3-6m of bare ground.

Bird use of the plots within units was monitoring by observation from an elevated tower. For 1 hr/day, between 7:30 and 10:30 AM (MDT?), all 6 units were observed. Numbers of birds using each plot were noted and recorded at 1-minute intervals. Researchers also collected, dried, and weighed "goose fecal deposits" from transect samples in each plot. After six days of observing birds and recording these data, one plot within each unit was given a sham treatment (mixed formulation minus MA) by use of a boom sprayer. The remaining plot was treated with the full MA formulation. The application rate for the mix was said to be 273 L/ha with the ReJeX-iT being delivered at 13 kg/ha (71 lbs/acre). To avoid contamination of equipment, all sham treatments were made before any of the MA treatments. Bird observations and scat collections were continued for another 19 days following treatment.

While there were no pretreatment differences in the bird use indicators between the "to-be-MA-treated" plots and the "to-be-sham-treated" plots, there were differences in both indices following treatment. Judging from line graphs presented in the report, the MA-related suppression of bird use of treated plots lasted for 3-4 days, while the suppression of scat weights lasted for 5 or 6 days. These results indicate short-term activity for MA. As only one application was made, the researchers did not determine whether the initial effect waned due to habituation by the animals, loss of MA from the substrate, or a combination of both factors.

The manner in which Cummings, et al (1993), summarize the results of this test appears to me to be appropriate.

> "ReJeX-iT AG-36 showed limited effectiveness to reduce Canada goose activity on treated grass plots. Even during the period when goose activity was reduced, geese continued to sample treated grass. The active ingredient . . . , methyl anthranilate, is considered to be a chemosensory repellent acting through taste, olfaction, and the common chemical sense . . . . It has no aversive postingestional effect that might cause food avoidance learning."

Thus, Cummings, et al (1993), suggest that birds might be able to either get used to MA or to tolerate it at lower concentrations because, unlike substances such as Methiocarb, MA does not make the birds sick. Repeated treatments would restore the strength of the flavor but, if the birds were learning to tolerate it, the effects of subsequent applications would be less pronounced than that of the first treatment. It has been known for more than 15 years that bad

flavor alone is not nearly the deterrent to feeding by herbivorous mammals that flavor paired with illness is. The same may be true for the relatively few extant types of herbivorous birds.

Cummings, et al (1993), suggest that certain "improvements in the encapsulation process" might make this type of formulation's effects last longer. This might be true, but I suspect that any extension achieved would only be for a few days. If repeated treatments can restore the original effect, it might be possible to use this product to keep geese off of certain areas for periods of several weeks. Such repeated treatments might be very costly however. It also is possible that under field use conditions, with the amount of untreated area greatly exceeding the area which has been treated, the effects of a single treatment might last a bit longer or that geese could be conditioned to avoid the areas which are treated from time to time. All that the data reviewed here would support is a claim that the effect lasts 3-4 days, much shorter than the 2-4 weeks suggested by the proposed label. At the rates at which ReJeX-iT AG 36 was applied, repeated treatments could be very expensive. The treatments also might discolor the grass.

The specification sheet dated 12/2/93 reports that this product is a "Light blue to tan, thick slurry" which has an odor "Reminescent[sic] of concord grape, a specific gravity of 1.00-1.05 at 25°C, and a pH of 5.2-6.0. An "Assay" of ReJex-iT AG-36 reportedly found it to be 14.6% MA. It is not clear that this analysis pertained to the product sample bioassayed by Cummings, et al (1993). Their study began in June of 1993.

The "FOR EXPERIMENTAL USE ONLY" sheet describes the product's appearance and odor as on the specification sheet, but lists the pH as 5.6. Bulk density is claimed to be 1.02 g/l (which I doubt, 1.02 g/ml would be more like it as the English system value given is 8.5 lbs/gal). The product is claimed to be "Miscible with water in any ratio," and to boil (like water) at "100°C, 212°F." This sheet reports the product to assay at "14.4% technical active." The sheet also claims that "All ingredients are food grade" and that the acute oral LD50 for rats is ">5000 mgt/kg body weight." This sheet is full of inaccuracies and what appear to be careless statements. At this point, I am unwilling to take PMC's word on anything.

Near the bottom of the "FOR EXPERIMENTAL USE ONLY" sheet, the following paragraph appears:

"USE:
To study the reduction of bird activity (such as geese, coots and other) on turf grass areas such as golf courses and parks. Apply **ReJeX-iT AG-36** at a rate of 60 lbs/acre (7 gal/acre) at 2-4 week intervals as increased bird activity might require. Best applied by spray equipment, such as any garden sprayer or commercial power sprayer after dilution with water at a ratio of 1:3. Spray evenly on affected grass area and let it dry. Do not spray during rain or immediately before expected rain."

The quality of these directions provides a shining example of why registration should be required for all pest control products, whether they are pesticides such as this one or pest control devices. The pests claimed include the category "other," while a "such as" list is supplied for the sites. Thus, both categories are open-ended. The range of possible application equipment also is open-ended.

The proposed label includes items which suggest that PMC paid some attention to the comments that we made regarding the labels of its other pending MA registration applications. However, the site list includes a "such as," and the product is claimed to repel "birds such as Canada geese." The application directions bear a strong resemblance to those on the "FOR EXPERIMENTAL USE ONLY" sheet.

