

IRB BRANCH REVIEW - TSS

Record Number(s)

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6/9/93
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IN _____ OUT _____ 6/9/93

EFFICACY

FILE OR REG. NO. 66550-R

PETITION OR EGP. PERMIT NO. _____

DATE DIV. RECEIVED 4/15/92, 4/22/93

DATE OF SUBMISSION 4/7/92, 4/13/93

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

DATA ACCESSION NO(S) 427402-01, 02, 03, 04; 425803-02, 03

PRODUCT MER. NO. 14

PRODUCT NAME(S) BIRD SHIELD REPELLENT CONCENTRATE

COMPANY NAME Dolphin Trust

SUBMISSION PURPOSE registration as "biochemical"

CHEMICAL & FORMULATION 26.41% Methyl Anthranilate liquid concentrate

Efficacy Review: BIRD SHIELD REPELLENT CONCENTRATE, 66550-R

Applicant:

Dolphin Trust
Spokane, WA 99201

Producer:

Bird Shield Corporation
Spokane, WA 99201

200.0 INTRODUCTION

200.1 Uses

A 26.41% Methyl Anthranilate concentrate proposed for Federal registration to be mixed with water to repel unspecified types of birds from "Small soft fruit and flower crops," "Structures, roosts, and nests," and "Water Impoundments and chemigation systems." This product also would contain [REDACTED], " according to the Confidential Statement of Formula (CSF) of 12/13/91.

200.2 Background Information

The package that occasioned in this review was submitted on 4/14/93 and received on 4/15/93. The package routed to me contains proposed labels, various forms, product chemistry and safety information, and reports of several efficacy studies and other research. The purpose of the routing, however, was not for review but rather to determine whether "the studies pass the scientific screen."

This bureaucratic nonsense is going on because OPP has classified the active ingredient, Methyl Anthranilate, in these product as a "biochemical." As a "biochemical" and a "reduced risk pesticide," Methyl Anthranilate is supposed to get favored treatment which would include waiving some studies and accelerating reviews. However, nearly 2 months have passed since these submissions were made, and OPP is still trying to decide whether to review them. I have decided to review the efficacy studies.

This review also discusses several efficacy-related items in the successful application for consideration of Methyl Anthranilate as a "Biochemical". That application was submitted on 4/6/92.

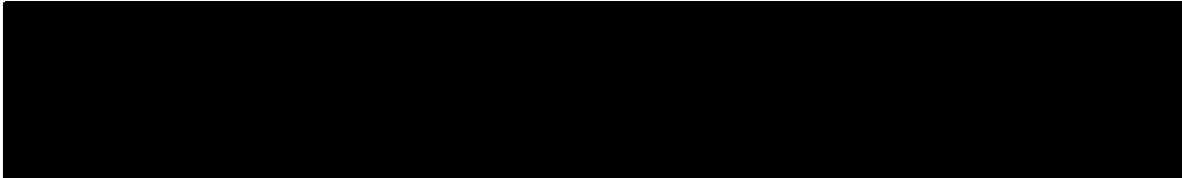
Dolphin Trust and Bird Shield Corporation have the same address.

Inert ingredient information may be entitled to confidential treatment

Methyl Anthranilate (MA, hereafter) is a GRAS listed material for which, nevertheless, the proposed label warns of potential eye irritation and oral and inhalation hazards. The proposed label also states

"This product is not hazardous to wildlife or fish."

201.0 DATA SUMMARY



The efficacy studies included in these submissions are discussed individually below, beginning with the items submitted in 1993. These reports deal with all of the proposed use patterns. Also discussed below is a report concerning phytotoxicity of this product to plants.

The efficacy submissions for the fruit uses are divided into three separate volumes, one each for cherries, grapes, and blueberries. At the beginning of each of these volumes is a copy of the same published report which refers to all three crops. Following this report are various assorted data sheets, protocols, and other items which researchers stick in their reports because of EPA's GLP requirements. In this review, I discuss the publication first, followed by discussions of the remaining items in the volumes on cherries, blueberries, and grapes.

1. Askham, L.R. (1992a) Efficacy of methyl anthranilate as a bird repellent on cherries, blueberries, and grapes. Proc. 15th Vertebrate Pest Conference (Borreco, J.E. and Marsh, R.E., eds.), Univ. California at Davis, 137-141.

This report describes results of various studies with MA including some directed at assessing photodegradation. Askham concluded that MA (mixed with lesser amounts of ethanol) is highly subject to photodegradation in sunlight, with the ultraviolet portion being mostly responsible for the effect. Significant photodegradation occurred in as few as 8 hr, with half of the material being gone in 16 hr in an indoor trial using a battery of artificial sources of fluorescent, UV, and incandescent light. Outdoors, in natural sunlight, the half life was about 2 days, with MA being essentially gone in 4 days. Adding PABA (para-aminobenzoic acid) to the MA/ethanol mixture did not extend the survival of MA, but placing MA in shade or under glass

in outdoor conditions extended the half life by about 2 and 4 days, respectively. Adding an unidentified "lipid molecular binding compound (MBC)" to the MA extended its halflife in sun to about 5 days and in shade to about 10.

Askham (1992a) also reports that phytotoxicity occurred when leaves of growing cherry, blueberry, grape, and raspberry plants were dipped into a 90% MA/10% ethanol formulation diluted with water to concentrations as low as 0.063% (660 ppm) and 0.125% (1320 ppm). For a formulation of MA + MBC (relative amounts not reported), much higher MA concentrations were needed before any "adverse effects were noted." On blueberries, grapes, and cherries, no phytotoxic effects were seen below the 8% (84489 ppm) treatment level. No phytotoxic effects were seen when MBC alone was applied to foliage of these four plant types.

