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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

March 14, 1988

MEMORANDUM

SUBJECT: Answers to Your Questions on Chlorothalonil

FROM: Paul F. Schuda, Chief
Exposure Assessment Branch *Paul F. Schuda*
Hazard Evaluation Division (TS-769C)

TO: Amy Sue Rispin, Chief
SIMS, HED (TS-769C)

We have answered the questions that you sent us about chlorothalonil; please find them attached. If there are any more questions, please contact E. Regelman or Brinson Conerly.

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Note to Amy S. Rispin:

Below are EAB's responses to your questions:

- 1) Why were studies that were deemed acceptable in the 1984 RS review found unacceptable? What prompted the review? Has policy changed that would make the studies no longer acceptable? This occurred for aerobic soil (00087351), confined rotational crops (00029409) and accumulation in fish (00086629, 00029411, and 00086630). We need a statement stating that although these studies were previously accepted they no longer meet requirements and the reason.

Answer:

aerobic soil -- The 1984 Standard indicates that there were recognized deficiencies in the study at that time, including material balance and degradation rates. A careful reading of the footnote which details these deficiencies would indicate that the study was accepted at that time in error.

confined rotational crops -- The confined rotational crop studies were acceptable for the purpose of determining the need for field studies. Field studies were done, and indicate the presence of residues. Although neither the confined or field studies were first-class, they do indicate that tolerances need to be set.

accumulation in fish -- These studies were accepted pending receipt of k_{ow} values according to the footnote in the 1984 Registration Standard. We have no record of additional information having been received, and the information we do have indicates a borderline value for the k_{ow} . The registrant may be able to repair previous studies.

- 2) The 1984 RS required a hydrolysis study at pH 9 for the degradate CTCBN to determine its decline and complete the hydrolysis profile for chlorothalonil. The study was submitted and found to be acceptable. Apparently, this study was not integrated with the previously performed chlorothalonil hydrolysis study. Since the registrant performed the study we required in the 1984 standard, why is the requirement only partially satisfied? What additional studies do we want performed and why?

Answer:

There was an inconsistency between the 1988 executive summary, which does not call for additional information, and the 1988 data table, which does. We have corrected this.

- 3) A photodegradation study in water was submitted in response to the 1984 RS. No DER was prepared for this study. Discussion states "study may eventually be acceptable if the registrant provides the information requested in the recommendations section located within the review of study". However, the review is not part of EAB's Chapter. What information is needed?

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Answer:

DERs for studies which had been deemed unacceptable were not included in the Chapter because of size constraints -- however, the information was transmitted to the registrant in Agency correspondence. We have revised the discussion in the Chapter to include a summary of the information needed.

- 4) Registrants submitted an anerobic aquatic metabolism study which was deemed acceptable. This study is not required for any current use of Chlorothalonil. However, Part 158 permits the use of this study to fulfill anaerobic soil metabolism study. We claim the registrant must do the anaerobic soil metabolism study. Why doesn't the anaerobic aquatic metabolism study satisfy this requirement?

Answer:

The inconsistency between the executive summary, where anaerobic soil metabolism was not listed as a data requirement, and the data table where it was, has been corrected. The requirement is fulfilled.

- 5) What was the basis for granting the 1986 waiver of laboratory volatility study? What new information results in withdrawing the waiver?

Answer:

The waiver was granted on the basis of the vapor pressure value, 5.72×10^{-7} torr at 25°C. At the time, toxicological characteristics of the compound were not known. Since then, chlorothalonil has been determined to be an oncogen. Further, it has greenhouse uses. For these reasons, we believe volatility to be a legitimate data requirement.

- 6) Rotational Crops -- Field studies from 1984 RS indicate the presence of chlorothalonil residues for at least one year after treatment except in leafy vegetables. Why do we need a new study? Shouldn't we be applying the rotational crop policy and asking for tolerances for rotational crops?

Answer:

We agree that there is little to be gained by insisting on a first-class study on field rotational crops, when residues have been demonstrated by information already submitted. We accept the old studies in fulfillment of the requirement, with the expectation that tolerance levels will be established for rotational crops.



Paul F. Schuda

EXECUTIVE SUMMARY

The following findings are derived from those reviewed studies which have met the requirements of 40 CFR 158.130 and the Subdivision N Guidelines, and were also deemed acceptable.

