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Reregistration Eligibility Decision

Flumetralin

List D

Case No. 4119

Reregistration Eligibility Decision (RED) Document for Flumetralin

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Glossary of Terms and Abbreviations

ai	Active Ingredient
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
G	Granular Formulation
GLN	Guideline Number
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)

TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Summary

The Environmental Protection Agency (hereafter referred to as "EPA" or "the Agency") has evaluated the risks from the supported uses of flumetralin and has determined that no unreasonable adverse effects will result from exposure to registered flumetralin products. The Agency has determined that the products containing flumetralin are eligible for reregistration provided the risk mitigation measures outlined in this document are adopted and label amendments are made.

Flumetralin is a plant growth regulator that is used to control axillary bud (sucker) growth on tobacco plants. Flumetralin was first registered for use in 1983, and can be applied using hand or ground spray equipment. The current average total annual domestic usage of flumetralin is approximately 60,000 pounds active ingredient (a.i.). There are no registered food or feed uses for flumetralin. There are no registered residential uses for flumetralin.

The Agency conducted a human health risk assessment to address potential exposure risks from all registered sources. There are no registered food or feed uses for flumetralin and thus no food-related dietary risk assessments were conducted. However, since flumetralin products are used outdoors on tobacco crops, there is potential for flumetralin to move to drinking water sources. Thus, a dietary risk assessment was conducted for acute and intermediate-term drinking water exposures only. Acute and intermediate-term risk estimates are below the Agency's level of concern. There are no residential uses for flumetralin. However, residential exposure to flumetralin can occur through the use of tobacco products (i.e., smoking). Since no acute hazard was identified for the tobacco smoking scenario, a residential risk assessment was not needed. Exposure through drinking water is the only exposure route and an aggregate risk assessment for flumetralin was not needed.

The Agency conducted a risk assessment on the occupational uses of flumetralin, including handlers that mix, load, and apply flumetralin in various ways. All occupational handler scenarios assessed for flumetralin have Margins of Exposure (MOEs) above 100 and therefore risk estimates are below the Agency's level of concern. Occupational post-application dermal exposures were not evaluated because there is no dermal hazard for flumetralin from short-term exposure durations. Intermediate- and long-term exposure durations are unlikely due to the current use pattern of one application per season. Potential inhalation exposures are not anticipated for the post-application worker scenarios because of the low vapor pressure of flumetralin.

An ecological effects risk assessment was also conducted for flumetralin. Based on the most sensitive endpoint for each of the taxa evaluated, only RQs for chronic exposure to mammals and acute exposure to terrestrial plants are exceeded. The RQ values for acute effects to listed freshwater fish and chronic effects to mammals and for non-target terrestrial plants exceed the Agency's level of concern for flumetralin. No data are available to assess risk to aquatic nonvascular plants and chronic risk to birds.

No human health risks of concern were identified for flumetralin. The current REI on flumetralin labels is 24 hours. However, based on the toxicity category III assigned to the most recent acceptable primary eye irritation studies, the REI on flumetralin labels may be decreased to 12 hours. Due to a residue chemistry data deficiency, all product labels must be modified to establish a 10-month plantback interval for all crops. If the registrant wants to establish a plantback interval shorter than 10 months, a confined rotational crop study with flumetralin must be conducted.

Due to the high persistence of flumetralin in the environment and to reduce potential exposure to flumetralin, the labeling statements shown in Table 8, the Labeling Changes Summary Table, must be added to the flumetralin labels.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984, and amended again by the Food Quality Protection Act of 1996 (FQPA) and the Pesticide Registration Improvement Act of 2003 (PRIA) to set time frames for the issuance of Reregistration Eligibility Decisions (RED). FIFRA calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all data submitted to the U.S. Environmental Protection Agency. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of a pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

This document presents the EPA's decision regarding the reregistration eligibility of all currently registered uses of flumetralin. The Agency made its reregistration eligibility determination based on the required data, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that current registered uses of flumetralin are eligible for reregistration provided the mitigation and labeling outlined in this RED are implemented. The revised risk assessment documents and related addenda are not included in this document, but are available on the Agency's web page, http://www.epa.gov/pesticides/registration/status, and in the Public Docket under docket number EPA-HQ-OPP-2007-0990.

II. Chemical Overview

A. Regulatory History

There is only one active ingredient in reregistration case 4119 for flumetralin. Only active product registrations containing this active ingredient were evaluated for this RED.

Flumetralin has been registered since 1983 for use only on tobacco. Currently, there are six active registrations in this case. Registrations are held by Syngenta Crop Protection, Inc., Drexel Chemical Co., and SRM Chemical LTD. Co. Each of the three registrants has one technical and one end-use product registration.

B. Chemical Identification

Flumetralin is registered as a plant growth regulator. It is a member of the 2,6-dinitroaniline class of chemicals. The chemical structure and properties of flumetralin are presented in Table 1 and Table 2.

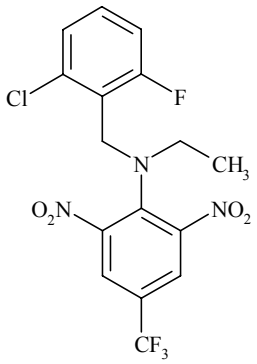
Table 1: Flumetralin Nomenclature	
Chemical structure	
Common name	Flumetralin
Molecular formula	$C_{16}H_{12}ClF_4N_3O_4$
Molecular weight	421.74 mol
PC Code	123001
IUPAC name	N-(2-chloro-6-fluorobenzyl)-N-ethyl-2,6-dinitro-4-(trifluoromethyl)aniline
CAS name	2-chloro-N-[2,6-dinitro-4-(trifluoromethyl)phenyl]-N-ethyl-6-fluorobenzenemethanamine
CAS registry number	62924-70-3

Table 2: Physicochemical Properties of Flumetralin		
Parameter	**Value**	**Reference**
Melting point/range	101-103 °C	Agrochemicals Handbook [1]
pH	Not available	-
Density	Not available	-
Water solubility	0.07 ppm at 20 °C	Pesticide Manual [2]
Solvent solubility	Not available	-
Vapor pressure	0.032 mPa at 25 °C	Pesticide Manual [2]
Dissociation constant, pK_a	Not available	-
Octanol/water partition coefficient, $Log(K_{OW})$	5.45 at 25 °C	Pesticide Manual [2]
UV/visible absorption spectrum	Not available	-

[1] Agrochemicals Handbook, 2nd Edition, RSC, Nottingham, UK 1987 (www.arsusda.gov/acsl/services/ppdb).
[2] Pesticide Manual, 10th Ed., British Crop Protection Council, and The Royal Society Of Chemistry, 1994 (www.arsusda.gov/acsl/services/ppdb).

C. Flumetralin Use Profile

Type of Pesticide: Plant growth regulator.

Summary of Use: Flumetralin is a plant growth regulator used on tobacco for control of axillary bud (sucker) growth. It is used for control of suckers on flue-cured, burley, Maryland, and cigar tobacco plants. Flumetralin is absorbed by the tobacco plant within a few hours after application and provides residual sucker control through the growing season.

Mode of Action: Flumetralin is in the 2,6-dinitroaniline class of chemicals. Dinitroanilines selectively inhibit the microtubules of plants and protozoa and do not act on fungal or vertebrate tubulins.

Formulation Type: Emulsifiable concentrate.

Application Methods: Flumetralin is applied as a hand spray or ground spray.

Application Rates: The currently labeled maximum application rate is 1.2 pounds of active ingredient per acre (lbs. ai/A). Current labels specify a re-entry interval (REI) of 24 hours.

Application Timing: Flumetralin is applied only once per growing season. It is typically applied between 3 and 7 days after the floral portion of tobacco plants have been topped.

Registrants: Syngenta Crop Protection, Inc.; Drexel Chemical Co.; SRM Chemical LTD. Co.

D. Estimated Usage

Based on Agency data, the current average total annual domestic usage of flumetralin is approximately 60,000 pounds active ingredient (a.i.) and the current maximum percent crop treated is 25 percent. Flumetralin is not registered for any other use other than as a plant growth regulator on tobacco.

III. Summary of Flumetralin Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of the human health and environmental risk assessments, and to help the reader better understand the conclusions reached in the assessments. These assessments and supporting documents referenced in Appendix C were used to formulate the safety finding and regulatory decision for the pesticidal use of flumetralin.

While the risk assessments and related addenda are not included in this document, they are available in the OPP Public Docket, docket number EPA-HQ-OPP-2007-0990, and may be accessed through the Agency's website at http://www.regulations.gov/. Hard copies of these documents may also be found in the OPP Public Docket under this same docket number.

- *Flumetralin: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED)* (M. Lloyd, et. al.; 6/21/07, D326449).
- *Environmental Fate and Ecological Risk Assessment in Support of the Reregistration Eligibility Decision for Flumetralin* (Kiernan, B. and Sutton, C., Ph.D.; 7/10/07, D326441).

A. Human Health Risk Assessment

Flumetralin is registered to be applied only to commercial tobacco crops, and it is considered to be a "non-food use" chemical. The human health risk assessment addresses potential exposure risks from all registered sources. Flumetralin exposure to handlers can occur in occupational environments. There are no registered food or feed uses for flumetralin and thus no food-related dietary risk assessments were conducted. However, since flumetralin products are used outdoors on tobacco crops, there is potential for flumetralin to move to drinking water sources. Thus, the risk assessment also considered drinking water exposures. There are no residential uses. Non-occupational exposure to flumetralin can occur through the use of tobacco products (i.e., cigarette smoking). For the complete human health risk assessment, refer to *Flumetralin: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED),* dated June 21, 2007, which is available in the public docket.

