IRB BRANCH REVIEW - TSS

Record Number(s)

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12/23/96
IN 1/31/97 OUT 7/1/97

EFFICACY

FILE OR REG. NO. 66550-1

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 12/11/96, 1/22/97

DATE OF SUBMISSION 12/11/96, 1/17/97

DATE SUBMISSION ACCEPTED 12/23/96, 1/31/97

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

DATA ACCESSION NO(S). none

PRODUCT MGR. NO. 14

PRODUCT NAME(S) BIRD SHIELD REPELLENT

COMPANY NAME Bird Shield Repellent Corporation

SUBMISSION PURPOSE discuss possible label changes, competitor's inquiry

CHEMICAL & FORMULATION 26.4% Methyl Anthranilate concentrate

Efficacy Review: BIRD SHIELD REPELLENT CONCENTRATE, 66550-1
Bird Shield Repellent Corporation
Pullman, WA 99163

200.0 INTRODUCTION

200.1 Uses

A 26.4% Methyl Anthranilate concentrate Federally registered

"1. 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.

2. to discourage ducks and geese (Family *Anatidae*) from using non-fishbearing bodies of water (tailing ponds, commercial or industrial water impoundment's [sic] and temporary pools of standing water located at or near airports; and

3. to reduce use of turf areas by Canada geese (*Branta canadensis*)."

Applications to ripening fruit are to be made by a "commercial or back-pack sprayer" or by "hand-held hose or pressure applicators." The label does not indicate specific application equipment for the turf and the aquatic uses.

200.2 Background Information

See efficacy reviews of 6/9/93, 5/5/95, 9/28/95, and 10/3/96. In the first of these reviews, 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 at least generous. Subsequently, the Directors of SRRD and RD decided that we would not require efficacy data submission for non-public-health claims for repellents.

In my review of 5/5/95, I examined data pertaining to a proposed use in water impoundments but did not accept any such claims at that time, noting various insufficiencies in the reporting of the data. I also noted that no data had been submitted to support the formerly proposed claim that the product repels starlings and swallows "from structures, roost and nest sites." I consider these to be public health claims which must be supported by efficacy data.

The efficacy review of 9/28/95 considered another efficacy report (MRID# 437202-01, submitted 7/10/95) pertaining to the proposed water impoundment use, the applicant's submission of 9/22/94 (which pertained to the study reported under MRID# 437202-01), and assorted other items. In that review, I concluded that the data reported suggested that concentration-dependent repellency of ducks (mallards) and geese (Canada) did occur. The effect clearly was present when at least 500 ml of concentrate were used for every 190 gallons of water in the body being treated.

In the lengthy efficacy review of 10/3/96, I considered 4 separate applications, concluded that limited claims for aquatic and turf sites could be accepted, and drafted a set of site-and-pest groupings similar to that quoted under "Uses" above.

This product was conditionally registered on 10/3/95. Subsequently, other labels submitted for this product were "ACCEPTED with COMMENTS" on 11/15/95 (when most of us were furloughed), 3/28/96, and 2/6/97. This product's current label was "ACCEPTED" on 3/10/97.

This review addresses:

1. a submission of 12/11/96 which includes a cover letter and a "draft" copy of a proposed revised label; and

2. a letter of 1/17/97 from RJ Advantage which asks why Bird Shield was claiming to be offering this product for turf use when it appeared not to have been on any EPA- or State-registered labels.

Methyl Anthranilate (MA, hereafter) is a GRAS-listed material which, nevertheless, poses certain ocular, oral, and inhalation hazards. The current accepted label for 66550-1 states that the product "Causes substantial but temporary eye injury" and is "Harmful if swallowed." The label also requires handlers to "Wear goggles and a face shield." The requirement for use of a specific type of respirator was dropped with the label accepted on 2/6/97 (see EPA's letter of 12/6/96). OPP has determined that MA is a "biochemical" worthy of reduced registration data requirements. However, the signal word on the accepted label for 66550-R is "**WARNING**".

201.0 DATA SUMMARY

No new efficacy data were submitted. See prior efficacy reviews for discussions of studies and data pertaining to the effectiveness of this product.

In his letter of 12/11/96, Bird Shield's Dr. Leonard Askham describes the following requests for label changes:

1. reducing the mix strength for the turf use from 2-8 gal. product/60 gal. mix to 1-3 gal. product/60 gal. mix;

2. altering the wording of the "mean high water mark" boilerplate sentence in the "**ENVIRONMENTAL HAZARDS**" section;

3. making "a 'less than full strength' application addition to the label" for the fruit uses; and

4. adding to the directions for treating ripening blueberries, cherries, and grapes the statement

> "<u>Do not use anti-transparants after application of the repellent</u>."

The "**ENVIRONMENTAL HAZARDS**" statement sought by Askham appears on the label "ACCEPTED" on 3/10/97. None of the other proposed changes listed is on that label.

I oppose the change in the treatment rate for turf which, unlike the 3 other changes listed above, does not appear on the draft label submitted on 12/11/96. Askham argues that the lower rates are equally effective, less expensive for users, and less likely to be phytotoxic. However, his own data for the turf use -- generated at Washington State parks located along the Snake River -- indicated that dilution rates below 2 gal. product/60 gal. mix applied at 60 gal. mix/acre produced somewhat more erratic results at one site than did higher rates and that the 8 gal. product/60 gal. mix/acre rate appeared to have been effective for 2 months. At the other site, due to confounding factors, numbers and total masses of bird droppings appeared to be largely independent of treatments or treatment rates. As this seems to me to be a "public health" use pattern and as treatment rate appears to be critical to what limited efficacy can be demonstrated for vertebrate animal repellents, I feel that we should not venture beyond what the data that we have reviewed suggest. No treatments at 3 gal. product/acre were made at either of Askham's turf-use study sites, although that rate was bracketed by the 2-gal. and 4-gal. rates.

