

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Warren U. Lehrenbaum  
Counsel for Nisus Corporation  
Pillsbury, Winthrop, Shall, Pittman L.L.P.  
2300 N Street N.W.  
Washington, D.C. 20037-1122

APR 10 2007

Subject: Petition to deny registration applications filed by Ensystem II, Inc., or in the alternative cancel such registrations if already granted

Dear Mr. Lehrenbaum:

I have reviewed your petition submitted to Ms. Mallory on January 30, 2007, on behalf of Nisus Corporation. For the reasons noted below, I am denying your petition.

In your petition, you request that OPP deny registration applications filed by Ensystem II, Inc. (Ensystem) for the registration of two pesticide products known as Borathor Plus and Borathor Max. In the alternative, you request that OPP cancel those registrations if OPP had already granted the registration request. You state that OPP may not grant a registration, or must cancel an already granted registration because you believe Ensystem has not submitted the necessary product performance data for registration of the relevant products, and that citation to product performance data on Bora-Care (EPA Reg. No. 64405-1), the Nisus product, is not sufficient to satisfy the need for such data for registration because the composition of Bora-Care is different from the composition of the two products Ensystem seeks to register. You state that OPP has historically required product performance data on each end use termiticide product and absent such product specific data OPP cannot conclude that the Ensystem products will perform its intended function without unreasonable adverse effects on the environment. You cite as authority for the filing of your petition the regulations at 40 C.F.R. §152.99, the Petition Clause of the First Amendment to the Constitution of the United States and inherent petition authority under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).<sup>1</sup>

<sup>1</sup> Because you have not identified a ground that is specified in 40 C.F.R. §152.99(a) for petitioning for the denial of applications or cancellation of registrations, EPA is not treating your petition as a petition subject to 40 C.F.R. § 152.99 standards or procedures.

OPP has historically required product performance data for the registration of termiticide products, but has not required such data on each and every termiticide product when existing data are sufficient for EPA to determine that the product meets the FIFRA standard for registration. If, in EPA's judgment, any difference in the composition of the termiticide products would not have any meaningful impact on the efficacy of the product for the listed pests and for comparable use sites in question, an applicant's offer to pay the submitter of the data the applicant cites is sufficient to satisfy the data requirement. Applicants may of course generate product performance data on each specific termiticide product. And indeed, when there is no existing data sufficient to appropriately evaluate an applicant's product, applicants must generate new data.

Consistent with this approach, Ensystem cited to the product performance data on Bora-Care to satisfy the product performance data requirement. Ensystem has also certified that it has offered to pay Nisus for citation of the Bora-Care product performance data. In response, OPP has determined that Ensystem's products are substantially similar to the Bora-Care product and that any differences between Bora-Care and the Ensystem product formulations would not be expected to have any meaningful impact on the efficacy of the Ensystem products for the listed pests for comparable use sites. As a result, Ensystem's citation to the product performance data on Bora-Care and its offer to pay for citation of that data satisfies the product performance data requirement for the Ensystem products that are the subject of your petition. The Agency accordingly has granted the Ensystem application requests. For these reasons, OPP denies your petition to deny the referenced applications and in the alternative to cancel the registrations if already granted.

Sincerely,



Lois Rossi, Director  
Registration Division