Hydrolysis studies:

Chlorothalonil (purity 99.8%), at 0.5 ppm, did not degrade in sterile aqueous buffered solutions adjusted to pH 5 and 7 (Szalkowski, 1976a, 00040539).

[¹⁴C]3-Cyano-2,4,5,6-tetrachlorobenzamide (DS-19221, 97.7% pure), a degradate of chlorothalonil, at 22.6 ppm, was stable to hydrolysis for 30 days in sterile aqueous buffered solutions of pH 5 and 7 maintained at 24 ±1°C (Nelson, 1985a, No MRID). In solutions of pH 9, 10% of the applied amount degraded during 30 days of incubation; 2,4,5,6-tetrachloroisophthalamide (DS-3133) was the sole degradate.

Anaerobic soil metabolism studies:

This data requirement is considered fulfilled because a satisfactory anaerobic aquatic metabolism study has been received and accepted.

Anaerobic aquatic metabolism studies:

Ring-labeled [¹⁴C]chlorothalonil (purity 98.8%), at 10 ppm, degraded with a half-life of 5-15 days in flooded silt loam and sandy loam soils incubated in the dark at 25°C under a nitrogen atmosphere (Nelsen, 1985c, 00153730). Degradates included 4-hydroxy-2,5,6-trichloroisophthalonitrile (DS-3701; 42.8 and 17.7% of the recovered in the silt loam and sandy loam soils, respectively), 3-cyano-2,4,5,6-tetrachlorobenzamide (DS-19221; 6.7 and 5.9%), 2-hydroxy-5-cyano-3,4,6-trichlorobenzamide (DS-47525; 3.5 and 4.4%), and 3-carboxy-2,5,6-trichlorobenzamide (DS-46851; 1.2 and 2.6%). Less than 0.1% of the [¹⁴C]residues volatilized during the study.

Leaching and adsorption/desorption studies:

Aged [¹⁴C]chlorothalonil (radiochemical purity 98.1%) was slightly mobile in sandy loam, silt loam, and clay loam soils, and mobile in sand soil based on soil column studies (Nelsen, 1985b, 00153730). The [¹⁴C]chlorothalonil degradates (7-14 day aging), 3-carboxy-2,5,6-trichlorobenzamide (DS-46851), 2-hydroxy-5-cyano-3,4,6-trichlorobenzamide (DS-47525), and 4-hydroxy-2,5,6-trichloroisophthalonitrile (DS-3701), were mobile in all four soils; 3-cyano-2,5,6- plus 3-cyano-2,4,5-trichlorobenzamide (DS-47524/3) were mobile in the sandy loam, silt loam, and sand soils.

[¹⁴C]Chlorothalonil (radiochemical purity >97%) was mobile in silty clay loam, silt loam, and sandy loam soils, and very mobile in sand soil (Capps et al., 00115105). Freundlich K_{ads} values were 26 for a silty clay loam soil, 29 for a silt soil, 20 for a sandy loam soil, and 3 for a sand soil equilibrated with 0.1-0.5 ppm of [¹⁴C]chlorothalonil (radiochemical purity >97%) in a 1:4 soil:0.03 N calcium sulfate slurry. The soils had been sieved through 250 µm (silty clay loam and silt soils) and 590 µm (sandy loam and sand soils) screens prior to use. Between 1.8 and 28.4% of the adsorbed chlorothalonil was desorbed from the soils.

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Confined accumulation studies on rotational crops: This data requirement is considered fulfilled despite the deficiencies in the studies listed below because the intent is to establish the need for a field crop rotation study. The field study has been done. Two studies were submitted. The first (Szalkowski, Stallard et al., 1979a, 00029409) is unacceptable because the analytical method (TLC) did not properly characterize plant degradates. In addition, this study would not fulfill data requirements because the soil was not analyzed for the degradates DS-47523/4, DS-47525, or DS46851; plant tissues were not analyzed for DS-46851; and residues comprising >10% of the radioactivity recovered from soil and plant tissues were uncharacterized. Also, studies were not conducted using a grain crop or with crops planted 200 and 360 days posttreatment. The second (Nelsen et al., 1983b, 00139550-A) is scientifically sound and provides supplemental information towards the registration of chlorothalonil. This study does not fulfill data requirements because the total [¹⁴C]residues in the soil were not reported except at 35 hours posttreatment, [¹⁴C]residues in the soil were expressed as percent of the recovered only, the concentration of parent chlorothalonil was not confirmed at the time of application, the pH of the soil was not reported, and there were no control samples.