202.0 CONCLUSIONS

1. We note that your Confidential Statement of Formula (CSF) reports that [redacted] is in the formulation for this product as an "Inert Ingredient." This substance is [redacted]

2. The efficacy study by Cummings, et al (1993), showed that a single spray treatment using this product at 71 lbs/acre reduced use of treated areas relative to sham-treated areas by Canada geese for a period of about 3-4 days. This study does not support claims for repellent effects for longer periods of time. Therefore, the "2-4 week" treatment intervals suggested on the label proposed for this product seem to be overpromising and misleading.

3. The sheet captioned "FOR EXPERIMENTAL USE ONLY" reports the product's bulk density to be 1.02 g/l. We suspect that 1.02 g/ml would be more like it as the English system value given is 8.5 lbs/gal, which is very close to the

density of water. We also were surprise to learn that this formulation boils at the same temperature as water.

4. The "DIRECTIONS FOR USE" proposed on the label that we received on December 28, 1993, are not acceptable as they are open-ended with respect to the sites and pests claimed and imply that one application may be effective for as long as two weeks. As far as we know, the efficacy testing of ReJeX-iT AG-36 is limited to the work of Cummings, et al (1993), who report a short term effect on captive examples of one species on one type of grass. The claims made for this product must be amended to reflect the data upon which the claims are based.

   Revise the "DIRECTIONS FOR USE" portion of the proposed label as indicated below.

"DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used to repel Canada geese from golf courses and other turf areas. This product must be applied using appropriate spray equipment. [Describe generically or specify the types of equipment that are appropriate for applying mixes made from this formulation.] Wear protective gloves and a face mask when applying or otherwise handling this product.

DILUTION DIRECTIONS: Mix ReJeX-iT AG-36 with water at a ratio 1 part product to 3 parts water. For example, mix 1 quart of product with 3 quarts of water to make 1 gallon of spray mixture. [Indicate any special procedures needed to dilute product fully and efficiently.]

APPLICATION DIRECTIONS: Apply spray mix at a rate of [__] gallons ([__] lbs spray/acre of turf area ([__] lbs ReJeX-iT AG-60/acre). Spray evenly on area to be protected to provide thorough coverage and allow material to dry before permitting human activity on treated area. Repeat treatment every 4 days or as warranted by goose activity. Do not apply when grass is wet or when rain is expected. Do not mow the treated area for several days after application."

Note that the text in brackets indicates where additional relevant information and directions might be added. Note also that we adopted your proposed 1:3 dilution ratio. The ratio used by Cummings, et al (1993), converted into English system units, could and probably should be used instead. As you develop more research data on this product, it may be possible to expand the pest claims and broaden the range of acceptable dilution ratios. The rate information provided by Cummings, et al (1994), converts (if our assumptions and calculations are correct) to about 11.6 lbs of product per acre and about 29.2 gallons of spray per acre.

5. Neither the labeling nor the material used to promote this or any other pesticide product may contain text that is false or misleading. Examples of such statements can be found in 40 CFR, §156.10(a)(5).

William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
March 10, 1994

* * * CASE/SUBMISSION INFORMATION * * *

ASE TYPE: REGISTRATION ACTION: 146 RESB NEW BIO-NON-FD-FED
ANKING : 40 POINTS (FOP)
HEMICALS: 128725 Methyl Anthranilate 14.6000%

)#: 058035-O REJEX-IT AG-36
OMPANY: 058035 PMC SPECIALTIES GROUP
RODUCT MANAGER: 14 ROBERT FORREST 703-305-6600 ROOM: CM2 219
M TEAM REVIEWER: DANIEL PEACOCK 703-305-5407 ROOM: CM2 221
ECEIVED DATE: 03/04/94 DUE OUT DATE: 08/01/94

* * * DATA PACKAGE INFORMATION * * *

)P BARCODE: 200275 EXPEDITE: Y DATE SENT: 03/10/94 DATE RET.: / /
HEMICAL: 128725 Methyl Anthranilate
)P TYPE: 001 Submission Related Data Package
CSF: N LABEL: N
SSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 06/23/94
)IV : RD / / / / NEGOT DATE: / /
3RAN: IRB / / / / PROJ DATE: / /
3ECT: PMT-14 / / / /
REVR : / / / /
CONTR: / / / /

* * * DATA REVIEW INSTRUCTIONS * * *

Bill,

Please review the attached protocol for the use of Rejex-it AG-36 on blueberries.

I think that you already have a label, CSF, and efficacy data. If not, contact me.

Dan 305-5407

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BARCODE: D198495

CASE: 040651 DATA PACKAGE RECORD DATE: 01/24/94
SUBMISSION: S456763 BEAN SHEET Page 1 of 2

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 146 RESB NEW BIO-NON-FD-FED
RANKING : 40 POINTS (FOP)
CHEMICALS: 128725 Methyl Anthranilate 14.6000%

ID#: 058035-O REJEX-IT AG-36
COMPANY: 058035 PMC SPECIALTIES GROUP
PRODUCT MANAGER: 14 ROBERT FORREST 703-305-6600 ROOM: CM2 219
PM TEAM REVIEWER: DANIEL PEACOCK 703-305-5407 ROOM: CM2 221
RECEIVED DATE: 01/14/94 DUE OUT DATE: 06/13/94

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 198495 EXPEDITE: Y DATE SENT: 01/24/94 DATE RET.: / /
CHEMICAL: 128725 Methyl Anthranilate
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 05/09/94
DIV : RD	/ /	/ /	NEGOT DATE: / /
BRAN: IRB	/ /	/ /	PROJ DATE: / /
SECT: PMT-14	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Bill Jacobs,

Please review the efficacy data (MRID 430450-03) for this 4th of 4 products submitted by PMC Specialialties of Cincinnati, Ohio. and containing the new biochemical, Methyl Anthranilate. You previously reviewed efficacy data for the other 3 products (58035-I, -A, -T.)

