UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

October 15, 2002

MEMORANDUM

SUBJECT: Response to "Assessment of Handler Exposure Resulting From the Commercial Application of Acetamiprid to Canola and Mustard Seed." MRID 456734-01. PC Code # 099050, DP Barcode 283286.

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Conditional Registration

This memo is a response to the comments from Aventis CropScience (May 8, 2002; MRID 456734-01) on the Agency's worker exposure and risk assessment (M. Collantes, 3/11/02, D264160) for use of acetamiprid (Adjust 70WP) as a commercial seed treatment insecticide in the United States and Canada.

Aventis correctly determined that the seed treatment study data used for seed handler (bagger/sewer) exposure assessment was lognormally distributed, and HED concurs that the use of the geometric mean is indicated, rather than the arithmetic mean in the Agency's assessment. HED has also concluded that Aventis' proposed engineering controls (closed system for wettable powder feeder), and label changes to reduce rate by half (to 0.25 lb ai/100 lb seed) and require coveralls as well as chemical resistant gloves should be sufficient mitigation to loader/applicator or seed handler exposure above the Agency's level of concern.

The engineering controls and rate reduction are proposed interim measures to be implemented until the replacement product (Assail 50FS) is introduced. HED recommends that the continued registration of Adjust 70 WP for seed treatment be conditional upon either (1) replacement by flowable formulation or (2) submission of data to support the exposure reduction produced by the closed loading system, no later than one year after registration approval.

Background

The registrant supplied much of the detailed information on seed treatment practices, and while these data are believed to reflect most practices, they may not reflect all of the potential exposure scenarios.

Seed Treatment Process

Adjust™ brand 70 WP contains 70% acetamiprid in a wettable powder formulation used for seed treatment (canola and mustard). The new, proposed maximum application rate is 0.25 lb ai per 100 lbs of seed. According to the registrant, seeds are treated during a maximum period of three to five months of the year in which seeds are treated for 70 days a year. Therefore short- and intermediate term exposure could occur; however, long-term exposure durations are not expected.

According to information provided by the registrant, the seed treatment market is dominated by the large seed companies which account for 90% of the market. Treatment involves large volumes of seeds over approximately a three to five month period. The large facilities are set up indoors with ventilation and dust control systems. The commercial seed treatment facilities use three to six people in the seed treatment process. Workers perform multiple functions during the day and are not restricted to unique functions such as just mixing/loading or just bagging. (Note that there are other facilities where workers do perform separate job functions.) The systems are set up with a treater and bagging bin allowing for minimal direct contact between the worker and the active ingredient. ADJUST ™ is automatically applied to the seed after the application equipment is calibrated to deliver the correct quantity of active ingredient to the seed. The wettable powder formulation is added to water to prepare the correct spray solution. Seeds are treated automatically as they are moved by augering systems with the acetamiprid solution sprayed onto the seed as it is augered from a hold area to the bagging area. Due to the small volume of spray applied per kilogram (kg) of seed, the seed does not require drying after treatment and the treated seed can be bagged immediately. The seeds are bagged in either 25 kg bags or larger bulk bags which are sewn shut, palletized and transported by forklift for distribution. A large treatment facility can treat 3,500,000 kg of seed during a three to five month period and will treat seed for 70 days handling 50,000 kg of seed per day.

Small treating facilities account for the remaining 10% of the market. The treatment window is typically one-month and the small operations employ two or three workers. The dust control systems generally consist of fans placed to blow air out of open doors, or the treatment is performed outdoors. The basic handling of the ADJUST ™ is similar to the large facilities. The formulation is open-poured into the spray tank and the spray solution is automatically sprayed onto the seed as it is augered into the bagging bins. The small facilities treat 6,800 kg to 91,000 kg of seed during a treatment year.

Two surrogate seed treatment studies (carbathiin and fipronil) were submitted in support of this action however, both studies used a liquid formulation. Therefore HED used the Pesticide Handler Exposure Database (PHED) data for wettable powder (WP) to determine exposure to loader/applicators and the liquid surrogate data for baggers, sewers and stackers. The exposure

and risk estimates that follow are from the March 11, 2002 document "EPA and PMRA Joint Review of Occupational and Residential Exposure Assessment for Section 3 Registration of Acetamiprid on Cotton, Leafy Vegetables, Cole Crops, Fruiting Vegetables,Citrus Fruits, Pome Fruits, Grapes, and Canola and Mustard Seed Treatment," (M. Collantes, D264160).

