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# Reregistration Eligibility Decision for Napropamide

**Case No. 2450**

**Reregistration Eligibility Decision**  
**for**  
**Napropamide**

**Case No. 2450**

**Approved By:**

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## **Glossary of Terms and Abbreviations**

ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CCA	Comparative Cholinesterase Assay
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EC	Engineering Control
EDWC	Estimated Drinking Water Concentration
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
FOB	Functional Observation Battery
G	Granular Formulation
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC <sub>50</sub>	Median Lethal Concentration. A statistically derived concentration of a substance that can be

	expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD <sub>50</sub>	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
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
NAWQA	USGS National Water Quality Assessment
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
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q <sub>1</sub> *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLN	Special Local Need (Registrations Under Section 24©) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UF <sub>db</sub>	Database Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard



## **Executive Summary**

The Environmental Protection Agency (EPA) has concluded its reregistration eligibility decision for napropamide and determined that the chemical is eligible for reregistration provided that (1) current data gaps and additional data needs are addressed and (2) the risk mitigation measures outlined in this document are adopted and label amendments are made to implement these measures. EPA has also reassessed the 27 tolerances for napropamide under section 408(q) of FFDCA, as amended by FQPA.

EPA has completed its review of public comments on the revised napropamide risk assessments and is issuing its risk management decision. The revised risk assessments are based on review of the required data supporting the use patterns of currently registered products and additional information received. After considering the risks identified in the revised risk assessment, comments, and mitigation suggestions from interested parties, EPA developed its risk management decision for uses of napropamide that posed potential risks of concern.

Napropamide is an herbicide registered to control broadleaf weeds and annual grasses on numerous food/feed and non-food/feed use sites, including fruits and nuts, vegetables, ornamentals, turf/lawns, forestry sites and tobacco. Napropamide was first registered in 1972. Approximately 368,000 pounds of napropamide active ingredient are applied annually. Sites on which napropamide has the highest percent of crop treated include cranberries (30%), pepper and strawberries (15%), eggplant, tobacco, and tomatoes (10%).

### Dietary Risk

Acute dietary risk was not assessed as there were no toxicological endpoints of concern attributable to a single exposure. The chronic dietary risk (food + water) of napropamide is well below the Agency's level of concern for the general U.S. population and all population subgroups. The most highly exposed subgroup was children, 1-2 years old, with the estimated exposure at 1.8% of the cPAD. Therefore, no mitigation is warranted at this time for dietary risks.

### Residential Risk

The estimated residential handler risks for all scenarios do not exceed the Agency's level of concern. The MOEs ranged from 19,000 to 190,000. Residential post-application risks were also below EPA's level of concern (the short term total MOE is 265). Therefore, no mitigation is warranted at this time for residential risks.

### Aggregate Risk

Short-and long term (chronic) aggregate risks assessments were conducted for napropamide. The short-term assessment considered both dietary (food + water) and residential exposures. The long-term assessment considered dietary exposure only, since the current uses of napropamide are not expected to result in long-term residential exposure.

Short-term aggregate risk is below EPA's level of concern for napropamide. Estimated short-term aggregate risk MOEs for adults and children (toddlers) are 14,340 and 260, respectively. The chronic aggregate risk estimates for the U.S. population and all subgroups are < 2% of the cPAD and, therefore, are also below the Agency's level of concern. Therefore, no risk mitigation is warranted at this time for aggregate risks.

### Occupational Risk

The Agency identified several occupational scenarios where exposure might occur. The occupational handler exposures estimated for all scenarios do not exceed the Agency's level of concern (i.e., MOEs > 100). Therefore, no risk mitigation is warranted at this time for occupational risks.

### Cumulative Risk

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to napropamide and any other substances, and napropamide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that napropamide does not share a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a

common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism of EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

### Ecological Risk

Based on high-end estimated environmental concentrations, chronic levels of concern (LOCs) were exceeded for mammals that feed on all food types the Agency assesses (i.e., short grass, tall grass, broadleaf plants and small insects, fruits/pods/large insects) for all modeled use rates. Risk quotient (RQ) estimates ranged up to 21 (LOC=1). For terrestrial and wetland/riparian plants (monocot and dicot), RQs for seedling emergence in areas adjacent to treated fields exceeded LOCs at all modeled application rates. RQ estimates ranged up to 12. EPA believes the risks can be substantially reduced through the implementation of the following mitigation measures: 1) requiring application rate reductions; and 2) cancelling use on a number of crops.

