PROTOCOL FOR PROCESSED COMMODITY (PC)

RESIDUE EVALUATION OF <*TEST SUBSTANCE*>

APPLIED TO <*TEST SYSTEM*>

EPA GUIDELINE OPPTS NO. 860.1520

Prepared By:

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PROTOCOL FOR PROCESSED COMMODITY <PC> RESIDUE EVALUATION OF <*TEST SUBSTANCE*> APPLIED TO <*TEST SYSTEM*>

STUDY DIRECTOR:
<Name>
LANDIS INTERNATIONAL, INC.
P. O. Box 5126
3185 Madison Highway
Valdosta, GA 31603-5126

ANALYTICAL TESTING FACILITY:
<Name>
<Address>
<Address>
Phone <number>

PROTOCOL NUMBER:

Trial No.	Location (EPA region)	Field Cooperator

TEST SYSTEM: <test system>

TEST SUBSTANCE: *<Pesticide Trade Name>*
Formulation: *<Percent active ingredient, type>*
Lot No.: Will be recorded in the study file
CAS No.: *<Number>*
CAS Name: *<Name>*
Common Name: *<Name>*
EPA Reg. No: *<Number>*
IUPAC Name: *<Name>*

PROTOCOL RECIPIENTS:
(1) Sponsor
(2) Study Director
(3) Quality Assurance Unit
(4) Field Cooperator(s)
(5) Analytical Laboratory

PROTOCOL FOR PROCESSED COMMODITY <PC> RESIDUE EVALUATION OF <*TEST SUBSTANCE*> APPLIED TO <*TEST SYSTEM*>

GLP NOTEBOOK RECIPIENT:
(1) Field Cooperator

SAMPLE ACTIVITY I.D. LOG RECIPIENTS:

(1) Sponsor
(2) Study Director
(3) Field Cooperator
(4) Analytical Laboratory
(5) Processing Laboratory

PROPOSED EXPERIMENTAL START DATE: <*Expected date of application at earliest test site*>

PROPOSED EXPERIMENTAL COMPLETION DATE: <*Date*>

OBJECTIVE

The objective of this study is to provide data from the analysis of residues of <*test substance*> in/on processed commodity (PC) samples of <*test system*> following multiple foliar spray applications of the end use product <*trade name and formulation*.> These data will be used for the registration of the compound according to the EPA Residue Chemistry Test Guideline OPPTS 860.1520. The product will be applied as a <*application method*> in <*number*> applications to <*test system*> to obtain <*concentration factor; eg., 5X*> the maximum per season rate. The elevated rate will assure residue on the RAC <test system>, which will allow assessment of the concentration or dilution of residues as a result of processing.

JUSTIFICATION OF THE TEST SYSTEM

Proposed Use: The proposed use of <*pesticide*> <*formulation type*> is for crop protection. <*Test system*> would be a likely candidate for this treatment to protect against <*product use*>. The maximum seasonal application rate as indicated on the label will be applied. The spray will be evenly distributed on the foliage of the test plants in each application.

Test Site Location: The field trial will be located in a region of commercial crop production in <*state(s)*>. The test plots may be designated areas within a commercial field(s). If a commercial field is used, the Field Scientist must have control over the maintenance pesticides used in the plots.

IDENTIFICATION OF TEST SYSTEM

Plot Size and Design: The trial will consist of two plots, one treated and one nontreated (control) established where no <*test substance*> has been applied for at least 3 years. The plots will be designed using the guidelines in LANDIS INTERNATIONAL SOP #3.2-Current Revision, *Plot Construction and Identification* (see GLP Field Notebook provided by LANDIS INTERNATIONAL, INC.). The plot size and design will be sufficient to obtain more than the required amount of crop material shown in **Tables 1** and **2**.

EXPERIMENTAL DESIGN

Test Substance:

Product Formulation:	<*Name, percent a.i., type*>
Active Ingredient:	<*Name*>
Lot Number:	Will be recorded in the study file
Appearance:	Will be recorded in the study file
Stability and homogeneity:	(The stability and homogeneity of the active ingredient within the formulated product will be documented before the start of the study, or concurrently.)