1. Toxicity of Flumetralin

The human health risk assessment utilized animal toxicity studies to estimate risk to humans exposed to flumetralin. The toxicological database on flumetralin is considered complete and the available data are sufficient for selecting endpoints for risk assessment.

Flumetralin has a low acute toxicity profile (Toxicity Category III or IV). It is a mild dermal irritant and is a positive dermal sensitizer. A new dermal sensitization study was submitted, but determined to be unacceptable. Table 3 describes the acute toxicity profile of flumetralin.

Table 3: Flumetralin Acute Toxicity Profile				
Guideline No.	**Study Type**	**MRID(s)**	**Results**	**Toxicity Category**
870.1100	Acute oral [rat]	471877-01	LD_{50} > 2000 mg/kg	III
870.1200	Acute dermal [rat]	471877-02	LD_{50} = >2000 mg/kg	III
870.1300	Acute inhalation [rat]	471877-03	LC_{50} = ≥2.22 mg/L	IV
870.2400	Primary eye irritation [rabbit]	471877-04	mildly irritating	III
870.2500	Acute dermal irritation [rabbit]	471877-06	mild irritant	III
870.2600	Skin sensitization [guinea pig]	00094001	positive skin sensitizer	N/A

Subchronic Studies

No systemic toxicity was observed in the 21-day rabbit dermal toxicity study at the limit dose. Dermal irritation was observed at all dose levels (500 mg/kg/day and above). No effects were reported in a rat 6-week smoking inhalation study (inhalation of smoke from cigarettes made of tobacco treated with flumetralin).

In the subchronic oral toxicity study in dogs, clinical signs of toxicity (weight loss, decreased food consumption, fever, dehydration, depression), which were progressive over a period of two to four weeks, occurred in both sexes at the high-dose level, with two dogs of each sex dying during the test (on days 40, 128). One male dog at the mid-dose level also died during the test following longer exposure (day 169).

Developmental Studies

The developmental and reproduction toxicity studies did not indicate an enhanced sensitivity or susceptibility to the young. Developmental/offspring effects occurred at doses higher than or equal to doses eliciting parental toxicity and were of comparable severity.

Developmental toxicity was observed in the rabbit, as evidenced by the increased incidence of litters with total resorption, increased post-implantation loss, increased incidence of external (flexure of forepaw at the wrist) and skeletal alterations (fused sternebrae and absent ossification of the caudal vertebral centers) at 100 and 200 mg/kg/day. In the rat, there was a slight increase in external and skeletal malformations at 400 mg/kg/day. Maternal toxicity occurred at the same doses as developmental toxicity in both species.

Reproductive toxicity was not observed in the rat following exposure to flumetralin. Decreased body weight was observed in the offspring at the high-dose level. In the maternal animal, a slight decrease in body weight was observed during the dosing period and throughout gestation and lactation at both the mid- and high-dose levels (*i.e.,* maternal toxicity was observed at a lower dose than developmental toxicity).

Carcinogenicity and Mutagenicity Studies

In the combined rat oral chronic toxicity/carcinogenicity study, there were no clinical signs of toxicity and no adverse effects on survival. Decreased body weight and body-weight gain were observed in both sexes throughout the study, but there were no consistent effects on food consumption. Increased liver weight and increased incidence of blood and kidney changes were observed.

In the mouse carcinogenicity study, there were no clinical signs of toxicity, and no adverse effects on survival, body weight/gain, food consumption, or hematology parameters. There was an increase in liver weight in both sexes at the two highest dose levels.

Flumetralin did not produce a tumorigenic response in either the rat or mouse carcinogenicity studies. The mutagenicity database is adequate and no mutagenicity was observed in the mutagenicity studies conducted with flumetralin.

Neurotoxicity Studies

There is no acute neurotoxicity study on flumetralin available. No clinical signs indicating neurotoxicity were observed in the chronic toxicity/carcinogenicity study in rats, the developmental toxicity studies in rats and rabbits, the carcinogenicity study in mice, or the 21-day dermal toxicity study in rabbits at the limit dose and twice the limit dose. The decreased motor activity and piloerection in the maternal rabbits that displayed total litter resorption are considered to be the result of high dose toxicity and not a neurotoxic effect.

2. Endpoint Selection

Table 4 summarizes the toxicological doses and endpoints used in the human health risk assessment of flumetralin.

Table 4: Toxicological Doses and Endpoints for Flumetralin for Use in Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty Factors**	**RfD/Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietary – Drinking Water Only (Females 13+)	NOAEL= 50 mg/kg/day	UF_A = 10x UF_H = 10x	aRfD = 0.5 mg/kg/day	**Developmental Toxicity – Rabbit** LOAEL = 100 mg/kg/day; an increased incidence of litters with total resorptions, increased post-implantation loss, and increased incidence of external (positional anomaly) and skeletal (fused sternebrae and absent ossification of the caudal vertebral centers) alterations.
Acute Dietary – Drinking Water Only (General population including infants and children)	Based upon available data, no toxicity is expected to the general population resulting from a single day exposure to flumetralin.			
Intermediate-Term Dietary – Drinking Water Only (All Populations)	NOAEL= 11.6 mg/kg/day	UF_A= 10x UF_H= 10x	LOC = MOE≤ 100	**Subchronic Oral Toxicity - Dog** LOAEL = 92.75 mg/kg/day for clinical signs (weight loss, decreased food consumption, pyrexia, dehydration, and depression), mortality, hematology/ clinical chemistry effects
Chronic Dietary – Drinking Water Only (All populations)	Chronic drinking water exposures are not expected, so a chronic dietary endpoint was not selected.			
Short-/Intermediate-Term Incidental Oral	There are no registered residential uses of flumetralin, thus no exposure is expected.			
Dermal Short - Intermediate-/Long-term	No dermal exposure is expected for this scenario based on current use patterns and no hazard was identified in the route-specific study.			
Acute Inhalation (smoking assessment)	No hazard was identified in the route-specific (smoking inhalation) study.			

Table 4: Toxicological Doses and Endpoints for Flumetralin for Use in Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty Factors**	**RfD/Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Short-Term Inhalation (1 to 30 days)	**oral** NOAEL= 11.6 mg/kg/day *toxicity via inhalation route considered to be equivalent to toxicity via oral route*	UF_A= 10x UF_H= 10x	LOC = MOE≤ 100	**Subchronic Oral Toxicity - Dog** LOAEL = 92.75 mg/kg/day for clinical signs (weight loss, decreased food consumption, pyrexia, dehydration, and depression), mortality, hematology/ clinical chemistry effects
Intermediate-/Long-Term Inhalation	No inhalation exposure is expected for this exposure duration based on current use patterns.			
Cancer (oral, dermal, inhalation)	A cancer risk assessment was not conducted since flumetralin did not produce a tumorigenic response in either the rat or mouse carcinogenicity study and mutagenicity was not observed in the battery of studies performed on flumetralin.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. UF = uncertainty factor, UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies), NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, MOE = margin of exposure, LOC = level of concern, RfD = Reference Dose

3. Dietary Exposure and Risk (Drinking Water Only)

There are no registered food or feed uses for flumetralin; therefore, a food-related dietary risk assessment is not needed and has not been conducted. However, since flumetralin products are used outdoors on tobacco crops, there is a possibility for exposure to flumetralin through drinking water. Considering the use pattern and environmental fate characteristics of flumetralin, the most likely durations for exposure to flumetralin from drinking water (surface water sources) are acute (one-day) and intermediate-term (1-6 months). Ground water estimates were much lower than the estimates from surface water sources, so surface water estimates were used in the drinking water assessment and are protective of all drinking water exposures.

Typically, the Agency uses the reference dose approach for estimating risk from acute and chronic dietary exposures only. Therefore, the Margin of Exposure (MOE) approach was used to assess the risk from the intermediate-term drinking water exposures from flumetralin.

Both approaches incorporate the exposure and toxicity of a pesticide. For acute assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which the Agency has concluded will result in no unreasonable adverse health effects). This dose is referred to as the reference dose (RfD). The RfD is equivalent to

point of departure (POD), in this case a NOAEL, divided by the appropriate uncertainty factors.

For intermediate-term exposures the risk is expressed as a Margin of Exposure (MOE), which is determined by dividing the point of departure by the estimated exposure. The MOE is typically compared to the level of concern (LOC), usually the product of all of the appropriate uncertainty factors, in this case 100.

For acute exposure assessments, individual one-day water consumption data are used on an individual-by-individual basis. The reported consumption amounts can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aRfD.

For intermediate-term dietary exposure assessment, an estimate of the residue level in water is multiplied by the average daily consumption estimate for water to produce a residue intake estimate. The resulting residue intake estimates for indirect and direct sources of water are summed to arrive at the total average estimated exposure. The exposure is expressed in mg/kg body weight/day and is divided by the point of departure for intermediate-term exposures to obtain the margin of exposure (MOE). This procedure is performed for each population subgroup.

The endpoints used in the drinking water assessment are outlined in Table 4.

Acute Drinking Water Only Risk

No hazard was identified for the general population, so an acute assessment was conducted for females aged 13-49, the subpopulation of concern. The acute exposure to flumetralin results in an estimated risk that is <1% of the acute reference dose, and is not of concern.