Margins of Exposure (MOE) for loader/applicators:
Minimal PPE (gloves) = 21
Maximum PPE (coveralls and OV respirator) = 41
Engineering Controls (WSB) = 610

Margins of Exposure (MOE) for Seed Handlers (Bagging, Sewing, Stacking)
[Carbathiin data] Maximum Dermal PPE (Coveralls), no respirator = 9
[Fipronil data] Maximum Dermal PPE (Coveralls), no respirator = 80

Aventis replied that it is not possible to package Adjust TM 70 WP into water-soluble bags (WSB) due to the amont of polymer that would be used. The number of bags that would be needed would be so large that the polymer would disrupt the seed treatment process. Therefore, Aventis proposed an alternative solution:

1. Add chemical resistant protective coveralls and an organic vapor (OV) respirator to the label-required personal protective equipment (PPE) for handlers.
2. Reduce the labeled use rate to 0.25 lb ai/100 lbs seed.
3. Restrict use to closed transfer systems with label language: "For use only in commercial seed treatment facilities with Closed Transfer System, Not for use with Open Pour Systems."

Additionally, Aventis reanalyzed the Agency's use of the seed treatment data for postapplication worker (seed handler/bagger/sewer/etc.) exposure assessment. The registrant stated qualitatively that the carbathiin data were of such poor quality that they should not be used. Instead, they focused on the fipronil seed treatment study, which had better quality control measures. The registrant refined the data set by removing those replicates who were not consistently wearing PPE (coveralls). Also, the registrant determined (and the Agency confirms) that the fipronil data set was lognormal in distribution and therefore the geometric mean of the data set should be used in exposure calculations.

Agency Discussion of Proposed Mitigation

The addition of coveralls over the standard clothing ensemble (long pants, long sleeved shirt, shoes and socks) decreases exposure to the arms, legs and torso by an estimated 50%. This estimate is considered conservative, and is therefore employed by the Office of Pesticides to estimate the additional protection factor for coveralls of any fabric type, including cotton and commercial non-woven chemical-resistant fabrics. By reducing the labeled use rate to 0.25 lb ai/100 lb seed, the estimated MOE cited in the original assessment for "maximum PPE" is doubled from 41 to 82. As the active ingredient has a relatively low vapor pressure (7.5×10^{-9}

Torr [10^{-6} Pa] at 25° C), an organic vapor respirator is not required; rather, a NIOSH approved half-face respirator for dusts and mists, type N, R, P or HE is appropriate.

The "Closed Transfer System" is described as attaching a "powder feeder" to the seed treater (this is a standard attachment); the Adjust 70WP will be fed into the powder feeder in a metered and controlled fashion. Aventis will ensure that each powder feeder is fitted with a manifold designed to accept the package spout. A package of Adjust 70WP will be suspended over the powder feeder and the spout will be extended into and attached to a manifold on the top of the powder feeder. Once the spout is attached, Adjust will be released into the manifold with no spillage and flow into the powder feeder. From there it will be metered into the treater or slurry tank at the recommend rate. The Agency was provided with a description of the powder feeder, but no data are available which quantify the reduction in exposure by this system. The Health Effects Division's Science Advisory Council for Exposure (ExpoSAC) reviewed these proposals in a meeting on September 26, 2002. The ExpoSAC noted that there were no available data on this system, but based on the available information, the system would result in a significant reduction in exposure over an open pour method. Aventis provided information that only about eight major seed treaters meet the criterion of 110,000 lb seed treated per day, therefore it is practical for the registrant to implement the proposed powder feeder with manifold in a short time frame.

Consequently, the Agency has recalculated the loader/applicator and seed handler exposure and risk estimates based on the reduced label application rate and the geometric mean of the fipronil data set for workers wearing coveralls. The new estimates are presented in the attached Table.