Field accumulation studies on rotational crops: The data requirement is considered to be fulfilled despite the deficiencies listed below because the intent of the study is to establish whether tolerances are needed. Results indicate the need for tolerances to be set. One study was submitted (Dillon, 00139550-B). This study is scientifically sound and provides supplemental information towards the registration of chlorothalonil. This study does not fulfill data requirements because the total treatment rate of 1.76 lb ai/A was not the maximum allowable agricultural use rate (16-18 lb ai/A); field test data were either unreported, illegible, or incomplete; storage intervals and conditions were not reported along with storage stability data on crops and soils; and, immature wheat samples were not analyzed for degradates.

Ancillary study - vapor pressure:

The vapor pressure of chlorothalonil is 5.72×10^{-7} torr at 25°C, 2.65×10^{-6} torr at 35°C, and 4.49×10^{-5} torr at 45°C (Spare, 00153732).

The following studies were deemed partially acceptable

Aerobic metabolism studies:

Ring-labeled [¹⁴C]chlorothalonil (radiochemical purity 99.3%), at 39 and 3.9 ppm, degraded with registrant-calculated half-lives of 36.5, 14.7, 12.8, and 10.3 days in nonsterile silt loam, loam, Texas sandy loam, and Ohio sandy loam soils, respectively (Szalkowski, 1976b, 00087351). The rate of chlorothalonil degradation was slower in sterile soils with registrant-calculated half-lives of 213.8, 31.3, 18.0, and 21.9 days in the respective soils. [¹⁴C]Chlorothalonil was degraded to 4-hydroxy-2,5,6-trichloroisophthalonitrile (DS-3701; up to 32% of the applied radioactivity at 60 days posttreatment) and 3-cyano-2,4,5,6-tetrachlorobenzamide (DS-19221; up to 7.4% of the applied radioactivity at 7 and 16 days posttreatment). Unextractable residues increased in both sterile and nonsterile soils over the study period, accounting for 40-75% of the applied radioactivity by day 90 in the four soils. The

soils were incubated at 25°C and 80% of field capacity in the dark for a total of 90 days. Further identification of degradates is required.

RECOMMENDATIONS:

Available data are insufficient to fully assess the environmental fate of chlorothalonil. The submission of data required for full registration for chlorothalonil is summarized below:

The following data are required:

Photodegradation studies in water: Three studies were submitted. The first study (Wolfe, 1972, 00087281) is unacceptable because there were no dark controls, the sampling protocol was inadequate, the material balance was incomplete, and the solutions were not sterile. This study does not fulfill data requirements because the intensity and spectral distribution of the light source was not adequately compared to natural sunlight, the degradates were not identified, the purity of the test substance was not reported, and the test solutions were not buffered. The second study (Nelsen, 1987, 40183418) is unacceptable because the sampling intervals were inadequate (the last sampling interval was 118 hours or 9.8 days). This study does not fulfill data requirements because the spectral distribution and intensity of the artificial light source were insufficiently compared to natural sunlight and because the exposure intervals were unclear and appeared to be somewhat random. However, this study may be acceptable if the registrant satisfactorily demonstrates the comparability of experimental conditions of the study to natural conditions. The third study (Szalkowski, 1976c, 00040540) is scientifically sound and provides supplemental information. This study does not fulfill data requirements because the study was conducted at 8°C rather than 25 ± 1°C; the analytical method was nonspecific (except at 24 and 90 hours in the acid solution); degradates were not identified; and the wavelength and intensity of the artificial light and its relationship to natural sunlight were not provided in a clear manner.

Photodegradation studies on soil: One study (Szalkowski, 19??, 00143751) was reviewed and is unacceptable because sampling intervals were inadequate to accurately establish the half-lives of chlorothalonil and DS-3701 (4-hydroxy-2,5,6-trichloroisophthalonitrile); soil TLC plates were analyzed for degradates only once at "the equivalent of 168 12-hour days" of irradiation. In addition, this study would not fulfill data requirements because the characterization of the light source was inadequate, wavelengths <290 nm were not filtered out, the exposure intervals were unclear, the incubation temperature was not reported, the CEC of the soil was not reported, and the soil extraction methods were not reported.

