REREGISTRATION ELIGIBILITY DOCUMENT

HEPTACHLOR

LIST A

CASE 0175

March, 1992

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION
WASHINGTON, D.C.

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as Reference Dose or RfD.
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LDT	Lowest Dose Tested
LEL	Lowest Effect Level
MP	Manufacturing-Use Product

GLOSSARY OF TERMS AND ABBREVIATIONS (cont.)

MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System.
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts Per Million
RfD	Reference Dose
RS	Registration Standard
TMRC	Theoretical Maximum Residue Contribution

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EXECUTIVE SUMMARY

Heptachlor is currently registered in the United States as an insecticide. The registrations containing heptachlor as an active ingredient fall into three distinct groups: fire ant control; termiticides; and a registration for export only. This Reregistration Eligibility Document (RED) addresses the eligibility for reregistration of products containing heptachlor for fire ant control. The only formulation of heptachlor for fire ant control is a 7% granular product.

A Registration Standard for heptachlor was issued in December 1986. The Registration Standard summarized the available data supporting the reregistration of products containing heptachlor for fire ant control and termite control and required additional data to assure that the proper use of the pesticide posed no potential adverse effects to man or the environment. The Agency has completed its review of the heptachlor data base including the data submitted in response to the 1986 Registration Standard.

The Agency has determined that the use of heptachlor to control fire ants will not cause unreasonable risk to man or the environment and is eligible for reregistration. The Agency is requiring additional product chemistry data to complete the generic data base. The product chemistry data are required to fill existing data gaps in the product chemistry data base.

Before reregistering the applicable products, the Agency is requiring that product specific data and revised labeling be submitted within 8 months of the issuance of this document. These data include product chemistry and acute toxicology testing. After reviewing these data and the revised labels, the Agency will reregister a product based on whether or not that product meets the requirements in Section 3(c)(5) of FIFRA.

All registrations of heptachlor for termiticidal use are subject to the terms of a negotiated settlement between EPA and Velsicol, the sole remaining registrant of heptachlor termiticidal products, agreed to on August 11, 1987. Any data requirements imposed in the 1986 Registration Standard were nullified as a result of that agreement and as such are no longer relevent to the reregistration of heptachlor.

Under the terms of that agreement, no termiticides containing heptachlor may be sold in the United States unless and until Velsicol generates certain specified air-monitoring data and the data demonstrate that indoor residues of heptachlor (and/or a related chemical, chlordane) can not be detected in treated homes. If no such tests are conducted, the registrations will automatically expire on August 11, 1994.

The terms of that agreement also specify that, if heptachlor termiticides are ever available for sale in the United States again, EPA will reevaluate the data requirements for the termiticide use of heptachlor in light of whatever application methods remain and, if additional data are required, will go forward with a data call-in at that time. The termiticide uses of heptachlor are not eligible for reregistration at this time.

Heptachlor products registered for export only are not eligible for reregistration at this time. The Agency currently is evaluating the legal appropriateness of this registration and the data that would be required to support an export-only registration if such registrations are determined to be appropriate.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for registration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration of heptachlor. The document consists of six sections. Section I is the introduction. Section II describes heptachlor, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV discusses the reregistration decision for heptachlor. Section V discusses the reregistration requirements for heptachlor. Section VI is the Appendices which support this Reregistration Eligibility Document. Additional details concerning the Agency's review of applicable data are available on request.[1]

[1] EPA's reviews of data on the set of registered uses considered for EPA's analysis may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Document:

Common Name: Heptachlor

Chemical Name: 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-methano-1H indene.

Chemical Family: Chlorinated cyclodiene

CAS Registry Number: 76-44-8

Office of Pesticide Programs Chemical Code: 044801

Empirical Formula: $C_{10}H_5Cl_7$

Trade and Other Names: Heptachlorotetrahydro-4,7-methanoindene; 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-methanoindene; E-3314; Velsicol 104.

Basic Manufacturer: Velsicol Chemical Corporation

B. Use Profile

The following is information on the active registered use with specific use sites and application methods. A detailed table of both eligible and ineligible uses of heptachlor is in Appendix A.

Type of Pesticide: Insecticide (chlorinated hydrocarbon).

Use Sites: Terrestrial non-food - Pad-mounted electric power transformers, telephone cable, and cable television pedestals.

Pests: Fire ants.

Formulation Types Registered: Granular - 7% heptachlor

Method and Rates of Application:

Equipment - Apply by Hand. Wear protective gloves.

Method and Rate - Apply the entire contents of the 4 ounce bag (0.017 lb a.i.) directly into the buried closure or hole. One bag will treat a buried closure size of 12" by 12" (1 sq. ft.).

Timing - When needed.

C. Data Requirements

Data required in the December 1986 Registration standard for Heptachlor included studies on toxicology, environmental fate, worker exposure, ecological effects (fish and wildlife), and product chemistry. These data were required to support the registrations of subterranean termiticide use, above-ground structural wood treatment for termite control, and for fire ant control in buried cable closures. Both generic data (Table A) and product specific data for manufacturing-use and end-use products (Tables B and C) were called-in. Please refer to **Appendix B** for details of the complete data base for heptachlor. Appendix B includes all data requirements identified by the Agency for current use groups that are needed to support reregistration plus data requirements being imposed as a result of the Agency's review. The data tables in Appendix B reflect the Agency's reassessment of the data required for the reregistration of heptachlor due to the changes in the use patterns being supported.

D. Regulatory History

Heptachlor was first registered in the United States in 1952. At that time it was used primarily as a broad spectrum insecticide on many agricultural crops. Other uses included seed treatment, home and garden uses, and termite control. On November 18, 1974, the EPA Administrator issued a notice in the Federal Register of intent to cancel all registered uses of heptachlor except those uses for subterranean termiticide control and dipping of non-food plants, because of evidence that heptachlor and its metabolite, heptachlor epoxide, demonstrated carcinogenic and developmental effects in mice and rats, as well as its persistence in the soil for many years and bioaccumulation throughout the food chain (39 FR 41298). The cancellation proceeding continued until November of 1977 at which time the parties entered into settlement negotiations. The negotiations resulted in an agreement which was ratified in a final Order issued by the Administrator on March 6, 1978 (43 FR 12372). The Final Order resulted in the eventual cancellation of all products subject to the original notice of intent to cancel. Some of the cancellations became effective on the date of the Final Order while other cancellations became effective according to a phase out schedule incorporated in the Order. Limitations on production and distribution of technical heptachlor for these phased out uses were imposed in PR Notice 78-2.

In accordance with a 1982 Federal Register publication entitled "Policy Statement on the Revocation of Tolerances for Canceled Pesticides" (47 FR 42956), it was recommended that tolerances for heptachlor be revoked and replaced with action levels to address unavoidable residues resulting from environmental contamination. On December 11, 1985, EPA proposed to revoke all tolerances for residues of heptachlor in or on food and feed commodities (50 FR 50643) and in 1989 all tolerances were finally revoked and replaced with action levels (54 FR 33693).