The date of test substance shipment, lot number, date of receipt, and method of shipment, as well as the amount and container size, will be documented. The test substance will be stored in an appropriate manner and storage conditions and daily temperature extremes will be recorded.

The sponsor will obtain a purity analysis and characterization for each lot number of the test substance used. Information regarding the stability and homogeneity of the test substance will be part of the study raw data package. A retention sample from each batch of the test substance will be archived by the Sponsor. All unused test substance and partially empty containers will be retained until the final report is signed, unless a prior waiver has been obtained from EPA. Product remaining at the completion of the study will be returned to <*Sponsor*>.

Application: The crop will be treated using the following parameters:

Test Substance:	<*pesticide*>
Formulation:	<*%a.i./type*>
Carrier:	<*water, clay, etc.*>
Application Rate:	<*active ingredient/area or volume*>
Rate of Formulation:	<*amount of formulated product/area or volume*>
Spray Volume:	<*minimum labeled spray volume*>
Number of Applications:	<*number*>
Timing:	<*spray interval(s)*>
Application Equipment:	< *type of sprayer/nozzle type*>
Crop Stage at Application:	<*stage at 1st application*>
Interval from last Application to Harvest:	<*number of days*>

The amount of <*test substance*> applied when all applications have been made will be <*number*> times the maximum seasonal use rate.

EXPERIMENTAL DESIGN (CONT'D)

Plot Maintenance: Once established, the plots should not be disturbed except for cultural practices, application of approved pesticides, or evaluation. The plot area will be maintained, as much as practical, according to local commercial grower practices. Pests including insects, rodents and weeds will be minimized and conditions maintained to optimize plant growth. Irrigation will be applied as needed to assure good plant growth; however, no overhead irrigation that will dislodge test material residues should occur within six hours following an application.

SAMPLING

Irrigation and Test Substance Mix Water and Product Samples: Prior to or at the time of the final application, at least 1L of irrigation water and 1L of the water used to mix the spray application will be collected and stored at ambient temperature. Also, two samples of approximately <*amount, ml or g*> each of test substance will be collected and stored at ambient temperature prior to shipment. These samples will be shipped to the analytical laboratory at ambient temperature along with a copy of the calibration records from the GLP Field Notebook and a photocopy of the Application Verification Product Sample Information form. Reference LANDIS INTERNATIONAL SOP #4.20-Current Revision, *Sprayate Method Validation and Recovery Determination* and SOP #4.18, Current Revision, *Collection of Irrigation Water for Analysis,* for further guidance in handling these samples.

Crop Sampling: <*Test system*> samples will be collected <*number*> days after the final application from the respective treated and nontreated plots. Samples will be collected from representative locations within each plot <*describe sampling procedure*>. The nontreated plot will be sampled before the treated plot. Each sample will consist of at least <*weight, unit*> of <*commodity*> from the treated and nontreated plots. At least <*weight, unit or number*> of <*commodity*> must remain after the removal of RAC residue samples, by the cooperator and processor, as described below. Samples will be collected at <*growth stage at sampling*>. The nontreated samples will be handled and stored separately from the treated samples. Special care must be taken to prevent contamination of the samples. The <*commodity*> may be mechanically harvested with commercial equipment or experimental harvest equipment that simulates commercial practices so long as neither cross-contamination between plots nor contamination from other areas will occur.

The sampling procedure and sample sizes will follow the recommendation in the EPA Guideline OPPTS 860.1500. After sampling, RAC samples will not be subject to post-harvest treatments (washing, wiping, waxing, etc.) even though harvested fruit may normally be handled in this manner. Four composite samples of <*commodity, number or weight*> each or more to give a minimum weight of <*amount*> each from the treated and nontreated bulk samples (cooperator RAC sample) will be collected by the Field Study Scientist and placed in appropriately labelled sample bags provided by LANDIS INTERNATIONAL. These samples will be frozen as soon as possible, preferably on dry ice, and transferred to a freezer maintained at approximately 15°F or colder for storage. RAC samples will be sent to the following address:

<*Laboratory Name*>
<*Address*>

SAMPLING (CONTINUED)

Processed Commodity Samples: The <*commodity bulk sample and amount (weight)*> from each plot will be shipped <*frozen/non-frozen*>, within approximately 24 hours after collection via overnight courier to the following processing facility:

<*Processing Facility Name*>
<*Address*>

Prior to the processing procedure, the processor will collect two RAC residue samples (one primary and one duplicate) from each bulk <*commodity*> sample. Each sample will consist of <*number of commodity*> or more per sample to give a minimum weight of <*amount*> each. The processor will record the weight of each RAC residue sample. These RAC samples will be placed in a labeled residue bag and frozen at the time of processing each respective bulk sample.