Intermediate-Term Drinking Water Only Risk

The results of the intermediate-term dietary exposure analysis indicate that the margins of exposure (MOE) for all population groups are greater than 100, the level of concern for this assessment, and therefore are not of concern. The most-highly exposed subgroup is infants less than 1 year old (MOE = 19100).

4. Residential (Non-Occupational) Exposure and Risk

Flumetralin is a plant growth regulator for use only on tobacco in occupational settings, and there are no residential uses of flumetralin. Non-occupational inhalation exposure to flumetralin can occur through the use of tobacco products (e.g. cigarette smoking).

For the acute (smoker) inhalation assessment, the NOAEL endpoint from a 6-week smoking study in rats (inhalation of smoke from cigarettes made of tobacco treated with flumetralin) was considered because the route of exposure is appropriate. No systemic toxicity was observed in the 6 week study at rates much higher than would be expected under normal use conditions. This study is most representative of the residential (smoking) exposure to flumetralin. Since no hazard was identified from the 6 week smoking study, a quantitative residential inhalation assessment is not needed.

The current use pattern and registered uses for flumetralin do not indicate intermediate- or long-term occupational/residential exposure durations. Consequently, intermediate- and long-term risk assessments *via* the inhalation route were not conducted.

5. Aggregate Exposure and Risk

The Agency has not conducted a quantitative or qualitative aggregate assessment for flumetralin. An aggregate exposure assessment considers the different pathways (food, water, occupational, and residential) through which exposure to flumetralin may occur. There are no food exposures to flumetralin, and while residential exposure to flumetralin can occur through the use of tobacco products (i.e., cigarette smoking), no acute hazard was identified in the relevant toxicological studies for a 'smoking' assessment and thus no quantification of risk is required for that exposure scenario. Therefore, exposure through drinking water is the only exposure route possible and an aggregate risk assessment for flumetralin is not needed.

6. Occupational Exposure and Risk

a) Occupational Handler/Application Assessment

Based on current use patterns, flumetralin exposure to occupational handlers can occur. The representative scenarios selected by the Agency for assessment were evaluated using maximum product label rates (i.e., 1.2 lbs ai/A for all occupational scenarios).

To assess the handler risks, the Agency used surrogate unit exposure data from the Pesticide Handlers Exposure Database (PHED). Only short-term (1-30 days) inhalation risks were evaluated because no dermal toxicity was observed in existing studies.

For the short-term inhalation exposure scenario for workers, the endpoint from a 6-month oral toxicity study in dogs was selected based on clinical signs of toxicity which were progressive over the first two to four weeks of exposure prior to death (2 males, one female) on day 40. Based on the current use pattern and registered uses for flumetralin, the EPA does not expect intermediate- or long-term occupational/residential exposures. Consequently, intermediate- and long-term risk assessments *via* the inhalation route were not conducted.

Endpoints selected for the occupational handler assessment are outlined in Table 4.

All occupational handler scenarios have Margins of Exposure (MOEs) above 100 and therefore risk estimates are below the Agency's level of concern. Table 5 presents the MOEs for occupational handler inhalation exposure to flumetralin.

Table 5: Flumetralin Short-term Inhalation MOEs for Agricultural Handlers

Exposure Scenario	Typical Crops	lb ai/acre	Acres per Day	MOE with Base-Line PPE[1]
Mixer/Loader (M/L): (1.2 µg/lb ai inhalation unit exposure)				
M/L Liquids for Groundboom application	tobacco	1.2	80	7,000
Applicator (APP): (0.74 µg/lb ai inhalation unit exposure)				
Groundboom Application	tobacco	1.2	80	11,000
Mixer/Loader/Applicator (M/L/A): (30 µg/lb ai inhalation unit exposure)				
M/L/A Liquids with LP Handwand	tobacco	1.2	1	23,000
M/L/A Liquids with Backpack Sprayer	tobacco	1.2	1	23,000

***All MOEs are greater than 100 and are therefore below EPA's level of concern (MOEs ≥ 100).**

1 – Baseline PPE = shoes + socks, long-sleeve shirt, long pants

b) Occupational Post-application Exposures

Occupational post-application dermal exposures were not evaluated because there is no dermal hazard for flumetralin from short-term exposure durations. Intermediate- and long-term exposure durations are unlikely due to the current use pattern of one application per season. Potential inhalation exposures are not anticipated for the postapplication worker scenarios because of the low vapor pressure of flumetralin (0.032 mPa at 25 °C).

For uses within the scope of the Worker Protection Standard for Agricultural Pesticides (40 CFR 170), a restricted entry interval (REI) is established to minimize exposure to workers that may pose risks of concern. The REI is based on the category assigned to the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient. The current REI for flumetralin is 24 hours. Based on the Toxicity Category III assigned to the most recent acceptable primary eye irritation studies, the REI on flumetralin labels may be decreased to 12 hours.

7. Endocrine Disruption

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) *"may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate."* Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupter Screening Program (EDSP) have been developed and vetted, flumetralin may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

8. Incident Reports

There are 16 incidents involving flumetralin in OPP's Incident Data System (IDS); no other system identified any incident reports involving flumetralin. Most were of mild to moderate severity and involved nausea and vomiting; six incidents involved localized skin irritation (typically a rash) that is consistent with toxicological data suggesting flumetralin is a dermal sensitizer. It is unclear from the available incident data whether proper protective clothing, as required by the label, was worn or whether hospitalization occurred after any of the flumetralin exposures.

B. Environmental Risk Assessment

The Agency conducted an environmental assessment for flumetralin for the purpose of making a reregistration decision. A summary of the environmental risk assessment findings and conclusions is provided below. For more detail on the flumetralin environmental exposure and risk assessment, refer to the *Environmental Fate and Ecological Risk Assessment in Support of the Reregistration Eligibility Decision for Flumetralin*, dated July 10, 2007, which is available in the public docket.

1. Environmental Fate and Transport

Based on K_{oc} values, flumetralin is hardly mobile to immobile (FAO Mobility Classes; K_{oc} range of 24,000-183,000) and is very persistent in aerobic soil, with a half-life of longer than 3 years in one foreign soil. In an anaerobic foreign soil, flumetralin degraded with a half-life of 42 days. Soil metabolism data obtained using U.S. soils were classified as "not acceptable." Flumetralin is stable to hydrolysis. All data submitted to assess photodegradation in water and on soil were classified as "not acceptable," so it is unknown whether that might be a significant potential route of degradation in the environment. Although both of the submitted terrestrial field dissipation studies were classified as "supplemental" for multiple reasons, the available parent concentration data

indicate that persistence and accumulation of the parent compound may be expected in the field. Also, some leaching (to the 15- to 30-cm depth) was observed in one of the two field studies. Submitted bioaccumulation data were also classified as "not acceptable," so the potential for flumetralin to bioaccumulate in aquatic organisms is not well defined.

There is a potential for flumetralin to reach surface water through spray drift or, because it is persistent in surface soils, through runoff either in solution or adsorbed to the soil. However, most soils used to grow tobacco undergo conventional tillage and flumetralin remaining on surface soils may move to subsurface soils where it could be expected to degrade or remain adsorbed to soil.

Based on the results of a terrestrial field dissipation study, in which leaching was observed (to 15-30 cm), flumetralin appears to have some potential to leach to groundwater. However, these results conflict with those of laboratory mobility studies which indicate high levels of adsorption to soil. Any potential to leach may be greater when there is an excessive rainfall or irrigation event, particularly if either of these occurs close to the time of application. Also, because adsorption of flumetralin is highly correlated to organic matter content, there may be a greater potential for leaching in lower organic matter soils, such as those used to grow tobacco.

2. Ecological Exposure and Risk

In ecological risk assessments, the ecological effects characterization describes the types of effects a pesticide can potentially produce in an animal or plant. This characterization is generally based on registrant-submitted studies that describe acute and chronic effects information for various aquatic and terrestrial animals and plants; however, these data may also be supplemented by data reported in ECOTOX or open/public literature sources that have met Agency criteria for acceptability.

Toxicity testing reported in this section does not include all species potentially affected by flumetralin usage. Only a few species for fish, aquatic invertebrates and birds are used to represent all species in the United States. For mammals, toxicity studies are limited to the laboratory rat. Also, neither reptiles nor amphibians are tested. The risk assessment assumes that estimates of risks to avian species are protective of reptilian and terrestrial-phase amphibians. The same assumption is used for fish and aquatic-phase amphibians. Terrestrial plant data are derived from the vegetative vigor and seedling emergence tests, typically on 10 agricultural crop species, and do not account for potential chronic or reproductive effects. Typically, five aquatic plant species are used to represent potential toxicity to all aquatic plant species.

Most of the studies with non-target organisms were conducted with flumetralin technical. A typical end-use product (TEP), Prime+®, was the test material in the terrestrial plant seedling emergence and vegetative vigor studies. These studies provide the effects basis for risk estimation. The acute and chronic toxicity endpoints used in this risk assessment are summarized in Table 7.

Based on available data, ecological risk for most tested species from flumetralin is below the Agency's level of concern. Although flumetralin toxicity is classified as high for fish and invertebrates in laboratory studies, the limited use pattern for this chemical limits exposure, and potential risk. Only 60,000 pounds of flumetralin are used annually; it is applied only to tobacco and only once per year.

a) Terrestrial Organisms

Avian Acute Oral, Dietary and Chronic

The acute oral toxicity of flumetralin to the mallard duck (*Anas platyrhynchos*) and Northern bobwhite quail (*Colinus virginiana*) was assessed in separate single-dose studies with 21-day observation periods. Birds were dosed at 1450 and 2150 mg ai/kg-bw. No mortalities or adverse effects were observed in either study. The NOAEL and LD_{50} are 2150 and >2150 mg ai/kg-bw, respectively. Flumetralin is classified as practically non-toxic to birds on an acute oral exposure basis.