EPA evaluated heptachlor and the other chlorinated cyclodienes for underground termite control in a November 1983 report entitled "Analysis of Risks and Benefits of Seven Chemicals Used for Subterranean Termite Control." Subsequently, in 1984, a Data Call-In (DCI) was issued requiring additional health and exposure data for a more comprehensive risk assessment.

A Registration Standard for heptachlor was issued in December 1986. This document along with the 1984 DCI required data to support the termiticide and fire ant control uses remaining for heptachlor. This Reregistration Eligibility Document reflects a reassessment of all data submitted in response to the registration standard which support only the reregistration of the fire ant control use of heptachlor.

There are currently five products containing heptachlor registered in the United States. The two termiticide products, an end-use product and its manufacturing-use technical are currently not on the market, and cannot be sold until adequate air-monitoring data are submitted. Of the three remaining products, one is a technical product for export only and the remaining two products, eligible for reregistration, are an end-use product for fire ant control in underground cable fixtures and its manufacturing-use product.

III. SCIENCE ASSESSMENT OF HEPTACHLOR

The Agency has conducted a thorough review of the scientific data base for heptachlor for the purposes of determining the reregistration eligibility of this pesticide. These finding are summarized below.

A. Product Chemistry Assessment

Heptachlor (1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-methano-1H indene) is a chlorinated cyclodiene with a molecular weight of 373.3. Technical heptachlor is a dark amber solid with a penetrating camphor-like odor at room temperature. It has a melting point of 50-73°C, and in the pure form of the active ingredient, it melts at temperatures of 96.5-97.5°C. The density of heptachlor at 20°C is 13.2 lbs/gal. At room temperature, heptachlor is practically insoluble in water (0.2 mg/100 ml) and soluble in either methanol or kerosene (29 gm/100 ml and 32 gm/100 ml, respectively); the octanol/water partition coefficient is $2.92 \times 10^3 \pm 0.4 \times 10^3$. Heptachlor does not oxidize or reduce, is not flammable, explosive or

corrosive, and is stable when stored at ambient temperatures for over 1 year. Additional product chemistry data requirements are listed in Section V.

B. Human Health Assessment

1. Hazard Assessment

The Agency has reevaluated the use patterns of heptachlor since the 1986 Registration Standard, and concludes that human exposure from the remaining use is negligible; and that this use is supported by existing toxicological data. The following assessment is based on the data available to the Agency.

a. Acute and Subchronic Toxicity

The LD_{50} for a 74 percent technical grade of heptachlor in male and female rats is 208 and 158 mg/kg, respectively. This is considered moderate toxicity and is classified as Toxicity Category II. Data available on a primary dermal irritation study with a 74 percent technical indicate Toxicity Category IV (mildly irritating).

The primary subchronic effects produced by heptachlor and its epoxide in rats and mice are on the liver, i.e., endoplastic reticulum hypertrophy, enlarged hepatic lobule cells, increased liver weight and liver lesions. This is consistent with results observed in chronic studies.

b. Chronic Toxicity and Carcinogenicity

Chronic oral administration of heptachlor in mice and rats resulted in cellular degeneration and histopathological changes in the liver referred to as the chlorinated hydrocarbon insecticide rodent liver type (CHIRL). Liver toxicity occurred at doses as low as 0.5 part per million (ppm) (0.0125 mg/kg/day) in a 60-week dog feeding study with heptachlor epoxide.

Long-term carcinogenicity studies have been conducted with heptachlor in rats and mice. A carcinogenic response was demonstrated in mice. Groups of 100 male and 100 female C3H mice were fed diets containing 0 or 10 ppm (0 or 1.5 mg/kg/day) heptachlor for 2 years. Survival was low with only 50 percent of the controls and 30 percent of the treated mice surviving until the end of the study. A twofold increase in benign liver tumors occurred in the treated mice compared to controls and a statistically significant increase in liver carcinomas was observed in treated male rats (64/87) and female rats (57/78) compared to controls (22/73 in males and 2/53 in females).

A second long-term study in mice revealed a significant dose-related increase of hepatocellular carcinomas in treated male and female B6C3F1

mice. Fifty male and 50 female mice were fed diets containing technical heptachlor with time-weighted averages of 6.1 or 13.8 ppm and 9 or 18 ppm, respectively (approximate doses of 0.9 and 2.1 mg/kg/day - males; 1.4 and 2.7 mg/kg/day - females). The treatment period was 80 weeks followed by a 10-week observation period. A statistically significant increase in the incidence of hepatocellular carcinomas occurred in the high-dose male and female groups when compared to controls.

There have been no indications of a treatment-related increase of tumors in long-term studies with rats. It was reported in an early study that there was no increase in tumors found in groups of 20 CF rats fed heptachlor in the diet at 1.5, 3.0, 5.0, 7.0, or 10.0 ppm (0.074, 0.15, 0.25, 0.35, 0.5 mg/kg/day, respectively) for 110 weeks. Liver lesions however, reported as the "chlorinated hydrocarbon" type were observed at 7.0 and 10.0 ppm (0.35 and 0.5 mg/kg/day, respectively).

Several long-term bioassays of heptachlor epoxide have been conducted. Groups of 100 male and 100 female C3H mice were fed 0 or 10 ppm (0 or 1.5 mg/kg/day) heptachlor epoxide for 2 years. Survival was generally low with 50 percent of controls and 9.5 percent of treated mice living 2 years. A twofold increase in benign liver lesions (hepatic hyperplasia and benign tumors) was reported for the treated group when compared to the controls. Further, a significant increase in liver carcinomas occurred in the treated group (77/81 in females and 73/79 in males) when compared to the controls (2/53 in females and 22/73 in males).

It was reported that there was no increase in tumors in groups of 25 male and 25 female CF rats fed diets containing 0.5, 2.5, 5.0, 7.5, or 10.0 ppm (0.025, 0.125, 0.25, 0.375, 0.5 mg/kg/day) heptachlor epoxide for 108 weeks. The study was reevaluated and it was reported that there was a significant increase of hepatic carcinomas in females in the 5.0 and 10.0 ppm (0.25 and 0.5 mg/kg/day, respectively) groups when compared to controls and a significant increase of hepatic nodules in males in the 10.0 ppm group compared to controls occurred.