In efficacy trials with captive starlings, Askham (1992a) states that it took only 5 minutes for birds to stop eating cherries or blueberries "presented on trays or suspended on branches from wires" if the fruits had been treated with MA + MBC at a concentration of 0.25% MA (v/v!). The birds continued to eat untreated fruits of the same type and consumed all that were offered within a 24-hr period.

In field efficacy trials with cherries, Askham (1992a) reported reductions in damage attributed to use of the 0.25% MA (v/v) formulation in a very small test involving "Early Ripening Cherries." The way in which the results were discussed in the report was confusing to me, however. He reports 19% damage in untreated trees, but states that damage over the 15-day study was reduced 13% by one treatment (Solo, backpack gasoline sprayer) and 54% by two treatments at a 7-day interval. I suspect that this means that the damage was about 16.5% for the single treatment and 9+% for the dual treatment. As overlaps among groups were extensive, this trial does not provide much support for repellent claims for MA on cherries. In this and subsequent studies with cherries, Askham reported that damage at tops of trees tended to occur at higher rates than at 6 feet above ground level.

In a 22-day test involving 10 mature Bing cherry trees, samples from the 4 untreated trees reportedly were damaged at a rate of 24.5% while cherries treated at 10- and 5-day intervals suffered 5.73% and 0.56% damage, respectively. These levels are 74% and 98% lower than that reported for untreated cherries. As in the prior trial, robins were the bird species responsible for most of the damage.

Askham (1992a) also studied the effects of commercial-like treatments on two

"1-ac blocks of randomly planted Bing, Sam, Ranier, Chinook and Lambert cherries at the Washington State University Tree Fruit Research and Extension Center (TFRC) at Wenatchee"

Half of each block was left untreated while the other half was treated at 7-day intervals with a 0.25% MA + MBC by use of a sprayer set to deliver 400 lbs/acre at 200 psi. Starlings, robins, and cedar waxwings foraged in the orchard.

Results in this trial are summarized below.

TIME SINCE TREATMENT	PERCENT DAMAGE		
	Treated	Check	% Effect
0 days	0.0%	0.0%	----
7 days	0.0%	0.0%	----
14 days	0.52%	5.34%	-90.3%
29 days	4.45%	7.67%	-42.0%

As is common with vertebrate animal repellents, the initial effects found were greater than those found at harvest. According to Askham (1992a), peculiar weather during the previous winter and wild, unexplained fluctuations in bird use of the orchard may have distorted the results obtained in this study.

Askham (1992a) also reported the results of efficacy trials in three highbush varieties of blueberries. Run at Washington State's facility in Puyallup, these were small-plot trials in which 3 rows of 20 plants per variety were treated and three were not. Only four treated plants per variety were monitored. Eight untreated plants were monitored. Four were covered with netting and four were left unprotected.

Although three varieties were tested, Askham (1992a) does not report results for the Rubel variety. For the others, results were reported in terms of differences between them and the netted plants. For the Pemberton variety, yield for the unnetted and untreated plants was 7 lbs and 25% below the netted, while the yield for the plants treated with 0.25% v/v MA+MBC was 2.6 lbs and 9% below that for the netted plants. For the Jersey variety, unnetted and untreated plants yielded 3.3 lbs and 19% less than the netted plants, but the yield for treated plants exceeded that for the netted plants by 0.4 lbs and 2.5%.

The tests in three types of wine grapes also were run at Puyallup. The procedures used in these trials resembled those used for the blueberry trials except that no plants were netted and the formulation applied was 0.50 w/w MA+MBC. Treatments were made with a Solo backpack sprayer

" . . . that forced the repellent under the leaf canopy to coat the fruit."

Askham (1992a) reported the results of this trial in terms of approximate percent of crop damaged. The results reported in the published account are summarized below.

VARIETY	PERCENT DAMAGE		PERCENT DAMAGE REDUCTION
	<u>Treated</u>	<u>Untreated</u>	
Gewurtzraminer	21%	9%	57%
Semillon	<10%	4%	62%
Limberger	30%	5%	80%

Obviously, the percent reductions reported for Semillon and Limberger were based upon numbers other than the relative percent damage levels reported. This issue will be discussed further when the remainder of the efficacy submission on grapes (document "4.") is discussed below.

Askham (1992a) reports that residue analyses were conducted on Bing cherries and Pemberton blueberries treated with MA+MBC. Detectable residues on cherries were not present after seven days from treatment had elapsed and, not surprisingly, were absent at harvest. Residues were not detected on blueberries at any time. Four fruit inspectors for the Washington State Department of Agriculture reportedly found fewer skin breaks and less decay on treated cherries than on untreated ones, although the treated ones were more extensively bruised. In triangle taste tests, human subjects could not reliably distinguish treated cherries from untreated cherries nor could they tell which blueberries had been treated.

2. Askham, L.R. (1992b) Effect of Bird Shield Repellent on reducing bird depredation of cherries. Department of Horticulture and Landscape Architecture, Washington State University, Pullman, WA, 68 pp.

MRID # 427402-01

This document includes a copy of Askham (1992a), data sheets for the cherry efficacy portion of that report, and assorted relevant protocols, SOPs, and correspondences.

