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Burlington Bio-Medical and Scientific Corporation  
100 Fairchild Avenue  
Plainview, NY 11803

Gentlemen:

Subject: Ro-pel  
EPA File Symbol 45735-E  
Your letter of April 13, 1984

Before we can complete our review of this product,  
we will need the information indicated below.

A. Toxicology Comments

Please submit the following on the submitted  
acute toxicity studies (Acc. No. 251101).

1. Name and address of the testing laboratory.
2. Dates of the tests.
3. Environmental conditions during tests.
4. Data on the control animals.
5. Strain, age, and weight of animals.
6. Clinical signs of toxicity.
7. Recovery times.
8. Necropsy findings.
9. Sex of animals (acute oral and dermal studies).
10. Data during observation period (acute oral and dermal studies).

B. Efficacy Comments

1. Submit a revised set of use directions, giving the species of animals to be controlled, type of damage controlled, the sites of application, dosage, and method of application for each possible use pattern.
2. Historically, the only use of the active ingredient in your product has been to protect dogs from chewing, licking, and gnawing. See attached label, EPA Reg.


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No. 499-139). We will have to restrict the use of this product to this use pattern unless you can clarify your use directions. If you will submit two copies of the available data, we will attempt to help you sort out this question. Some of the proposed sites on your label would appear to be inappropriate for certain of the pests. Others may require residue data, establishment of tolerances, and other data.

3. You should delete any actual or implied claims for a mode of action other than that of taste.
4. Would you expect the inert ingredients listed second and third on your confidential statement of formula to provide any repellency active, by themselves?
5. Revise your "Storage and Disposal" Statements in accordance with the enclosed information.

Contact us if questions arise.

Sincerely,

  
William H. Miller  
Product Manager 16  
Insecticide-Rodenticide Branch  
Registration Division

- Enclosures 1. Label for EPA Reg. 499-139  
2. Storage/Disposal information

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