Aventis is also applying to register substitute liquid formulation (Assail 50FS) to replace the Adjust 70WP formulation. Liquid formulations have lower exposure potential for handlers than the same quantity of wettable powder.

Conclusions and Recommendations

The reduction in labeled maximum rate of application results in reducing all worker risks by half. The addition of a closed system to control the emission of particulates during pouring of wettable powder will also result in exposure reduction; however, this reduction cannot be quantified without data. Because the total MOE is 82 with coveralls and a dust/mist respirator, it is likely such a closed system would result in MOEs equal to or greater than the target of 100.

The registrant, Aventis, has correctly noted the lognormal distribution of the exposure data from the fipronil seed treatment study used to describe seed handler (bagger/sewer). Using the geometric mean of the data, and adjusting for the maximum label rate reduction, results in an estimated MOE of 440 using all of the data, or 540 using only the data for workers wearing coveralls over work clothing and chemical resistant gloves. The carbathiin seed treatment study used in the Agency review of seed handler exposure had very poor quality control, and therefore the data and computations of exposure and risk are of very low confidence.

The conclusion of this assessment is that, with the rate reduction, a closed system of loading, and the addition of coveralls and NIOSH approved dust/mist respirator, worker risks will not exceed the Agency's level of concern. While this risk assessment used the best available surrogate data, very few seed treatment studies exist, most are old or of poor quality, and some are proprietary. Therefore, more studies are needed which determine worker and bystander exposure to seed treatments using current generation equipment.

Conditional Registration

Registration for Adjust 70WP for canola and mustard seed treatment is recommended based on the weight of evidence and proposed exposure controls as cited above. Aventis will introduce the flowable replacement, which is expected to have lower exposure potential, within the next year. However, if Aventis wishes to continue the use of the wettable powder beyond one season, an exposure study should be conducted to document the efficacy of the closed system control measure.

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Revised Handler Exposure and Risk Calculations for Seed Treatment for Acetamiprid											
Exposure Scenario/ Study	Mitigation Level [1]	Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (mg/lb ai)	Proposed Application Rate (lb ai/lb seed)	Amount Handled per/day (lb ai/day)	Dermal Dose (mg/kg/day)	Dermal MOE	Inhalation Dose (mg/kg/day)	Inhalation MOE	Total Dose (mg/kg/day)	Total MOE
Loader/Applicator											
Wettable Powder (PHED)	Dermal -Min PPE (gloves) Inhalation - Baseline	0.17	0.043	0.0025	110,000	0.234	76.5	0.20	91	0.43	41
	Dermal -Max PPE (coveralls) Inhalation - (Dust/Mist Respirator)	0.13	0.0086			0.1788	100	0.0394	454	0.22	82
	Engineering Control (WSB)*	0.0098	0.00024			0.0135	1300	0.0011	16,000	0.0146	1200
Loader/Applicator, Seed Handler (Bagger, Sewer, Stacker, etc)											
MRID-44904526 Liquid	Dermal - Max PPE (coveralls) Inhalation-Baseline	0.682	0.00516	0.0025	110,000	0.94	19	0.0237	760	0.97	19
MRID - 45442701 Liquid	Dermal - Max PPE (coveralls) Inhalation-Baseline **geometric mean of dermal data for all replicates**	0.01694	0.00387			0.023	770	0.018	1000	0.041	440
	geometric mean of dermal data for replicates wearing coveralls	0.012	0.00369			0.0165	1100	0.017	1100	0.033	540

*Aventis states polymer from water soluble bags will cause problems with seed treatment equipment

Amount handled (treated) per day = 50,000 kg seed/day(information provided by registrant) x 2.2 lb/kg = 110,000 lb seed/day

$$\text{Dose (mg/kg/day)} = \frac{\text{Rate (lb ai/lb seed)} \times \text{UE (mg /lb ai)} \times \text{DA (0.3)} \times \text{Amount Treated (lb seed/day)}}{\text{BW (60 kg)}}$$

Total Dose = Dermal Dose (mg/kg/day) + Inhalation Dose (mg/kg/day)

$$\text{Total MOE} = \frac{\text{Short and Intermediate NOAEL (17.9 mg/kg/day)}}{\text{Total Dose}}$$