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MEMORANDUM

DATE: 18 JANUARY 2006

SUBJECT: ACEPHATE - Review of "PRECISE"™ Granular Formulation Designed to Reduce Dustiness.

PC Code: 103301 DP Code: 318423 MRID 46484301, 46484302

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INTRODUCTION

In response to the acephate registration eligibility document (RED) and pursuant to meetings (22 January 2004) with representatives of the Office of Pesticide Programs (OPP), Pursell Technologies Inc conducted a study ("Determination of Friability and Dustiness of Precise® Acephate and Pinpoint® 15 Granular") (MRID 46484302) and subsequent occupational exposure and risk assessment ("Occupational Exposure and Risk Assessment for Precise™ Greenhouse & Nursery Insecticide A Granular Insecticide for use on Container and Field Grown Nursery Crops") (MRID 46484301) in support of registration of Precise® Greenhouse & Nursery Insecticide. Precise® is a granular formulation which contains 4.0 % by weight acephate active ingredient (ai).

DISCUSSION

The Precise® granular product (Precise) is formulated using different technologies than are used

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for typical granular formulations that use substrates such as clay, as the basis of the granules. According to Pursell's submission, "the PRECISE granules are manufactured using a patented technology where the polymer is formed on the insecticide substrate by applying monomers in layers. By applying the monomer in layers, a very durable, hard polymer coating is created over and around the insecticide substrate. After application, the acephate is released across the polymer membrane coating of the granule through osmosis." "The PRECISE granule is quite different from conventional granules where the active ingredient is absorbed onto a substrate such as clay, which can be quite dusty. The PRECISE granule is virtually dust-free and the polymer membrane reduces the potential for dermal and inhalation exposure to acephate compared to conventional granules."

The friability study compared the dustiness of Precise® granules with Pinpoint® 15 Granular which is a registered product and was obtained from channels of trade. The friability study followed guidance from CIPAC Method MT 171 (1) and the USP Method 1216 (2). In summary, the study involves pouring approximately 30 g of formulation into a small drum which is rotated 100 revolutions and the contents poured into a specialized metering device that measures the amount of weight loss due to dustiness. The average percent weight loss for Pinpoint® 15 Granular was 0.99 %. According to the study authors, "A fine coating of dust was left in the friability tester drum after each replicate." The average percent loss for Precise® Acephate was 0.05 %. In different terms, the average amount of dust collected for Pinpoint® 15 Granular was 5.1 mg dust. The average amount of dust collected for Precise® Acephate was "-0.4 mg".

The study authors (ABC Laboratories, Inc. Columbia Missouri) concluded that "The friability test showed a greater weight loss for Pinpoint® 15 Granular (0.99 %) than for Precise® Acephate (0.05%). The dustiness test showed a larger collection of dust for Pinpoint® 15 Granular (5.1mg) than for Precise® Acephate (-0.4mg).

Based largely upon the information presented above and upon additional considerations, the registrant proposes that with the use of Precise Acephate, acceptable Margins of Exposure (MOE) are achieved. A discussion of Pursell's hypotheses follows. As background information, Pursell indicates that the PRECISE® label directs applicators to wear personal protective equipment (PPE) consisting of long sleeved shirt, long pants, chemical resistant gloves and shoes plus socks. Pursell cites the RED discussion of "belly-grinder" application parameters. The label use rate is 2.87 lb product per 1000 sq. ft. That is equivalent to 0.1148 lb ai/1000 sq ft. For purposes of exposure assessment in the RED, the Agency assumed 87,000 sq ft would be treated per day (i.e., 2 A/day). The RED also cites the Pesticide Handlers Exposure Database (PHED) SURROGATE EXPOSURE GUIDE (Vers 1.1, August 1998) Scenario 30 as a basis for estimating handler exposure.

Belly Grinder Mixer/Loader/Applicator Unit Exposures

head and neck exposure	0.711 mg/lb ai handled
upper and lower body exposure	7.21 mg/lb ai handled
hands exposure (no gloves)	2.49 mg/lb handled
Total Dermal Exposure	10.4 mg/lb ai handled
Inhalation Exposure	62 µg/lb ai handled

*From scenario 30 of PHED

Pursell suggests a number of adjustments to the exposure assessment in the RED may be appropriate. First, Pursell notes that the PHED replicates for hand with gloves is of 'low' quality and that the PHED data for 'no gloves' is of higher quality therefore Pursell suggests applying the Agency's 90 % protection factor for the use of gloves to the PHED 'no gloves' unit exposure. Pursell also suggests using a 50 % protection factor utilized by the Agency for coveralls worn over a single layer of work clothing. Therefore, according to Pursell, the hand exposure would be:
0.1 * 2.49 mg/lb handled = 0.249 mg/lb handled.

With the addition of coveralls over a single layer of work clothing, the unit exposure for upper and lower body would be:
0.5 * 7.21 mg /lb handled = 3.6 mg/lb handled so that "new adjusted dermal exposure" would then be

Revised Belly Grinder M/L/A Unit Exposures Using Protection Factors

head and neck exposure	0.711 mg/lb ai handled
upper and lower body exposure	3.6 mg/lb ai handled
hands exposure (gloves)	0.249 mg/lb handled
Total Dermal Exposure	4.56 mg/lb ai handled

The registrant presents the following assessment.
EPA assumption - 87,000 sq ft treated per day = 2 acres.
The label rate of application is 2.87 lb product/1000 sq ft = 0.1148 lb ai/1000 sq ft.
0.1148 lb ai/1000 sq ft * 87,000 sq ft/day = 9.9876 lb ai/day.