### Endangered Species

Based on EPA's screening level assessment, RQs for napropamide exceed acute levels of concern for direct effects to endangered species of mammals, mollusks, marine/estuarine crustaceans, aquatic vascular plants and terrestrial and semi-aquatic plants (both dicots and monocots). RQs were also exceeded for chronic direct effects to mammals. Further, based on screening level assessments of potential direct effects to these taxa, the potential for indirect effects to all taxa of listed species can not be precluded at this time. These findings are based solely on EPA's screening level assessment and do not constitute "may affect" finding under the Endangered Species Act.

### Next Steps

The Agency is issuing this RED document for napropamide as announced in a Notice of Availability published in the *Federal Register*. In the near future, EPA will issue generic DCI for additional data necessary to confirm the conclusions of this RED for the active ingredient napropamide. EPA will also issue a product specific DCI for data necessary to complete product reregistration for products containing napropamide.

## **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. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the 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 the 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.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food. FQPA also requires EPA to review all tolerances in effect on August 2, 1996 by August 3, 2006. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern and the Agency concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

As mentioned above, FQPA requires EPA to consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposures to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at [http://epa.gov/pesticides/cumulative/.](http://epa.gov/pesticides/cumulative/)]

Unlike other pesticides for which EPA has considered cumulative risk based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for napropamide. The Agency has found no information indicating napropamide shares a common mechanism of toxicity with other substances. Napropamide does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of tolerance reassessment and a decision on reregistration eligibility, EPA has assumed that napropamide does not share a common mechanism of toxicity with other compounds. In the future, if additional information suggests napropamide shares a common mechanism of toxicity with other compounds, additional testing may be required and a cumulative assessment may be necessary.

This document presents EPA's revised human health and ecological risk assessments and the reregistration eligibility decision for napropamide. This document consists of six sections and appendices. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments based on data, public comments, and other information received in response to the preliminary risk assessments. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV. The appendices in Section VI list related and supporting documents, studies submitted to support EPA's data requirements for reregistration, and generic and product Data Call-Ins (DCIs), and provide information on how to access related documents. The preliminary and revised risk assessments for napropamide are available in the Public Docket, under docket number(s) OPP-2004-0162 and on the Agency's web page, <http://www.epa.gov/edockets>.

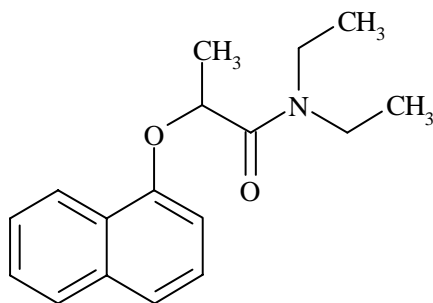


## II. Chemical Overview

### A. Regulatory History

Napropamide has been registered in the United States since 1972 for use as a herbicide. A Data Call-In (DCI) was issued in 1989 requiring the submission of additional data on product and residue chemistry, toxicity, environmental fate, and ecological effects. Subsequent DCIs were issued in 1991, 1994 and 1995 which required additional product chemistry, environmental fate, processing and residue crop field trial studies. This Registration Eligibility Decision (RED) reflects a reassessment of all data which were submitted in response to the DCIs.

### B. Chemical Identification



**Common Name:** Napropamide

**Trade Name:** Devrinol®.

**Chemical Name:** N,N-diethyl-2-(1-naphthalenyloxy)propanamide

**Chemical Family:** Amide

**Case Number:** 2450

**CAS Registry Number:** 15299-99-7

**OPP Chemical Code:** 103001

**Molecular weight:** 271.4

**Empirical Formula:** C<sub>17</sub>H<sub>21</sub>NO<sub>2</sub>

**Basic Manufacturers:** United Phosphorus Inc.

**Table 1: Physicochemical Properties of Napropamide**

Parameter	Value
Melting point	68-70 °C
pH	8.9 at 22 °C
Density, bulk density, or specific gravity	0.584 g/mL at 22 °C
Water solubility	74 mg/L at 25 °C
Solvent solubility at 20 °C	Miscible with acetone, chlorobenzene, ethanol, and dichloromethane 4.5 g/100 mL in kerosene 17.7 g/100 mL in n-octanol 55.5 g/100 mL in xylene
Vapor pressure	1.7 x 10 <sup>-7</sup> torr or 2.3 x 10 <sup>-5</sup> Pa at 25 °C
Dissociation constant, pK <sub>a</sub>	Not applicable; napropamide is neither an acid nor a base.
Octanol/water partition coefficient	2.1 x 10 <sup>3</sup> (log K <sub>OW</sub> = 3.3)
UV/visible absorption spectrum	Neutral (201.8 nm): A=1.1144, ε = 58560mol <sup>-1</sup> Acidic (215nm): A=1.1198, ε=58844mol <sup>-1</sup> cm <sup>-1</sup> Basic: unstable in alkaline solution

### C. Use Profile

The following is information on the currently registered uses, including an overview of use sites and application methods.

