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PESTICIDE REGISTRATION
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Ms. Ann Hanger
Registration Branch
California Department of Pesticide Registration (CDPR)
1001 I Street
P.O. Box 4015
Mail Stop 3D
Sacramento, California 95812-4015

Subject: Pursuant to section 13149(b) of the California Food and Agricultural Code Monsanto Requests Hearing to Address Notice of Alachlor Degradation Product Detections in California Groundwater

Reference: CDPR letter dated March 21, 2016 Notifying Registrant of Decision to Cancel Alachlor Product Registrations

Monsanto Reference ID: 2016-OTN165

Dear Ms. Ann Hanger,

On March 21, 2016 Monsanto Company received a notification from the California Department of Pesticide Registration (CDPR) regarding the detection in ground water of two alachlor degradation products, alachlor ethanesulfonic (AESA) and alachlor oxanilic acid (AOXA). As a result of these findings CDPR is pursuing canceling the registration of Monsanto's alachlor agricultural use products listed below:

- INTRRO Premergent Herbicide, EPA Reg. No. 524-314
- Micro-Tech Herbicide, EPA Reg. No. 524-344

Monsanto stands behind our alachlor products that have undergone rigorous, science-based risk assessments to ensure they pose no unreasonable risk to humans, the environment or non-target animals and plants when used according to label directions. Indeed, the June 2012 CDPR report, on which these Decisions to Cancel are largely based, stated that the amounts of AESA and AOXA "do not constitute a significant human health risk from drinking water intake" (Bergin and Nordmark, 2012). As detailed more fully below, Monsanto does not believe that such cancelations are warranted.

"Pollute", per FAC section 13142 (j), is the introduction of a "pesticide product into the groundwaters of the state resulting in an active ingredient, other specified ingredient, or a degradation product of a pesticide above a level that does not cause adverse health effects, accounting for an adequate margin of safety." Monsanto believes that AESA and AOXA have not polluted, and do not threaten to pollute, the groundwater in California, as defined above.

The California Department of Public Health (CDPH) Maximum Contaminant Levels (MCL) for alachlor is 2 parts per billion (ppb), while the Office of Environmental Health Hazard Assessment (OEHHA) Public Health Goal is 4 ppb. The levels of AESA and AOXA detected in groundwater in California ranged from 0.05 to 1.38 ppb, which are below the guidance values established for the parent molecule alachlor. In addition, AESA and AOXA are much less toxic than the parent alachlor (EPA 2007; Gadagbui, 2010). Further, as noted above, the June 2012 CDPR report which stated that the amounts of AESA and AOXA detected are low, and "do not constitute a significant human health risk from drinking water intake" (Bergin and Nordmark, 2012). Indeed, the State of Minnesota has set a Risk Assessment Advice (RRA) level in water for both AESA and AOXA at 60 ppb, and the State of Wisconsin has set an Enforcement Standard (ES) level in water for AESA at 20 ppb (Minnesota Department of Health, Toxicological Summary for: Alachlor ESA and Alachlor OXA, Dec. 2015; Wisconsin Department of Natural Resources, Drinking Water & Groundwater Quality Standards/Advisory Levels, Mar. 2011).

Accordingly, we believe that the presence of these degradates in groundwater does not represent "pollution" as defined by FAC and does not justify cancellation of the alachlor registration. Alternatively, pursuant to section 13149(b) of the California Food and Agricultural Code (FAC), Monsanto hereby requests a hearing to address the conclusions for the detection of AESA and AOXA in ground water, and will submit toxicity data generated for alachlor ESA and OXA and evaluations from other regulatory agencies and independent experts to support our position.

If you have any questions regarding this request for a hearing or need additional information please do not hesitate to contact me at 314-694-1904 or 314-694-8888 or at shazia.a.brown@monsanto.com or registration.state@monsanto.com.

Sincerely,

Shazia Brown
Chemistry and Seed State Regulatory Affairs Lead
Monsanto Company

Enclosures: References

cc: Annette Kirk, Monsanto Federal Regulatory Affairs Manager
Joel Kronenberg, Monsanto Senior Lead Scientist, Toxicology
John Rebman, Monsanto Corporate Counsel, Regulatory Law

References

Bergin, R. and C. Nordmark. 2012. Study GW 09: Ground Water Protection List Monitoring for Metolachlor and Alachlor, Available at: http://www.cdpr.ca.gov/docs/emon/grndwtr/rpts/gwp1_0001.pdf (verified August 10, 2015). California Department of Pesticide Regulation, Sacramento, California.

Environmental Protection Agency. (2007). Alachlor: PP#8F05000 and 8F5025. FQPA Human Health Risk Assessment for Section 3 New Use on Cotton, Sunflower, and for Inadvertent Tolerances on Various Rotational Crops (Cereal Grains and Nongrass Animal Feeds). PC Code: 090501. DP Barcode D330812. Washington DC: U.S. Environmental Protection Agency.

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Minnesota Department of Health, Health Based Guidance for Water, Health Risk Assessment Unit, Environmental Health Division, Dec. 2015. Toxicological Summary for: Alachlor ESA and Alachlor OXA. Available at: http://www.health.state.mn.us/divs/eh/risk/guidance/gw/alachloresaoxa.pdf.

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