The IR-4 protocol #5026, "Methyl Anthranilate: Magnitude of the Residue on Cherry," identifies the test substance as

". . . 25% methyl anthranilate . . . in 75% inert ingredients (2.29 lb ai/gal)."

The dates in this protocol and the correspondence related to it indicate, however, that these documents were completed one to three months after the conference at which Askham's (1992a), perhaps incomplete, paper was delivered.

According to Askham's field notes, there were 3 dozen robins, 2 dozen starlings, 8-10 crows, and "about twenty-five gulls" in the orchard on the day before the first treatment. There were 12 untreated controls and 16 treated trees (3 times at 7-day intervals). Treated trees were assessed for damage one day later than untreated trees were.

The results of this experiment are summarized below.

TREATMENT	REPLICATION	YIELD lbs/tree	% DAMAGE
None	1	241.50	7%
	2	309.00	2%
	3	193.00	5%
	4	273.50	5%
	Mean	254.25	4.75%
MA mix 9.17 lbs/ acre	1	332.00	2%
	2	387.50	4%
	3	182.00	3%
	4	121.00	7%
	Mean	255.62	4.00%

The yields were virtually identical between treated and untreated trees, and the mean percent damage was only 15.8% less than the treated plots. Askham claimed that there was about 1% damage to the crop before treatment. The total level of damage reported was relatively low (for birds in cherries) in all plots. No phytotoxicity was noted in either plot. The mean grade for treated plants was numerically lower than that for untreated plants, but the results for individual plots overlapped greatly. All in all, it is difficult to make a case for the effectiveness

of Bird Shield from these data alone.

3. Askham, L.R. (1992c) Effect of Bird Shield Repellent on reducing bird depredation of blue berries. Department of Horticulture and Landscape Architecture, Washington State University, Pullman, WA, 63 pp.

MRID # 427402-02

This document includes a copy of Askham (1992a), data sheets for the blueberry efficacy portion of that report, and assorted relevant protocols, SOPs, and correspondences. This study was run in mid-Summer of 1991. From Askham's study notes, I have learned that the Rubel berries were heavily damaged by the "scorch" virus. Presumably, this was the reason that results in this variety were not mentioned by Askham (1992a).

According to the "FIELD DATA REPORTING FORM" (5028.9), BIRD SHIELD was applied to the treated bushes at a rate of 1.37 lbs a.i./acre for the efficacy portion of this study. The spray mixtures were prepared by adding 0.57 lbs of product to enough water to equal 25 gal total. (Askham's field notes state that 1/2 gal of product was mixed with enough water to make 50 gal of product. The amount was reduced, however, for the efficacy studies to be consistent with expected "worse case" practices by growers: applying 60 gallons of mix/acre rather than 100.)

The reporting form also includes the following estimates of numbers of birds using the test area:

DATE	ROBINS	STARLINGS	SPARROWS	CEDAR WAXWINGS
7/17/91	12	15	10	18
7/24/91	24-48	30	15	28-30
7/31/91		No Counts Attempted		
8/7/91	24-26	18-20	12	28-30
8/14/91		No Counts Attempted		
8/21/91	28-30	24-26	18-19	30-36

Efficacy results for Pemberton blueberries appear in the tables immediately below. These data suggest that the treatments significantly arrested new damage, except possibly in replication 3 where the initial damage rate had

been low and the final rate was typical of the treated plots. Compared to the plants that were unnetted and untreated, treated plants were damaged initially at a rate almost twice (188%) as high before treatment. After treatment, the mean rate of new damage on treated plants was 70% that of unnetted and untreated plants.

Yields on treated plants were consistently closer to those on netted plants that were those on untreated/unnetted plants.

In the phytotoxicity portion of this study, plants were treated at rates of 2.29 and 4.58 lbs a.i./acre with no damage being apparent to Pemberton or Jersey blueberry bushes.

TREATMENT GROUP	REP. NO.	% FRUIT MISSING OR DAMAGED (8" Sample)		
		PEMBERTON VARIETY		
		<u>Pretreatment</u>	<u>Posttreatment</u>	<u>Change?</u>
CONTROL	1	33.3%	63.0%	+89.2%
	2	6.3%	55.7%	+784.1%
	3	50.0%	72.6%	+45.2%
	4	16.7%	83.3%	+158.3%
	Mean	26.6%	68.6%	Comp Mean +157.9% +269.2%
TREATED (1.37 lbs a.i./acre)	1	75.0%	27.5%	-63.3%
	2	40.0%	26.2%	-34.5%
	3	10.0%	24.6%	+146.0%
	4	75.0%	3.7%	-95.1%
	Mean	50.0%	20.5%	-11.7%

DATE OF HARVEST	MEAN AMOUNT (g) OF PEMBERTON BLUEBERRIES HARVESTED				
	<u>Netted Plants</u>	<u>Unnetted/ Untreated Plants</u>		<u>Treated Plants</u>	
		Amount	% <> Netted	Amount	% <> Netted
7/23/91	1715 g	1310 g	-23.6%	1387 g	-19.1%
7/30/91	3697 g	2959 g	-20.0%	3326 g	-12.7%
8/6/91	3112 g	2654 g	-14.7%	3179 g	+2.2%
8/13/91	2093 g	1499 g	-28.4%	2055 g	-1.8%
8/20/91	1488 g	866 g	-41.8%	1243 g	-16.5%

8/27/91 566 g 224 g -60.4% 315 g -44.3%

In the Jersey variety, there was no initial damage, and all treated plants monitored received new damage at rates less than those suffered by all unnetted and untreated plants. Overall, the mean rate of new damage to treated plants was 59% less than that for untreated plants.

