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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

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SUBJECT: Preliminary Review of Prospective Ground Water (PGW) Monitoring Studies for Isoxaflutole (Balance™) and Registrant's Request to Terminate PGW and Indiana Tile Drain Studies

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THRU: Tom Bailey, Branch Chief
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Thomas M. Steyer for Tom Bailey 5/24/01

This memorandum is in response to Aventis CropScience's request (D275059) to terminate Prospective Ground Water (PGW) studies in Iowa, Nebraska, and Indiana, and two Tile Drain studies in Indiana. EFED concurs with the request to terminate the PGW studies in Iowa and Nebraska. However, as we have not yet seen study reports for the Indiana PGW study or the two Indiana Tile Drain studies, we cannot recommend study termination at this time.

Background

Under the conditional registration of Balance™, Aventis was required to perform several small-scale Prospective Ground Water (PGW) studies. These studies are designed to determine if use of the pesticide will result in ground water contamination, and thereby contaminate drinking water or irrigation water. The concentrations of parent chemical and degradates are monitored in soil, and eight clusters of lysimeters (which monitor soil pore water at various depths) and ground water monitoring wells.

PGW studies are normally conducted in "vulnerable" soils, i.e., sandy soils with less ability to sorb organic chemicals, that are more likely to result in ground water contamination. The studies reviewed in this memorandum, however, were conducted in "heavier" soils (loams and silt loams) less conducive to ground water contamination, since sandy soils have already been labeled-off for this chemical. The three studies do *not* therefore represent worst-case scenarios.

Three PGW studies are currently in progress, in Indiana, Iowa, and Nebraska. The Indiana study was begun only in April, 2000, so the results submitted so far are limited to the first two months of the study. This review is based on the most recent submissions for each study (September 1, 2000).

Conclusions

EFED believes that the three PGW studies have already produced results that may be used to make judgements about the mobility of isoxaflutole in ground water. The Iowa and Nebraska studies may be terminated, and final study reports may be submitted by the registrant. EFED requires that a draft study report for the Indiana PGW site be provided for our review before deciding to terminate that study.

EFED has not received any reports on the two "Tile Drain with Automatic Sampling" studies being conducted in Indiana and so cannot recommend termination at this time.

All three of these studies confirm EFED's concern about the high mobility of isoxaflutole and its first degradate RPA-202248 (isoxaflutole-DKN) and their potential to cause contamination of shallow ground water. DKN reached the three to six-foot depths within weeks or a few months at all three sites. EFED remains concerned about isoxaflutole's potential to contaminate shallow ground water (less than about 10 feet to the water table) *in areas with soils that are not normally considered vulnerable*. This is in addition to the soils that were labeled-off in the conditional registration.

Aventis has cited "preferred flow paths" as the explanation for rapid downward movement of the chemical (as opposed to slower, more uniform flow through a solid, porous medium). This is not a reason to discount the results of these studies. Preferred flow paths, be they worm burrows, animal dens, or sand lenses in the soil, are real and are a factor in ground water contamination, especially in soils (e.g., clays) that are otherwise resistant to this problem. Further label restrictions regarding allowable soil types and water table depth may be necessary for this active ingredient.

Indiana PGW study (MRID 452458-04)

This study is being conducted in LaPorte County, in a field consisting of Coupee silt loam and Tracy loam soils.

Preliminary results show that the active degradate RPA-202248 (isoxafluole-DKN) reached the 3-foot depth in 2 of 8 lysimeters in one week; 4 of 8 in two weeks; 5 of 8 in 1 month; and 6 of 8 in 2 months. Levels detected ranged from 7 to 302 parts-per-trillion. These results confirm the expected high mobility of isoxaflutole-DKN.

Nebraska PGW study (MRID 452458-02)

This study is being conducted in Merrick County, in a field consisting of Cozad loam soil. The water table at this site is very shallow, being about three to six feet below the ground surface. Only one lysimeter depth (about 3 feet) was used. Thirteen months' worth of data are available.

The conservative tracer (bromide ion) which tracks the movement of water through the soil reached a peak concentration in all eight lysimeters between 2 months and 12 months. The degradate isoxaflutole-DKN reached the lysimeters at least as quickly as bromide, again indicating this chemical's high mobility.

Isoxaflutole-DKN reached 6 of 8 ground water wells within two to five months, at concentrations of 100 to 1,150 parts-per-trillion. The highest result may have been the result of a preferred flow path (for example an earthworm burrow), as the ground water result was higher than in the corresponding lysimeter.

Iowa PGW study (MRID 452458-03)

This study is being conducted in Sioux County, in a field consisting of Spillville loam soil. Twelve months' worth of data are available. Lysimeters were installed at 3, 6, and 9-foot depths.

The conservative tracer, bromide ion, was detected in all 3-foot lysimeters by 3 to 10 months, and in all 6-foot lysimeters by 5 to 12 months. Bromide had been detected in only three of eight 9-foot lysimeters by 6 to 12 months, and had not been detected in any of the ground water wells. This means that water contaminated with isoxaflutole residues (if any) has not yet reached the ground water.

Isoxaflutole-DKN was detected in two of eight 3-foot lysimeters within one month, at levels of 204 to 276 ppt. It was below the quantitation limit after 5 months. (The data for the two three-foot lysimeters (clusters 1 and 2) are attached as a graph.) DKN was detected in five of eight 6-foot lysimeters within two weeks to three months, at 3 to 11 ppt. It has not been detected at the 6-foot depth since four months.

At the 9-foot depth, isoxaflutole-DKN was detected in only two of eight lysimeters. One of these was below 10 ppt at two months and twelve months, and the other was 21 ppt at one month, and non-detectable after four months.

Additional Information to Include in Final Study Reports

Aventis should add the following items to the final and draft final study reports.

1. Rainfall and evapotranspiration data or hydraulic head data to indicate whether there was a net increase or decrease in water stored in the aquifers.

2. A graphical data presentation, consisting of box-and-whisker plots that combine concentration data for all lysimeters or wells at a certain depth, displayed as a function of time. The parent and the two degradates should be plotted on separate graphs, but on the same page for easy comparison. Concentration data should be displayed in parts-per-trillion, and on a log scale if needed to visualize all data points. Non-detects should be treated as being detected at the Limit of Detection.

3. A discussion of any phytotoxic symptoms observed in the corn crops, other crops grown nearby, or other non-target plants, with supporting observations and data. This should include severity and duration of symptoms.