The use pattern of this product is:

Sites: golf courses & turf
Pests: canada geese & "other birds"

You will also find the following other background documents with this data package:

1. last submitted label (received 12/28/93)
2. letter of 10/27/93 and table of contents listing all the data and the final listing of MRID numbers
3. CSF dated 10/13/93, received 1/11/94, annotated 01/12/94 per tel. conv. with Cathy Shea of ERM
4. Data Reference Sheet (with some MRID citations of some of the previously submitted data.

DP BARCODE: D198495

CASE: 040651 DATA PACKAGE RECORD DATE: 01/24/94
SUBMISSION: S456763 BEAN SHEET Page 1 of 2

* * * DATA REVIEW INSTRUCTIONS * * *

The company has submitted a Reduced Risk Application according to PR Notice 93-3, which will be forwarded to Stephanie Irene. The results of that process will determine the priority given to the review. If you wish to see a copy of the rationale submitted to us, let me know. Since you normally finish your reviews so quickly, the results of that process will probably not affect you.

Dan Peacock, 305-5407 or -6600

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

ReJeX-iT™ AG-36 has been formulated from Food Grade ingredients that meet or exceed U.S. Food Chemical Codex (FCC) and U.S. Pharmacopeia (USP) specifications and comply with the British Pharmacopeia.

CAUTION: Excessive exposure may cause eye and skin irritation. Wear rubber gloves for long-term and repeated contact. Wear safety glasses when handling. Wear respirator upon application of the product. Keep from freezing. Keep container closed when not in use.

ENVIRONMENTAL HAZARDS

Do not discharge into lakes, streams, ponds, or public waters unless in accordance with an NPDES permit or as per use directions. For guidance, contact your Regional Environmental Protection Agency office.

DIRECTION FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used to repel birds such as Canada geese from golf courses and other turf areas. Wear protective gloves when applying or otherwise handling product for long-term and repeated contact.

Turf areas such as Golf Courses and Parks: Apply ReJeX-iT™ AG-36 at a rate of 60 lbs/acre (7 gal/acre) of turf area at 2-4 week intervals. Adjust timing of subsequent applications as required by bird activity. Best applied by spray equipment, such as any garden sprayer or commercial power sprayer after dilution with water at a ratio of 1:3 (1 quart ReJeX-iT™ AG-36 with 3 quart of water to make one gallon of spray/mixture). Spray evenly on affected grass area to provide thorough coverage and let dry. Do not spray during rain or *immediately before expected rain. Do not mow the area for several* days after application.

11/93

ReJeX-iT™ AG-36

ACTIVE INGREDIENT:

ReJeX-iT™ MA	14.5%
INERT INGREDIENTS	85.5%
	100%

ReJeX-iT™ MA is the trade name for the Technical Grade Active Ingredient, Methyl Anthranilate.

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

On contact with eyes, wash with water for 15 minutes. Wash exposed skin with soap and water. Wash contaminated clothing before reusing.

Manufactured for

PMC SPECIALTIES GROUP

501 Murray Road, Cincinnati, Ohio 45217

1-800 543-2466 FAX (513) 482-7377

EPA EST. No. 058035-OH-001 EPA REG. No. 580-35

STORAGE & DISPOSAL

STORAGE: Store only in original container, in a dry place inaccessible to children, pets, and domestic animals. Store apart from pesticides, fertilizers, food, or feed that may cause cross-contamination from odor.

DISPOSAL: Spray mixture or rinse water that cannot be used according to label instructions must be disposed of according to Federal or approved State procedures. Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Triple rinse. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedure approved by State and local authorities.

WARRANTY STATEMENT

NOTICE: The manufacturer warrants that this product conforms to the chemical description on its label. When used in accordance with label directions under normal conditions, this product is reasonably fit for its intended purposes. Since timing, method of application, weather, plant and soil conditions, mixture with other chemicals, and other factors affecting the use of this product are beyond our control, no warranty is given concerning the use of this product contrary to label directions, or under conditions which are abnormal or not reasonably foreseeable. The buyer and/or user assumes all risks of any such use.

12/93

Received 12/28/93

058035-O

PMC Specialties Group
A DIVISION OF PMC, INC.
501 Murray Road Cincinnati, Ohio 45217 Phone: (513) 242-3300

December 2, 1993

PRODUCT SPECIFICATIONS
(Internal Use Only)

X20 RJ7012
ReJeX-iT™ AG-36
Code: AG-36

TEST	SPECIFICATIONS	METHOD
Physical Appearance	Light blue to tan, thick slurry	Visual
Odor	Reminescent of concord grape	Smell
Specific gravity (25°)	1.00 - 1.05	26 - 120293
pH	5.2 - 6.0	26 - 120493
Assay		
Methyl anthranilate (MA)	14.6% (13.9 - 15.3%)	26 - 120693

Approved:

Product Sales Manager — Date: 12-2-93

Operations Manager — Date: 12/2/93

Technical Manager — Date: 12/2/93

Research & Development — Date: 12/2/93

"FOR EXPERIMENTAL USE ONLY"

PMC Specialites Group

A DIVISION OF PMC, INC.