In another study, a mixture of 75 percent heptachlor and 25 percent heptachlor epoxide was tested in the diet of groups of 25 female CD rats at 5.0, 7.5, 10.0, and 12.5 ppm (0.25, 0.375, 0.5, 0.625 mg/kg/day) for a period of 2 years. Although no malignant tumors of the liver were observed, hepatocytomegaly was increased in animals in the three high dose groups. Two additional studies were conducted in which there was no increase in the incidence of hepatocellular carcinomas when the mixture was administered to Wistar rats by gavage or to Osborne-Mendel rats via the diet.

c. Other Toxicological Effects

Reproduction

Several reproduction studies have been conducted with heptachlor or heptachlor epoxide. In one study, male and female rats were administered heptachlor at dosages of 1.5, 3.0, 5.0, 7.0, or 10.0 ppm (0.075, 0.15, 0.25, 0.35, 0.5 mg/kg/day) for 7 weeks. Increased pup mortality was observed at 7.0 and 10.0 ppm (0.35 and 0.5 mg/kg/day, respectively). Reproductive effects were not observed in rodents at 5.0 ppm (0.25 mg/kg/day) heptachlor or less. In a second study, a limited number of dogs (4/sex) were administered heptachlor epoxide at dosages of 1, 3, 5, 7, or 10 ppm (0.025, 0.075, 0.125, 0.175, 0.25 mg/kg/day) in the diet. There was increased pup mortality at the top two doses. Pups born to dams in the 3 ppm (0.075 mg/kg/day) group exhibited liver effects. The NOEL is established at 1 ppm (0.025 mg/kg/day) based on the liver effects.

Mutagenicity

Gene mutation assays indicate that heptachlor is not mutagenic in bacteria or mammalian liver cells. Negative results were reported in two dominant lethal assays using male germinal cells. DNA repair assays indicate that heptachlor is not genotoxic in rodent hepatocytes but demonstrated qualitative evidence of unscheduled DNA synthesis in human fibroblasts.

Gene mutation assays indicate that heptachlor epoxide is not mutagenic in bacteria. Heptachlor epoxide failed to induce major chromosomal aberrations in male germinal cells. Qualitative evidence of unscheduled DNA synthesis has been reported to occur in SV40 transformed human fibroblasts in the presence of hepatic homogenates and heptachlor epoxide.

Metabolism

Heptachlor is metabolized to heptachlor epoxide in biological systems. In studies with rats, it has been reported that heptachlor epoxide can be further metabolized to di- and trihydroxylated derivatives of dihydrochlordene and excreted. Heptachlor is also postulated to be converted to either 1-hydroxy-chlordene or 1-chloro-dihydrochlordene via another metabolic pathway and further metabolized to excretion products by conjugation with glucuronic acid. The Agency concludes that there is not sufficient evidence that the production of the 1-chloro-dihydrochlordene species is a major degradative pathway of heptachlor.

Reference Dose (RfD) for Chronic Oral Exposure

The RfD for heptachlor was determined to be 0.0005 mg/kg/day based on the results of a 2-year feeding study with CF rats. The NOEL was 3 ppm (0.15 mg/kg/day) with a LEL of 5 ppm (0.25 mg/kg/day) due to the occurrence of liver lesions characteristic of chlorinated hydrocarbons (hepatocellular swelling and peripheral arrangements of cytoplasmic granules of cells of the central zone of the liver lobules) and/or increases in relative liver weight. An uncertainty factor (UF) of 300 and a modifying factor (MF) of 1 was used to derive the RfD for heptachlor.

The RfD for heptachlor epoxide was determined to be 0.000013 mg/kg/day based on the results of a 60-week feeding study with beagle dogs. The NOEL could not be established because there were treatment-related increases in the liver-to-body weight ratios at all dosage levels. The LEL was 0.5 ppm (0.0125 mg/kg/day). An uncertainty factor of 1000 and a modifying factor of 1 was used to derive the RfD for heptachlor epoxide.

Epidemiology

There are several epidemiologic studies of workers exposed to chlordane and/or heptachlor. One retrospective cohort study of pesticide applicators showed marginal statistically significant increased mortality from bladder cancer (3 observed) yet was considered to be inadequate in sample size and duration of follow-up. Other studies were retrospective cohort studies of pesticide manufacturing workers. None of these indicated any statistically significant increased cancer mortality. All of the populations had confounding exposures from other chemicals. There were 11 case reports involving central nervous system effects, blood dyscrasias, and neuroblastomas in children with pre-/postnatal exposure to chlordane and heptachlor. There are no epidemiologic evaluations of heptachlor epoxide.

2. Exposure Assessment

a. Dietary Exposure

All food uses for heptachlor were canceled prior to the 1986 Registration Standard; therefore, there are no residue chemistry data requirements.

There are no minor use considerations for heptachlor. The Codex Maximum Residue Levels (MRLs) are established for extraneous residues of heptachlor and heptachlor epoxide (i.e., unavoidable residues due to their persistence in the environment) in or on meat, milk, poultry, eggs and vegetable crops.

b. Occupational and Residential Exposure

Heptachlor meets the Agency's toxicity criteria for requirement of both applicator exposure monitoring data and postapplication exposure monitoring data. However, based on current active registered use patterns, the Agency has determined that heptachlor no longer meets the exposure criteria for requirement of applicator and postapplication exposure monitoring data. Since the termiticide uses of heptachlor are not active registrations, the only remaining use of heptachlor is to control fire ants in underground power cable boxes. The end use product is a 7% granular formulation packaged in a 4 ounce plastic bag. The product is applied by pouring the contents of the plastic bag directly into a metal or concrete enclosure. The enclosure is rarely accessed after application, thus postapplication human exposure is not expected. Concerning applicator exposure, the 1986 Registration Standard required applicator exposure monitoring data for the use of heptachlor in underground power cable boxes; however the Agency has determined that human exposure resulting from this use is expected to be negligible when the product is used according to label directions. The current label precautions, which include the use of protective gloves during application remain adequate and will mitigate any risk associated with this use. No additional human exposure monitoring data are required to support the reregistration of the use of heptachlor to control fire ants in underground power cable boxes.

3. Risk Assessment

Heptachlor is in the EPA Carcinogen Group B_2 (probable human carcinogen). The supporting data include studies on three strains of mice (of both sexes), in which heptachlor produced benign and malignant liver tumors. The metabolite, heptachlor epoxide, is also a Group B_2 carcinogen, based on liver carcinomas produced in two strains of mice (both sexes) and in female rats. Several structurally related compounds (chlordane, aldrin, dieldrin, and chlorendic acid) are also liver carcinogens.

Heptachlor exhibits moderate acute oral toxicity in the rat. Chronic oral administration of heptachlor to rodents produces histopathological changes typical of several chlorinated insecticides. The abbreviated heptachlor data on reproductive toxicity indicate less sensitivity for this endpoint than for liver toxicity. Assays for gene mutation and chromosome aberrations are negative. Unscheduled DNA synthesis, however, is qualitatively evident in human fibroblasts.

There are no registered food uses for heptachlor. The only remaining fully active registered use is the application into underground power-cable boxes. The technique involves pouring a seven percent granular formulation from a four-ounce plastic bag directly into the metal or concrete enclosure, which is rarely accessed thereafter.

The Agency has determined that applicator exposure is negligible for the only use of heptachlor that is active; and that the hazard of this use is also negligible, when the applicator properly follows current label precautions, including the use of chemical-resistant gloves. In addition, the use pattern is such that there is a potential only for acute exposure. Therefore it is inappropriate to assess risk based on a cancer endpoint.