**Type of Pesticide:** Herbicide

**Target organism(s):** Napropamide is registered to control numerous broadleaf weeds and annual grasses.

**Mode of action:** Napropamide controls weeds by preventing root cell elongation, thus disrupting the growth process during germination.

**Use Sites:**

Food uses:

- Berries/small fruit (blackberry, boysenberry, loganberry, raspberry, blueberry, strawberry, cranberry, currant, grape)
- Brassica and leafy vegetables (broccoli, Brussels sprouts, cabbage, cauliflower, asparagus)
- Citrus (grapefruit, lemon, orange, tangerine, tangelo)
- Fruiting vegetables (eggplant, pepper, tomato)



- Nuts (almond, pistachio, pecan, filbert, walnut)
- Pome Fruit (apple, pear)
- Stone Fruit (apricot, cherry, nectarine, peach, plum, prune)
- Tropical Fruit (kiwi, persimmon, avocado, pomegranate)
- Additional Crops (artichoke, fig, mint, olive, rhubarb, sweet potato)

*Non-Food, Greenhouse & Residential Uses:*

- Tobacco
- Trees/Ornamentals (conifer, shade tree, ornamental tree, ground cover, herbaceous, plants, woody shrubs, vines, lawns, turf, potting soil)

**Use Classification:** General Use Pesticide

**Formulation Types:** Napropamide is formulated as dry flowable, granular and liquid formulations.

**Application Methods:** Aerial application, ground boom, hand-held sprayers, granular application equipment, and chemigation equipment.

**Application Rates:** Napropamide is applied at rates between 2 and 6 pounds active ingredient per acre (lbs a.i./A) on all crops/sites except cranberries, where applications at up to 15 lbs a.i./A are allowed. Aerial applications are allowed for cranberries only. Applications for all other uses are made using ground equipment, including groundboom and hand-held sprayers, granular application equipment, and chemigation equipment.

**Application Timing:** Timing ranges across different stages of plant development in both agricultural and ornamental plant settings.

**D. Estimated Usage of Pesticide**

Table 2 below summarizes the best available estimates for the pesticide usage of napropamide with “screening level” usage data for agricultural crops. This information was retrieved from EPA’s principal pesticide usage databases using current estimates. In addition, this table reflects only the highest usage sites. Based on Agency data, the average total annual domestic usage of napropamide was approximately 368,000 pounds. The predominant usage is in California. The highest usage, by crop, is on cranberries with 30% crop treated.

**Table 2: Napropamide Crop Usage Summary**

Crop	Lbs. A.I.	% Crop Treated
Cranberries	50,000	30
Strawberries	30,000	15

Crop	Lbs. A.I.	% Crop Treated
Tomatoes	60,000	10
Peppers	20,000	15
Tobacco	40,000	10
Eggplant	<500	10

### III. Summary of Napropamide Risk Assessment

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in **Appendix C** were used to reach the safety finding and regulatory decision for napropamide. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket OPP-2004-0162 and may be accessed on the Agency's website at <http://epa.gov/edockets>. Paper copies of these documents may be found in the OPP Public Docket under the above docket number. The OPP public docket is located in Room 119, Crystal Mall II, 1801 South Bell Street, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

#### A. Human Health Risk Assessment

EPA released its preliminary risk assessments for napropamide for public comment on March, 16, 2005 (Phase 3 of the public participation process). During the public comment period, the registrant (United Phosphorus, Inc.) proposed reducing the maximum application rate for cranberries. United Phosphorus also indicated that the company will not support existing tolerances for cucurbit vegetables and coffee. The changes proposed by the registrant would result in lower estimates of dietary and non-dietary exposure to napropamide. However, because the estimated risks based on the Agency's previous exposure assessments are well below EPA's level of concern, a revised risk assessment reflecting the proposed changes is not warranted and has not been conducted.

