



US EPA

Office of Pesticide Programs

Pesticide Registration Manual

**Appendix B – Example Letter for Registration or
Amendment Applications Document**

December 2010

EXAMPLE LETTER FOR A PRODUCT REGISTRATION OR AMENDMENT

Date

Courier Address:

Document Processing Desk (Distribution Code)
Attn: (enter EPA Contact if known),
Office of Pesticide Programs (Mail Code)
U. S. Environmental Protection Agency
Rm S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

US Postal Service

Document Processing Desk (Distribution Code)
Attn: (enter EPA Contact if known),
Office of Pesticide Programs (Mail Code)
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Ladies and Gentlemen:

Subject: Application for New Product Registration or Product Amendment
(Product Name)

EPA Reg. No. – (enter company number – if no number, see directions to get number)
(Company Name and full address)

Please find enclosed an application for registration of the (Company Name) pesticide produce (Product Name). This product contains the active ingredients (xxx). This is an application for a new Product Registration or amendment. *(If this is an application associated with PRIA, please include the proposed PRIA code and the fee associated with that code.)*

This application includes the following enclosed documents *(include only the forms that are necessary for your application/amendment)*:

- An Application Form (EPA Form 8570-1).
- Transmittal Document.
- Five (5) copies of the product label.
- Two (2) signed original Basic Confidential Statements of Formula (EPA Form 8570-4).
- Formulator's Exemption Form (EPA Form 8570-27).
- Citation of Data Form (EPA Form 8570-34).
- Data Matrix Table (EPA Form 8570-35).
- List of Data Submitters receiving Offer to Pay Letters
- Summary of the Physical/Chemical Properties (EPA Form 8570-36)
- Self-Certification Statement for Physical/Chemical Properties (EPA Form 8570-37)
- Three (3) copies of each study identified on the data matrix and transmittal documents.

You may want to provide the purpose of your application/amendment in the cover letter, including identifying some of the unique characteristics of your application. This could include identifying the product registration number of substantially similar or identical product to your proposed product, the use rates, new uses, pH changes, or one or more of the following examples listed below.

Relationship to any previous submission(s):

(Describe connection to other, earlier submissions. Include original product you are citing for this me-too submission, including EPA Registration Number and Product Name.)

Confidential Statement of Formula:

(Describe any unusual sources or raw materials or percent numbers on the CSF. The dye information is explained later in this letter.)

Alternate Test Material Names:

(Enter all alternate sample or brand names that are listed in the attached studies or accompanying info that are the same formulation as the Brand Name. Example: Efficacy Test Material RLD 523 and Product Chemistry Test Material ABC 234 are the same as Product Name.)

Product Chemistry:

(Describe method for supporting product chemistry requirements, including study submission for manufacturing process while using EPA Form 8570-36 + 37 for physical/chemical properties. While the registrant is required to run storage stability and container stability studies by GLP, such studies used to support non-public health products do not normally need to be submitted unless requested by EPA.)

Acute Toxicity:

(Indicate you are citing existing acute toxicology studies and that offer to pay letters were sent to data owners identified for the active ingredients. Include the list of companies that received offer to pay by certified mail. Data owners can be found at <http://www.epa.gov/opppmsd1/DataSubmittersList/>)

Efficacy:

(Describe efficacy test methods your product was tested against for public health claims. Efficacy studies for non-public health microorganisms do not need to be submitted unless requested by EPA.)

Identification of Microorganisms:

(Describe public health microorganisms tested, including their ATCC identification Numbers.)

General Labeling:

(Describe label examples where wording was previously approved by EPA – reference original registration on which this product is based. Discuss unusual claims and why they should be acceptable.)

Fragrances on CSFs:

(If applicable, identify any previously approved registrations using the same fragrance, include EPA Registration Number. If new, have fragrance supplier submit complete ingredient list and percentages to EPA either separately or in a sealed envelope with the application. A separate submission needs to be coordinated with Fragrance Supplier so registration and fragrance ingredient packages arrive close together at EPA.)

Please call me at (area code) xxx-xxxx if you have any questions regarding this submission.

Sincerely,

Name, Title
Company
Phone number
Fax number
E-mail address

Enclosures