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Efficacy Review: BIRD SHIELD REPELLENT CONCENTRATE, 66550-R

Applicant:

Dolphin Trust
Pullman, WA 99163

Producer:

Bird Shield Corporation
Pullman, WA 99163

200.0 INTRODUCTION

200.1 Uses

A 26.4% Methyl Anthranilate concentrate proposed for Federal registration. According to a proposed "Master Label", this product is to be mixed with water for non-aerial applications to

"limit feeding by robins (Turdus migratorius), starlings (Sturnus vulgaris), Cedar waxwings (Bombycilla cedrorum), jays, magpies and crows (Corvidae), ravens (Corvus spp.), finches and sparrows (Fringillidae) on ripening cherries, blueberries, and grapes. This product also may be used to repel starlings and swallows (Hirundinidae) from structures, roost and nest sites as well as ducks (Anatinae and Aythyinae), geese (Anserinae), gulls and terns (Laridae) from water impoundments and chemigation systems."

The submission also includes separate labels for use of the product

1. "to limit feeding by birds on ripening blueberries"; and
2. "to limit feeding by robins (Turdus migratorius), starlings (Sturnus vulgaris), Cedar waxwings (Bombycilla cedrorum), jays, magpies and crows (Corvidae), ravens (Corvus spp.), finches and sparrows (Fringillidae) on ripening cherries".

200.2 Background Information

See efficacy review of 6/9/93. In that review, I accepted claims for repelling robins, starlings, cedar waxwings, and "native sparrows (Family Fringillidae)" from blueberries, cherries, and grapes. As the data examined were very

limited in scope, my acceptance of these claims was most generous and perhaps a trifle foolhardy. I did not, however, accept proposed claims for water impoundment uses not did I accept the claim of protection of "Small soft fruit and flower crops" that was originally proposed

In addition to the proposed "Master" and a label for the use on cherries(?), Dolphin Trust's submission of 2/13/95 includes a letter and a report of an efficacy study pertaining to the water impoundment use. The package routed for review includes copies of a letter and crop-specific labels for blueberries and cherries(?) that were "FAXed" to EPA on 1/24/95, and a memorandum of 3/17/95 from Daniel B. Peacock of PM Team 14 to "Correspondence Files".

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 "Master Label" bears safety claims but also includes statements such as

"May cause severe irritation to skin, mouth, or eyes";

"Avoid direct contact or prolonged breathing of fumes"; and

"Slightly toxic to fish."

OPP has determined that MA is a "biochemical" worthy of reduced registration data requirements. However, the signal word on the proposed label for 66550-R is "WARNING" and Peacock's memo raises the issue of intensifying this to "DANGER" on the basis of the 9.7 pH of the formulation unless the company comes up with Eye Irritation data which indicate that a milder signal word is warranted. The "ENVIRONMENTAL HAZARDS" section of the "Master Label" states that the product is "Slightly toxic to fish."

201.0 DATA SUMMARY

In addition to MA, this product also would contain

Ingredients which perform only these functions are considered to be inert.

Inert ingredient information may be entitled to confidential treatment

The efficacy report included in the submission of 2/13/95 is discussed below. The citation for this study appears to be as follows:

1. Askham, L.R. (1995) Effective repellency concentration (EC_R Bird Shield RepellentTM) with Methyl Anthranilate to exclude ducks and geese from impoundment's [sic]. Manuscript intended for publication In: Masters, R. (ed.) Proceedings: 12th Great Plains Wildlife Damage Control Workshop, 12, 5 pp.

Given that the report was submitted to EPA about two months prior to the scheduled dates of the conference (4/10-13/95), its pagination in the proceedings was not available at the time of its submission to us. The manuscript is 5 pages long. The first page and some of the second are devoted to the abstract and introduction sections. The last two pages and part of the third page list references cited in the first three pages. The "meat" of the report amounts to less than 2 pages of text, with no data tables or figures presented.

The trials were conducted in two outdoor aviaries ("12.5 ft. X 7.0 ft. X 42 ft." in size). Three circular "children's wading pools" 4'8" in diameter (1/2" narrower than standard-gauge railroad rails) were placed in the aviaries. Five barnyard geese (Branta? domesticus) were placed in one aviary and 9 mallards (Anas platyrhynchos) were placed in the other. Initially, untreated water (3.8 gal, or 190 L) was placed in each pool. During treatment phases, measured amounts of Bird Shield were added to two of the pools, while the third remained untreated. After three weeks in the treated condition, there was a "buffer" period in which (presumably) all three pools in each aviary were filled with untreated water. Three test phases were run, giving Askham the opportunity to load the 25% MA product into pools in both aviaries once in each of the following amounts: 31 ml, 63 ml, 125 ml, 250 ml, 500 ml, and 100 ml. Effects on pool use reportedly were assessed by direct(?) and videotaped observations, and

"by the amount of soil deposited from the feet of the birds in the bottoms and the number of feathers floating on the water of each pool."