#### 1. Toxicity of Napropamide

The available toxicity data on napropamide are adequate to assess the chemical's hazard potential. The most common effect in animal studies (dogs, mice and rats) from long-term oral exposure was a decrease in body weight or body weight gain, with females being more sensitive than males to effects on body weight. Technical napropamide has low acute toxicity (category III/IV) via the oral, dermal and inhalation routes of exposure. It is moderately irritating to the eye (category II) but does not cause skin irritation or dermal sensitization.

Further details on the toxicity of napropamide can be found in the "*Napropamide: Revised HED Chapter of the Reregistration Eligibility Decision (RED)*," dated February 23, 2005 .

### a. Acute Toxicity Profile

Table 3 below lists the acute toxicity categories for the different routes of exposure.

**Table 3: Acute Toxicity Data for Napropamide**

Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.11	Acute oral [rat]	40362902	LD <sub>50</sub> = >5000 mg/kg	IV
870.12	Acute dermal [rabbit]	40362902	LD <sub>50</sub> = >2000 mg/kg	III
870.13	Acute inhalation [rat]	42231501	LC <sub>50</sub> = >4.8 mg/L	IV
870.24	Acute eye irritation [rabbit]	40362902	moderate	II
870.25	Acute dermal irritation [rabbit]	40362902	none	IV
870.26	Skin sensitization [guinea pig]	40362903	negative	Nonsensitizing

### b. Developmental & Reproductive Toxicity/FQPA Safety Factor

The Federal Food Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) directs the Agency to use an additional tenfold (10X) safety factor to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FFDCA authorizes the Agency to modify the tenfold safety factor only if reliable data demonstrate that the resulting level of exposure would be safe for infants and children.

Napropamide did not cause developmental toxicity in fetuses from either rats or rabbits and did not adversely affect reproductive parameters in rats over three generations. There is no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses after *in utero* and/or postnatal exposure to napropamide in the developmental and reproduction studies. Dose-response relationships are well-characterized and clear NOAELs/LOAELs have been identified for the critical effects. No evidence of neurotoxicity was observed in any study. Based on the weight of evidence, a developmental neurotoxicity (DNT) study is not required for napropamide, and adequate chemical specific data, surrogate data, and modeling outputs are available to assess dietary and residential exposures. EPA has high confidence that results do not under estimate exposure. Therefore, the special FQPA safety factor can be reduced to 1X.

### c. Carcinogenicity

No evidence for carcinogenicity was seen in mice or rat studies. Napropamide has been classified a Group “E” carcinogen (no evidence of carcinogenicity). Therefore, a cancer assessment was not conducted.

**d. Endocrine Effects**

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 recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the 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. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the available toxicity studies on napropamide, there was no estrogen, androgen, and/or thyroid mediated toxicity. Future testing with appropriate screening and/or testing protocols could better characterize effects related to endocrine disruption.

**e. Toxicological Endpoints for Risk Assessment**

The toxicological endpoints used in the human health risk assessment for napropamide are listed in Table 4. The safety factors used to account for interspecies extrapolation, intraspecies variability and the FQPA safety factor are also described in Table 4. No toxicological endpoint was selected for the acute dietary exposure scenario, since an endpoint attributable to a single exposure was not identified from the available database. Therefore, no acute dietary assessment was performed.

**Table 4: Summary of the Toxicology Endpoint Selection**

Chronic Dietary Endpoint			
Exposure Scenario	Dose & Uncertainty Factors	Endpoint	Study
Chronic Dietary	NOAEL=12 mg/kg/day	Decreased weight gain in females and an increased incidence of liver lesions in males at a LOAEL of 48/55 mg/kg/day (m/f)	Rat Chronic/Oncogenicity Study. MRID Nos. 42189102 & 43068801
	UF = 100x FQPA Safety Factor = 1x	Chronic PAD = 0.12 mg/kg/day	

Exposure Scenario	Dose & Uncertainty Factors	Endpoint	Study
Incidental Oral Short-Term (1-30 days) & Incidental Oral Intermediate (1-6 month)	NOAEL = 30 mg/kg/day	Based on decreased body weight in adult females, adult males, and pups at a LOAEL = 100 mg/kg/day	Reproductive Toxicity - Rat. MRID No. 92125069
	UF = 100x FQPA Safety Factor = 1x	MOE of Concern = 100	
Inhalation Short-Term (1-30 days) & Inhalation Intermediate-Term (1-6 months)	Oral Study NOAEL = 30 mg/kg/day (Inhalation absorption rate=100%)	Based on decreased body weight in adult male, adult female, and pups at a LOAEL = 100 mg/kg/day	Reproductive Toxicity - Rat. MRID No. 92125069
	UF = 100x FQPA Safety Factor = 1x	MOE of Concern = 100	
Cancer (oral, dermal, inhalation)	<b>Classification:</b> No evidence of Carcinogenicity		