ReJeX-iT™

WILDLIFE MANAGEMENT

Order Entry No: X20RJ7012

20525 Center Ridge Rd., Rocky River, OH 44116
PHONE: 216-356-0700

501 Murray Road, Cincinnati, OH 45217
PHONE: 513-242-3300 FAX: 513-482-7377

TECHNICAL BULLETIN # BA-4811

ReJeX-iT™ AG-36

ReJeX-iT™ AG-36 has been formulated from Food Grade ingredients that meet or exceed US Food Chemical Codex (FCC) and US Pharmacopeia (USP) Specifications and comply with the British Pharmacopeia (BP). ReJeX-iT™ AG-36 is an aqueous slurry and is miscible with water in any ratio.

TYPICAL PROPERTIES:

Appearance	Light blue to tan, thick slurry.
Odor	Reminiscent of concord grape.
pH	5.6.
Bulk Density	1.02 g/l, 8.5 lbs/gal.
Solubility	Miscible with water in any ratio.
Boiling Point	100°C, 212°F.
Assay	14.4% technical active.
Toxicity	All ingredients are food grade. Acute oral LD_{50} in rats is >5000 mg/kg body weight.
Safe Handling	Avoid excessive exposure. As a general precaution, good personal and general hygiene and good housekeeping should be followed. For spraying use a face mask.

USE:

To study the reduction of bird activity (such as geese, coots and other) on turf areas such as golf courses and parks. Apply **ReJeX-iT™ AG-36** at a rate of 60 lbs/acre (7 gal/acre) at 2-4 week intervals as increased bird activity might require. Best applied by spray equipment, such as any garden sprayer or commercial power sprayer after dilution with water at a ratio of 1:3. Spray evenly on affected grass area and let it dry. Do not spray during rain or immediately before expected rain.

CUSTOMER SERVICE/ORDER ENTRY: 800/543-2466

EPA

U.S. ENVIRONMENTAL PROTECTION AGENCY
REGISTRATION DIVISION (TS-767)
WASHINGTON, D.C. 20460

DATA REFERENCE SHEET

(See instructions on the back of the last page before completing.)

1. PAGE OF 4

2. EPA REGISTRATION NO./FILE SYMBOL

3. APPLICANT'S NAME AND ADDRESS
PMC Specialities Group
Division of PMC, Inc.
501 Murray Road
Cincinnati, Ohio 45217

4. PRODUCT NAME
ReJeX-iT AG-36

5. PRODUCT MANAGER
Dan Peacock

6. TO ACCOMPANY APPLICATION FOR REGISTRATION DATED:

7. NAME OF STUDY	SOURCE STUDY a. APPLICANT CONDUCTED STUDY (mark 'X')	b. OBTAINED FROM EPA (mark 'X')	c. OBTAINED FROM ANOTHER FIRM OR SOURCE (give name and address)	d. OBTAINED FROM PUBLIC LITERATURE (give reference)	e. OTHER (explain)	f. ACCESSION NUMBER (if known)
Product Identity	X					42606891
Manufacturing Process	X					42606991
Discussion of formation of unintentional ingredients	X					42606991
Analysis of Samples	X					
Certification of limits	X					
Analytical Method					Previously Submitted	42606991
PHYSICAL/CHEMICAL PROPERTIES						
Color (Technical Bulletin)	X					
Physical State (Technical Bulletin)	X					
Odor (Technical Bulletin)	X					
Density, bulk-density, or specific gravity (Technical Bulletin)	X					
Solubility in water (Toxikon, 1993)	X					
pH (Technical Bulletin)	X					

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U.S. ENVIRONMENTAL PROTECTION AGENCY
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Dan Peacock

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Oxidizing/reducing reaction (Toxikon, 1993)	X					
Flammability					WAIVER	
Explodability					WAIVER	
Storage stability (Toxikon, 1993)	X					
Miscibility					WAIVER	
Corrosion characterisitics (Toxikon, 1993)	X					
Dielectric breakdown voltage					WAIVER	
Viscosity					WAIVER	
RESIDUE DATA REQUIREMENTS						
Residue data					WAIVER	
TOXICOLOGY						
Acute oral toxicity, LD50, rat, (Hazelton, 1993)	X					
Acute dermal toxicity, LD50, rabbit, (Hazelton, 1993)	X					
Acute inhalation toxicity					WAIVER	

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U.S. ENVIRONMENTAL PROTECTION AGENCY
REGISTRATION DIVISION (TS-767)
WASHINGTON, D.C. 20460