Yields produced by treated plants were estimated to be higher than those produced by untreated and unnetted Jersey bushes for all but the last of six harvests. Yields for treated bushes were above those reported for netted bushes for three of the harvests. These results suggest to me that not enough bushes were sampled to cancel out influences from factors other than bird pressure that might have influenced yields. These results are summarized below.

JERSEY VARIETY

REP.	% FRUIT MISSING OR DAMAGED (8" Sample)	
	UNETTED/UNTREATED	TREATED (1.37 lbs a.i./acre)
1	33.7%	24.8%
2	44.3%	16.2%
3	60.9%	15.3%
4	51.0%	21.4%
Mean	47.5%	19.4%

DATE OF HARVEST MEAN AMOUNT (g) OF JERSEY BLUEBERRIES HARVESTED

DATE OF HARVEST	<u>Netted Plants</u>		<u>Unnetted/Untreated Plants</u>		<u>Treated Plants</u>	
	Amount	% <> Netted	Amount	% <> Netted	Amount	% <> Netted
7/23/91	313 g		188 g	-39.9%	207 g	-33.9%
7/30/91	1094 g		880 g	-19.6%	1218 g	+11.3%
8/6/91	2150 g		2201 g	+2.4%	2121 g	-1.3%
8/13/91	1585 g		1416 g	-10.7%	1821 g	+14.9%
8/20/91	1102 g		978 g	-11.3%	1336 g	+21.2%
8/27/91	772 g		561 g	-27.3%	488 g	-36.8%

4. Askham, L.R. (1990) Effect of Bird Shield Repellent on reducing bird depredation of grapes. Department of Horticulture and Landscape Architecture, Washington State University, Pullman, WA, 23 pp.

MRID # 427402-03

This compilation also includes a copy of Askham (1992a), field report forms, and other documents. It does not contain field notes. The sole treatment, at 9.17 lbs product/acre was made on 9/29/90 and the lone assessment of efficacy was made on 10/10/90. There were estimated to be 1-12 robins and 10-15 sparrows in the vineyard on the day of treatment.

Results of this test are summarized below. All of the means shown below were calculated by me from the results reported for the individual replications. The values in the document do not represent arithmetic means of the individual scores. The number within quotation marks for treated replication "1" for Semillon may have been incorrect. The mean reported in Askham (1990) for this group was 3.81. Askham claims 59% reduction in damage for both Semillon and Gewurtztraminer, and 77% reduction for Limberger.

CULTIVAR	REP.	% BUNCHES DAMAGED/MISSING	
		CHECK	TREATED
Gewurtztraminer	1	26.84%	18.62%
	2	34.98%	2.48%
	3	7.65%	6.64%
	4	16.22%	9.21%
	Mean	21.42%	9.24%
CULTIVAR	REP.	% BUNCHES DAMAGED/MISSING	
		CHECK	TREATED
Semillon	1	13.68%	"40.7"
	2	5.82%	5.36%
	3	4.38%	4.59%
	4	14.29%	0.48%
	Mean	9.54%	12.78%
Limberger	1	37.05%	4.55%
	2	30.71%	11.90%
	3	22.96%	4.22%
	4	29.08%	3.90%
	Mean	29.95%	6.14%

No phytotoxicity was noted in this study.

5. Askham, L.R. (1993) Magnitude of Phytotoxicity of Bird Shield Repellent to plants. Department of Horticulture and Landscape Architecture, Washington State University, Pullman, WA, 151 pp.

MRID # 427402-04

This study was run in the Spring of 1992, after the conference at which the Askham (1992a) paper was presented. Perhaps, Askham presented a partial report at the meeting and embellished his paper as additional data became available. I was at the conference but do not remember exactly what Askham presented. This study appears to have been run concurrently with the cherry efficacy study reported by Askham (1992b). The field notes included in Askham's (1993) compilation for phytotoxicity are the same ones which appeared in Askham (1992b), Askham (1992c), and Askham (1990). Much of the bulk of Askham's (1993) report is comprised of items which also appear in Askham's efficacy compilations for cherries, blueberries, and grapes.

Askham exposed vegetation of cherries, blueberries, grapes, and raspberries to MA mixed with the "nonionic surfactants" Tween and Regulaid, and to MA+MBC (BIRD SHIELD REPELLENT). Foliar applications were made to runoff (2.29 lbs MA/100 gal mix).

As can be seen below, MA+Tween and MA+Regulaid damaged grape and raspberry plants extensively at all MA levels used and damaged cherries and blueberries at all but the two lowest levels. However, water plus emulsifier alone caused no apparent damage at all. When BIRD SHIELD REPELLENT was used, there was no apparent damage until the highest concentrations used (8% and 16% MA). These levels caused only slight damage.