C. Environmental Assessment

1. Environmental Fate

The only use of heptachlor being considered for reregistration eligibility is the terrestrial use in underground power cable boxes. This use does not require any environmental fate data.

a. Environmental Fate and Transport

Heptachlor is practically insoluble in water, and in environmental systems, and is metabolized to heptachlor epoxide in biological systems. It has been reported that heptachlor epoxide metabolizes to dihydroxylated derivatives and trihydroxylated derivatives of dihydrochlordene. There is not sufficient evidence that the production of the 1-chloro-dihydrochlordene derivatives is a major degradation pathway. Available supplementary data however, do indicate general trends of persistence, immobility, and soil binding behavior in the environment.

Heptachlor residues slowly increased in the upper 2 inches of a treated muck soil in New York in a six week period. These heptachlor residues then declined from a maximum of 0.6 ppm after the final application to nondetectable at 289 days posttreatment. Heptachlor dissipated from the upper 6 inches of treated New York sandy loam and silty clay loam with an average of 26% for unconfined field plots and 53% for confined cylinders of applied remaining at 21 months posttreatment. Therefore, dissipation appeared to be most rapid in the muck soil. Exposure of the treated plots to full sun, shade, or twice the normal rainfall was reported to have no effect on the dissipation rate of heptachlor residues. Heptachlor residues had a half-life of $\approx$23 days in the upper 1 inch of an uncharacterized soil treated with heptachlor. Incorporation of heptachlor into a silt loam soil at an 7.5 cm depth resulted in a reported dissipation from the surface 0-23 cm with a half-life of 336-551 days. Further data reported within a year of application indicate heptachlor epoxide increased to, then remained constant at, 0.01 ppm level during years 2-4.5 posttreatment. In field studies using heptachlor epoxide, an estimated half-life of 5-6 months was determined for a loam soil. However, long-term studies in Maryland estimated half-lives ranging from 2 to 4 years. Long-term

experiments in Hawaii at application rates of 89 to 503 ppm had reported 0.68 to 8.28 ppm heptachlor-heptachlor epoxide concentrations at 7 years posttreatment.

Heptachlor appears to be immobile in both silty clay loam and sandy loam soils based on upward movement in subirrigated soil columns. Heptachlor is not expected to leach, since it is insoluble in water and should adsorb to the soil surface, as well. However, based on untreated plots containing heptachlor residues, concentration of 0.33 to 0.52 ppm, the long-term Hawaii studies did indicate other means of transport may occur.

b. Environmental Fate Risk Assessment

There are no environmental fate data requirements needed for the reregistration of heptachlor as the registered active use is not expected to lead to any environmental exposure. Available supplementary data do indicate general trends of persistence, immobility, and soil binding behavior in the environment.

2. Ecological Effects

No new ecological effects data have been submitted since the issuance of the 1986 Registration Standard. The Agency has reviewed the available information for heptachlor and has determined that all ecological effects data requirements are satisfied.

a. Ecological Hazard

1. Ecological Effects Data

An acute oral study on mallard duck showed that heptachlor has an $LD_{50} \geq 2080$ mg/kg. These data indicate that heptachlor *per se* when administered by gavage is practically non-toxic to waterfowl. In three subacute dietary studies on bobwhite quail, pheasant, and mallard duck, technical heptachlor when present in food, was found to be highly toxic with LC_{50} values averaging 92, 224, and 480 ppm, respectively. These studies fulfill Agency minimum data requirements to establish the toxicity of heptachlor in birds.

Studies have been submitted determining the LC_{50} values in freshwater ecosystems. Forty-eight hour toxicity tests were performed using both the technical product and end-use products containing 19.6% active ingredient on the freshwater invertebrate *Daphnia magna* with LC_{50} values averaging 42

μg/L and 245 μg/L, respectively. The 96-hour LC_{50} values for two fish species, rainbow trout (coldwater species) and bluegill sunfish (warmwater species), averaged 7.4 μg/L and 13 μg/L, respectively, in a study using the technical material. Two studies were submitted using a formulated end-use product of heptachlor on freshwater fish. One study used a 33% a.i. product on rainbow trout and showed an LC_{50} value of 0.130 μg/L. A 19.6% a.i. product on bluegill sunfish showed an LC_{50} value of 0.092 μg/L. The second study was performed using an end-use product of 19.6% a.i. on both species and LC_{50} values were 9.0 μg/L and 56 μg/L, respectively. The minimum data requirements to establish the acute toxicity of heptachlor on freshwater fish and invertebrates have been met.

The 96-hour LC_{50} for grass shrimp is reported to average 10.6 μg/L for a 19.6% a.i. formulation end-use product and for pink shrimp, the LC_{50} averaged 1.3 μg/L using a 26.9% a.i. product. No data on the toxicity of technical heptachlor on estuarine and marine organisms were submitted. The Agency has determined that studies using technical heptachlor and/or formulation studies on other estuarine/marine species are not applicable to the use of this pesticide. Therefore the Agency concludes that no further data depicting the acute toxicity of heptachlor in estuarine or marine organisms are required.

2. Hazard Characterization

Aquatic

Technical heptachlor is characterized as very highly toxic to warmwater and coldwater fish with LC_{50} values of 13 μg/L and 7.4 μg/L, respectively. Heptachlor is characterized as very highly toxic to freshwater invertebrates with a 48 hour LC_{50} value of 42 μg/L.

Terrestrial

Technical heptachlor when present in the diet, is highly toxic to both upland game birds and waterfowl with subacute dietary LC_{50} values of 92 ppm and 480 ppm, respectively. It is classified as practically non-toxic to waterfowl (when administered by gavage) with an acute oral LD_{50} value equal to or greater than 2080 mg/kg. Heptachlor is classified as moderately toxic to mammals with an average LD_{50} value in the rat of 180 mg/kg.

b. Ecological Effects Risk Assessment

No ecological effects risk assessment has been conducted for this chemical because there is expected to be no exposure to the environment from

the use pattern. However, it should be noted that this chemical can bioaccumulate in fish and fresh-water invertebrates and is very highly toxic to warmwater and coldwater fish, very highly toxic to freshwater invertebrates and highly toxic to both upland game birds and waterfowl. Precautionary labeling is required: "This pesticide is toxic to fish, aquatic invertebrates and birds. Do not contaminate water when disposing of equipment washwaters."

Although heptachlor is very toxic to fish, aquatic invertebrates, and birds, the Agency believes there is negligible risk to nontarget organisms, based on the limited exposure of the chemical to the environment with this use pattern (fire ant control in buried electrical cable boxes).