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Primary eye irritation, rabbit, (Hazelton, 1993)	X					
Primary dermal irritation, rabbit, (Hazelton, 1993)	X					
Dermal sensitization, guinea pig, (Hazelton, 1993)	X					
Immune Response					WAIVER	
NONTARGET ORGANISM FATE AND EXPRESSION Tier 1 Avian Acute Oral (mallard) (Wildlife International, 1992)					Previously Submitted	42606087
Avian Dietary (mallard) (Wildlife International, 1992)					Previously Submitted	42606088
Freshwater Fish LC50 (rainbow trout) (L. Clark, et al, 1992)					Previously Submitted	42698902
Freshwater Fish LC50 (catfish) (L. Clark, et al, 1992)					Previously Submitted	42712102
Freshwater Fish LC50 (bluegill) (L. Clark, et al, 1992)					Previously Submitted	42698903
Freshwater Invertebrate LC50 (USDA, 1992)					Previously Submitted	42712103
Nontarget Plant Studies					WAIVER	
Nontarget Insect Testing					WAIVER	

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Division of PMC, Inc.
501 Murray Road
Cincinnati, Ohio 45217

4. PRODUCT NAME
ReJeX-IT AG-36

5. PRODUCT MANAGER
Dan Peacock

6. TO ACCOMPANY APPLICATION FOR REGISTRATION DATED:

7. NAME OF STUDY	SOURCE STUDY a. APPLICANT CONDUCTED STUDY (mark 'X')	b. OBTAINED FROM EPA (mark 'X')	c. OBTAINED FROM ANOTHER FIRM OR SOURCE (give name and address)	d. OBTAINED FROM PUBLIC LITERATURE (give reference)	e. OTHER (explain)	f. ACCESSION NUMBER (if known)
Tier II						
Octanol/Water Partition Coefficient (L. Clark and E. Aronov, 1993)	X					
Hydrolysis (L. Clark and E. Aronov, 1993)	X					
Aerobic Aquatic Biodegradation (Toxikon, 1993)	X					
Aquatic Photodegradation (L. Clark and E. Aronov, 1993)	X					
ENVIRONMENTAL FATE						
Soil Dissipation					WAIVER	
PRODUCT PERFORMANCE						
Turf Test (Denver Wildlife Research Center, 1993)	X					

Final Listings of MRID numbers

PMC Specialties Group
501 Murray Road Cincinnati, Ohio 45217 Phone: (513) 242-3300
A DIVISION OF PMC, INC.

27 October 1993

430556-00

Reference: ReJeX-iT™ AG-36

EPA Establishment Number: 058035-OH

Office of Pesticide Programs
Document Processing Desk (Reduced Risk application)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, FA 22202

Dear Sir:

Enclosed is a FIFRA registration package for ReJeX-iT™ AG-36, another end use bird aversion agent containing Methyl Anthranilate as an active ingredient. This product uses an already registered material (ReJeX-iT TP-40) that has been encapsulated in gelatin to control its release rate. This material exhibits the same reduced risk characteristics exhibited by the other ReJeX-iT products submitted by PMC Specialties Group.

More specifically, ReJeX-iT AG-36 has a very low acute toxicity, like the other MA products. In fact, MA has been approved by the Food and Drug Administration for inclusion on the GRAS List (generally recognized as safe) for food additives and has been in common food and fragrance use for over 20 years. MA is a naturally occurring biochemical that biodegrades rapidly under aerobic and anaerobic conditions and does not represent an environmental hazard. ReJeX-iT AG-36 has also been demonstrated to be an effective agent to control birds on turf. Additionally, all other chemical bird aversion agents have been withdrawn from the market prior to reregistration due to their high toxicity. Only sticky agents remain and these are of limited benefit. ReJeX-iT products are therefore filling a recognized need for a safe but effective avian control agent.

We are targeting ReJeX-iT AG-36 for use on turf and ornamentals to reduce damage from birds. It will find its main use on parkland, golf courses, institutional lawns and other similar areas which attract resident bird populations. These birds represent a health hazard as well as a nuisance. They damage the turf and foul drainage ponds and other low lying areas.

We are requesting an expedited review of this biochemical product in light of its reduced risk and because its efficacy is based on an active ingredient that is already reviewed (MA and ReJeX-iT TP-40). There is considerable market interest in this product and it is our hope that

review can be accomplished in sufficient time that we can make it available for the spring bird season which will have the effect of discouraging nesting in these turf areas. An accelerated review will be in the best interest of all concerned since it will reduce the use of poisons and shooting to control these bird populations.

Please find a list of the contents of this registration submittal on the attached pages. The registration package consists of an administrative portion, which is unbound, as requested, and the supporting test data portion, which is bound and submitted in triplicate.

Sincerely,

Peter F. Vogt

Peter F. Vogt, Ph.D.
PMC Specialties Group

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58035-0

ERM Program
Management Company

7926 Jones Branch Drive
Suite 210
McLean, VA 22102
(703) 734-9327
(703) 734-9394 (Fax)

703-305-
5407

March 3, 1994

Mr. Dan Peacock
Office of Pesticide Programs (Team 14)
MS CM-2 7504C
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Reference: ReJeX-iT AG-36

Dear Dan:

I am enclosing a copy of a protocol for a test of ReJeX-iT AG-36 on blueberries in five states. This protocol was developed by the U.S. Department of Agriculture's Denver Wildlife Center and is designed to be implemented simultaneously at test plots in five states by the Blueberry Grower's Assn. We are asking for rush review of the protocol since we want to be able to implement it in May when the first blueberries are ripening. I spoke to Bill Jacobs and he is alerted to the review and is waiting to receive it from you.