The subacute dietary toxicity of flumetralin to the mallard duck and Northern bobwhite quail was assessed over eight days. Flumetralin was administered to the birds in the diet at mean-measured levels of 225, 560, 1220, 3050 and 4800 mg ai/kg diet. No mortalities or adverse effects were observed in either study. The NOAEC and LC_{50} were 4800 and >4800 mg ai/kg diet, respectively. Flumetralin is classified as practically non-toxic to bobwhite quail and mallard duck on an acute dietary exposure basis.

No studies evaluating the chronic toxicity of flumetralin to birds have been submitted.

Mammalian Acute and Chronic

In an acute limit study on rats (*Rattus norvegicus*; MRID 00093998) reviewed by the Health Effects Division, flumetralin was administered by gavage to five male and five female albino rats. The rats were observed for 15 days, with no mortality. Some nasal bleeding was observed in male rats; no other clinical signs were observed. The acute oral LD_{50} value was >5000 mg ai/kg-bw. Flumetralin is classified as practically nontoxic to rats on an acute oral exposure basis.

In a 2-generation reproduction study (MRID 00149532), flumetralin was administered *via* the diet to groups of 15 male and 30 female CD-Crl:CD (SD)BR rats per group at dose levels of 0, 30, 300, 1000, or 1500 ppm. The premating period of dosing was 15 weeks [F0]/18 weeks [F1]. The F1 parents were bred twice. Mating was accomplished by cohabitating one male with two females for up to 14 days [F0]/21 days [F1]. Although there were several deaths, there was no dose response. All of the control animals survived, but two F0 females at 30 ppm and 1500 ppm, one F0 female at 1000 ppm, one F1 male at 30 ppm and 300 ppm, two F1 males at 1500 ppm, one F1 female at 300 ppm and 1000 ppm, and two F1 females at 1500 ppm died. The only clinical sign noted was an orange coloration of the urine and fat tissue, which was attributed to the test material color (yellow-orange crystals).

The parental toxicity NOAEL is 300 ppm based on a slight decrease in body weight (~10%) during the dosing period and throughout gestation and lactation at 1000 ppm. The offspring systemic toxicity NOAEL is 1000 ppm based on decreased body weight of pups. The reproductive toxicity NOAEL is 1500 ppm, which was the highest dose tested. Chronic effects to mammals are mainly associated with parental weight loss; there were no reproductive effects.

Non-target Invertebrates

In a 48-hour acute contact toxicity study (MRID 41761507), honey bees were exposed to flumetralin, administered topically at the nominal rates of 6.25, 12.5, 25, 50 and 100 µg ai/bee. There was 10% mortality in the 100 µg ai/bee treatment level and 2% in the 25 µg ai/bee treatment level. No abnormal behavior was reported. Based on the 48-hour LC_{50} of >100 µg ai/bee, flumetralin is classified as practically non-toxic to honey bees on an acute contact basis.

Terrestrial Plants

In a 21-day seedling emergence study, a total of four monocotyledonous species (corn (*Zea mays*), oat (*Avena sativa*), onion (*Allium cepa*) and ryegrass (*Lolium* spp.)) and six dicotyledonous species (carrot (*Daucus carota*), cucumber (*Cucumis sativus*), cabbage (*Brassica oleracea*), soybean (*Glycine max*), lettuce (*Lactuca sativa*) and tomato (*Lycopersicon esculentum*)) were exposed to a single application of the TEP, Prime+® at rates from 0.019 lbs ai/A to 1.2 lbs ai/A. A continuation study was conducted, at rates as low as 0.0003 lbs ai/A. There was no effect on emergence or survival in any species except rye grass, the most sensitive species in the study. Plant height was unaffected in soybean, carrot and corn; biomass was unaffected in soybean, carrot, corn, oat cabbage and onion. The most sensitive species is ryegrass with an EC_{25} of 0.006 lbs ai/A and the NOEC is 0.0048 lbs ai/A, based on plant height. The most sensitive dicot was tomato, based on biomass, with an EC_{25} of 0.039 lbs ai/A and a NOEC of 0.019 lbs ai/A.

A vegetative vigor study was conducted using the same rates and species as the seedling emergence study. There was no effect on the plant height of carrot and corn, and no effect on the biomass of carrot, oat, corn and onion. The most sensitive dicot, based on plant height, was tomato with an EC_{25} of 0.014 lbs ai/A and a NOEC of 0.0048 lbs ai/A. The most sensitive monocot species (based on biomass) was ryegrass, with an EC_{25} of 0.027 lbs ai/A and a NOEC of 0.019 lbs ai/A.

b) Aquatic Organisms

Freshwater Fish

In a 96-hour acute toxicity study (MRID 43456601), bluegill sunfish (*Lepomis macrochirus*) were exposed to flumetralin at mean-measured concentrations of 6.0, 7.8, 18, 33 and 58 µg ai/L. No mortality was observed in the two lowest concentrations;

mortalities of 15, 95 and 100% were observed in the 18, 33 and 58 µg ai/L concentrations, respectively. Sublethal effects (loss of equilibrium, erratic swimming behavior) were observed in the range-finding study at concentrations as low as 13 µg ai/L; sublethal effects were not reported at the lowest concentration in the definitive study. The 96-h LC_{50} and NOAEC values, based on mortality, were 23 and 7.8 µg ai/L, respectively. Flumetralin is classified as very highly toxic to freshwater fish on an acute exposure basis.

The chronic toxicity of flumetralin to fathead minnow (*Pimephales promelas*; MRID 00116598) was assessed in a 38-day study, conducted under flow-through conditions. The fish were exposed to the mean-measured concentrations of 0.46, 0.77, 2.4, 3.8, and 20 µg ai/L. Percent hatch was unaffected (>77%) at all treatment concentrations. Survival was significantly reduced at the 3.8 and 20 µg ai/L concentrations (20% and 0% survival, respectively). Both mean length and mean wet weight were significantly reduced at the 2.4 and 3.8 µg ai/L treatment concentrations (there were no surviving fish to measure in the highest test concentration). The 38-day NOAEC, based on length and weight, was 0.77 µg ai/L.

Although flumetralin exhibits both acute and chronic toxicity to freshwater fish in laboratory studies, environmental exposure is limited and thus risk quotients are below the level of concern, except for listed species.

Freshwater Invertebrates

An acute 48-hour static toxicity study was conducted to determine the effects of flumetralin on daphnids (*Daphnia magna*; MRID 43456602). The mean-measured test concentrations were 33, 47, 69, 100 and 160 µg ai/L. At 48 hours, there was 10, 15 and 5% immobilization observed in the 69, 100 and 160 µg ai/L concentrations, respectively. Therefore, the 48-h EC_{50} value was >160 µg ai/L and the 48-h NOAEC was 33 µg ai/L. Flumetralin is classified as very highly toxic to daphnids on an acute exposure basis.

A chronic 21-day (life-cycle) flow-through toxicity study (MRID 00116600) was conducted to determine the effects of flumetralin on daphnids. The nominal test concentrations were 0.63, 0.91, 2.1, 3.8 and 8.8 µg ai/L, to which first instars were exposed. There were no effects on growth, survival or reproduction reported at any test concentration. The 21-day NOAEC was 8.8 µg ai/L.

Although flumetralin exhibits acute toxicity to freshwater invertebrates in laboratory studies, environmental exposure is limited and thus risk quotients are below the level of concern.

Estuarine/Marine Fish

In an acute flow-through toxicity study, sheepshead minnow (*Cyprinodon variegatus*; MRID 43456603) were exposed to flumetralin at mean measured concentrations of 40, 51, 80, 140 and 250 µg ai/L; mortality was reported at all concentrations (5, 25, 10, 5 and

5%, respectively). Surviving fish were reported to exhibit loss of equilibrium at all concentrations. Therefore, the 96-hour LC_{50} and NOAEC values were >250 and <40 µg ai/L, respectively. Flumetralin is classified as highly toxic to estuarine/marine fish on an acute exposure basis.

No data are available to evaluate chronic effects to estuarine/marine fish.

Although flumetralin exhibits acute toxicity to estuarine/marine fish in laboratory studies, environmental exposure is limited and thus risk quotients are below the level of concern.

Estuarine/Marine Invertebrates

A 96-hour acute toxicity study was conducted under flow-through conditions to determine the effect of flumetralin on mysid shrimp (*Mysidopsis bahia*; MRID 43456605). The shrimp were exposed to mean measured concentrations of 33, 34, 58, 71 and 180 µg ai/L. Immobilization was 35 and 95% and in the two highest concentrations respectively. Erratic swimming was observed at concentrations as low as 34 µg ai/L (although no effect was reported in the 33 µg ai/L concentration). The 96-hour EC_{50} and NOAEC were 93 and 33 µg ai/L, respectively. Flumetralin is classified as very highly toxic to the mysid shrimp on an acute exposure basis.