The remaining <*commodity and approximate weight*> of each bulk sample will be processed into <*list (describe) processed commodities*>. The processor will collect two samples from each processed fraction from the nontreated bulk sample, and one sample from each treated processed commodity sample, and transfer them to a freezer maintained at 15°F or colder for storage.

Processing will be done according to the appropriate processor Standard Operating Procedures. Processor-handled samples will be frozen at the processing facility immediately after collection. The primary samples will be shipped frozen to the analytical laboratory. Once the primary samples have arrived safely at the analytical lab, the Study Director will direct the processor as to the disposition of the duplicate samples. <*Commodity*> processed samples can be seen in **Table 2**.

The PC samples will be sent to <*laboratory name*> (refer to the RAC Samples Section for complete address).

SAMPLE HANDLING

All residue samples will be collected and frozen in residue bags provided by LANDIS INTERNATIONAL, INC. and shipped frozen via overnight or other approved courier. On the day of shipping, the Field Study Scientist (Cooperator) must contact LANDIS personnel by TELEPHONE - 800-526-3471, TELEFAX - 229-242-1562 or E-Mail - projectmanager@landisintl.com.

The **"white"** and **"yellow"** copies of the packing/shipping form will be sent with the samples to the selected laboratory. Upon receipt at the laboratory, they will complete the section at the bottom of the form and retain the **"yellow"** copy for their files and return the **"white"** copy to LANDIS INTERNATIONAL, INC. The Field Study Scientist will provide the **"pink"** copy for LANDIS INTERNATIONAL, INC. archives and retain the **"gold"** copy for the GLP Field Notebook.

All samples will be packed and shipped according to LANDIS INTERNATIONAL SOP #4.14 - Current Revision, *Packing and Shipping Samples*. **IT IS IMPERATIVE THAT SAMPLE SHIPPING BE COMMUNICATED TO LANDIS INTERNATIONAL VIA TELEPHONE, FAX OR E-MAIL ON THE DAY OF SHIPPING. FAILURE TO DO SO IS A DEVIATION TO BOTH PROTOCOL AND STANDARD OPERATING PROCEDURES.**

Table 1. Number of Residue Samples: Cooperator RAC and Bulk Samples Collected by the Field Scientist

PLOT	NUMBER OF SAMPLES	MATRIX	AMOUNT NO./WT.
Nontreated	1	Commodity <*RAC*>	<*number or weight*>
Treated	1	Commodity <*RAC*>	<*number or weight*>
Treated	1	Commodity <*RAC*>	<*number or weight*>
Nontreated	1	Bulk commodity	<*number or weight*>
Treated	1	Bulk commodity	<*number or weight*>
Treated	1	Bulk commodity	<*number or weight*>

Table 2. Number of Residue Samples: Processor RAC and Processed Samples Collected by the Processor

PLOT	TYPE OF SAMPLE (NO.)	MATRIX	AMOUNT *<NO./WT.>*
Nontreated	Processor RAC (1)	*<Commodity>*	*<number or weight>*
Treated	Processor RAC (1)	*<Commodity>*	*<number or weight>*
Treated	Processor RAC (1)	*<Commodity>*	*<number or weight>*
Nontreated	Processed sample A (1)	*<Fraction>*	*<weight>*
Nontreated	Processed sample A (1)	*<Fraction>*	*<weight>*
Treated	Processed sample A (1)	*<Fraction>*	*<weight>*
Treated	Processed sample A (1)	*<Fraction>*	*<weight>*
Nontreated	Processed sample B (1)	*<Fraction>*	*<weight>*
Nontreated	Processed sample B (1)	*<Fraction>*	*<weight>*
Treated	Processed sample B (1)	*<Fraction>*	*<weight>*
Treated	Processed sample B (1)	*<Fraction>*	*<weight>*

STATISTICS

None required.