If there are questions, please feel free to telephone me or Cathy Shea at 703-734-9327.

Sincerely,

Judith M. Hushon

Judith M. Hushon, Ph.D.
Principal

DRAFT

DENVER WILDLIFE RESEARCH CENTER
Animal Damage Control
Animal and Plant Health Inspection Service
United States Department of Agriculture
Florida Field Station
2820 East University Avenue
Gainesville, Florida 32601

QA-374

STUDY PROTOCOL

I. STUDY PROTOCOL TITLE:

Large scale field evaluation of methyl anthranilate as a bird repellent in blueberries.

II. SPONSOR: USDA/APHIS/ADC/DWRC; North American Blueberry Council; PMC Specialties Group.

III. STUDY DIRECTOR AND PARTICIPANTS: Michael L. Avery*, John L. Cummings

IV. OBJECTIVE/HYPOTHESES:

To determine the effectiveness of methyl anthranilate for reducing bird damage to blueberries under standard test procedures at several test sites throughout the country.

V. JUSTIFICATION AND BACKGROUND:

Bird damage to small fruit and berry crops is a nationwide problem that results in millions of dollars of lost income annually (Besser 1985, Avery et al. 1992). In recent years, growers of blueberries, cherries, and other small fruit crops have experienced increasing difficulties managing bird damage to their crops. This is largely the result of the nonavailability of the chemical methiocarb for use as a bird repellent (Tobin and Dolbeer 1987). Although methiocarb appears to pose no lethal threat to target or nontarget species (Dolbeer et al. 1994), the previous registrations for its use on fruit crops lapsed when the manufacturer opted not to meet the demand for additional data by the U.S. Environmental Protection Agency (Tobin and Dolbeer 1987, Avery et al. 1993).

* Study Director

With the loss of methiocarb as a bird management tool, there has been increasingly a need for an alternative material that will safely and effectively deter avian depredators. One promising compound is methyl anthranilate (MA), a fruit flavored food additive approved for human consumption by the U.S. Food and Drug Administration that is offensive to birds (Kare 1961, Mason et al. 1989). Although MA has proven effective as a feeding deterrent in a variety of situations (e.g., Cummings et al. 1991, Mason et al. 1991), investigations of its effectiveness as a bird repellent on fruit crops have produced mixed results. Some (Askham 1992, Askham and Fellman 1989) have reported successful reductions in bird damage to blueberries and cherries, while others (e.g., Avery 1992, Cummings et al. 1993) have reported no effects of MA treatments.

Because of MA's inconsistent performance, confusion exists as to its potential utility for fruit crop use. At least some of the inconsistency of performance can be attributred to the lack of a standard testing and evaluation procedure that would allow for ready comparisons across studies.

One objective of this project is to standardize field test procedures so that MA effectiveness under various conditions in several States can be compared. By adopting this approach, we will determine cost-effectiveness under a variety of agronomic, environmental, and avian depredation conditions. This will be accomplished through collaborative research with State experiment stations and blueberry producers at 4 or 5 locations throughout the country. We will then be better able to develop use patterns for which MA will be most effective. This will be an important step toward eventual registration.

VI. ANIMAL CARE AND USE:

A. Where applicable, the number, body weight range, sex, source of supply, species, strain, substrain, and age of the test system:

Free-ranging birds of several species will likely be exposed to the treatment. These include American robins (Turdus migratorius), cedar waxwings (Bombycilla cedrorum), European starling (Sturnus vulgaris), and house finch (Carpodocos mexicanus).

B. The procedure for identification of the test

system. N/A

C. Identification of chemicals with chemical abstract number (CAS), materials, or devices to be used or tested.

methyl anthranilate CAS No. 134-20-3

D. Rationale for involving animals, the appropriateness of the species and the number of animals to be used.

This is a bird repellent. The only way to evaluate its effectiveness is to expose birds to it. We will not control the birds' access to the test plots.

E. Source:

Free-ranging birds.

F. Trapping: N/A

G. Handling/Restraint: N/A

H. Transport: N/A

I. Housing/Maintenance/Diet: N/A

J. Quarantine: N/A

K. Euthanasia: N/A

L. Disposition of Animals: N/A

M. Provide written assurance that the activities do not unnecessarily duplicate previous experiments. This must illustrate a good faith effort on the part of the researcher to find if this experiment duplicates previous experiments.

No large scale field trials involving methyl anthranilate at the proposed application rate have been performed. No field data collected in a standard manner are available from multiple sites in different parts of the country.

N. In regard to potential pain in animals for this experiment.

1. That you have considered alternatives to any

painful procedures and, if unavailable, you have indiciated the principal sources that have been consulted in considering the alternatives (e.g. Biological Abstracts, the Animal Welfare Information Center).

Repeated testing of methyl anthranilate has demonstrated no adverse impact to any bird species. No painful procedures are proposed.

2. When more than slight pain is reasonably expected and sedatives or analgesics will not be used, the reasons for this procedure are scientifically justified.

No painful procedures are proposed.

3. That procedures which cause more than slight or momentary pain must involve in their planning consultation with the attending veterinarian of the Denver Wildlife Research Center.

No painful procedures are proposed.

4. If the animals may experience severe or chronic pain that cannot be relieved, they will be euthanized at the end of the procedure or, if appropriate, during the procedure.