IV. RISK MANAGEMENT AND REREGISTRATION DECISION FOR HEPTACHLOR

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of all the generic (i.e., active ingredient specific) data required to support reregistration of products containing heptachlor as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of certain products containing heptachlor. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of heptachlor, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency only to assess certain registered uses of heptachlor and to determine that these uses of heptachlor can be used without resulting in unreasonable adverse effects to man and the environment. The Agency therefore finds that only products containing heptachlor as the active ingredient that are used to control fire ants in buried pad mounted electric power transformers, cable television and telephone pedestals are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document. The generic data base is insufficient to support the products of heptachlor with subterranean termiticide uses; thus these products are ineligible for reregistration.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Although the Agency has found that certain products containing heptachlor are eligible

for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing heptachlor, if new information comes to the Agency's attention or if the data requirements for reregistration (or the guidelines for generating such data) change.

The following is a summary of the regulatory positions and rationales for heptachlor. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

Eligibility Decision

The Agency has sufficient information on the health effects of heptachlor and on its potential for causing adverse effects in fish and wildlife and the environment when used to control fire ants in buried pad mounted electric power transformers, cable television and telephone pedestals. The Agency therefore concludes that products containing heptachlor for these uses are eligible for reregistration. Only certain product chemistry data on the manufacturing-use product are still needed. The Agency has determined that heptachlor products, labeled and used as specified in this Reregistration Eligibility Document, will not pose unreasonable risks or adverse effects to humans or the environment.

Eligible and Ineligible Uses

The Agency has determined that the buried cable box/transformer use of heptachlor is eligible for reregistration at this time. The subterranean termiticide uses and use for export only are ineligible for reregistration. Heptachlor products with these uses are ineligible for reregistration because adequate data to support these uses have not been submitted.

B. Regulatory Position

Tolerances and Action Levels

Prior to the cancellation of all food and feed uses for heptachlor, tolerances for total residues of heptachlor and heptachlor epoxide resulting in or on raw agricultural commodities from application of heptachlor were established as listed in 40 CFR §180.104 and 40 CFR §180.319. Tolerances were not revoked concurrently with these cancellations because of heptachlor's slow rate of degradation and its persistence in the environment. Tolerances were ultimately revoked in 1989 and replaced with action levels (54 FR 33693). These action levels are presently established at 0.01-0.03 ppb, except for the fat of meat from goats, cattle, hogs, horses, sheep, poultry and rabbits, which are presently set at 0.3 ppm. Action levels are substituted for

tolerances to allow for the legal movement in commerce of food and feed commodities that contain residues due to environmental contamination. These levels will continue to be lowered as available data indicate.

Restricted Use Classification

The Agency has determined that based on the confined use pattern, heptachlor no longer meets the exposure criteria for requirements of applicator and postapplication exposure data, and concludes that human exposure resulting from single limited use is expected to be minimal when the product is used according to the label instructions. The single use on fire ants in buried cable boxes will not adversely affect the worker and thus does not warrant the restricted use classification.

V. ACTIONS REQUIRED BY REGISTRANTS

This section is designed to assist the registrant by listing all of the data requirements and responses necessary for the reregistration of both manufacturing-use (generic) and end-use (product specific) products.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of heptachlor products used for fire ant control has been reviewed and determined to be substantially complete. Although some of the generic product chemistry data requirements are acceptable, additional data are required to support the reregistration of technical heptachlor. These generic data requirements are listed in Appendix F. Registrants are also reminded that any changes, since the Registration Standard was issued in 1986, in the manufacturing process for technical heptachlor, and any detection of new impurities since that time, must be reported to the Agency.

2. Labeling Requirements for Manufacturing-Use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10. Instructions in the Pesticide Reregistration Handbook describe the requirements with respect to labels and labeling.

Based on the reviews of the generic data, the following additional (or revised) label statements are required:

a. In the directions for use, the first statement regarding acceptable use patterns must appear: "For formulation into end-use products intended only for the control of fire ants in buried pad mounted electric power transformers, cable television and telephone pedestals."

b. The current label claim for technical heptachlor must be revised to reflect the nominal concentrations of the active ingredients as required in PR Notice 91-2.

c. In the Environmental Hazards section the first statement must be revised as follows: "This pesticide is toxic to fish, aquatic invertebrates and birds".

The remaining label warnings remain appropriate and must be present on the label.

B. End Use Products

1. Additional Product-Specific Data Requirements

Based on the reviews of the generic data for the active ingredient heptachlor, the products containing heptachlor for the control of fire ants are eligible for reregistration. Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

The product specific data were called in 1986 with the issuance of the Registration Standard. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix G; Attachment D) and if not, commit to conduct new studies. If the registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10. Please follow the instructions in the Pesticide Reregistration Handbook with respect to labels and labeling.

The Agency has determined that the current label precautions are still applicable and are required for product reregistration. The following additional (or revised) label statements are required:

a. The labels must include the following protective clothing statement: "Wear chemical-resistant gloves when handling or applying this product."

b. In the Environmental Hazards section revise the current statement as follows: "This pesticide is toxic to fish, aquatic invertebrates and birds. Do not contaminate water when disposing of equipment washwaters."

APPENDIX A

Table of Heptachlor Use Patterns Subject to Reregistration

APPENDIX A

HEPTACHLOR

SITE — Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations: Allowed	Geographic Limitations: Disallowed	Use Limitations (code)
NON-FOOD/NON-FEED USES - ELIGIBLE FOR REREGISTRATION										
Nonagricultural Uncultivated Areas/Soils — Use Group(s): Terrestrial Non-Food Crop										
Soil treatment (specialized), When needed, By hand	G	na	0.017 lb ai/sq ft	not spec	not spec	not spec	not spec			78
Wide Area/General Outdoor Treatment — Use Group(s): Terrestrial Non-Food Crop										
Soil treatment (specialized), When needed, By hand	G	na	0.017 lb ai/sq ft	not spec	not spec	not spec	not spec			78
NON-FOOD/NON-FEED USES - INELIGIBLE FOR REREGISTRATION										
Wood Protection Treatment to Buildings/Products Outdoor — Use Group(s): Terrestrial Non-Food Crop, Outdoor Residential										
Soil contact nonfumigation, When needed, Low pressure ground	EC	na	0.017 lb ai/linear ft	not spec	not spec	not spec	not spec			76

Abbreviations used

Header: max = maximum; min = minimum; apps = applications; not spec = not specified; na = not applicable
Form: EC = emulsifiable concentrate; G = granular
Rate: ai = active ingredient; ft = foot; sq ft = square foot

Chemical Use Limitations:

76 = Do not annually retreat entire premises. Retreatment should be made as a spot application to these areas.
78 = Apply only while wearing prescribed gloves.