In requesting lower specified dilution rates Askham argues

> "I am primarily concerned that the end user not apply more than is necessary to achieve the desired results. Applying more than is

necessary, in my opinion, becomes counter productive because of the added cost without benefit. I concur that a higher rate might be appropriate to ensure efficacy and that lower rates, ie. less than 2 gal./ac., are allowable under law. However, most users, particularly home owners, are not aware of this exemption and will either follow the label directions, which will provide the desired results, or possibly double the application rates which may lead to phytotoxicity problems. Furthermore, the repeated application of the repellent, at the lower rates, appears to be as effective and possibly more effective, than single applications at the higher rates. This is particularly relevant when turf is frequently mown as demonstrated in the Phase II trials."

Because the current label prescribes a lowest treatment rate of 2 gal. product/acre, the discussion at that end deals with whether the label should show 1 gal./acre as the lowest rate. §2(ee) of FIFRA covers treatments by users below labeled rates but does not permit treatments which exceed label rates. (OPP has a ULV -- ultra-low volume -- policy statement which affects dilution rates, but it seems not to be applicable here.)

The phytoxicity allusion appears to be based upon speculations of 2X label-rate treatments (16 gal. product/acre?) which Askham feels would occur if homeowners received labels which allowed up to 8 gal. product/acre. Most homeowners have less than an acre of land, and much of that is occupied by the house, patio, driveway, etc. In addition, homeowners often use rather crude application equipment. Consequently, whether they approximate any specified per-acre treatment rate is more or less a crap-shoot. Treatment rates on labels sold in homeowner markets probably should be phrased in terms of pints or fluid ounces/so-many square feet.

The arguments offered in support of the "less than full strength" statement for the fruit-tree claims are essentially an abridged form of the arguments advanced with respect to the turf use. As proposed, this statement appears as

> "**Apply at less than full strength if additional repellency is needed 3 to 5 days prior to harvest.**"

The current label indicates that crops should be harvested 6-8 days after the last treatment

"or after all odor of the product has dissipated (whichever occurs last).

I feel that Askham's proposed new statement would conflict with that direction and could lead to contaminated/off-flavored fruit. Therefore, I recommend against accepting the proposed statement.

Askham seeks to add the statement

"**Do not use anti-transparants after application of the repellent**"

to the application directions for treating fruit trees because

"We have found that there is a potential to seal the repellent to the fruit for a prolonged period of time thus extending harvests longer than necessary or physiologically appropriate."

This proposed change seems to me to be appropriate, although the correct term would appear to be "anti-transpirants".

RJ Advantage's letter of 1/17/97 expresses concern that Bird Shield had jumped the gun on advertising this product for turf use and that this might have put RJ at a disadvantage in the silent bidding at the Golf Courses Superintendents Association of America convention in February. As the turf use was accepted by EPA on 2/6/97, the problem -- from EPA's standpoint -- seems to have resolved itself. It is not unusual for pesticide companies (and other companies) to advertise products which, for one reason or another, they cannot yet market. Whether running an ad is the same as "offering for sale" is something that attorneys might wish to argue. Had it been documented that Bird Shield actually had sold product with turf uses claimed on the label before such a label had been accepted, there clearly would have been a violation. No evidence of such sales was presented by RJ.

202.0 CONCLUSIONS

We have reviewed your letter of December 11, 1996, in which four categories of label changes were discussed. Our comments on them appear below.

1. The proposed changes to the "**ENVIRONMENTAL HAZARDS**" text appear on this product's current label, which we accepted on March 10, 1997.

2. The statement

> "Do not use anti-transpirants after application of repellent"

would be acceptable for addition to item "1." (cherries, blueberries, and grapes) of the "**USE RESTRICTIONS**" portion of the "**DIRECTIONS FOR USE**."

3. We have concluded that the rates for the turf use which appear on the label accepted on March 10, 1997, should remain. Product performance in the studies that we reviewed last year was somewhat erratic at application rates below 2 gallons of product per acre. The rate of 8 gallons of product per acre was the only one tested for one month following a single treatment. Therefore, these rates appear to bracket the effective range of product application rates as inferred from the rather limited reports that we were provided for this public-health use pattern. While §2(ee) of FIFRA permits users to apply products at rates lower than those specified on the label, exceeding specified upper limits is not permitted. Therefore, the proposed label change would have eliminated the only rate that had been tested for effectiveness over a one-month period.

   It would be acceptable for the label to be amended to recommend treatments at 2-4 gallons of product per acre for circumstances in which weekly or bi-weekly mowing was anticipated.

4. We reject the proposed addition of the statement

> "**Apply at less than full strength if additional repellency is needed 3 to 5 days prior to harvest.**"

   This statement would authorize treatments which the current label discourages (i.e., those less than 6 days before harvest). Consequently, this statement appears likely to encourage problems of the sort that the "anti-transpirants" statement is intended to prevent.

At the next printing of this product's label, change "impoundment's" to "impoundments" under item "2." of the "**USE RESTRICTIONS**".

William W. Jacobs
Biologist
Insecticide-Rodenticide Branch
July 1, 1997