No painful procedures are proposed.

VII. METHODS:

A. Protocol:

The study will be conducted at sites in North Carolina, New Jersey, Michigan, Oregon, and Washington. In each State, we will attempt to locate 3 suitable test sites as replicates. Each test site will consist of 2 paired plots, at least 1 ac each, distinctly separated (by open ground, hedgerows, ditches, etc.) from other nontest blueberry plantings. Test sites should be at least 10 km apart for statistical independence. One of the plots at each site will be randomly selected for treatment, the other will serve as a control. At a given site control and test plots should be separated by at least 100 m.

The initial MA application will be 7 days before

the first anticipated picking. On the day of initial treatment, we will prepare an aqueous solution of formulated MA. The units designated as treated will be sprayed with a FMC(R) 1029 airblast sprayer or similar equipment calibrated to deliver the appropriate volume of formulation per hectare. Calibration of spraying apparatus will be made prior to treatment. Calibration data will be recorded and application rate will be reported per hectare and per 378.5 liters of spray. If birds persist in frequenting the treated plot, methyl anthranilate will be reapplied 7 and 14 days after the initial spray. At the time of treatments, air temperature, relative humidity, precipitation, wind speed and direction will be recorded. Daily precipitation will be recorded throughout the test.

Prior to the initial treatment, 50 blueberry bushes will be randomly selected within each treated and control plot. The total number of bushes in each plot will be divided by 50 to derive a uniform subsampling interval (in bushes). The location of the first bush will be randomly selected between bush 1 and the bush interval. For example, if 500 bushes are in the plot, then the sampling interval will be 10 bushes (500 bushes divided by 50 sample bushes = 10 bushes). The next sample bush will be the bush interval from the previously surveyed bush. These bushes will be marked at the base with numbered flagging tape for subsequent surveys of bird damage (1, 3, 7, 14, 21, and 28 days posttreatment). On each sample bush, a randomly selected limb consisting of 20 blueberries will be used to assess bird damage. If the limb contains more than 20 berries, then excess berries will be removed. The limb will be identified with a numbered tag. The number of berries present on the limb will be recorded immediately before treatment and 1, 3, 7, 14, 21, and 28 days after initial treatment.

After the berries on each branch are counted, the observer will pick all ripe berries from the branch, record the number picked on the data form, and also record the number of berries left on the branch. The observer will also record the number of berries with peck marks. Then, the observer will pick all ripe fruit from the entire bush and store the berries in a labeled paper bag before moving to the next marked bush. Berries will be

considered ripe if they have a uniform blue color.

When all counts in a plot are completed, the bagged berry samples will be weighed and recorded separately for each bush on a data form. Because berries will be counted and harvested from marked bushes at regular intervals, we will assume that natural droppage will be negligible and that it will be equal in treated and control plots.

At least 2 weeks before the initial field trial, PMC Specialties will ship to the Denver Wildlife Research Center 5 20-g samples of the formulated product from the same lot that will be used in the field trials. This will allow for verification of MA content prior to actual spray application. A 40-ml sample of aqueous spray formulation will be collected and frozen for subsequent analysis prior to each spray. In addition, 25 g samples of blueberries will be clipped from unmarked bushes 1 day pretreatment and 1, 3, 7, 14, 21, and 28 days posttreatment at 4 randomly selected locations within each treated and control plot. Samples will be labeled, frozen, and shipped to the Denver Wildlife Research Center for residue analysis.

In prior studies, attempts to quantify bird activity have proved ineffective. In this study observers will record bird species present during the damage assessment visits and will rank the species in abundance rather than count individuals.

B. Analytical Chemistry:

The following analytical chemistry services will be needed.

1. Verification of MA content in formulation.
2. Verification of MA content in spray mixture.
3. MA residues on berries and leaves (7 sampling periods/plot).

C. Bait Formulation:

No baits will be used.

D. Location of Work:

North Carolina, New Jersey, Michigan, Oregon, Washington. Exact locations will be determined later.

E. Cooperators and consultants:

North American Blueberry Council and local State blueberry growers' groups. PMC Specialties Group.

F. Related Study Protocols:

QA-258, QA-305

G. Justification for selection of the test system:

See VI D.

H. A description and/or identification of the diet used in the study as well as solvents, emulsifiers and/or other materials used to dissolve or suspend the test or control substances before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications:

The spray formulation contains approximately 15% MA (g/g). We will apply MA at a rate of 35 kg/ha.

I. The route of administration and the reason for its choice:

Birds will be exposed to the treatment through their normal feeding activity.

J. Each dosage level, expressed in milligrams per kilogram of body weight or other appropriate units of the test or control substance to be administered and the method and frequency of administration:

35 kg MA/ha

K. A description of experimental design, including the methods for the control of bias:

See VII A.

L. Statistical analysis:

Two responses will be analyzed: percent berry loss from marked branches and total harvest from marked bushes. These data will be compared between

treated and control plots among sites within each State following analysis of variance procedures described by McKone and Lively (1993).

M. Environmental conditions of the study:

Outdoors.

N. Accountability of the Test Substance: N/A

O. The records to be maintained.

Study Area:

Map/site/location.
Site size/treated area.

Chemicals:

Source and disposition.
Analysis of chemical formulations.