APPENDIX B

Table of The Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for the pesticide heptachlor covered by this Reregistration Eligibility document. It contains generic data requirements that apply to heptachlor in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A Terrestrial food
B Terrestrial feed
C Terrestrial non-food
D Aquatic food
E Aquatic non-food outdoor
F Aquatic non-food industrial
G Aquatic non-food residential
H Greenhouse food
I Greenhouse non-food
J Forestry
K Residential
L Indoor food
M Indoor non-food
N Indoor medical
O Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Heptachlor

Requirement		Use Pattern	Citation
§158.120 Product Chemistry			
61-2	Beginning Materials and Manufacturing Process	All	40251501, 41636001
61-3	Formulation of Impurities	All	40251501, 41636001
62-3	Analytical Methods	All	40251501, 41636001
63-2	Color	All	40251502
63-3	Physical State	All	40251502
63-4	Odor	All	40251502
63-5	Melting Point	All	40251502
63-7	Density	All	40251502
63-8	Solubility	All	40251502
63-10	Dissociation Constant	All	40251502
63-11	Octanol/Water Partition Coefficient	All	40251502
63-12	pH	All	40251502

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Data Supporting Guideline Requirements for the Reregistration of Heptachlor

Requirement		Use Pattern	Citation
§158.130 Environmental Fate			
163-1	Leaching and Adsorption/Desorption	C	00104106, 00122690
164-1	Soil Field Dissipation	C	00041784, 00070305, 00122687
§158.135 Toxicology			
81-1	Acute Oral Toxicity - Rat	C	00050054
81-5	Primary Dermal Irritation	C	00050054
83-1	Chronic Toxicity	C	GS0175-001, 00061912 00062599, 00086208
83-2	Oncogenicity	C	GS0173-004, 00059319, 00062599, 00062676, 00063609, 00086208, Cabral *et. al.*, Epstein (1976), Reuber
83-4	Rat Reproduction	C	GS0175-001, 00062599, 00084115

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Data Supporting Guideline Requirements for the Reregistration of Heptachlor

Requirement		Use Pattern	Citation
84-2	Gene Mutation	C	00142044, 00142047, 00142048, 00142051, 00142054, 00144999, 00145000, Epstein (1972)
84-2	Structural Chromosomal Aberration	C	00142051, 00145000 Epstein (1972)
84-4	Other Genotoxic Effects	C	Epstein (1972)
85-1	General Metabolism	C	USEPA (1987)
§158.145 Ecological Effects			
71-1	Acute Avian Oral Toxicity - Quail/Duck	C	Hudson, *et. al.*
71-2	Avian Dietary Toxicity - Quail/Duck	C	00085950
72-1	Freshwater Fish Toxicity - Bluegill/Trout	C	00003503, 00108085 00086221, 00103882
72-2	Freshwater Invertebrate Toxicity	C	00003503, 00086221

APPENDIX C

HEPTACHLOR BIBLIOGRAPHY

Citations Considered to be Part of the Data Base Supporting the Reregistration of Heptachlor

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Data Supporting Guideline Requirements for the Reregistration of Heptachlor

Requirement		Use Pattern	Citation
§158.120 Product Chemistry			
61-2	Beginning Materials and Manufacturing Process	All	40251501, 41636001
61-3	Formulation of Impurities	All	40251501, 41636001
62-3	Analytical Methods	All	40251501, 41636001
63-2	Color	All	40251502
63-3	Physical State	All	40251502
63-4	Odor	All	40251502
63-5	Melting Point	All	40251502
63-7	Density	All	40251502
63-8	Solubility	All	40251502
63-10	Dissociation Constant	All	40251502
63-11	Octanol/Water Partition Coefficient	All	40251502
63-12	pH	All	40251502

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§158.135 Toxicology			
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84-4	Other Genotoxic Effects	C	Epstein (1972)
85-1	General Metabolism	C	USEPA (1987)
§158.145 Ecological Effects			
71-1	Acute Avian Oral Toxicity - Quail/Duck	C	Hudson, *et. al.*
71-2	Avian Dietary Toxicity - Quail/Duck	C	00085950
72-1	Freshwater Fish Toxicity - Bluegill/Trout	C	00003503, 00108085 00086221, 00103882
72-2	Freshwater Invertebrate Toxicity	C	00003503, 00086221

APPENDIX C

HEPTACHLOR BIBLIOGRAPHY

Citations Considered to be Part of the Data Base Supporting the Reregistration of Heptachlor

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears

as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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MRID	Citation
GS0173-004	U.S. EPA (1985) Carcinogenicity Risk Assessment for Chlordane and Heptachlor/Heptachlor Epoxide. Unpublished report prepared by Carcinogen Assessment Group. 138 p. EPA/600/6-87/004.
GS0175-001	U.S. EPA (1972) Pesticidal Aspects of Heptachlor in Relation to Man and the Environment. Unpublished report prepared by Special Pesticide Review Group. 79 p.
00003503	Johnson, W.; Finley, M. (1980) Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates. USDI Publication 137, Wash. DC.
00041784	Nash, R.G.; Woolson, E.A. (1967) Persistence of chlorinated hydrocarbon insecticides in soils. Science 157:924-927.
00050054	Goldenthal, E.I.; Wazeter, F.X.; Dean, W.P. (1974) Acute Toxicity Studies in Rats and Rabbits: IRDC Report No. 163-294. (Unpublished study received January 7, 1977 under 876-7; prepared by International Research and Development Corp. Chicago, IL; CDL:227550-A)
00059319	Davis, K. (1965) Pathology Report on Mice Fed Aldrin, Dieldrin, Heptachlor and Heptachlor Epoxide for Two Years. Internal FDA Memorandum to Dr. A.J. Lehman, July 19??.
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00062599	Witherup, S.; Cleveland, F.P.; Shaffer, F.E.; Schlecht, H.; Minsen, L. (1955) The Physiological Effects of the Introduction of Heptachlor Into the Diets of Experimental Animals in Varying Levels of Concentration: Report of Experiment No. 2. Kettering Laboratory, submitted by Velsicol Chemical Corporation.
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Heptachlor Bibliography

MRID	Citation
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00070305	Bess, H.A.; Hylin, J.W. (1970) Persistence of termiticides in Hawaiian soils. Journal of Economic Entomology 63(2):633-638.
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00086208	Jolley, W.P.; Stemmer, K.L.; Jolley, L. (1966) The Effects of Feeding Diets Containing a Mixture of Heptachlor and Heptachlor Epoxide to Female Rats for Two Years, Kettering Laboratory, Submitted by Velsicol Chemical Corporation.
00086221	Union Carbide Corporation (1976) Acute Toxicity of Clorohepton #6 to Bluegill Sunfish, *Lepomis macrochirus Rafinesque*, Rainbow Trout, *Salmo gairdneri Richardson*, and the Water Flea, *Daphnia magna Staus*, (Unpublished study received Dec. 22, 1976 under 876-181; submitted by Velsicol Chemical Corp., Chicago, IL; CDL:227407-I)
00103382	Bently, R. (1974) Acute Toxicity of gold Crest Termide to Rainbow Trout (*Salmo gairdneri*). (Unpublished study received Jan 29, 1975 under unknown admin. no.; prepared by Bionomics, EG & G Environmental consultants, submitted by Velsicol Chemical Corp., Chicago, IL; CDL:235576-A)

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00122687	Freeman, H.; Taylor, A.; Edwards, W. (1975) Heptachlor and dieldrin disappearance from a field soil measured by annual residue determinations. J. Agric. Food Chem. 23(6):1101-1105.
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00142048	Maslansky, C.J.; Williams, G.M. (1981) Evidence for an Epigenetic Mode of Action in Organochlorine Pesticide Hepatocarcinogenicity: A Lack of Genotoxicity in Rat, Mouse and Hamster Hepatocytes. J. Toxicol. & Environ. Health. 8:121- 130.
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40251502	Harrison, J.; Templer, D. (1987) Physical and Chemical Characteristics of Technical Heptachlor/Termite..., Technical Heptachlor/Export..., Technical Heptachlor/Cable Closures: No. VCC/TH/PC-2. Unpublished compilation prepared by Velsicol Chemical Corp. 26 p.
41636001	Harrison, J. (1990) Product Identity and Composition of Technical Heptachlor/Termite..., Technical Heptachlor/Export..., Technical Heptachlor/Cable Closures (Revised): Lab project Number VCC/TH/PC-1. Unpublished compilation prepared by Velsicol Chemical Corp. 52 p.