## 2. Dietary Exposure and Risk from Food and Drinking Water

### a. Exposure Assumptions (Food)

The chronic dietary exposure and risk analysis for napropamide was conducted using the Lifeline™ Model Version 2.0, which uses food consumption data from the United States Department of Agriculture's (USDA's) Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. In this analysis, the chronic dietary exposure and risk estimates resulting from food intake were determined for the general U.S. population and various population subgroups. The chronic analysis assumed 100% crop treated and tolerance-level residues (Tier 1) for all commodities. As such, this is considered an unrefined assessment (Tier 1).

### b. Exposure Assumptions (Drinking Water)

The Tier II screening models, Pesticide Root Zone Model and Exposure Analysis Modeling System (PRZM-EXAMS), with the Index Reservoir and Percent Crop Area adjustment (IR-PCA PRZM/EXAMS), were used to estimate napropamide residues in surface water used for drinking water.

Estimated ground water concentrations are based on the Screening Concentration in Ground Water (SCI-GROW) model, which is a Tier 1 assessment that provides a high-end estimate. The SCI-GROW model generates a single Estimated Drinking Water Concentration

(EDWC) value of pesticide concentration in ground water used for drinking water and provides a ground water screening concentration for use in determining potential risk to human health from drinking water contaminated with a pesticide.

Napropamide is persistent but not particularly mobile, and therefore, is not expected to pose a significant risk of ground water contamination. Surface water contamination is possible through run-off from treated fields. Estimated concentration from napropamide in ground water is 4.5 ppb. From the original drinking water assessment (“*Drinking Water Assessment for Napropamide for Terrestrial Uses*”, dated August 17, 2004), the estimated concentration is 0.5 ppb in surface water. The highest estimated chronic drinking water concentration (4.5 ppb) from ground water modeling was used for the dietary analysis.

In a memo, “*Revised Drinking Water Assessment for Napropamide*” dated November 12, 2004, the Agency revised the chronic estimate for surface water (5.1 ppb). The revised chronic surface water estimate of 5.1 ppb is slightly higher than the drinking water estimate used in this assessment (4.5 ppb); however, because of the minimal impact the revised estimate would be expected to have on overall dietary (and aggregate) risk, the Agency determined that a new dietary assessment was not warranted.

#### **c. Population Adjusted Dose**

Chronic dietary risk is calculated by using the average consumption values for foods and average residue values on those foods. A risk estimate that is less than 100% of the chronic Population Adjusted Dose (cPAD) (the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected) is below the Agency’s level of concern. An uncertainty factor of 100x was applied to the chronic dietary assessment for inter- and intraspecies variations, and the FQPA safety factor was reduced to 1x as discussed in the dietary risk section.

#### **d. Chronic Dietary Risk Estimates**

The Tier 1 chronic dietary assessment indicates that the combined exposure to napropamide from food and water is well below the Agency’s level of concern, with estimated exposures representing <2% of the cPAD for the U.S. population and all population subgroups, including infants and children. Please note that this is a Tier 1 assessment; and therefore, risks are considered to be upper end estimates.

### **3. Residential Exposure and Risk**

Residential exposure assessment considers all potential non-occupational pesticide exposures, other than exposure due to residues in foods or in drinking water. Exposure may occur during and after application on lawns and turf and ornamental plants. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a

Margin of Exposure (MOE), which is the ratio of estimated exposure to an appropriate No Observed Adverse Effect Level (NOAEL) dose. Napropamide products are marketed for homeowner use on residential lawns and landscape ornamental plants. Napropamide containing products are also marketed for use by professional applicators (Lawn Control Operators [LCOs]) on residential turf, golf courses, other turf such as recreational/commercial areas, and on ornamental plantings. Based on these uses, napropamide has been assessed for the residential mixing/loading/applicator (or “handler”) exposure and for children’s post-application exposure that may occur from turf contact and hand-to-mouth transfer.

Further details on residential exposure and risk of napropamide can be found in the “*Napropamide: Revised HED Chapter of the Reregistration Eligibility Decision (RED)*”, dated February 23, 2005 and, “*Napropamide: Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document*” dated February 20, 2005.