Treatment:

Site and unit number.
Chemical concentration and application rate.
Method of application/equipment.
Sprayer calibration.
Samples/date/location.
Air temperature/relative humidity/precipitation/wind speed and direction.

Damage Assessment:

Observers location.
Site/unit number/survey date.
Berries present, picked, left.
Mass of berries picked/bush.
Species and rank order abundance of birds.

Residues:

Site/unit/chemical.
Plot/location/date.
Treatment dosage/application date/harvest date.

Laboratory data will be permanently recorded in a bound laboratory research notebook.

P. Authority and permits:

Permits to field test MA will be negotiated by the manufacturer, PMC Specialties.

Q. Standard Operating Procedures (SOPs).

WRC-337 Personal Protective Clothing

VIII. COMPLIANCE WITH ENDANGERED SPECIES ACT (SECTION 7):

This study poses no threat to any endangered species.

IX. COMPLIANCE WITH THE NATIONAL ENVIRONMENTAL POLICY ACT:

This study has no potential for significant impact on the environment.

X. EMPLOYEE SAFETY:

USDA/APHIS/ADC safety regulations will be followed (SOP WRC-337).

XI. SCHEDULE:

Proposed experiment start date	May 1994
Proposed experiment completion date	September 1994
Study completion date	March 1995

XII. STAFFING:

	FTE
Wildlife biologist (FL)	0.20
Wildlife biologist (CO)	0.20
Biological technician (FL)	0.15
Biological technician (CO)	0.15
Program assistant	0.02
Quality assurance	0.01
Biological technician (temporary)	0.25

XIII. COST ESTIMATE FOR EACH FISCAL YEAR:

A.	Salaries and Benefits	$55,000.
B.	Facilities (in addition to existing facilities or space costs)	0.
C.	Equipment	0.
D.	Supplies	1,500.
E.	Operating costs (travel, misc. services):	
	Travel, per diem	12,500.
	Overtime	3,500.
	Analytical chemistry	6,500.
	Total	$79,000.

XIV. QUALIFICATIONS OF STAFF:

Study participants have documentation supporting education, experience, and training which qualify them for the work they will be performing in this study.

XV. ARCHIVING:

All raw data, documentation, protocols, specimens and final reports are transferred to the archives at the close of the study (which is the day the final report is signed).

XVI. REFERENCES:

Askham, L. R. 1992. Efficacy of methyl anthranilate as a bird repellent on cherries, blueberries, and grapes. Proc. Vertebr. Pest Conf. 15:137-141.

Askham, L. R., and J. K. Fellman. 1989. The use of DMA to reduce robin depredation on cherries. Proc. Great Plains Wildl. Damage Control Workshop 9:116-119.

Avery, M. L. 1992. Evaluation of methyl anthranilate as a bird repellent in fruit crops. Proc. Vertebr. Pest Conf. 15:130-133.

Avery, M. L., J. W. Nelson, and M. A. Cone. 1992. Damage to blueberries in North America. Proc. East. Wildl. Damage Control Conf. 5:105-110.

Avery, M. L., J. L. Cummings, D. G. Decker, J. W. Johnson, J. C. Wise, and J. I. Howard. 1993. Field and aviary evaluation of low-level application rates of methiocarb for reducing bird damage to blueberries. Crop Protection 12:95-100.

Besser, J. F. 1985. A growers guide to reducing bird damge to U.S. agricultural crops. Denver Wildl. Res. Center, Bird Damage Res. Rep. 340. 90 pp.

Cummings, J. L., J. R. Mason, D. L. Otis, and J. F. Heisterberg. 1991. Evaluation of dimethyl and methyl anthranilate as a Canada goose repellent on grass. Wildl. Soc. Bull. 19:184-190.

Cummings, J. L., M. L. Avery, P. A. Pochop, T. E. Davis, Jr., D. G. Decker, H. W. Krupa, and J. W. Johnson. 1993. Evaluation of ReJeX-iT(R) methyl anthranilate formulations for reducing bird damage to blueberries. Crop Protection. In prep.

Dolbeer, R. A., M. L. Avery, and M. E. Tobin. 1994. Assessment of field hazards to birds from methiocarb applications to fruit crops. Pesticide Science. In press.

Kare, M. 1961. Bird repellent. U.S. Patent Office, patent 2,967,128.

Mason, J. R., M. A. Adams, and L. Clark. 1989. Anthranilate repellency to starlings: chemical correlates and sensory perception. J. Wildl. Manage. 53:55-64.

Mason, J. R., M. L. Avery, J. F. Glahn, D. L. Otis, R. E. Matteson, and C. O. Nelms. 1991. Evaluation of methyl anthranilate and starch-plated dimethyl anthranilate as bird repellent additives. J. Wildl. Manage. 55:182-187.

McKone, M. J. and C. M. Lively. 1993. Statistical analysis of experiments at multiple sites. Oikos 67:184-186.

Tobin, M. E., and R. A. Dolbeer. 1987. Status of Mesurol® as a bird repellent for cherries and other fruit. Proc. East. Wildl. Damage Control Conf. 3:149-158.

XVII. APPENDICES:

13544

R151348

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

PC Code: 128725
HED File Code: 41600 BPPD Other
Memo Date: 3/10/1994
File ID: *00000000*
Accession #: 000-00-9003

HED Records Reference Center
9/21/2007