PLANT TYPE	PHYTOTOXICITY RATING									
	% MA									
	<u>0</u>	<u>.13</u>	<u>.25</u>	<u>.5</u>	<u>1.0</u>	<u>2.0</u>	<u>4.0</u>	<u>8.0</u>	<u>16.0</u>	
	<u>Tween</u>									
Cherries	0	0	0	10	10	10	10	10	10	10
Blueberries	0	0	0	10	10	10	10	10	10	10
Grapes	0	5	10	10	10	10	10	10	10	10
Raspberries	0	10	10	10	10	10	10	10	10	10

PLANT TYPE	PHYTOTOXICITY RATING								
	% MA								
	<u>0</u>	<u>.13</u>	<u>.25</u>	<u>.5</u>	<u>1.0</u>	<u>2.0</u>	<u>4.0</u>	<u>8.0</u>	<u>16.0</u>
	<u>Regulaid</u>								
Cherries	0	0	0	10	10	10	10	10	10
Blueberries	0	0	0	10	10	10	10	10	10
Grapes	0	5	10	10	10	10	10	10	10
Raspberries	0	10	10	10	10	10	10	10	10
	<u>Bird Shield Repellent</u>								
Cherries	0	0	0	0	0	0	0	1	2
Blueberries	0	0	0	0	0	0	0	1	2
Grapes	0	0	0	0	0	0	0	0	1
Raspberries	0	0	0	0	0	0	0	0	1

RATING SCALE:

0 = "No visible damage"
 1 = "Some browning of leaf veins, edges and of maturing fruit"
 2 = ??
 5 = "Approximately 50% of leaves and maturing fruit desiccated"
 10 = "All leaves and maturing fruit desiccated."

NOTE: The S.O.P. for "Phytotoxicity Data" on cherries called for use of a six-point (0-5) scale for rating damage. It is possible that that scale was used for the BIRD SHIELD phase of the study and that the scale presented above (except for "2") was used for the other materials.

6. Askham, L.R. (1991a) Effect of Methyl Anthranilate on reducing bird use of perches and nest sites. Department of Horticulture and Landscape Architecture, Washington State University, Pullman, WA, 15 pp.

MRID # 425803-02

In this report, Askham (1991a) presents, in outline form, accounts of trials with captive starlings in an aviary and with free-ranging starlings and cliff swallows.

In the aviary study, one of two special perches to which birds had been acclimated was treated with a 25% MA formulation at full strength. A strong repellent effect was claimed for 4-5 days. By the end of the sixth day, the effect appeared to have waned.

In the trial with free-ranging starlings, sites at which pairs were building nests were treated with a "1% solution of bird repellent." Repellent effects were claimed to have been immediate and to have caused nest abandonment. Thirty days after treatment, birds were seen "landing near and on treated site." No observations were reported for the time period between 24 hours posttreatment to 30 days post-treatment.

The conduct of the study of treated nest site of cliff swallows was similar to that of the trial in which starling's nest sites had been treated. In this case, the repellent effect was claimed to be intact 30 days after treatment.

So little quantitative information was provided in this report that it is hard to take it very seriously. Four of the 15 pages were taken up by a protocol which dealt with applications to cherries. The report of the trials on nest sites and starling perches was barely three pages long.

7. Askham, L.R. (1991b) Effect of Methyl Anthranilate on reducing bird use of water impoundments and chemical application systems (chemigation) use. Department of Horticulture and Landscape Architecture, Washington State University, Pullman, WA, 10 pp.

MRID # 425803-03

The "meat" of this report was only two pages of an outline-form account which pertains only trials with starlings in an aviary in which the treated "Water Impoundment" consisted of

"one five-gallon container of fresh water treated with one tablespoon of repellent concentrate (25% Methyl anthranilate, 75% inert ingredients)."

The birds were permitted to acclimate to the aviary for a week. At the start of the test, water containers were removed for 16 hr. A treated container then was placed in the aviary. Thirty minutes later, a container of untreated water was added. After five days, the container of untreated water was removed (for 30 min?) and then reintroduced.

According to the account, birds immediately drank from the treated container when it was placed but soon exhibited signs of distress ("beak rubbing, ruffled feathers, squacking [sic]"). They drank readily from the untreated water container when it was added. The report implies that the repellent effect of the treated water persisted through

the entire test, which lasted about 7 days.

This report comes nowhere near supporting claims for use of MA in water impoundments and chemigation systems. Accepted at face value, it only states that starlings do not like to drink or bathe in water in a 5-gallon pail if it has been treated with MA.

Much of the material in the application for consideration of MA as a "biochemical" pertains to issues other than its effectiveness as a vertebrate animal repellent. Although I examined the entire volume, the only material reviewed below is that pertaining directly to efficacy.

8. Schafer, E.W., Jr. and Bowles, W.A. (1985) Acute oral toxicity and repellency of 993 chemicals to house and deer mice. Archives of Environmental Toxicology, 14, 111-129.

These authors report an LD50 of 1250 mg/kg/day and a FR (food reduction) index of 0.00% for Methyl Anthranilate. The FR score was determined by offering deer mice 25 white wheat seeds treated with MA at 2.0% a.i. per day for three days. Besides the treated seeds, the mice were given laboratory rodent pellets and water. The FR score was the percent of treated seeds that were not eaten. Therefore, the score of 0.00% means that the mice ate all 75 seeds that they were presented and that this compound probably would not make it as a treatment to protect seeds from depredations by deer mice.

9. Schafer, E.W., Jr., Bowles, W.A., and Hurlbut, J. (1983) Acute oral toxicity, repellency, and hazard potential of 998 chemicals to one or more species of wild and domestic birds. Archives of Environmental Toxicology, 12, 355-382.

This report lists for MA an "R50" value of "+1.00%" for red-winged blackbirds. A "R50" is the concentration of a material in food which is needed to reduce its consumption to half of that which would have occurred in the absence of the chemical.

10. Askham, L.R. (undated) Efficacy of methyl anthranilate as a bird repellent on cherries, blueberries, and grapes. Manuscript, 21 pp.

This manuscript appears to be an early draft of the Askham (1992a) paper. However, the manuscript includes a number of tables that did not make it into the published version. These tables show from where Askham (1992a) got some of the values that he reported.