#### **a. Residential Exposure & Duration**

Short-or intermediate-term dermal exposures or risks were not assessed for napropamide, since an appropriate dermal toxicological endpoint was not identified. EPA assessed short-term inhalation exposure for handlers and short-term incidental oral postapplication exposure for children in treated areas. Since exposure scenarios for napropamide are only considered to be short-term in nature due to the episodic use patterns, EPA does not anticipate long-term exposures. Therefore, no long-term dermal or inhalation exposures or risks were assessed. The toxicological endpoints used for the residential risk assessment are provided in the Table 4.

#### **b. Residential Handler**

##### **1. Exposure Scenarios, Data, and Assumptions**

There is a potential for exposure in residential settings during the application process for homeowners who use products containing napropamide. Homeowner-use products are available in granular form. Napropamide can be applied by hand or by using shaker cans, push-type spreaders, and belly grinders. A number of standard assumptions, such as adult body weight and area treated per application, are made by the Agency for residential risk assessment. Also, note that residential handlers are addressed somewhat differently than occupational handlers in that homeowners are assumed to complete all elements of an application (mix/load/apply) without use of protective equipment (assessments are based on an assumption that individuals will be wearing short pants, short-sleeved shirts, shoes and socks). This is to ensure that EPA does not underestimate potential risks.

The quantitative exposure/risk assessment developed for residential handlers is based on these scenarios:

- (1) Applying granulars by hand application
- (2) Applying granulars with a shaker can
- (3) Loading/applying granulars with a belly grinder application
- (4) Loading/applying granulars with a push type spreader application

Chemical-specific data to assess the above exposure scenarios were not submitted to the Agency in support of reregistration. Instead, exposure estimates for these scenarios are derived from the Pesticide Handlers Exposure Database (PHED, Version 1.1 August 1998) which is used to assess handler exposures when chemical-specific monitoring data are not available. In addition to PHED data, this risk assessment relies on data from the Outdoor Residential Exposure Task Force (ORETF) and proprietary studies.

The following assumptions were used in the exposure calculations:

- Maximum application rates allowed by labels were used to conduct the risk assessment.
- Residential risk assessments calculations were based on what would reasonably be treated by homeowners such as the size of a lawn, or the size of a garden.

### c. Residential Handler Risk Estimates

A Margin of Exposure (MOE) greater than or equal to 100 (10x for interspecies extrapolation and 10x for intraspecies variation) is considered adequately protective for this assessment. As noted above, only handler inhalation risks were assessed since no appropriate dermal endpoint was identified in the toxicity database for napropamide. The estimated risks for all scenarios do not exceed the Agency's level of concern for inhalation risk assessments. The MOEs ranged from 28,000 to 190,000.

**Table 5: Napropamide Short-Term Residential Handler Risk**

Exposure Scenario	Crop or Target	Application Rate (lb ai/unit)	Amount Handled Daily	Inhalation Dose (mg/kg/day)	Inhalation MOE
<b>Mixer/Loader/Applicator</b>					
Applying Granulars for Hand application (1)	ornamentals	6	0.023	0.0011	28000
Applying Granulars for Shaker can application (2)	ornamentals	6	0.023	0.0011	28000
Loading/Applying Granulars for Belly Grinder application (3)	turf	3	0.5	0.0016	19000
Loading/Applying Granulars for Push-type spreader application (4)	turf	3	0.5	0.00016	190000

### d. Residential Post-application Risk

Different segments of the population, including toddlers and adults, can be exposed to napropamide by various activities in a residential setting. The scenarios chosen in the risk assessment represent these activities, and are considered to represent upper-end estimates of



exposure. For the purpose of this assessment, it was assumed that both children and adults may be exposed following applications of napropamide to treated areas, with toddlers having the greatest potential exposure. An MOE of 100 (or more) is below the Agency's level of concern for this assessment.

The Standard Operating Procedures for Residential Exposure Assessment define several scenarios that apply to uses specified in the current napropamide labels. The Agency used this guidance to define the toddler exposure scenarios included in this post-application exposure assessment.

The quantitative exposure/risk assessment for post-application risk to children is based on these scenarios:

- *Hand-to-mouth transfer from treated turf:* Post-application exposure to children from the "incidental" ingestion of pesticide residues on treated turf from hand-to-mouth transfer (i.e., those residues that end up in the mouth from children touching turf and then putting their hands in their mouth).
- *Object-to-mouth transfer from treated turf:* Post-application exposure to children from incidental ingestion of pesticide residues on treated turf from object-to-mouth transfer (i.e., those residues that end up in the mouth from a child mouthing objects that contact of treated turf).
- *Soil ingestion activity:* Post-application exposure to children from incidental ingestion of soil in a treated area.