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MRID Citation

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U.S. EPA (1987a) Health Risk Assessment of Heptachlor and Heptachlor Epoxide, Washington, DC (as abstracted from IRIS, 3/1/92)

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Wang, H.H., MacMahon, B. (1979b) Mortality of Workers Employed in the Manufacturing of Chlordane and Heptachlor. J. Occupational Medicine 21(11):745-748.

APPENDIX D

List of Available Related Documents

The following is a list of available documents related to heptachlor. Its purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for heptachlor and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Heptachlor RED Fact Sheet

4. PR Notice 91-2 (included in this RED) pertains to the Label Ingredient Statement

Federal publications on heptachlor are available and may be purchased from the National Technical Information Service (NTIS) 5285 Port Royal Road, Springfield, VA 22161.

1. Pesticide Fact Sheet (No. 107.2) entitled "Heptachlor: Prohibition of Continued Sale or Use of Heptachlor Products for Seed Treatment:" NTIS Stock No. PB-89-190854.

2. "Heptachlor in Relation to Man and the Environment:" NTIS Stock No. PB-25-72444.

3. "Pesticidal Aspects of Chlordane and Heptachlor:" NTIS Stock No. PB-25-83391.

4. "Actions to Cancel and Suspend Use of Chlordane/Heptachlor" NTIS Stock No. PB-258-340/9.

5. Guidance for the Reregistration of Pesticide Products Containing Heptachlor as the Active Ingredient (The 1986 Registration Standard): NTIS Stock No. PB-87-175808.

6. " Analysis of Risks and Benefits of Seven Chemicals Used for Subterranean Termite Control:" NTIS Stock No. PB-87-115259.

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

MAY 2 199

2

PR NOTICE 91-2

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section 10(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE**," all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be set **based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient statements must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 158.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentration" on the application form. These types of amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 557-5024.

Anne E. Lindsay

Anne E. Lindsay, Director
Registration Division (H-7505

APPENDIX E

Pesticide Reregistration Handbook

APPENDIX F

Generic Data Call-In

Attachment A

Chemical Status Sheet

HEPTACHLOR: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing technical heptachlor.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of heptachlor. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment B), (3) the Requirements Status and Registrant's Form (Attachment C), (4) a list of registrants receiving this DCI (Attachment D), (5) the EPA Acceptance Criteria (Attachment E), and (6) the Cost Share and Data Compensation Forms in replying to this Heptachlor Generic Data Call-In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for heptachlor are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on technical heptachlor are needed. These data are needed to fully complete the reregistration of all eligible heptachlor products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Herman T. Toma at (703) 308-8055.

All responses to this Notice for the generic data requirements should be submitted to:

Herman T. Toma, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: HEPTACHLOR

Attachment B

Generic Data Call-In Response Forms (Form A) plus Instructions

United States Environmental Protection Agency
Washington, D.C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
000876 VELSICOL CHEMICAL CORP 10400 W HIGGINS RD SUITE 600 ROSEMONT IL, 60018	0175 Heptachlor Chemical # and Name 044801 Heptachlor	GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
876-330					

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative _____

9. Date

10. Name of Company Contact

11. Phone Number

Attachment C

Requirements Status and Registrants' Response Forms (Form B) plus Instructions

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address 000876
VELSICOL CHEMICAL CORP
10400 W HIGGINS RD SUITE 600
ROSEMONT IL 60018

2. Case # and Name
0175 Heptachlor
Chemical # and Name 044801
Heptachlor

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number		5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	*	Chemical Identity					all	TGAI	12 mos.	
61-2(a)	*	Begin. mat. & mnfg. proc					all	TGAI	12 mos.	
62-1	*	Preliminary Analysis					all	TGAI	12 mos.	
62-2	*	Certification of limits					all	TGAI	12 mos.	
62-3	*	Analytical Method					all	TGAI	12 mos.	
63-9	*	Vapor Pressure					all	TGAI/PAI	12 mos.	
63-13	*	Stability					all	TGAI	12 mos.	
63-20	*	Corrosion characteristics					all	MP	12 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0175 Heptachlor
Chemical # and Name
044801 Heptachlor

GUIDELINE	COMMENT
61-1	A revised Confidential Statement of Formula is required. The CSF should list the active ingredient, each intentionally added inert ingredient (only if applicable), impurities, nominal concentration, certified limits as required (i.e., upper and lower certified limits of the active and inert ingredients, if applicable, and upper certified limits of the impurities), and purpose of each component. This includes the "related compounds" in the product that should be identified, quantified, and listed separately. (Refer also to comments under guideline 62-2). The related compounds are included (without designation as related compounds) within the total percentage of inerts in the label if these do not have any pesticidal activity. However, if one or more of the related compounds are found to be active, the active compounds must be specifically identified and quantified by percentage and grouped under the active ingredient heading of the label ingredients statement. Data should be provided to support this claim. The current label claim for Technical Heptachlor should be revised to reflect the nominal concentrations of the active ingredients as required in PR Notice 91-2.
61-2(a)	The suppliers, specifications and material safety data sheets for the beginning materials as well as the description of the beginning materials and the manufacturing process including the physical conditions controlled and quality assurance methods are all described in MRID 40251501. However, one of the materials used in the manufacturing process must be identified. In addition, a flow chart with chemical equations of each intended chemical reaction at each step of the process is required. Although the information submitted in MRID 41636001 was submitted specifically for EPA Reg. No. 876-288 (Technical Heptachlor for export only), it is assumed that the revised process applies to all Velsicol Heptachlor Technical products, specifically EPA Reg. No. 876-330. However that registrant must affirm, certify and state that the additional data contained in MRID 41636001 applies to all their Heptachlor Technical products.