Table 2 in the manuscript presents the following results for the early maturing variety of cherries:

<u>Treatment</u>	<u>Pretreatment</u>	<u>Posttreatment</u>	<u>Change (%)</u>
Control	0	18.6	
1, 15-day application	1.1	16.2	12.9
2, 7-day applications	1.50	8.4	54.8

The figures for "Pretreatment" and "Posttreatment" damage evidently pertained to percent of crop damages. These data show that my suppositions (above, in discussion of Askham, 1992a) were close to the mark.

For one set of trials with Bing cherries, the following results are reported in the manuscript:

<u>Treatment</u>	<u>Pretreatment</u>	<u>Posttreatment</u>	<u>Change (%)</u>
Control	0	24.5	
10-day applications	0	5.7	76.7
5-day applications	0	0.6	97.6

These results were consistent with what was presented in the text of Askham (1992a).

In the Bing-cherry study in which treatments and evaluations were made at 7-day intervals, the manuscript's Table 4 reports no damage in treated or untreated areas before and for the first week after treatment. Fourteen days after treatment, the treated area was 0.52% damaged while the check area was damaged at 5.34%. From that point on, the differences between treatments decreased until the rate of damage on the treated plants (4.45%) was just 42% lower than that on the untreated trees (7.67%).

For the Pemberton and Jersey blueberries, Table 5 of the manuscript reports the following data:

TREATMENT	PEMBERTON		JERSEY	
	% DAMAGED		% DAMAGED	
	TOTAL	RIPE CROP	TOTAL	RIPE CROP
PRETREATMENT	16.1%	38.3%	0.00%	0.00%
POSTTREATMENT				
Control	65.4%	68.7%	43.9%	47.5%
Treated	18.2%	20.5%	17.6%	19.4%

These data are consistent with results presented in Askham (1992c) if one assumes that the pretreatment damage values for plants assigned to treated and control groups were averaged in the data presented above.

The manuscript also reports the phytotoxicity data discussed above (Askham, 1993). In the manuscript, the three test materials formulations were rated on the same "0-5" scale. The following results were reported:

CONCENTRATION (%)	MA + ETHYL ALCOHOL			
	Cherries	Blueberries	Grapes	Raspberry
0.063%	0	0	0	1
0.125%	0	0	1	5
0.25%	1	1	5	5
0.5%	3	3	5	5
1.0%	5	5	5	5
2.0%	5	5	5	5
4.0%	5	5	5	5
8.0%	5	5	5	5

CONCENTRATION (%)	MOLECULAR BINDING COMPOUND (MBC)			
	Cherries	Blueberries	Grapes	Raspberry
0.063%	0	0	0	0
0.125%	0	0	0	0
0.25%	0	0	0	0
0.5%	0	0	0	0
1.0%	0	0	0	0
2.0%	0	0	0	0
4.0%	0	0	0	0
8.0%	0	0	0	0

CONCENTRATION (%)	MA + MBC			
	Cherries	Blueberries	Grapes	Raspberry
0.063%	0	0	0	0
0.125%	0	0	0	0
0.25%	0	0	0	0
0.5%	0	0	0	0
1.0%	0	0	0	0
2.0%	0	0	0	1
4.0%	0	0	0	3
8.0%	1	1	1	5

Foliar Burn Rating:

- 0 - No visual discoloration
- 1 - Slight discoloration
- 2 - Yellow/brown margins
- 3 - Most of leaf curled brown
- 4 - Curled and brown
- 5 - Completely desiccated

The manuscript reports the same damage data for Gewurtztraminer and Limberger grapes that were reported by Askham (1990). For Semillon, for which Askham (1990) reported a "40.7%" damage score for one of four replicates, the manuscript presents the following results:

<u>Treatment</u>	<u>Damage %</u>	<u>Change in Damage %</u>
Control	9.52	
Treated	3.63	61.90

Considering the data for the other replications reported in Askham (1990), a value of "4.07%" damage would have given a mean of 3.63%. However, the data sheets in Askham (1990) were closer to the original source than were the manuscript or Askham's (1992a) published account.

The manuscript also presents specifics of the grading data and taste tests with Bing cherries, and the taste-test results for Pemberton and Jersey blueberries. As I understand the data, fully 45% of the untreated cherries were damaged. For about half of these, the damage was rated as "Serious." Twenty-seven percent of the treated cherries were damaged, with six of them being "Serious." The difference in bruising reported by Askham (1992a), was based upon 12 treated fruits and 8 control fruits having been damaged.

The taste test data suggest that members of the panel actually were somewhat able to distinguish between treated and untreated cherries. The 50% correct choice score exceeded the 33% predicted value, and the "Significance level (%)" was said to have been 1.0%.

11. Mason, J.R., Adams, M.R., and Clark, L. (1989) Anthranilate repellency to starlings: chemical correlates and sensory perception. Journal of Wildlife Management, 53:1, 55-64.

Already on file as MRID # 426753-03

The research described in this report was conducted with captive starlings at the Monell Chemical Senses Center. The birds were adapted to a 6-hr-light:18-hr-dark artificial photoperiod

"that maximized feeding, without reducing the total quantity of food consumed."

Food was available to birds for nearly all of the 6-hr light period. Prior to tests, birds were conditioned to 2-hr presentations of one or two bowls, each containing 20 g

of PFBC, which took place at the start of the light phase. After 2 hr, the bowls and residual food were weighed and the birds were offered PFBC and grit ad libitum (and not monitored) for the remainder of the light phase. Two-bowl presentations preceded choice tests, while one-bowl presentations preceded no-choice tests. Apparently, birds were singly caged for these trials. Birds often were used in more than one experiment.

