Q&A: LBAM Acute Toxicity Study Review

November 2008

What is a "six-pack" study?

The U.S. Environmental Protection Agency (U.S. EPA) has specific standards to evaluate the acute (short-term) toxicity of pesticides that consists of a "six pack" of tests:

- Acute oral toxicity
- Acute inhalation toxicity
- Acute dermal toxicity
- Eye irritation
- Dermal irritation
- Dermal sensitization

Which products were tested?

Checkmate LBAM-F (sprayed aerially in Santa Cruz and Monterey counties in 2007), NoMate LBAM MEC, Splat LBAM and Disrupt Bio-Flake LBAM.

What did the studies conclude?

State scientists' review of toxicity studies on four LBAM pheromone products concluded that there is a very low likelihood of health problems from touching, breathing or ingesting any of the pheromone products. Although, some sensitive individuals could have an allergic reaction, much like some people react to pollen, dust and animal dander.

Results of five out of six toxicity studies for each product tested showed all had very low acute toxicity, as well as low potential for irritation. The sixth study, using two separate tests was inconsistent. One study showed that three of the products had the potential to cause an allergic reaction in laboratory animals. However, the other test, also looking at the potential for allergic reaction did not show the same effect.

Results of the toxicity studies support the conclusions of both the November 2007 consensus statement and the April 2008 symptoms report by the Department of Pesticide Regulation (DPR), Office of Environmental Health Hazard Assessment (OEHHA), and the California Department of Public Health (CDPH).

Who conducted the tests?

At the request of the Governor, DPR requested that the California Department of Food and Agriculture (CDFA) and the U.S. Department of Agriculture (USDA) conduct the tests. USDA contracted with Stillmeadow Inc., an independent toxicology laboratory based in Sugar Land, Texas.

Concurrently, Bedoukian Research Inc. of Connecticut, a manufacturer of the pheromone active ingredient (AI), submitted an acute oral study, a dermal

irritation study and a dermal sensitization study on the LBAM pheromone active ingredients. LBAM pheromone mixtures similar to those submitted for testing by Bedoukian Research are in all four pheromone products. DPR did not request these studies, but Bedoukian Research submitted them voluntarily to assist in the overall toxicity evaluation. An independent contract laboratory, MB Research Laboratories, conducted these studies. For more information about Bedoukian Research, see http://bedoukian.com/index.asp

Why were the manufacturers allowed to conduct their own studies?
This is standard procedure for regulatory agencies at the state and federal level. Companies that wish to market regulated products such as pharmaceuticals and pesticides must provide data to support the safe use of their products. Data requirements are set in law and regulation. Government scientists review and evaluate the data as well as the test protocols used to generate the data. Regulatory agencies also hold authority to scrutinize laboratory standards and laboratory practices.

Who reviewed the tests?
U.S. EPA and DPR reviewed and analyzed the results of the series of acute toxicity studies on four potential LBAM eradication products as well as the LBAM pheromone active ingredient, and both found the studies were conducted appropriately. CDPH and OEHHA also evaluated these data, and DPR, CDPH and OEHHA jointly prepared this review. The review and related materials are available on DPR's Web site, www.cdpr.ca.gov/docs/pressrls/2008/081104.htm

For questions about CDFA's efforts to eradicate the light brown apple moth, please see its Web site at:
http://www.cdfa.ca.gov/phpps/PDEP/lbam/lbam_main.html