9.9876 lb ai/day * 4.56 mg/lb ai handled = 45.54 mg ai/day ÷ 70 kg bw = 0.65 mg a.i./kg bw/day for **dermal exposure** (emphasis added).

For inhalation (no respirator) the exposure is 62 µg/lb ai handled ÷ 1000 µg/mg * 9.9876 mg ai/day = 0.6192 mg/day ÷ 70 kg bw = 0.0088 mg a.i./kg bw/day.

NOTE: In Pursell's submission, the inhalation average daily dose was evidently calculated using the adjusted total dermal unit exposure (4.56 mg/lb ai handled) and should have used the 9.9876 lb ai/day as calculated earlier for dermal exposure.

For purposes of risk assessment, Pursell proposes using a 50 % reduction in the unit exposures in light of the friability testing. Pursell says "The study results show the PRECISE granules had 95 % less weight loss due to friability compared to conventional clay based granule Pinpoint 15 G. Given the extremely low formation of dust from PRECISE granules we propose that the Agency reduce the estimated dermal exposure by the conservative value of 50 %. The results of the dust and friability testing indicate that the reduction is likely to be much higher".

Pursell then presents the adjusted dermal unit exposure which is further reduced by 50 % (0.65 mg a.i./kg bw/day * 0.5 = 0.325 mg a.i./kg bw/day) and the MOE is

RED NOAEL 50 mg a.i./kg bw/day ÷ 0.325 mg a.i./kg bw/day = 154.

For inhalation risk, RED NOAEL 0.28 mg a.i./kg bw/day ÷ 0.0088 mg a.i./kg bw/day = 32. Pursell calculated the inhalation MOE as being 140 but that was the result of calculations using the dermal unit exposure figure and not the correctly calculated amount of ai used per day i.e., 9.9876 lb ai/day.

If the inhalation average daily exposure is reduced by 50 % (0.0088 mg a.i./kg bw/day * 0.5 = 0.0044 mg a.i./kg bw/day) the inhalation MOE is NOAEL 0.28 mg a.i./kg bw/day ÷ 0.0044 mg a.i./kg bw/day = 64

The "corrected" dermal MOE is > 100 and therefore does not exceed HED's level of concern. The "corrected" inhalation MOE is < 100 and therefore does exceed HED's level of concern. Use of a dust mist filtering mask could reduce inhalation exposure by 80% according to information in the PHED. For inhalation,
0.0044 mg a.i./kg bw/day * 0.20 = 0.00088 mg a.i./kg bw/day and therefore

NOAEL 0.28 mg a.i./kg bw/day – 0.00088 mg a.i./kg bw/day = 320.

CONCLUSIONS

The unit exposure figures for PHED Scenario Number 30 are based on "traditional", older granular formulations i.e., not based upon the multilayer monomer formulation process used for "Precise ™ " granules. Dustiness is the primary cause of exposure for granular formulations. The study data indicate that there is approximately a 95 % reduction in dustiness using the "Precise" formulation process. Therefore, the original unit exposures from the PHED Scenario No. 30 may be reduced by 95 %. For dermal exposure 10.4 mg/lb ai handled * 0.05 (%) = 0.52 mg/lb ai handled. And inhalation exposure would be 0.062 mg/lb ai handled * 0.05 (%) = 0.0031 mg/lb ai handled.

Therefore for dermal exposure 9.9876 lb ai handled/day * 0.52 mg/lb ai handled = 5.19 mg/day ÷ 70 kg bw = 0.074 mg a.i./kg bw/day.

MOE = NOAEL ÷ Dose = 50 mg a.i./kg bw/day ÷ 0.074 mg a.i./kg bw/day = 675.

For inhalation, 9.9876 lb ai handled/day * 0.0031 mg/lb ai handled = 0.031 mg/day ÷ 70 kg bw = 0.00044 mg a.i./kg bw/day.

MOE = NOAEL ÷ Dose = 0.28 mg a.i./kg bw/day ÷ 0.00044 mg a.i./kg bw/day = 635.

Although the study data indicate approximately 95 % reduction in dustiness, the HED ExpoSAC suggests comparing the results from a hypothetical 75 % reduction in dustiness. The hypothetical comparison serves as a measure of confirmation that occupational handlers are adequately protected. The results are as follows.

For dermal: 10.4 mg/lb ai handled * 0.25 (%) = 2.6 mg/lb ai handled.

9.9876 lb ai handled/day * 2.6 mg/lb ai handled = 25.97 mg ai/day ÷ 70 kg bw = 0.37 mg a.i./kg bw/day.

MOE = NOAEL ÷ Dose = 50 mg a.i./kg bw/day ÷ 0.37 mg a.i./kg bw/day = 135.

For inhalation: 0.062 mg/lb ai handled * 0.25 (%) = 0.0155 mg/lb ai handled.

9.9876 lb ai handled/day * 0.0155 mg/lb ai handled = 0.155 mg ai/day ÷ 70 kg bw = 0.00221 mg a.i./kg bw/day.

MOE = NOAEL ÷ Dose = 0.28 mg a.i./kg bw/day ÷ 0.00221 mg a.i./kg bw/day = 127.

A Margin of Exposure of 100 is adequate to protect occupational pesticide handlers. Since estimated MOEs are > 100, the use with the proposed new formulation does not exceed HED's level of concern. The use of a dust/mist respirator is not required as is reflected by the estimated exposures and risks.

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