Laboratory volatility: Although this requirement was previously waived (1986, H. Boyd), all data are required because of current toxicological (parent compound determined to be an oncogen), reentry, and greenhouse use concerns.

Terrestrial field dissipation studies: Four studies were reviewed (three unacceptable and one scientifically sound). The first study (Wolfe, 1972, 00087286) is unacceptable because the sampling protocol (one sampling interval) was inadequate to accurately assess the field dissipation of chlorothalonil. This study would not fulfill data requirements because the test soil was

incompletely characterized, field test data were not provided, and the patterns of formation and decline of degradates were not determined. The second study (Wolfe et al., 1965, 00087300) is unacceptable because soils were sampled at an insufficient number of intervals to construct a decline curve for chlorothalonil dissipation from soil, and the method of analysis was neither referenced nor described. In addition, this study would not fulfill data requirements because patterns of formation and decline of degradates were not addressed; the test soil was not characterized; and meteorological data, including rainfall and irrigation amounts, were not provided. The third study (Stallard et al., 00087332) is unacceptable because the sampling intervals were inadequate to accurately assess the dissipation of chlorothalonil in soil (first samples were not taken until 30-221 days posttreatment) and contamination of control samples was not explained. In addition, this portion of the study would not fulfill data requirements because the patterns of formation and decline of degradates were not determined; meteorological data such as soil and air temperature and rainfall were not provided, and the test soils were not characterized (except for the South Dakota site). The fourth study (Stallard et al., 1972, 00087296) is scientifically sound and provides supplemental information. This study does not fulfill data requirements because data for the untreated control plot were not reported; the soil was not analyzed for the degradates DS-19221 (3-cyano-2,4,5,6-tetrachlorobenzamide), DS-47523/4 (3-cyano-2,4,5-trichlorobenzamide and 3-cyano-2,5,6-trichlorobenzamide), DS-47525 (2-hydroxy-5-cyano-3,4,6-trichlorobenzamide), and DS-46851 (3-carboxy-2,5,6-trichlorobenzamide); and the CEC and pH of the soil were not reported. Furthermore, additional data are still required for a second site using a WP (or FLC) formulation, and two sites using the D formulation.

Accumulation studies on irrigated crops: No studies were submitted. Since chlorothalonil may be applied through irrigation equipment, all data are required.

Laboratory studies of pesticide accumulation in fish: Five studies were submitted. Three studies were found unacceptable; (#1: Szalkowski and Stallard, 1980b, 00029417; Szalkowski, Stallard, et al., 1979c, 00029416; Szalkowski, Marciniszyn et al., 1987b, 00086633; and Szalkowski, Stallard, et al., 1980a, 00086632), (#2: Sleight, 1972b [no MRID]), (#3: Szalkowski, Marciniszyn et al., 1981a, 0086631). Two studies pertaining to the exposure of fish to [¹⁴C]chlorothalonil residues provide supplemental data towards the registration of chlorothalonil, (#4: Cryberg, 00138142; Szalkowski, Marciniszyn, et al., 1981c, 0086630; Szalkowski, Stallard et al., 1979b, 00029411; and Szalkowski, Stallard, et al., 1980b, 00086629), (#5: Sleight, 1972a, no MRID). The Sleight study does not fulfill data requirements because radioactive residues in the water and fish were not identified, residues in whole fish were not determined, visceral tissues were analyzed only on day 28 of exposure, and bioconcentration factors were not calculated. The #4 study does not fulfill data requirements because fish were not exposed to a constant concentration of chlorothalonil, but were exposed to a radioactive mixture that consisted of approximately 50% chlorothalonil and approximately 50% other degradates. One document from study (Cryberg, 00138142) reports an octanol/water partition coefficient of 925 and 548 at 10⁻⁴ M and 10⁻⁶ M, respectively, without any supporting documentation. The registrant should either provide a description of the test substance along with the analytical methods, water characteristics, and supporting data used to obtain these coefficients, or else, submit an acceptable accumulation study.

