



**US Environmental Protection Agency
Office of Pesticide Programs**

**EPA Response to Petition for
Fenpropathrin**

September 25, 2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 25 2006

Mr. Eric J. Maurer
Federal Registration Manager
Valent U.S.A. Corporation
2033 K Street, N.W. Suite 850
Washington, DC 20006

Re: Establishing New Exclusive Use
Protection Period for Data Submitted
to Support the Registration of
Danitol 2.4 EC Spray
on Minor Crops

DANITOL 2.4 EC Spray
EPA Reg. No. 59639-35

DANITOL Technical
EPA Reg. No. 59639-76
Your Application Dated March 15, 2005

Dear Mr. Maurer,

I am writing in reply to your March 15, 2005 letter petitioning the U.S. Environmental Protection Agency (EPA) for exclusive use protection for certain data submitted to EPA in support of amendments adding what you assert to be minor new uses to the registration of fenpropathrin (Danitol 2.4 EC Spray). In your letter, you assert that the initial exclusive use period for fenpropathrin expired on December 22, 1999, that this registration therefore does not currently retain any period of exclusive use, and that the following data, as identified by MRID number, are eligible for an additional 10 years of exclusive use data protection: MRID Nos. 45668700, 45317200, 45454700, 45454701, 45439801, 45919601, 46385310, 46385302, 46385303, 46385304, 46385305, and 46385306. For the reason provided below, EPA has determined that these data are not eligible for the exclusive use protection sought by Valent.

FIFRA allows for extending exclusive use protection to data in support of a new minor use that does not retain exclusive use protection when a registrant requests such an amendment to its registration and that request complies with FIFRA section 3(c)(1)(F)(vi). Specifically, FIFRA section 3(c)(1)(F)(vi) provides:

With respect to data submitted after the date of enactment of this clause by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such data shall not, without written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. **The applicant or registrant at the time the new minor use is requested shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph.**

As to what constitutes a "minor use," FIFRA section 2(l) defines minor use as "the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where—

(1) the total United States acreage for the crop is less than 300,000 acres, . . .; or

(2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and—

(A) there are insufficient efficacious alternative registered pesticides available for the use;

(B) the alternatives to the pesticide use pose greater risk to the environment or human health;

(C) the minor use pesticide play or will play a significant part in managing pest resistance; or

(D) the minor use pesticide plays or will play a significant part in an integrated pest management program.

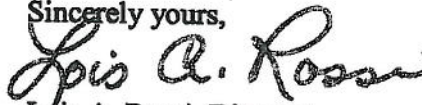
In this instance, we need look no further than the statutory language contained in FIFRA section 3(c)(1)(F)(vi) in order to respond to your request. Specifically, Section 3(c)(1)(F)(vi) requires an applicant to request exclusive use protection "at the time the new minor use is requested." As highlighted in your March 15, 2005 letter, Valent's submittal dates for the purported new minor uses at issue here were June 2001, April 2003, and October 2004. Accordingly, any requests for exclusive use protection for the data submitted in connection with those purported new minor uses should have been made in June 2001, April 2003, and October 2004, respectively. Instead, your March 15, 2005 letter is the first time Valent requested exclusive use protection for any of the data at issue. Because this request came well after the time the purported new minor uses were requested, the Agency must decline your request in full.

Having declined your request in full, the Agency nonetheless, for instructional purposes only, would like to note some additional problems with your request. First, some of the new uses being added do not, in fact, appear to be minor uses. For instance, the new uses associated with MRID No. 46385301 are all crop groups, and not minor uses. Similarly, in connection with MRID Nos. 46385302 and 46385306, neither almonds nor pecans meet the acreage definition of a minor crop. See *The United States Environmental Protection Agency Report on Minor Uses of Pesticides*, found at http://www.epa.gov/pesticides/minoruse/minor_use_rpt.pdf. Accordingly, even if Valent had timely made its request for exclusive use protection, it is questionable whether this particular data would be eligible for such protection.

Second, because the studies identified as MRID Nos. 45317200, 45454700, and 45919601 were generated in connection with Interregional Research Project No. 4 (IR4), an initiative funded by the federal government, Valent would not be entitled to exclusive use rights for any of this data even if Valent had timely made its request for exclusive use protection in the first place. See 40 CFR 152.94(b) ("In no circumstances does submission of a public literature study or government-generated study confer any rights on the data submitter to exclusive use of data or compensation") Similar concerns potentially apply to MRID No. 45454701, which is characterized as an unpublished study prepared by the University of Maryland.

If you have any questions concerning EPA's determination that the data identified by MRID Nos. 45668700, 45317200, 45454700, 45454701, 45439801, 45919601, 46385310, 46385302, 46385303, 46385304, 46385305, and 46385306 are not eligible for the exclusive use protection sought by Valent, please contact George LaRocca at (703) 305-6100.

Sincerely yours,



Lois A. Rossi, Director
Registration Division

cc: Marion Johnson, OPP
George LaRocca, OPP
Chris Kaczmarek