

BioSpotVictims.org

November 24, 2009

Office of Pesticides Program (OPP) Regulatory Public Docket (7502P)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

RE: Indoxacarb; Application for new spot-on use on dogs; Request for comments; Federal Register Vol. 74, No. 205, P. 54999-55003, October 26, 2009; Docket No. EPA-HQ-OPP-2009-0739; Registration Number/File Symbol: 773-OU

Dear Sir or Madam:

Thank you for the opportunity to comment on the receipt of an application from Schering-Plough to register the pesticide, indoxacarb, for a new spot-on use on pets. These comments are being submitted on behalf of BioSpotVictims, a non-profit organization which seeks to educate the public on the potential hazards of pet pesticide products, and provide alternatives that are less toxic for pets and children who are exposed to treated pets.

BioSpotVictims firmly opposes the registration of indoxacarb for a new spot-on use on pets. Spot-ons are highly concentrated pesticide products, which are applied to the animal's back as a spot or stripe to control fleas and ticks. Spot-ons represent one of the most dangerous residential pesticide exposure scenarios for infants and toddlers. The proposed application would, for the first time, expose children and pets to high concentrations of indoxacarb.

The EPA has become increasingly concerned by the number of adverse incidents from spot-on products that are reported each year. Over 44,000 adverse incidents were reported to the EPA in 2008 – a 53% increase over 2007. The majority of these incidents were categorized as mild to moderate, but hundreds involved major events such as seizures and the death of pets. Even moderate events may have been severe enough to require veterinary care.

Indoxacarb was developed by DuPont, and initially registered by the EPA in October 2000. It is currently registered for agricultural use and products used by professional applicators. Products containing low concentrations of indoxacarb have recently been registered for residential use.

Indoxacarb is designated as a “reduced risk” pesticide, which entitles registration applications to an expedited review. According to the EPA's website, the review of Schering-Plough's application is scheduled to be completed by the third quarter of 2010.

Despite being a “reduced risk” pesticide, toxicity studies have shown that the effects of indoxacarb on rats and dogs are similar to the effects of pyrethroids – a class of pesticide found in many spot-on products. In addition, long-term studies indicate that the targets of indoxacarb toxicity in rats and dogs are the red blood cells, which can lead to hemolytic anemia.

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Here is the Material Data Safety Sheet for Dupont Steward Insecticide, which contains 14.5% indoxacarb as its active ingredient (far less of a concentration than most spot-on products):

http://msds.dupont.com/msds/pdfs/EN/PEN_09004a2f80007809.pdf

Excerpts:

"CAUTION! Harmful if swallowed. Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing....Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."

"Based on data from animal testing, Dupont Steward Insecticide may cause mild eye irritation with tearing, pain or blurred vision."

"Based on data from animal testing, Dupont Steward Insecticide may cause irritation with itching, burning, redness, swelling or rash. Dupont Steward Insecticide may cause skin sensitization with allergic rashes."

"Based on data from animal testing, ingestion of large amounts of Dupont Steward Insecticide may cause alteration in blood cell counts and/or anemia."

"Dupont Steward Insecticide in high single oral doses caused gait abnormalities, incoordination, hypoactivity, convulsions, tremors, hypothermia, hair loss, labored respiration, discharge, and vocalization in rats."

Here is an evaluation of Dupont Steward Insecticide, published by the Australian Pesticides and Veterinary Medicine Authority:

http://www.apvma.gov.au/publications/downloads/prs_indoxa%28s%29.pdf

Excerpt:

"The dog seems to be the most sensitive species to the effects of indoxacarb."

Here is a report concerning indoxacarb, published by the European Commission's Scientific Committee on Plants:

http://ec.europa.eu/food/fs/sc/scp/out132_ppp_en.pdf

Excerpt:

"Short-term and long-term studies indicate that the targets of indoxacarb toxicity in rats and dogs are the red blood cells (RBC)."

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Here is the EPA's Pesticide Fact Sheet on indoxacarb:

<http://www.epa.gov/opprd001/factsheets/indoxacarb.pdf>

Excerpt:

"90-Day oral toxicity in nonrodents - dogs: LOAEL = 19 mg/kg/day based on hemolytic anemia, as indicated by decreased HGB, RBCs; increases in platelets, increased reticulocytes; and secondary histopathologic findings indicative of blood breakdown."

Indoxacarb acts by binding to sodium channels similar to the pesticide, metaflumizone – the active ingredient in ProMeris (another spot-on product for pets).

Last April, the EPA issued an Advisory concerning spot-on products and launched an investigation to determine if further restrictions are necessary to better protect pets. The Advisory listed seven products that it said were responsible for 80% of the 44,000 reports of adverse incidents that the EPA received in 2008. ProMeris was one of the products on the Advisory.

The number of adverse incidents reported each year from the use of spot-on products is appalling, and is clearly indicative of a failed regulatory system – one that greatly underestimates the risks that spot-on products pose to children and pets.

Spot-ons containing a high concentration of indoxacarb would not pose less risk to people, pets and the environment than existing alternatives. To the contrary, indoxacarb-based spot-ons may lead to higher incidents of hemolytic anemia in pets – a condition that can be fatal.

BioSpotVictims urges the EPA to reject Schering-Plough's application to register indoxacarb for a new spot-on use on pets.

Sincerely,

James TerBush
Website Administrator