Askham writes that essentially no effects on pool use were observed for the three lowest doses, which he calculated to have provided 90 ppm, 180 ppm, and 360 ppm, respectively, of MA(?). At the three highest doses (claimed to yield MA[?] concentrations of 727 ppm, 1445 ppm, and 2890 ppm), Askham writes that the total amount of pool use was reduced and

"Significant differences ($p=0.01$) were recorded between the number of times both test species used the untreated pools and the treated pools. After an initial head dunking or drink all of the birds avoided the pools treated with the latter concentrations for the remainder of each trial period."

Askham does not, however, present the numbers that were used to calculate the reported "Significant differences". If the second sentence quoted above describes what actually happened, the differences in data collected from treated and untreated pools would be expected to be rather dramatic (all the more reason to wonder why the data were not shown). From his results, Askham reports that the EC_{50} for Bird Shield (or MA?) "appears to be 727 ppm or greater" when the product is used "in standing pools of water".

Askham writes that, in pools given Bird Shield treatments of 63 ml or greater, a "uniform brown precipitate or residue" formed within a day of application, but adds that

"None precipitated to the bottom of the pools nor coalesced on top of the water as noted in the Re-JeX-iT trials."

"Re-JeX-iT" is a trade name for another company's MA products, some of which already registered. Askham's discussions claim that Bird Shield's "patented" formulation disperses in water better than do the Re-JeX-iT products that have been tested in pools, puddles, and impoundments.

This report comes nowhere near living up to its title or to supporting claims for use of Bird Shield in actual water impoundments and chemigation systems. Accepted at face value, it only states that captive mallards and barnyard geese do not seem to like water in a child-size wading pool if it has been treated with Bird Shield at a level of 250 ml/190 L (1.32 ml/L). It would be premature to accept the data at face value, however, as we have not been shown the numbers upon which an inference of product effectiveness was drawn by Askham."

The "**Directions for use**" portion of the proposed label is much improved over the version discussed in the efficacy review of 6/8/93. The revised version incorporates some of the changes that were indicated in the earlier review.

This revised proposed label bears claims of safety of the sort that would render a product "misbranded." I am not sure whether any of our new "safer pesticides" initiatives would allow such statements, but 40 CFR, §156.10(a)(5)

still prohibits them for all pesticides. As there seem to be risks associated with the use and handling of this product, such statements would appear to be "false or misleading".

Specific comments on the label appear under "CONCLUSIONS."

202.0 CONCLUSIONS

1. The efficacy report that was included in your submission of February 13, 1995, describes results of very limited testing conducted with captive birds. The information in this report is insufficient to fully assess, much less to support, proposed claims that this product repels

"ducks (Anatinae and Aythinae), geese (Anserinae), gulls and terns (Laridae) from water impoundments and chemigation systems."

If you supply the raw data that formed the basis for the inferences drawn in this report and provide complete descriptions of the methods used to collect the data, we will be able to assess the merits of the entire study. Because the research was limited to work with captive birds in artificial pools, the scope of any claims that the results might support could be very limited.

2. To date, we have not seen data adequate to support the proposed claims that this product will

"repel starlings and swallows (Hirundinidae) from structures, roost and nest sites."

This "public health" claim either must be supported or dropped from your proposed label(s).

3. Delete all safety claims from your proposed label(s). Such claims are considered to be "*False or misleading statements*" and would make the product "misbranded", as indicated in 40 CFR, §156.10(a)(5). Examples of the safety claims that must be dropped include
 - a. "Biodegradable";
 - b. "Nontoxic"; and
 - c. "has been formulated from food grade ingredients that are Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration to meet or exceed U.S. Pharmacopoeia (USP) standards".

Note that items (ix) and (x) of 40 CFR, §156.10(a)(5) indicate that safety claims misbrand pesticide products and that item (vii) prohibits use of a

"true statement . . . in such a way as to give a false or misleading impression to the purchaser."

Information presented elsewhere (apart from the safety claims) on the labels indicates that the formulation poses a number of potential hazards to humans and nontarget animals.

4. The "**Directions for use**" on the proposed "master" label submitted February 13, 1995, must be modified as indicated below.
- a. Capitalize all letters in the main heading and center it on the page as indicated below.

DIRECTIONS FOR USE

This change will make it clear to readers that subsections such as "**Use Restrictions**" and "**Preparation and Mixing Directions**" are components of the "**DIRECTIONS FOR USE**".

- b. Delete all claims and directions pertaining to use of mixes made from this product in "structures, roost and nest sites" and in "water impoundments and chemigation systems". These sites may be proposed again at such time, if any, that data which fully support claims for them become available.
- c. Capitalize the first letter of "**directions**" to make the subheading for the mixing portion of the use directions read "**Preparation and Mixing Directions**". Change the third "sentence" of this subsection to read

"Apply mixtures made from Bird Shield Repellent early in the morning or late in the afternoon."

Note that the product is to be diluted prior to application for all of the uses which have been accepted at this time. Adjustment of this sentence would be appropriate if the water impoundment and chemigation system claims were supported in the future.