Reentry data: Studies as listed in the Data Table are required due to current toxicological concerns and currently registered use patterns.

The following data requirements are partially fulfilled:

Aerobic soil metabolism studies: Five studies were submitted, out of which four were unacceptable (Stallard et al., 1967, 00087332; Szalkowski, 1976d, 00040544 and Szalkowski, 1976g, 00087352; Wolfe, 1971, 00087284; [metabolism of DS-3701]: Wolfe et al., 1968, 00087286). The fifth study (Szalkowski, 1976b, 00087351) was acceptable and partially fulfills data requirements by providing information on the degradation of chlorothalonil and on the formation and decline of two chlorothalonil degradates (DS-3701 and DS-19221) in silt loam, loam, and two sandy loam soils for 90 days. Additional [¹⁴C]residues must be identified. Also, additional data on the aerobic soil metabolism of DS-3701 and DS-19221 may be required.

The following data requirements are reserved:

Field volatility studies: This study may be required pending the results of the laboratory volatility study.

Long-term field dissipation studies: This study may be required pending the results of the field dissipation studies utilizing the highest rate recommended and the greatest number of multiple applications.

Ground-water monitoring: These data may be required based on a more complete environmental fate data base and reassessment.

The following data requirements are fulfilled:

Hydrolysis studies: One study was submitted pertaining to the hydrolysis of chlorothalonil and its degradate DS-3701 (Szalkowski, 1976a, 00040539) and one was submitted pertaining to the hydrolysis of DS-19221, another degradate of chlorothalonil (Nelsen, 1985a, no MRID). The portion of the first study (Study 1) conducted with chlorothalonil at 0.5 ppm in solutions adjusted to pH 5 and 7 is acceptable. The portion of the study conducted with chlorothalonil at 0.5 ppm at pH 9 is unacceptable because material balances were not provided. The portion of the study conducted with chlorothalonil at 1.5 ppm is unacceptable because the application rate exceeded the solubility limit of chlorothalonil (0.6 ppm). The portion of the study conducted with degradate DS-3701 is unacceptable because the experimental design was inadequate to accurately establish the half-life of DS-3701 (samples were analyzed for DS-3701 only at 28 and 72 days posttreatment). This study partially fulfills data requirements by providing information on the hydrolysis of chlorothalonil at pH 5 and 7. The second study (Study 2) was acceptable and partially fulfills data requirements by providing information on the hydrolysis of DS-19221, a chlorothalonil degradate, at pH 5, 7, and 9.

Anaerobic aquatic metabolism studies: One acceptable study was submitted (Nelsen, 1985c, 00147975). This study fulfills data requirements by providing information on the anaerobic aquatic metabolism of [¹⁴C]chlorothalonil.

Leaching and adsorption/desorption studies: Eight studies were submitted. The first six are unacceptable (Szalkowski, 19??, 00143751; Szalkowski, Mar-nion, et al., 00029407; Szalkowski and Stallard, 1980a, 00029406; Wolfe et al., 1968, 00087286 [mobility of DS-3701 in columns]; Nelsen, Marks et al.,

1983a, 001372321; Szalkowski, 1976f, 00040546). The last two studies are acceptable and fulfill data requirements by providing information on the adsorption and desorption of unaged (batch equilibrium, Capps et al., 00115105) and aged (column studies, Nelsen, 1985b, 00153730) chlorothalonil in four soils.

Ancillary study - vapor pressure: One study was submitted (Spare, 00153732) and was acceptable.

The following data requirements are currently not required:

Aerobic aquatic metabolism studies: No data were submitted; however, no data are required because chlorothalonil currently has no registered aquatic uses.

Aquatic field dissipation studies: No data were submitted; however, no data are required because chlorothalonil currently has no registered aquatic uses.

Forestry dissipation studies: No data were submitted; however, data are not required because chlorothalonil has no registered forestry uses.

Dissipation studies for combination products and tank mix uses: No data were reviewed; however, these data requirements are currently not being imposed.

Field accumulation studies on aquatic nontarget organisms: One study was submitted (Shults et al., 00137146) and was scientifically sound. This study does not fulfill data requirements because the treatment rate of 10.65 lb ai/A was not at the maximum registered use rate for food crops (approximately 18 lb ai/A) or ornamental turf (22.65 lb ai/A), and fish tissues were not fractionated into edible or visceral tissues. However, no additional data are required because chlorothalonil currently has no registered aquatic uses.

