

<b>STANDARD OPERATING PROCEDURE</b>		
SOP NO.: GLP-DA-03		Page No.: 1 of 3
Title: <b>AUDITING INSECTICIDE EFFICACY STUDIES</b>		
Revision: Original	Replaces: N/A	Effective: 06/07/99

1. **PURPOSE**

This Standard Operating Procedure (SOP) has been developed to provide guidance in auditing Insecticide Efficacy studies submitted to the Environmental Protection Agency in support of registration and regulated by the Federal Insecticide, Fungicide, and Rodenticide Act

2. **SCOPE**

This SOP may be used when auditing studies conducted to determine insecticide product performance. This SOP should be consulted when an employee of the EPA / Office of Compliance (OC) / Agriculture and Ecosystems Division (AED) or a Senior Environmental Employee (SEE) or EPA Regional inspector is auditing Insecticide Efficacy studies.

3. **OUTLINE OF PROCEDURES**

- C General
- C Conduct of the Audit

4. **REFERENCES**

- 4.1 Product Performance Test Guidelines, 810 Series, EPA, OPPTS, March 1998.
- 4.2 40 CFR § 160 Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Good Laboratory Practice Standards; Final Rule, August 17, 1989.
- 4.3 40 CFR § 169 Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Books and Records of Pesticide Production and Distribution, August 15, 1980.

- 4.4 Good Laboratory Practice Standards Inspection Manual, EPA 723-B-93-001, September 1993 and EPA 723-K-96-001, May 1996.
- 4.5 Determining Compliance of Audited Studies with GLP Standards Requirements, LDIB SOP-C-02, October 1, 1990
- 4.6 Evidence Requirements for Documenting GLP Standards and Study Audit Deficiencies, LDIB SOP-S-02, February 15, 1991

## 5. SPECIFIC PROCEDURES

### 5.1 GENERAL

This procedure is not meant to take place of the referenced material and only outlines the significant details that should be reviewed during a Insecticide Efficacy study audit.

Reference 4.1 should be reviewed prior to the inspection to determine what is required by the Office of Prevention, Pesticides and Toxic Substances (OPPTS) Guideline.

### 5.2 CONDUCT OF THE AUDIT

The inspector should conduct audits of Insecticide Efficacy studies using similar procedures employed in other audits. The inspector should be thoroughly familiar with the regulations, and use the procedures provided in the OPPTS Guidelines, Good Laboratory Practice Standards Inspection Manual and existing SOPs.

If the EPA's Office of Pesticide Programs (OPP) accepts a study for review that is submitted for registration, an inspector should review the compliance statement prior to the audit of that study. If the compliance statement states that the studies were conducted in accordance with the GLP Regulations, then a complete GLP inspection should take place. If OPP has accepted a study that contains a compliance statement stating the study was not conducted in accordance with the GLP regulations, then the inspection should be conducted under the Books and Records regulation 169.2(k). (Reference 4.3)

In addition to normal auditing procedures, special attention should be paid to test substance administration and the environmental conditions of the test. These items may be the greatest variables in affecting the outcome of the test. The auditor should be assured that the test substance is administered in a manner that is consistent with appropriate guidelines and protocols. The rate of administration should be consistent throughout the study such as unit weight of test substance verses unit weight of active ingredient. The environmental conditions of the test should be such that the auditor is assured that the outcome of the study is a result of the effectiveness of the insecticide, rather than a result from outside environmental factors.

/s/ \_\_\_\_\_

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06/01/99

Date

/s/ \_\_\_\_\_

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