- d. Insert "**Application Directions**", as a left-justified subheading to the "**DIRECTIONS FOR USE**", immediately below the "**Preparation and Mixing Directions**" paragraph and immediately above the paragraph that is captioned "Blueberries, cherries and grapes".
4. The proposed crop-specific labels that you submitted on January 24, 1995, included "ADDITIONAL DIRECTIONS FOR USE" that were not included on the "Master Label" that was submitted on February 13, 1995. The text in the "ADDITIONAL DIRECTIONS FOR USE" consists of assorted ancillary claims and bits of advice regarding mixing, application, retreatments, and coordinating treatment and harvesting schedules. To the extent that this information is thought to be useful, it should be inserted in the relevant sections of the "**DIRECTIONS FOR USE**". If it becomes necessary to continue the use directions from one column to another, indicate the column where the use directions resume at the bottom of the column where these directions begin. To do so, use a statement such as

"Continued at top of right column."

The place where the use directions resume should be indicated by use of language such as the following:

"DIRECTIONS FOR USE

(Continued from left panel)".

If you decide to try to add items from your "ADDITIONAL DIRECTIONS FOR USE" to your proposed "Master Label", the material added must be acceptable to us. To be acceptable, such material must be accurate and potentially helpful to those who would use the product. While much of the language that you have developed for the "ADDITIONAL DIRECTIONS FOR USE" appears to be of value, some of the items should be changed.

The caption "**CAUTION:**" may not be used. "**CAUTION**" is used as a signal word for pesticide products in Toxicity Categories III and IV. On a label for this product, "**CAUTION**" would contradict the required signal word ("**WARNING**", at this point). If a heading is desired for this paragraph, the word used may not be one that also is used as a signal word. The type size and face used for the caption should be less prominent than that used for the subheading under which the paragraph falls. The word "Note:" might be suitable. Another way to draw attention to the paragraph would be

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to emphasize key words within it. Consider the example presented below.

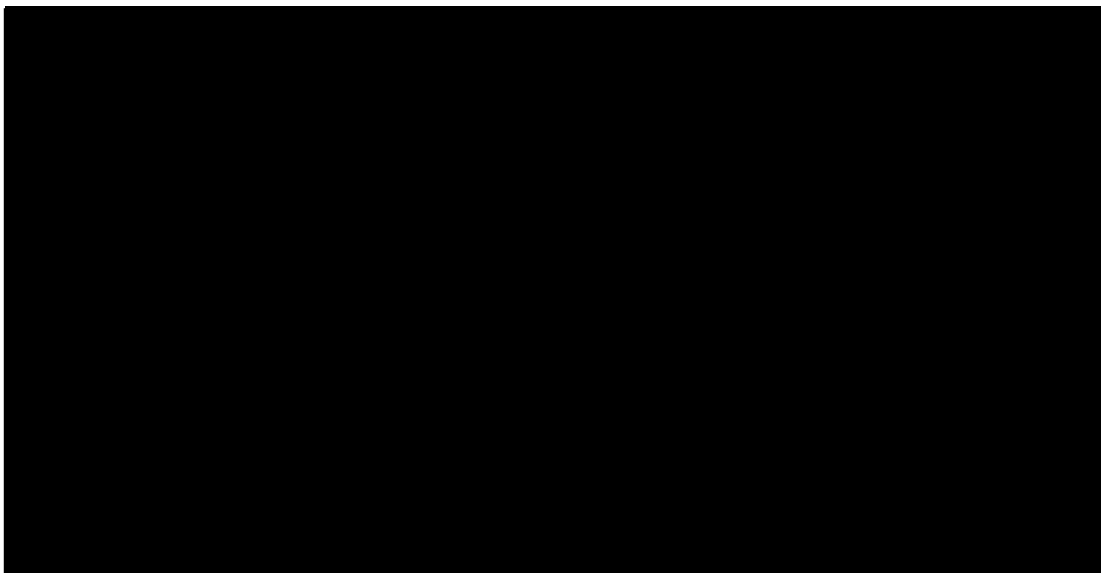
"Mix carefully. If too little of the repellent concentrate is mixed with water before it is applied to fruit, the mixture will not keep the birds away. If too much of the repellent concentrate is mixed with water before it is applied, the flavor of the repellent may last too long, and the crop might not be palatable to humans."

The discussions of the flavors of the product, concord grapes, and product-treated fruit must be accurate. The expression "bitter tasting" clearly applies to a perception reported by humans, not by birds. We are not sure what is meant by "bitter . . . smelling".

The claim that "birds will not eat" concord grapes could be proven wrong by a single example of a bird of any species eating any amount of this fruit. Unless you can provide evidence that no bird ever would be expected to eat any amount of concord grapes, the expression must be softened to something like "a fruit that most birds strongly reject" (if such a statement were accurate).

The words "inedible" and "edible" appear to us to be inappropriate for what is being discussed in the sentences in which they appear. However unpleasant the experience might be, it is possible to ingest and digest treated grapes. Consequently, "unpalatable" and "palatable" would appear be more accurate than "inedible" and "edible", respectively.

5.



Inert ingredient information may be entitled to confidential treatment

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May 5, 1995



13544

R140288

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128725

HED File Code: 41600 BPPD Other

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