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0175 Heptachlor
Chemical # and Name
044801 Heptachlor

GUIDELINE	COMMENT
62-1	No data were submitted in response to the 1986 Registration Standard. Data from five or more representative samples from different batches of the product are required. The active ingredients, any inert ingredient (if applicable) and each impurity for which certified limits are required must be analyzed. In addition, the analytical methods used must be described and a statement of the precision and accuracy of the methods must be submitted.
62-2	More information is required on the certified limits which appear on the CSF. See comments under guidelines 61-1 and 62-1. An explanation must be submitted on how each certified limit was established (e.g. by analysis) and what is known about the accuracy and precision of the procedures used to establish the limit.
62-3	Data are needed to evaluate the adequacy of the method contained in MRID 40251501 and to determine whether the active ingredient is within the certified limits reported for the product.
63-9	Data are required depicting the vapor pressure and the method for determination described.
63-13	Data must include consideration and discussion of the sensitivity of the active ingredient to metal ions or metal, sensitivity to sunlight and stability at normal and elevated temperatures.
63-20	Data on the material tested (e.g. nature of the liner used) must be specified.

Attachment D

List of Registrants Receiving this Data Call-In

List of All Registrants Sent This Data Call-In Notice

Case # and Name

0175 Heptachlor

Chemical # and Name

044801 1,4,5,6,7,8,8-Heptachlorotetrahydro-4,7-methanoind

Company Number	Company Name	Additional Name	Address	City & State	Zip
000876	VELSICOL CHEMICAL CORP		10400 W HIGGINS RD SUITE 600	ROSEMONT IL	60018
013283	REGWEST	AGENT FOR: RAINBOW TECHNOLOGY CORP	BOX 2220	GREELEY CO	80632

Attachment F

Cost Share and Data Compensation Forms

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	Company Number
Chemical Name	**EPA Chemical Number**

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)

   [ ] All companies on the data submitters' list for the active ingredient listed on this form (Cite-All Method or Cite-All Option under the Selective Method). (Also sign the General Offer to Pay below.)

   [ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	Company Number
Chemical Name	**EPA Chemical Number**

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

APPENDIX G

Product Specific Data Call-In

Attachment A

Chemical Status Sheet

ATTACHMENT A

HEPTACHLOR: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing heptachlor.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of heptachlor. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment B), (3) the Requirements Status and Registrant's Form (Attachment C), (4) a list of registrants receiving this DCI (Attachment D), (5) the EPA Acceptance Criteria (Attachment E), and (6) the Cost Share and Data Compensation Forms in replying to this Heptachlor Product Specific Data Call-In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for heptachlor are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional data on heptachlor are needed for specific products. While product specific data requirements were imposed in the 1986 Registration Standard, a complete listing is provided in Attachment C. If you as a registrant of a heptachlor product, responded to the 1986 Registration Standard and submitted the data relating to your specific product, simply choose response number 6 and cite the MRID number that was assigned to your study. Otherwise these data are required to be submitted to the Agency within the timeframe listed. These data are needed to fully complete the reregistration of all eligible heptachlor products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of heptachlor, please contact Herman T. Toma at (703) 308-8055.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact George LaRocca (703) 305-6100.

All responses to this Notice for the Product Specific data requirements should be submitted to:

George LaRocca, Product Manager Team 13
Insecticide/Rodenticide Branch
Registration Division (H7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: HEPTACHLOR

Attachment B

Product Specific Data Call-In Response Forms (Form A) plus Instructions

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
REGWEST AGENT FOR: RAINBOW TECHNOLOGY CORP. BOX 2220 GREELEY CO 80632	0175 Heptachlor	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
13283-4		N.A.	N.A.		

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

SPECIFIC INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORM

Product Specific Data

This form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1-4 will have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

Attachment C

Requirements Status and Registrants' Response Forms (Form B) plus Instructions

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
REGWEST AGENT FOR: RAINBOW TECHNOLOGY CORP. BOX 2220 GREELEY CO 80632	0175 Heptachlor EPA Reg. No. 13283-4	PRODUCT SPECIFIC ID# 13283-RD-1862

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					C	EP	8 mos.	
61-2(a)	Descrip of starting materials, production & formulation proc (1,2)					C	EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					C	EP	8 mos.	
62-1	Preliminary analysis (1,4)					C	EP	8 mos.	
62-2	Certification of limits (1,5)					C	EP	8 mos.	
62-3	Analytical method (1)					C	EP	8 mos.	
63-3	Physical state					C	EP	8 mos.	
63-7	Density					C	EP	8 mos.	
63-12	pH (9)					C	EP	8 mos.	
63-14	Oxidizing or reducing action (10)					C	EP	8 mos.	
63-15	Flammability (11)					C	EP	8 mos.	
63-16	Explodability (12)					C	EP	8 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
REGWEST
AGENT FOR: RAINBOW TECHNOLOGY CORP.
BOX 2220
GREELEY CO 80632

2. Case # and Name
0175 Heptachlor

EPA Reg. No. 13283-4

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 13283-RD-1862

4. Guideline Requirement Number	5. Study Title		Protocol	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-17	Storage stability						C	EP	8 mos.	
63-18	Viscosity	(13)					C	EP	8 mos.	
63-19	Miscibility	(14)					C	EP	8 mos.	
63-20	Corrosion characteristics						C	EP	8 mos.	
63-21	Dielectric breakdown voltage	(15)					C	EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,36,37)					C	EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,37)					C	EP	8 mos.	
81-3	Acute inhalation toxicity-rat	(3)					C	EP	8 mos.	
81-4	Primary eye irritation-rabbit	(2)					C	EP	8 mos.	
81-5	Primary dermal irritation	(1,2)					C	EP	8 mos.	
81-6	Dermal sensitization	(4)					C	EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0175 Heptachlor

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product. [NOTE: If a product is a 100 percent repackage of another registered product that is purchased, and any use for the product does not differ from those of the purchased and registered source, users are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop	B - Terrestrial food feed crop	C - Terrestrial nonfood crop	D - Aquatic food crop	E - Aquatic nonfood outdoor
F - Aquatic nonfood Industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 Required to support the registration of each manufacturing-use product (including registered TGAIs) as well as end-use products produced by an integrated system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the development state, a rudimentary product analytical method and data will suffice to support an experimental use permit.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0175 Heptachlor

Footnotes (cont.):

which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.

37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

Attachment D

List of Registrants Receiving this Data Call-In

United States Environmental Protection Agency
Washington, D. C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0175 Heptachlor

Co. Nr.	Company Name	Additional Name	Address	City & State	Zip
000876	VELSICOL CHEMICAL CORP		10400 W HIGGINS RD SUITE 600	ROSEMONT IL	60018
013283	REGMEST	AGENT FOR: RAINBOW TECHNOLOGY CORP	BOX 2220	GREELEY CO	80632

Attachment F

Cost Share and Data Compensation Forms

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	Company Number
Chemical Name	**EPA Chemical Number**

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)

   [ ] All companies on the data submitters' list for the active ingredient listed on this form (Cite-All Method or Cite-All Option under the Selective Method). (Also sign the General Offer to Pay below.)

   [ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
ıme and Title (Please Type or Print)	

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	Company Number
Chemical Name	**EPA Chemical Number**

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	