Inhalation risks were not assessed for postapplication scenarios because inhalation exposure is considered negligible given the low vapor pressure of napropamide. As noted above, no appropriate dermal endpoint was identified. Therefore, only incidental oral exposures were assessed.

Napropamide may be applied as granular product to turf, and episodic ingestion of these granules by children may occur which would be considered on acute exposure. An episodic granular ingestion assessment for children was not performed since no acute dietary endpoint of concern was identified for napropamide.

#### **e. Post-application Risk Estimates**

For napropamide, MOEs greater than or equal to 100 do not exceed the Agency's level of concern. This incorporates the standard uncertainty factors of 10x for interspecies variability and 10x for intraspecies variability. Risks were calculated for incidental oral hand-to-mouth, object to mouth and soil ingestion pathways. The estimated short term total MOE is 265, and risk is, therefore, below EPA's level of concern.

**Table 6: Short-Term (Aggregate) Napropamide Residential Scenarios for Post-Application Risk Estimates**

Exposure Scenario		Margins of Exposure (MOEs) (UF=100)			
		Dermal	Oral (Non-Dietary)	Total Non-Dietary Risk <sup>a</sup>	
<b>Short-term Exposures</b>					
Toddler	Turf: 6 lb ai/A	Hand to Mouth	N/A	335	265
		Object to Mouth	N/A	1340	
		Incidental Soil Ingestion	N/A	10000	

#### 4. Aggregate Exposure and Risk

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require “that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there is reliable information.” Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure.

A toxicological endpoint of concern attributable to a single dose has not been identified for napropamide. Therefore, an acute aggregate risk assessment has not been conducted. Intermediate term exposure durations are not expected for napropamide use pattern. Therefore, an intermediate aggregate assessment has not been conducted.

##### a. Short-Term Aggregate Risk

Short-term aggregate exposure takes into account residential exposure plus average exposure levels from residues of napropamide in food and water. The MOE level of concern for short-term aggregate risk is 100. Since the estimated short-term aggregate risk MOE for the most highly sensitive population (children 1 to 2 years old) is 260, short-term aggregate risk is below EPA’s level of concern for napropamide.

**Table 7: Napropamide Short-Term Aggregate Risk**

Population	Short -Term Scenario					
	NOAEL mg/kg/day	Level of Concern	Max Exposure mg/kg/day	Average Food + Water Exposure mg/kg/day	Residential Exposure mg/kg/day	Aggregate MOE (food and residential)
Children, 1- 2 yrs. old	30	MOE ≤100	0.3	0.00222	0.113	260

##### b. Chronic Aggregate Risk

The chronic aggregate risk assessment considered exposures from food and water only because there are no residential uses expected to result in chronic exposures for this chemical.

The chronic aggregate risk estimates for the U.S. population and all subgroups are < 2% of the cPAD and, therefore, below the Agency's level of concern.

## **5. Cumulative Risk**

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to napropamide and any other substances, and napropamide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that napropamide does not share a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism of EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

## **6. Occupational Risk**

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of napropamide include workers in agricultural areas and workers applying napropamide on ornamental plants. Occupational risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL). In the case of napropamide, risk estimates resulting in MOEs greater than 100 do not exceed the Agency's level of concern.

Occupational risk is assessed for exposure at the time of application (termed "handler" exposure) and exposure following application (termed post-application exposure). Application parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), the equipment required to deliver the chemical to the use site, and the application rate required to achieve an efficacious dose. Post-application risk is assessed for activities such as scouting, irrigating, pruning, and harvesting and is based primarily on dermal exposure estimates.

For more information on the assumptions and calculations of potential risk of napropamide to workers, see the "*Napropamide: Revised Occupational and Residential Exposure Assessment*" dated February 20, 2005.

### **a. Occupational Toxicity**

No short- or intermediate-term occupational dermal endpoint of concern was identified for napropamide. The short and intermediate-term occupational inhalation endpoint of concern exposure was selected from a reproduction study in rats. A profile of the toxicity and endpoints for napropamide is outlined above in Table 4.

## **b. Occupational Handler Exposure**

Occupational handler risk estimates have been assessed for both short- and intermediate-term exposure durations. Napropamide exposures may occur over a single day or up to two weeks at a time. For many use-patterns intermittent exposures over several weeks also may occur. However, long-term (i.e., > 6 months) handler exposures are not expected.