A 96-hour acute toxicity study was conducted under flow-through conditions to determine the effect of flumetralin on Eastern oysters (*Crassostrea virginica*; MRID 43456604). The oysters were exposed to mean measured concentrations of 7.1, 18, 45, 180 and 550 µg ai/L. No mortality was observed at any concentration tested, but shell deposition was significantly reduced at the highest test concentration (28%). The 96-hour EC_{50} and NOAEC were reported as 600 and 100 µg ai/L, respectively. Flumetralin is classified as highly toxic to the Eastern oyster on an acute exposure basis.

No data are available to evaluate chronic effects to estuarine/marine invertebrates.

Although flumetralin exhibits acute toxicity to estuarine/marine invertebrates in laboratory studies, environmental exposure is limited and thus risk quotients are below the level of concern.

Aquatic Plants

In a 14-day static toxicity test, duckweed (*Lemna gibba*; MRID 434566-06) was exposed to flumetralin at initial measured concentrations of 8.2, 16, 30, 60, 71, 130 and 220 µg ai/L. After 14 days, inhibition of frond production ranged from 4.5% at 8.2 µg ai/L to 59% at 220 µg ai/L when compared to the solvent control. Inhibition in biomass ranged from 7% to 35% at the highest dose. The NOEC and EC_{50} values, based on frond production, are 16 and 160 µg ai/L, respectively.

No studies are available to evaluate the effect of flumetralin on nonvascular aquatic plants.

Table 6 lists the most sensitive endpoints used in the flumetralin risk assessment.

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Table 6: The Most Sensitive Endpoints Used in the Flumetralin Risk Assessment						
Environment	**Taxa**	**Type of Risk**	**Type of Endpoint**	**Endpoint**	**Units**	**MRID**
Aquatic	Freshwater Fish	Acute	LC_{50}	23	µg ai/L	434566-01
		Chronic	NOAEC	0.77	µg ai/L	001165-98
	Freshwater Invertebrates	Acute	EC_{50}	>160	µg ai/L	434566-02
		Chronic	NOAEC	>8.8	µg ai/L	001166-00
	Estuarine/Marine Fish	Acute	LC_{50}	>250	µg ai/L	434566-03
		Chronic	NOAEC	No data		
	Estuarine/Marine Invertebrates	Acute	EC_{50}	93	µg ai/L	434566-05
		Chronic	NOAEC	No data		
	Plants	Acute	EC_{50}	160	µg ai/L	434566-06
		Listed	NOAEC	16	µg ai/L	434566-06
Terrestrial	Avian	Acute	LD_{50}	2150	mg ai/kg-bw	000940-16
		Chronic	NOAEC	No Data	mg ai/kg-diet	
	Mammalian	Acute	LD_{50}	>5000	mg ai/kg-bw	000939-98
		Chronic	NOAEC	300	mg ai/kg-diet	001495-32
	Plants	Acute	EC_{25}	0.006	lb ai/A	418470-01
		Listed	NOAEC	0.0048	lb ai/A	418470-01

c) Risk Characterization

The risk quotient (RQ) approach is used in this assessment to reach conclusions regarding the potential for adverse effects associated with the proposed use of flumetralin. The basis of the RQ approach is a comparison of the ratio of exposure concentrations to effects endpoints with predetermined levels of concern (LOCs). Specifically, estimated environmental concentrations (EECs) are divided by acute and chronic toxicity values to calculate RQs. If the RQs exceed the LOCs, the Agency presumes there is a potential to affect species in that taxa. Laboratory environmental fate, laboratory ecological effects, and use data provide the basis for these risk quotients and have been discussed previously in the assessment. Although risk is often defined as the likelihood and magnitude of adverse ecological effects, the risk quotient-based approach does not provide a quantitative estimate of likelihood and/or magnitude of an adverse effect. These LOCs are indicators of whether a pesticide, used as directed on the label, has the potential to cause adverse effects on non-target organisms.

Based on the most sensitive endpoint for each of the taxa evaluated, the RQ values for acute effects to listed freshwater fish and chronic effects to mammals and for non-target terrestrial plants exceed the LOC for flumetralin. No data are available to assess the risk to aquatic nonvascular plants and chronic risk to birds.

A summary of RQs is presented in Table 7.

Table 7: The Highest RQs for Listed Taxa in the Flumetralin Risk Assessment

Environment	Taxa	Type of Risk	Type of Endpoint	Endpoint	Units	RQ
Aquatic	Freshwater Fish	Acute	LC_{50}	23	µg ai/L	0.10
		Chronic	NOAEC	0.77	µg ai/L	0.43
	Freshwater Invertebrates	Acute	EC_{50}	160	µg ai/L	<0.01
		Chronic	NOAEC	8.8	µg ai/L	<0.05
	Vascular Plants	Acute	EC_{50}	160	µg ai/L	0.00001
		Listed	NOAEC	16	µg ai/L	0.000001
Terrestrial	Avian	Acute	LD_{50}	2150	mg ai/kg-bw	No effects
		Chronic	NOAEC	No Data	mg ai/kg-diet	No data
	Mammalian	Acute	LD_{50}	>5000	mg ai/kg-bw	No effects
		Chronic	NOAEC	300	mg ai/kg-diet	6.0
	Plants	Acute	EC_{25}	0.006	lb ai/A	22
		Listed	NOAEC	0.0048	lb ai/A	27.5

The Agency has considered the ecological risks associated with the use of flumetralin. Based on the EPA's baseline assessment and taking into account its limited use pattern, the use of flumetralin according to label directions should not result in direct acute or chronic effects to fish, aquatic invertebrates or aquatic vascular plants. The LOC for direct acute effect to listed freshwater fish (and aquatic-phase amphibians) is exceeded. Although there are no data regarding the chronic effects to estuarine/marine animals, acute-to-chronic ratio analysis suggests potential risk to these organisms will be low. Risk is presumed for aquatic nonvascular plants in the absence of data. The potential for acute risk to birds and mammals appears to be low. There is potential for chronic risk to mammals, and chronic risk to birds, terrestrial-phase amphibians and reptiles is presumed in the absence of avian chronic toxicity data. Indirect effects to terrestrial or aquatic wildlife cannot be ruled out due to the potential for flumetralin to affect terrestrial and semi-aquatic plants which may lead to changes in food supply or habitat.

d) Endangered Species

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data and considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. When conducted, these analyses take into consideration any regulatory changes

recommended in this RED being implemented at that time.

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by the pesticide. Rather, this assessment serves as a screen to determine the need for any species-specific assessment that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. The species-specific assessment refines the screening-level assessment to take into account information such as the geographic area of pesticide use in relation to the listed species and the habits and habitat requirements of the listed species. If the Agency's specific assessments for flumetralin result in the need to modify use of the pesticide, any geographically specific changes to the pesticide's registration will be implemented through the process described in the Agency's *Federal Register* Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

IV. Risk Management and Reregistration Decision

The Agency has determined that flumetralin is eligible for reregistration provided that the risk mitigation measures and label amendments specified in this RED are implemented. The following is a summary of the rationale for managing risks associated with the use flumetralin.

A. Human Health Risks

No human health risks of concern were identified for flumetralin.

The current REI on flumetralin labels is 24 hours. Based on the toxicity category III assigned to the most recent acceptable primary eye irritation studies, the REI on flumetralin labels may be decreased to 12 hours.

Due to a residue chemistry data deficiency, all product labels must be modified to establish a 10-month plantback interval for all crops. If the registrant wants to establish a plantback interval shorter than 10 months, a confined rotational crop study with flumetralin must be conducted.

B. Ecological Risks

Due to the high persistence of flumetralin in the environment and to reduce potential ecological exposure to flumetralin, the following statements must be added to the flumetralin label:

The following statements must be added to the "Environmental Hazards" statements on the label:

- "The product is toxic to fish and aquatic invertebrates. Do not apply to water, or to areas where surface water is present, or to areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or

rinsate. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas."

- "This product has a potential for runoff for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product. A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams and springs will reduce the potential for contamination of water from runoff. In order to reduce runoff of this product it is recommended that applications are not made within 48 hours of a predicted rainfall event. Sound erosion control practices will reduce this product's contribution to surface water contamination."

The following statements must be added to the "Spray Drift" statements on the label:

- "Non-target terrestrial plants can be adversely affected when exposed to this product. Avoid spray drift to non-target terrestrial plants during application.
- Do not apply this product if the wind direction does not favor on-target deposition. "
- "Must not be applied greater than 4 feet above crop or crop canopy."

Also, the current requirement for a "coarse" spray must be maintained on all flumetralin labels.

V. What Registrants Need to Do

The Agency has determined that products containing flumetralin (PC 123001) are eligible for reregistration provided that the risk mitigation measures identified in this document are adopted and label amendments are made to reflect these measures. Additional data are required to fill data gaps identified and to confirm this decision. The Agency intends to issue Data Call-In Notices (DCIs) requiring product specific data and generic (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product specific data, the registrant will have 8 months to submit data and amend labels. For generic data, due dates can vary depending on the specific studies being required.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of flumetralin has been reviewed. The risk assessments identified the potential need for certain ecological, environmental fate, and residue chemistry data. The studies are as follows:

- Direct Photolysis Rate of Parent and Degradates in Water
- Photodegradation of Parents and Degradates in Soil

- Aerobic Aquatic Metabolism
- Anaerobic Aquatic Metabolism
- Terrestrial Field Dissipation
- Fish BCF
- Whole Sediment Acute Toxicity Invertebrates, Freshwater
- Avian Reproduction Test
- Aquatic Plant Toxicity Test Using *Lemmna sp*p. Tiers I and II
- Aquatic Plants Field Study, Tier III
- Confined Accumulation in Rotational Crops

However, the Agency may be refining these data requirements based on the limited annual usage and use pattern for this chemical.