The following data requirements have been waived:

Photodegradation studies in air: No data were submitted; however, data requirements have been waived (EAB review dated 3/8/86; H.L. Boyd, Chemist).

TABLE A
 GENERIC DATA REQUIREMENTS FOR CHEMICAL: Chlorothalonil

Data Requirement	Composition ¹	Use Pattern ²	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must/When ³ Additional Data be Submitted
158.130 Environmental Fate					
<u>DEGRADATION STUDIES-LAB:</u>					
161-1	Hydrolysis Photodegradation	PAIRA or TGAI	A, B, E, F, H	Yes	00040539 No
161-2	in Water	PAIRA or TGAI	A, B	No	Yes 3/
161-3	on Soil	PAIRA or TGAI	A, B	No	Yes 3/
161-4	in Air	PAIRA or TGAI	N.A.	No	No
<u>METABOLISM STUDIES-LAB:</u>					
162-1	Aerobic Soil	PAIRA or TGAI	A, B, E, F, H	Partially	00087351 Yes 3/
162-2	Anaerobic Soil	PAIRA or TGAI	A	Yes	00147975 No
162-3	Anaerobic Aquatic	PAIRA or TGAI	N.A.	Yes	00147975 No
162-4	Aerobic Aquatic	PAIRA or TGAI	N.A.	No	No
<u>MOBILITY STUDIES:</u>					
63-1	Leaching and Adsorption/Des.	PAIRA or TGAI	A, B, E, F, H	Yes	00153730 No
63-2	Volatility (lab)	TEP	A, E, F	No	00115105
63-3	Volatility (field)	TEP	A, E, F	No	Yes 3/ Reserved
<u>DISSIPATION STUDIES-FIELD:</u>					
64-1	Soil	TEP	A, B, H	No	Yes 3/
64-2	Aquatic (Sediment)	TEP	N.A.	No	No
64-3	Forestry	TEP	N.A.	No	No
64-5	Soil, Long-Term	TEP	A	No	Yes 6/
<u>CUMULATION STUDIES:</u>					
55-1	Rotational Crops (Confined)	PAIRA	A	Yes	0029409, 00139550 No 8/
55-2	Rotational Crops (Field)	TEP	A	Yes	00139550 No 8/
55-3	Irrigated Crops	TEP	A	No	Yes 3/
55-4	In Fish	PAIRA/TGAI	A, B	No	Yes 3/
55-5	In Aquatic Non-Target Organism	TEP	N.A.	No	Reserved

¹ Composition: TGAI=Technical Grade of the Active Ingredient, PAIRA=Pure Active Ingredient, Radiolabeled, TEP= Typical End-Use Product.
² Use Patterns are coded as follows: A=Terrestrial, Food Crop; B= Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor
³ Data for individual studies must be submitted no later than the dates assigned by the PM. Pending toxicology considerations.
 Required on case-by-case basis depending on product use and other pertinent factors.

TABLE A
 GENERIC DATA REQUIREMENTS FOR CHEMICAL: Chlorothalonil

<u>Data Requirement</u>	<u>Composition 1/</u>	<u>Use 2/ Pattern</u>	<u>Does EPA have data to satisfy require't (Yes, No, partially)</u>	<u>Biblio- graphic Citation</u>	<u>Must/When 3 Additional data be submitted.</u>
<u>\$158.130 Environmental Fate</u>					
Subpart K Re-entry					
132-1 Foliar Dissipation	TEP	A,B	No		Yes /3
132-1 Soil Dissipation	TEP	A,B	No		Yes /3
133-3 Dermal Exposure	TEP	A,B	No		Yes /3
133-4 Inhalation Exposure	TEP	A,B	No		Yes /3
Ground Water Monitoring	TEP		No		Reserved ,

6/ Required if pesticide residues do not readily dissipate in soil.

7/ Ground water monitoring study protocol must be submitted, reviewed, and approved prior to conducting study.

8/ Although the studies were deficient and did not completely conform to Guidelines studies, they indicate the probable need for tolerance setting by RCB