In Experiment 1, 20 starlings were given 5-days of choices between untreated PFBC and PFBC treated to make 1% concentrations of one of the following Anthranilates: Ethyl, Isobutyl, Isobutyl Methyl, Methyl, and Dimethyl. Each bird was tested with all 5 test materials, but the order of presentation varied randomly among birds.

Relative to consumption of untreated PFBC, consumption of "Anthranilated" feed was suppressed significantly. No significant differences among the various compounds used were detected.

Experiment 2 was run similarly to Experiment 1, but the materials used to taint PFBC were Dimethyl Anthranilate, Linalyl Anthranilate, Phenyl Ethyl Anthranilate, Propriionyl Methyl Anthranilate, and Isobutyl-N-N-Dimethyl Anthranilate. Once again, there were no significant differences among the various Anthranilates.

In Experiment 3, each the nine Anthranilate compounds used in the first two experiments was used to treat PFBC at concentrations of 0.2%, 0.4%, 0.6%, 0.8%, 1.0%, 1.2%, 1.4%, and 1.6%. Nine groups of 4 birds each were exposed no-choice to "baits" made from one of these concentrates. In random order, each bird received each of the concentrations twice.

In this regime, there were differences among the Anthranilates, but take dropped with increasing concentrations for all compounds. In most cases, a hyperbolic relationship was suggested, but the drop was practically linear for Linalyl and Isobutyl-N-N-Dimethyl Anthranilates. The most precipitous drop in take between concentration steps occurred with Methyl Anthranilate where mean consumption was over 6 g/animal/test for untreated PFBC and under 1 g/animal/test at 0.2% MA. Statistically, Methyl, Dimethyl, Isobutyl, Ethyl, and Isobutyl Methyl Anthranilates were more aversive than Isobutyl-N-N-Dimethyl, Linalyl, Propriionyl Methyl, and Phenyl Ethyl Anthranilates. The last of these appeared to be the least aversive of the materials tested.

The four remaining experiments all dealt with birds in which the olfactory or the olfactory and the trigeminal nerves had been cut bilaterally. In choice tests, the Anthranilates remained aversive after olfactory nerves were severed. In no-choice tests, the effect of increased aversiveness with increasing concentration remained for the materials used, but the effect appeared to be weaker. For example, take of MA did not drop precipitously until the jump from 0.8% to 1.0% whereas the crash with intact birds took place before 0.2%.

Wiping out olfactory nerves and the primary trigeminal trunk from the nasal cavity did not remove preferences for untreated PFBC in choice tests but seemed to completely destroy suppression of feeding in the no-choice regime. In fact, take of all concentrations by birds with both sets of lesions was numerically higher for Anthranilate-tainted PFBCs than for untreated PFBC.

The application for consideration of MA as a "biochemical" also includes collections of notes, correspondences, and data sheets pertaining to use of MA in cherries and blueberries. These materials were included in Askham (1992b) and Askham (1992c) and will not be discussed again here.

The efficacy reports submitted for BIRD SHIELD REPELLENT and other information that I have seen pertaining to the efficacy of MA as a bird repellent, show that it has powerful effects in tightly controlled situations such as trials with captive animal and some repellent effects in actual use situations.

Collectively, the information on use of BIRD SHIELD in cherries, blueberries, and grapes suggests enough efficacy to support the claims. Because the data were presented in terms of yields rather than percent residual activity, I feel that the usual 60% repellency criterion should not be regarded as an absolute standard. Instead, evidence that the treatment is of some value in protecting the crops should be sufficient. Although only a few plants were involved in some of the studies, I have concluded that the evidence is adequate to demonstrate pesticidal activity for a "non-public-health" use pattern.

The information submitted to support the "public health" use patterns ("Structures, roosts, and nests") suggested some usefulness but was not of a quality adequate to support the claims. The same can be said for the two-page outline report submitted to support claims for use of BIRD SHIELD in "Water Impoundment's [sic] and chemigation systems."

The "Directions for use" portion of the proposed label includes separate sections for the three categories of proposed use sites. While none of these sections tells potential users how to apply the product, the section structural and standing water uses are particularly inadequate.

Users are instructed to prepare the concentrate for dilution with water "by pouring back and forth between two containers." As this material also may cause eye and skin irritation, I feel that another method of preparing the concentrate should be developed and suggested on the label.

The "ENVIRONMENTAL HAZARDS" section of the label boldly states

"This product is not hazardous to wildlife or fish."

This seems to be a claim of safety of the sort that would render a product "misbranded." I am not sure what the effects of our new "safer pesticides" initiative would be on the admissibility of such statements. Personally, I feel that they should not be permitted as they might invite careless use of the product.

Specific comments on the label appear under "CONCLUSIONS."

202.0 CONCLUSIONS

The efficacy studies which you have submitted, along with other information which has come to our attention, suggest that Methyl Anthranilate can have significant bird-repellent effects in some situations. However, none of the studies submitted shows practical effects in a treatment program approaching operational scope.

Taken at face value, the results which you submitted for uses in cherries, grapes, and blueberries are adequate to support these claims. The data were based upon very small numbers of plants and showed effects that were far from absolute. Therefore, these results do not support extrapolation from your studies to "Small soft fruit and flower crops" in general. We also feel that it is premature to allow claims for repelling birds in general.