ANALYSIS OF RESIDUE SAMPLES

The analytical portion of the protocol will be added at a later date via protocol amendment.

RECORD KEEPING

The following records and site specific information will be collected:

1. A weather station will be positioned in a clear area to record air and soil temperatures, rainfall and relative humidity at the site. Alternatively, data will be collected from an appropriate weather station located within 20 miles (32 kilometers) of the test plots. When using this second approach, on-site weather information will be recorded on the days of application.

2. A description of the test site, including a map of the test plots indicating their location, topography and size, slope, and location and size of the control plot in relation to the test plot will be provided.

3. A description of the plots including row and plant spacing will be provided.

4. Crop and pesticide use history on the plots for at least three years, and preferably five years preceding this study will be provided.

5. Cultural agronomic practices prior to application and during the course of the study will be provided.

6. The variety of <*test system*> used in the trial will be recorded as specified in LANDIS INTERNATIONAL SOP #4.19-Current Revision, *Seed/Plant Source Record*.

7. The planting, if available, and treatment(s) dates will be provided.

8. Climatic and edaphic conditions at each application will be provided.

9. Description of any post-treatment maintenance, such as use of fertilizers and pesticides, irrigation and weeding will be provided.

10. A description of the source and amount of irrigation water will be provided if irrigation was used on the plots.

11. A description of the test material (lot number, purity, and identifying codes) will be provided.

RECORD KEEPING (CONTINUED)

12. The date of each sampling, description of the sampling technique, condition of the sample, the number of plants/roots making up each sample, and sample weights will be provided.

13. The GLP Field Notebook will be completed and returned to LANDIS INTERNATIONAL, INC., as soon as possible after collecting the final samples.

REPORTING

A draft report will be issued to the Sponsor upon receipt of all pertinent information from the Field Study Scientist. Upon approval by the Sponsor, a final report will be issued. The report will include, but not be limited to the following:

1. Name and address of the facilities involved in performing the study and the dates on which the study was initiated and completed.

2. Objectives and procedures stated in the approved protocol, including changes in the original protocol.

3. The test and control articles identified by name, code, number, composition, and stability as supplied by the Sponsor.

4. A description of the agricultural practices and analytical methods used.

5. A description of the test system.

6. A description of the application equipment, spraying procedures, and existing conditions at the time of application.

7. A description of all circumstances that may have affected the integrity of the study.

8. The name of the Study Director and other scientists and supervisory personnel involved in the study.

9. A description of the transformations, calculations or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.

10. The signed and dated reports of each of the individual scientists or other professionals involved in the study.

11. The locations where all samples, raw data, and the final report will be stored.

REPORTING (CONTINUED)

12. The statement prepared and signed by the Quality Assurance Unit which specifies the dates inspections were made and the dates findings were reported to management.

13. The signed and dated statement of the Study Director indicating that the study was conducted in compliance with the U.S. EPA Good Laboratory Practice Standards in 40 CFR part 160.

The final report will be transferred to the Sponsor upon study completion. Additions or corrections to the final report will be in the form of an amendment by the Study Director. The amendment will clearly identify that part of the final report that is being amended or corrected, the reasons for the additions or corrections, and will be signed and dated by the person responsible.

All test material remaining at the end of the study will be returned to the Sponsor or dispersed according to local regulations.

QUALITY CONTROL AND QUALITY ASSURANCE

LANDIS INTERNATIONAL, INC., will be responsible for assuring that practices conform to the U. S. Environmental Protection Agency Good Laboratory Practices (GLP). This protocol will be reviewed by the Quality Assurance Unit of LANDIS INTERNATIONAL, INC., and the Sponsor. The study will be audited at critical phases and reports of findings submitted to the Study Director and Study Director Management.

The Quality Assurance Unit of the analytical laboratory and processing facility will provide the Study Director with all facility, data, process, and report audits to meet Environmental Protection Agency GLP requirements.

PROTOCOL SIGNATURE PAGE

Sponsor	Date
Study Director	Date
Auditor, Quality Assurance Unit	Date