2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. In order to be eligible for reregistration, the technical registrants also must amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The technical and MP labeling should also bear the labeling statements contained in Table 8, the Label Changes Summary Table.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g) (2) (B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding a pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrations Response Form provided for each product.

A product-specific data call-in, outlining specific data requirements will be issued in the near future.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 8, the Label Changes Summary Table.

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 8: Summary of Labeling Changes for Flumetralin		
Description	**Amended Labeling Language**	**Placement on Label**
For all Manufacturing Use Products	"Only for formulation into a plant growth regulator for use on tobacco."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements

End Use Products Intended for Occupational Use		
PPE Requirements Established by the RED[1] For Liquid Formulations	"Personal Protective Equipment (PPE)" "All mixers, loaders, applications and other handlers must wear: - Long sleeved shirt, - Long pants, - Shoes plus socks."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

Environmental Hazards	"The product is toxic to fish and aquatic invertebrates. Do not apply to water, or to areas where surface water is present, or to areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas." "This product has a potential for runoff for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product. A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams and springs will reduce the potential for contamination of water from runoff. In order to reduce runoff of this product it is recommended that applications are not made within 48 hours of a predicted rainfall event. Sound erosion control practices will reduce this product's contribution to surface water contamination."	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for Agricultural Pesticides (WPS)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.	Directions for Use, Under Agricultural Use Requirements Box
Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: * coveralls, * shoes plus socks * chemical-resistant gloves made of any waterproof material."	Direction for Use Agricultural Use Requirements box

General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Direction for Use directly above the Agricultural Use Box.
Spray Drift	"**SPRAY DRIFT MANAGEMENT**" "Non-target terrestrial plants can be adversely affected when exposed to this product. Avoid spray drift to non-target terrestrial plants during application. Do not apply this product if the wind direction does not favor on-target deposition. " "Must not be applied greater than 4 feet above crop or crop canopy."	Directions for Use
Additional Application Restrictions	All product labels must be modified to establish a 10-month plantback interval for all crops other than tobacco.	Directions for Use

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

[2] If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped.

I. APPENDIX A. USE PATTERNS SUBJECT TO REREGISTRATION OF FLUMETRALIN (PC CODE 123001)

Use Site	Application Timing	Maximum Application Rate	Formulation[2]	Maximum Number of Applications per Year	Minimum Application Interval	Application Equipment /Type
TERRESTRIAL NON-FOOD USES						
tobacco crops	typically applied between 3 and 7 days after the floral portion of tobacco plants have been topped	1.2 lb. a.i./acre	emulsifiable concentrate	1	NA	hand spray or ground spray (groundboom, LP handwand, and backpack sprayer)

II. APPENDIX B. TABLE OF GENERIC DATA REQUIREMENTS AND STUDIES USED TO MAKE THE REREGISTRATION DECISION

GUIDE TO APPENDIX B

Appendix B contains a listing of data requirements which support the reregistration for active ingredients within the flumetralin case covered by this RED. It contains generic data requirements that apply flumetralin in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which is 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 is no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

Data Supporting Guideline Requirements for the Reregistration of Flumetralin			
New Guideline Number	**Study Description**	**Use Pattern**	**Citation(s)**
TOXICOLOGY			
PRODUCT CHEMISTRY			
830.6302	Color	All	Data Gap
830.6304	Physical state	All	Data Gap
830.6313	Stability	All	Data Gap
830.6314	Oxidation/Reduction Potential	All	Data Gap
830.7000	pH	All	Data Gap
830.7200	Melting Point	All	Agrochemicals Handbook, 2nd Edition, RSC, Nottingham, UK 1987 (www.arsusda.gov/acsl/services/ppdb).
830.7300	Density	All	Data Gap
830.7370	Dissociation Constants in Water	All	Data Gap
830.7550	Octanol Water Partition Coefficient	All	Pesticide Manual, 10th Ed., British Crop Protection Council, and The Royal Society Of Chemistry, 1994 (www.arsusda.gov/acsl/services/ppdb).
830.7840	Solubility	All	Pesticide Manual, 10th Ed., British Crop Protection Council, and The Royal Society Of Chemistry, 1994 (www.arsusda.gov/acsl/services/ppdb).
830.7950	Vapor Pressure	All	Pesticide Manual, 10th Ed., British Crop Protection Council, and The Royal Society Of Chemistry, 1994 (www.arsusda.gov/acsl/services/ppdb).
ECOLOGICAL EFFECTS			

Data Supporting Guideline Requirements for the Reregistration of Flumetralin			
New Guideline Number	**Study Description**	**Use Pattern**	**Citation(s)**
850.1010	Freshwater Aquatic Invertebrate Acute Toxicity – Daphnid	All	43456602
850.1025	Estuarine/Marine Invertebrate Acute Toxicity – Oyster	All	43456604
850.1035	Estuarine/Marine Invertebrate Acute Toxicity – Mysid	All	43456605
850.1075	Freshwater Fish Acute Toxicity – Bluegill Sunfish	All	43456601
850.1075	Estuarine/Marine Fish Acute Toxicity – Sheepshead Minnow	All	43456603
Non-Guideline	Freshwater Aquatic Invertebrate Chronic Toxicity – Daphnid	All	00116600
850.1350	Estuarine/Marine Invertebrate Chronic Toxicity	All	Data Gap
850.1400	Freshwater Fish Chronic Toxicity – Fathead Minnow	All	00116598
850.1500	Estuarine/Marine Fish Chronic Toxicity	All	Data Gap
850.2100	Avian Acute Oral Toxicity	All	00094016
850.2200	Avian Dietary Toxicity	All	Data Gap
850.2300	Avian Reproduction	All	Data Gap
850.3020	Honey Bee Acute Contact Toxicity	All	41761507
850.4225	Seedling Emergence, Tier II	All	41847001
850.4250	Vegetative Vigor, Tier II	All	41847001
850.4400	Aquatic Plant Toxicity Test, Tiers I and II – Lemna gibba	All	Data Gap

Data Supporting Guideline Requirements for the Reregistration of Flumetralin			
New Guideline Number	**Study Description**	**Use Pattern**	**Citation(s)**
850.4450	Aquatic Plants Field Toxicity, Tier III	All	Data Gap
850.5400	Algal Plant Toxicity, Tiers I and II	All	Data Gap
TOXICOLOGY			
870.1100	Acute Oral Toxicity – Rat	All	00093998
870.1200	Acute Dermal Toxicity – Rabbit	All	00093999
870.1300	Acute Inhalation Toxicity – Rat	All	00094002
870.2400	Primary Eye Irritation – Rabbit	All	00094000
870.2500	Primary Dermal Irritation – Rabbit	All	00104250
870.2600	Skin Sensitization – Guinea Pig	All	00094001
870.3100	Subchronic Oral Toxicity: 90-Day Study Rodent	All	00094013
870.3150	Subchronic Oral Toxicity – Nonrodent	All	00094012
870.3200	21/28-Day Dermal Toxicity – Rabbit	All	00116594
870.3465	90-Day Inhalation Toxicity (Fischer 344 rat) – Non-Guideline Smoking Study	All	00117622
870.3700A	Developmental Toxicity – Rat	All	00094011
870.3700B	Developmental Toxicity – Rabbit	All	43862801
870.3800	Reproduction and Fertility Effects (CD-Crl:CD (SD)BR rats)	All	00149532, 00145793

Data Supporting Guideline Requirements for the Reregistration of Flumetralin			
New Guideline Number	**Study Description**	**Use Pattern**	**Citation(s)**
870.4100a	Chronic toxicity (SD Rat)	All	42061603, 42061604
870.4200	Carcinogenicity (Rat)	All	42061603, 42061604
870.4300	Carcinogenicity (Mouse)	All	42061601, 42061602
870.5265	Gene Mutation – Ames Assay	All	00094009
870.5385	Micronucleus Assay (Mouse)	All	00094010
870.5550	Other Effects – Rat Hepatocyte/DNA Repair Test - UDS	All	42061605
ENVIRONMENTAL FATE			
835.1240	Leaching/Adsorption/Desorption	All	Data Gap
835.2120	Hydrolysis	All	41761508
835.2240	Direct Photolysis Rate of Parent and Degradates in Water	All	Data Gap
835.2410	Photodegradation of Parent and Degradates in Soil	All	Data Gap
835.4100	Aerobic Soil Metabolism	All	42566201a (supplemental – from foreign soil; no U.S. data available)
835.4200	Anaerobic Soil Metabolism	All	42566201b (supplemental – from foreign soil; no U.S. data available)
835.4300	Aerobic Aquatic Metabolism Half-life (days)	All	Data Gap
835.4400	Anaerobic Aquatic Metabolism Half-life (days)	All	Data Gap
835.6100	Terrestrial Field Dissipation	All	Data Gap
850.1730	Fish BCF	All	Data Gap
RESIDUE CHEMISTRY			

Data Supporting Guideline Requirements for the Reregistration of Flumetralin			
New Guideline Number	**Study Description**	**Use Pattern**	**Citation(s)**
860.1850	Confined Rotational Crops	All	Data Gap

III. APPENDIX C. TECHNICAL SUPPORT DOCUMENTS

Additional documentation in support of this RED is maintained in the OPP docket EPA-HQ-OPP-2007-0990. This docket may be accessed in the OPP docket room located at Room S-4900, One Potomac Yard, 2777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m. All documents may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.regulations.gov.