There was insufficient detail and quantitation in the reports pertaining to claims for use of BIRD SHIELD in "Structures, roosts and nests" and "Water Impoundment's [sic] and chemigation systems." Consequently, these claims are not accepted at this time.

The use directions on the proposed label submitted on or about April 13, 1993, do not tell potential users how to apply the product (i.e., what types of equipment to use). In light of potential eye and skin irritation, we also are concerned about the instruction for repeated decanting of the product prior to diluting it with water. While we note the proposed label's requirements for protective clothing, we suspect that there might be a less hazardous and error-prone way to prepare the product for dilution.

The use directions should be restructured. A format is provided below. This format is provided under the assumptions that the application rates and schedules which you have proposed are appropriate, that the effects in fruit crops were consistent across the major bird species present, and that you will eventually support claims for repelling various types of birds from roosting and nesting sites and from standing water. If any of these assumptions is not correct, modify the "DIRECTIONS FOR USE" accordingly.

"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 limit feeding by robins (Turdus migratorius), Starlings (Sturnus vulgaris) Cedar waxwings (Bombycilla cedrorum), and native sparrows (Family Fringillidae [indicate Genera or species of greatest concern]) on ripening cherries, blueberries and grapes. This product also may be used to repel starlings and swallows (Family Hirundinidae) from structures, roosting, and nesting sites. This product also may be used to repel starlings from water impoundments and chemigation systems.

This product may be applied manually [?] or by use [indicate the appropriate type of] spray equipment]. Do not apply by use of aircraft.

Mixes made from product should be applied in early morning or late afternoon. Do not apply to wet surfaces. Do not mix with other pesticides or with fertilizers. Wear protective gloves and appropriate eye and face protection when mixing, applying or otherwise handling product.

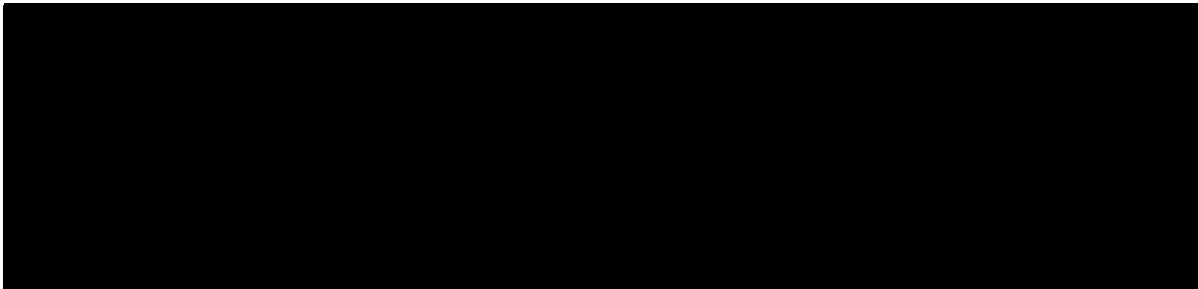
PREPARATION AND MIXING DIRECTION: In the sun or in a water bath, warm product to 75° F. Using [Indicate appropriate procedures] mix product thoroughly so that ingredients are evenly distributed and any solidification of product that might have occurred is no longer present. Make sure that formulation is fully and freshly mixed before adding it to water.

APPLICATION DIRECTIONS:

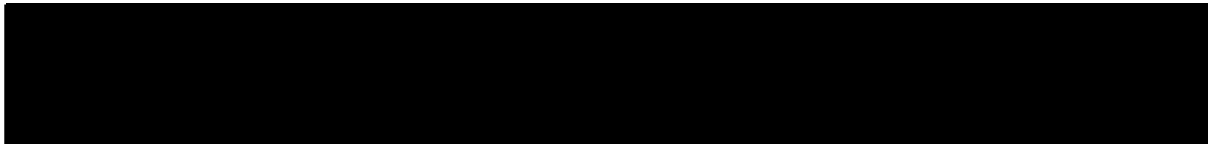
Blueberries, Cherries, and Grapes: Mix 1 part of BIRD SHIELD REPELLENT CONCENTRATE with 99 parts of water. Agitate mixture well before application. Using [appropriate, please describe] spray equipment, thoroughly wet all fruit and foliage until run-off occurs. Make first application when fruit begins to ripen or when birds begin to feed on crop. Repeat applications every 7 days or when odor of product no longer can be detected. Repeat applications as necessary to maintain repellency. Harvest fruit 6-8 days after last treatment or after all odor of product has dissipated, whichever comes last.

Structures, Roosts, and Nests: Using [indicate appropriate equipment - paint brush, hand-held sprayer, backpack sprayer, and/or whatever] apply concentrate at full strength or diluted 1 part BIRD SHIELD to 1 part water. Reapply as needed to maintain repellency.

Water Impoundments and Chemigation Systems: Mix 1 part BIRD SHIELD to 99 parts water and apply [indicate appropriate methods] to system to be treated. Reapply as necessary to maintain repellency. [We were not sure whether this use was intended to be, as stated on the proposed label, a 1:99 dilution applied to water or whether the product was to be mixed with the water already in the system at a 1:99 ratio. Whichever is the case should be stated clearly on the label.]"



Inert ingredient information may be entitled to confidential treatment



William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
June 8, 1993

Inert ingredient information may be entitled to confidential treatment



13544

R149152

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

PC Code:

128725

HED File Code: 41600 BPPD Other

Memo Date: 6/9/1993

File ID: 00000000

Accession #: 412-07-0183

HED Records Reference Center

7/23/2007