These documents include:

HED Documents:

Flumetralin: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED). Dated June 21, 2007.

Flumetralin: Addendum to HED Chapter of the Reregistration Eligibility Decision Document (RED). Dated September 20, 2007.

Flumetralin: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision. Dated March 28, 2007.

Flumetralin. Residue Chemistry Chapter of the Reregistration Eligibility Decision Document. Dated April 2, 2007.

Flumetralin Acute and Intermediate Term Dietary (Drinking Water Only) Exposure and Risk Assessments for the Reregistration Eligibility Decision. Dated June 21, 2007.

EFED Documents:

Environmental Fate and Ecological Risk Assessment in Support of the Reregistration Eligibility Decision for Flumetralin. Dated July 10, 2007.

EFED Response to Error Only Comments and the Revised Environmental Fate and Ecological Risk Assessment in Support of the Reregistration Eligibility Decision of Flumetralin. Dated September 13, 2007.

Tier II Drinking water Assessment for the Flumetralin Reregistration Eligibility Decision. Dated June 5, 2007.

IV. APPENDIX D. CITATIONS CONSIDERED TO BE PART OF THE DATA BASE SUPPORTING THE REREGISTRATION ELIGIBILITY DECISION

00093998 Reagan, E.L.; Becci, P.J.; Parent, R.A. (1981) Acute Oral Toxicity in Rats: (CGA-41065 Technical): FDRL Study No. 6818A. (Unpub- lished study received Jan 28, 1982 under 100-EX-72; prepared by Food and Drug Research Laboratories, Inc., submitted by Ciba- Geigy Corp., Greensboro, NC; CDL:246679-B)

00093999 Becci, P.J.; Siglin, J.C.; Parent, R.A. (1981) Acute Dermal Toxicity Study in Rabbits: (CGA 41065 Technical): FDRL Study No. 6818A. (Unpublished study received Jan 28, 1982 under 100-EX- 72; prepared by Food and Drug Research Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:246679-C)

00094000 Siglin, J.C.; Becci, P.J.; Parent, R.A. (1981) Primary Eye Irrita- tion Study in Rabbits: FDRL Study No. 6818IA^. (Unpublished study received Jan 28, 1982 under 100-EX-72; prepared by Food and Drug Research Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:246679-E)

00094001 Siglin, J.C.; Becci, P.J.; Parent, R.A. (1981) Guinea Pig Sensitization Study: Modified Buehler Test for Ciba-Geigy Corporation Product CGA-41065 Technical; 96.4%; FL 810009: FDRL Study No. 6963B. (Unpublished study received Jan 28, 1982 under 100- EX-72; prepared by Food and Drug Research Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:246679-F)

00094002 Morgan, J.M.; Horath, L.L.; Sabaitis, C.P.; et al. (1981) Four- hour Acute Aerosol Inhalation Toxicity Study in Rats of CGA- 41065 Technical in Acetone: Study No. 420-0703. (Unpublished study received Jan 28, 1982 under 100-EX-72; prepared by Whit- taker Corp., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:246679-G)

00094009 Godek, E.G.; Naismith, R.W.; Matthews, R.J. (1981) Ames Salmon- ella/Microsome Plate Test: Study Nos. PH 301-CG-001-81 and PH 301-CG-001-81A. (Unpublished study received Jan 28, 1982 under 100-EX-72; prepared by Pharmakon Research International, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 246679-N)

00094010 Sorg, R.M.; Naismith, R.W.; Matthews, R.J. (1981) Genetic Toxicol- ogy: Micronucleus Test (MNT): PH 309A-CG-001-81. (Unpublished study received Jan 28, 1982 under 100-EX-72; prepared by Phar- makon Research International, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:246679-O)

00094011 Harris, S.B.; Holson, J.F.; Fite, K.R.; et al. (1981) A Teratol- ogy Study of CGA-41065 Technical in Albino Rats: CGA/SAI 281004. Final rept. (Unpublished study received Jan 28, 1982 under 100- EX-72; prepared by Science Applications, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:246680-A)

00094012 Beck, L.S.; DeWard, J.; Kitchen, D.N.; et al. (1981) Six Month Sub- chronic Oral Toxicity Study with CGA-41065 Technical in Beagle Dogs: Project No. 1628. (Unpublished study received Jan 28, 1982 under 100-EX-72; prepared by Elars Bioresearch Labora- tories, Inc. and Westpath Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:246682-A)

00094013 Hamada, N. (1981) Three-month Oral Toxicity Study in Rats: CGA- 41065 Technical: LBI Project No. 22102. Final rept. (Unpub- lished study received Jan 28, 1982 under 100-EX-72; prepared by Litton Bionetics, Inc., submitted by Ciba-Geigy Corp., Greens- boro, N.C.; CDL:246680-B; 246681)

00094016 Fletcher, D.W. (1981) Report to Ciba Geigy Corporation, Agricul- tural Division: Acute Oral Toxicity Study with CGA-41065, Tech- nical in Bobwhite Quail: BLAL No. 81QD3. (Unpublished study received Jan 28, 1982 under 100-EX-72; prepared by Bio-Life Associates, Ltd., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:246683-C)

00094038 Collins, P.F.; Tabor, D.G.; Williams, S.C.; et al. (1982) Uptake, Balance and Characterization of (NO2)2-Phenyl-14C-CGA-41065, Halo-Phenyl-14C-CGA-41065 and Metabolites in Greenhouse Grown Bright Tobacco, and the Balance and Characterization of Their Radioactive Cigarette Smoke Products: M1-52-2P, 25: M1-52-4P, 45: Report No. ABR-81056. (Unpublished study received Jan 28, 1982 under 100-EX-72; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:246686-G)

00094039 Collins, P.F.; Tabor, D.G.; Williams, S.C.; et al. (1982) Uptake, Balance and Characterization of a 1:1 Mixture of (NO2)2-Phenyl-14C-CGA-41065 and Halo-Phenyl-14C-CGA-4106 in Field Grown Bright Tobacco and the Balance for Cigarette Smoke Products of This Tobacco: M1-52-6P, 6S: Report No. ABR-81057. (Unpublished study received Jan 28, 1982 under 100-EX-72; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:246686-H)

00094040 Collins, P.F.; Tabor, D.G.; Williams, S.C.; et al. (1982) Uptake, Balance and Characterization of Halo-Phenyl-14C-CGA-4106 in Field Grown Bright Tobacco: M1-52-7P, 75: Report No. ABR-81060. (Unpublished study received Jan 28, 1982 under 100-EX-72; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 246686-I)

00104250 Siglin, J.C.; Becci, P.J.; Parent, R.A. (1981) Primary Skin Irri- tation in Rabbits: FDRL Study No. 6818IA^. (Unpublished study received Jan 28, 1982 under 100-EX-72; prepared by Food and Drug Research Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:246679-D)

00116592 Ciba-Geigy Corp. (1982) CGA-41065--Tobacco: Report No. ABR-82059. (Compilation; unpublished study received Oct 4, 1982 under 100-640; CDL:248443-A)

00116594 Larson, E.; Matthews, R.; Naismith, R.; et al. (1982) 21 Day Dermal Toxicity Study in Rabbits: CGA-41065: Study No. PH 430-CG-001- 81. (Unpublished study received Oct 4, 1982 under 100-640; prepared by Pharmakon Research International, Inc., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:248444-B)

00116598 Forbis, A.; Franklin, L.; Boudreau, P.; et al. (1982) Early Life Stage Toxicity of CGA-41065 to Fathead Minnows (Pimephales promelas, Rafinesque) in a Flow-through System: Report #29218. Final rept. (Unpublished study received Oct 4, 1982 under 100- 640; prepared by Analytical Bio-Chemistry Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:248445-B)

00116600 Forbis, A.; Boudreau, P.; Franklin, L.; et al. (1982) Chronic Toxicity of CGA-41065 to Daphnia magna under Flow-through Test Conditions: ABC #28969. Final rept. (Unpublished study re- ceived Oct 4, 1982 under 100-640; prepared by Analytical Bio- Chemistry Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:248446-B)

00117622 Coate, W.; Fieser, S.; Hardy, R.; et al. (1982) Subacute Inhalation Study in Rats: CGA-41065 Treated Cigarettes: Project No. 483- 216. Final rept. (Unpublished study received Nov 3, 1982 under 100-640; prepared by Hazleton Laboratories America, Inc., sub- mitted by Ciba-Geigy Corp., Greensboro, NC; CDL:248737-C)

00145793 Science Applications, Inc. (19??) [Two-generation Reproduction Study with CGA-41065 Technical in Albino Rats]: Addendum: Report No. CGA/SAI 281023. Unpublished study. 24 p.

00149532 Holson, J. (1985) Two Generation Reproduction Study of CGA-41065 Technical in Albino Rats Volume I and II: CGA/SAI 281023. Un- published study prepared by Science Applications, Inc. 587 p.

41670501 Collins, P. (1990) Uptake, Balance and Characterization of (NO2)2-phenyl-[carbon 14]-CGA-41065 and Halo-phenyl-[carbon 14]-CGA-41065 in Greenhouse Bright Tobacco from Treated Soil and Their Fate in Soil: Flumetralin: Lab Project Number: ABR/82042. Unpublished study prepared by CIBA-GEIGY Corp. 20 p.

41670502 Williams, S. (1990) Uptake, Balance and Characterization of (NO2)2-phenyl-[carbon 14]-CGA-41065 and Halo-phenyl-[carbon 14]-CGA-41065 in Greenhouse Rotational Winter wheat, Soybeans, Carrots, Lettuce, and Corn: Lab Project Number: ABR/82047. Unpublished study prepared by CIBA GEIGY Corp. 22 p.

41761507 Kirkland, R. (1991) CGA-41065 Technical: Acute Contact Toxicity of CGA-41065 to Honey Bees (Apis Mellifera L.): Lab Project Number: CAR 198-90. Unpublished study prepared by California Agricultu- ral Research, Inc. 32 p.

41761508 Pluecken, U. (1991) CGA-41065: Hydrolysis of CGA-41065 (CGA-254567) under Laboratory Conditions: Lab Project Number: 51/90: 90UP02. Unpublished study prepared by Ciba-Geigy Corp. 42 p.

41761509 Schaffer, A. (1991) CGA-41065: Aqueous Photolysis of CGA-41065 (CGA -254567) under Laboratory Conditions: Lab Project Number: 49/90. Unpublished study prepared by Ciba-Geigy Ltd. 42 p.

41761510 Killer, A. (1991) CGA-41065: Soil Photolysis of CGA-41065 (CGA- 254567) under Laboratory Conditions: Lab Project Number: 50/90. Unpblished study prepared by Ciba-Geigy Ltd. 42 p.

41761512 Abildt, U. (1991) CGA-41065: Adsorption/Desorption of CGA-41065 (CGA-254567) in Various Soil Types: Lab Project Number: 52/90. Unpublished study prepared by Ciba-Geigy Ltd. 46 p.

41847001 Chetram, R. (1991) Tier 2 Seedling Emergence Nontarget Phytotoxi- city Study Using Prime + (CGA-41065): Lab Project Nos. LR90-431; TX-90-0158. Unpublished study prepared by Pan-Agricultural Laboratories, Inc. 126 p.

42061601 Becci, P. (1986) CGA-41065 Technical: Lifetime Dietary Oncogenicity Study in Albino Mice: Lab Project Number: 7076-9. Unpublished study prepared by Food and Drug Research Labs., Inc. 3066 p.

42061602 Tisdale, M. (1991) CGA-41065 Technical: Supplement to Lifetime Dietary Oncogenicity Study in Albino Mice: Lab Project Number: 7076-9. Unpublished study prepared by Ciba-Geigy Corp. 18 p.

42061603 Keller, J. (1986) CGA-41065 Technical: Combined Chronic Toxicity/ Oncogenicity Study in Rats: Lab Project Number: 22146. Unpub- blished study prepared by Litton Bionetics, Inc. 4194 p.

42061604 Tisdale, M. (1991) CGA-41065 Technical: Supplemental To: Combined Chronic Toxicity/ Oncogenicity Study in Rats: Lab Project No: 22146. Unpublished study prepared by Ciba-Geigy Corp. 25 p.

42061605 Naismith, R. (1982) CGA-41065 Technical: Rat Hepatocyte Primary Culture/DNA Repair Test: Tests for Other Genotoxic Effects: Lab Project Number: PH 311-CG-001-81. Unpublished study prepared by Pharmakon Research International, Inc. 27 p.

42566201a Kirkpatrick, D. (1992) Flumetralin: The Degradation of Flumetralin in Soil Under Aerobic, Anaerobic and Sterile Conditions at 20 degrees celsius: Lab Project Number: 90JG01. Unpublished study prepared by Huntingdon Research Center Ltd. 78 p.

42566201b Kirkpatrick, D. (1992) Flumetralin: The Degradation of Flumetralin in Soil Under Aerobic, Anaerobic and Sterile Conditions at 20 degrees celsius: Lab Project Number: 90JG01. Unpublished study prepared by Huntingdon Research Center Ltd. 78 p.

43014004 Craig, L. (1982) Supplement to: "Bioaccumulation , Depuration, and Metabolism of CGA-41065 in Bluegill Sunfish" Part A (Bioaccumulation and Depuration) and Part B (Metabolism): (MRID 00117114): Lab Project Number: 698-1. Unpublished study prepared by Analytical Development Corp. and Environmental Research and Technology, Inc. 39 p.

43014005 Kahrs, R. (1983) Uptake of (14C)-CGA-41065 in Field Rotational Soybeans, Carrots and Corn: Lab Project Number: ABR-83019: M1-52-19PR: 19SR. Unpublished study prepared by Ciba-Geigy Corp. 23 p.

43456601 Bettencourt, M. (1994) CGA-41065: Acute Toxicity to Bluegill Sunfish (Lepomis macrochirus) Under Flow-Through Conditions: Final Report: Lab Project Number: 94/8/5428: 1781/0394/6438/ 105. Unpublished study prepared by Springborn Labs, Inc. 75 p.

43456602 Putt, A. (1994) CGA-41065: Acute Toxicity to Daphnids (Daphnia magna) Under Flow-Through Conditions: Lab Project Number: 94/9/5487. Unpublished study prepared by Springborn Labs, Inc. 78 p.

43456603 Bettencourt, M. (1994) CGA-41065: Acute Toxicity to Sheepshead Minnow (Cyprinodon variegatus) Under Flow-Through Conditions: Final Report: Lab Project Number: 94/9/5479: 1781/0394/6435/ 505. Unpublished study prepared by Springborn Labs, Inc. 74 p.

43456604 Dionne, E. (1994) CGA-41065: Acute Toxicity to Eastern Oyster (Crassostrea virginica) under Flow-Through Conditions: Final Report: Lab Project Number: 94/7/5391: 1781/0394/6436/504. Unpublished study prepared by Springborn Labs, Inc. 81 p.

43456605 Bettencourt, M. (1994) CGA-41065: Acute Toxicity to Mysids (Mysidopsis bahia) Under Flow-Through Conditions: Final Report: Lab Project Number: 94/10/5493: 1781/0394/6434/515. Unpublished study prepared by Springborn Labs, Inc. 79 p.

43456606 Hoberg, J. (1994) CGA-41065: Toxicity to Duckweed (Lemna gibba): Final Report: Lab Project Number: 94/8/5425: 1781/0394/ 6437/410. Unpublished study prepared by Springborn Labs, Inc. 72 p.

43710702 Sheets, T.; Seltmann, H.; Yelverton, F. (1994) Residues of MH, flumetralin, and butralin on flue-cured tobacco. Tobacco Science 38:25-29. 8 p.

43862801 Khalil, S. (1995) CGA-41065 Technical: Teratology Study in Rabbits: (Final Report): Lab Project Number: 931152: TOX-1114C2MT. Unpublished study prepared by Ciba-Geigy Ltd. 309 p.

44565404 Glaza, S. (1998) Acute Dermal Toxicity Study of CGA-41065 15EC-Exp in Rabbits: Final Report: Lab Project Number: 71005057: 277-97. Unpublished study prepared by Covance Labs., Inc. 20 p.

V. APPENDIX E. LIST OF AVAILABLE RELATED DOCUMENTS AND ELECTRONICALLY AVAILABLE FORMS

Pesticide Registration Forms are available via the Agency's website at *http://www.epa.gov/opprd001/forms/*.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed).
2. The completed form(s) should be submitted in hard copy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at *williams.nicole@epa.gov*.

The following Agency Pesticide Registration Forms are currently available via the Internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	*http://www.epa.gov/opprd001/forms/8570-1.pdf*
8570-4	Confidential Statement of Formula	*http://www.epa.gov/opprd001/forms/8570-4.pdf*
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	*http://www.epa.gov/opprd001/forms/8570-5.pdf*
8570-17	Application for an Experimental Use Permit	*http://www.epa.gov/opprd001/forms/8570-17.pdf*
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	*http://www.epa.gov/opprd001/forms/8570-25.pdf*
8570-27	Formulator's Exemption Statement	*http://www.epa.gov/opprd001/forms/8570-27.pdf*
8570-28	Certification of Compliance with Data Gap Procedures	*http://www.epa.gov/opprd001/forms/8570-28.pdf*

8570-30	Pesticide Registration Maintenance Fee Filing	*http://www.epa.gov/opprd001/forms/8570-30.pdf*
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	*http://www.epa.gov/opprd001/forms/8570-32.pdf*
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf*
8570-35	Data Matrix (PR Notice 98-5)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf*
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf*
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf*

VI. PESTICIDE REGISTRATION KIT

http://www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

a. 83-3 Label Improvement Program--Storage and Disposal Statements
b. 84-1 Clarification of Label Improvement Program
c. 86-5 Standard Format for Data Submitted under FIFRA
d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at *http://www.epa.gov/opppmsd1/PR Notices*

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
b. EPA Form No. 8570-4, Confidential Statement of Formula
c. EPA Form No. 8570-27, Formulator's Exemption Statement
d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).

a. Registration Division Personnel Contact List
b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
c. Antimicrobials Division Organizational Structure/Contact List
d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
e. 40 CFR §156, Labeling Requirements for Pesticides and Devices (PDF format)
f. 40 CFR §158, Data Requirements for Registration (PDF format)
g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' website.

2. The booklet "General Information on Applying for Registration of Pesticides in the United States," PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161-0002

The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Information Center (NPIC) can provide information on active ingredients, uses, toxicology and chemistry of pesticides. You can contact NPIC by telephone at (800) 858-7378 or through their website at *http://www.ncis.orst.edu*.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

- Date of receipt;
- EPA identifying number; and
- Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.