Occupational handler assessments are conducted using increasing levels of protection. The Agency typically evaluates all exposures with minimal or baseline protection and then considers additional protective measures using a tiered approach (going from minimum to maximum levels of protection) until predicted risks are below EPA's level of concern. In the case of napropamide, MOEs for every occupational exposure scenario are above 100 at baseline PPE (long-sleeved shirt, long pants, socks, and shoes). While the generic assessment for napropamide does not indicate a need for additional PPE, evaluation of end-use product toxicity data may require additional protection. End-use product PPE will be determined on a product-by-product basis.

## **c. Occupational Handler Risk Summary**

The Agency has determined that there are potential exposures to workers who mix, load, apply, and otherwise handle napropamide consistent with the usual napropamide use patterns. Fifteen major occupational handler exposure scenarios were identified as follows:

- (1) mixing/loading dry flowables for groundboom applications;
- (2) mixing/loading dry flowables for chemigation application;
- (3) mixing/loading granulars for tractor-drawn spreaders applications;
- (4) mixing/loading granulars for aerial applications;
- (5) mixing/loading liquids for chemigation application;
- (6) mixing/loading liquids for groundboom application;
- (7) mixing/loading liquids for high-pressure handwand application;
- (8) applying sprays for groundboom application;
- (9) applying sprays for high-pressure handwand application;
- (10) applying granulars with a tractor-drawn spreader;
- (11) applying granulars for aerial application;
- (12) loading/applying granulars for belly-grinder applications;
- (13) loading/applying granulars for push-type spreader application;
- (14) mixing/loading/applying liquid for handgun (lawn) application;
- (15) flagging for granular application.

### Occupational Handler Exposure Assumptions and Data

Chemical-specific data to assess the exposure scenarios were not available for napropamide. Analyses were completed using acceptable surrogate exposure data. Several handler assessments were completed using data from the Pesticide Handler Exposure Database (PHED version 1.1). Some handler assessments (i.e., handheld handgun equipment, push-type spreader) were completed using data from the Outdoor Residential Exposure Task Force (ORETF).

The following assumptions and factors were used:

- The average body weight of an adult female handler (i.e., 60 kg) is used to complete the risk assessment.
- Risk are assessed at maximum label rates.
- The occupational workday was 8 hours.
- The daily treatment areas treated are defined for each handler scenario by determining the amount that can be reasonably treated in a single day.

#### **d. Occupational Handler Risk Estimates**

Short- and intermediate-term inhalation Margin of Exposure estimates for occupational handler scenarios are greater than 100 at the baseline level of protection (i.e., long-sleeved shirt, long pants, shoes plus socks, no respirator). Short- and intermediate-term inhalation MOEs range from 200 to more than 33,000. Therefore, short- and intermediate-term occupational risks are not of concern.

#### **e. Occupational Post-application Risk**

Since no dermal endpoint has been identified for systemic toxicity, and post-application inhalation exposure is expected to be negligible, no occupational post-application exposure and risk assessment is warranted.

### **7. Human Incident Data**

Relatively few incidents of illness have been reported due to napropamide. However, it appears to be irritating to eyes and skin and has been associated with difficulty breathing when used in enclosed spaces. The following data bases have been consulted for the poisoning incident data on the active ingredient napropamide.

The Agency's Incident Data System (IDS) contains reports of incidents from various sources since 1992. These reports represent anecdotal reports or allegations only, unless otherwise stated. Typically no conclusions can be drawn implicating the pesticide as a cause of

the reported health effect. In the case of napropamide, IDS reported 2 incidents. One user accidentally ingested the product and reportedly had symptoms of oral burns, laryngeal swelling, and excess secretions. The other user was exposed working in a greenhouse and had difficulty breathing and pain in the chest. No further information on the disposition of either case was reported.

A total of six exposures were reported to Poison Control Centers for the nine year period 1993-2001. Three of these cases reported minor symptoms, primarily dermal irritation. 20 cases were reported to the California Pesticide Illness Surveillance Program (1998-2002). In nine of these cases, napropamide was determined to be the primary cause of illness. The principle symptoms reported involved irritation of the eyes.

For the National Institute of Occupational Safety and Health, out of the 4,221 reported cases from 1998-2002, just two involved napropamide alone. In a Florida case, the worker splashed napropamide on himself and developed blisters. A Texas case reported a user having difficulty breathing when using napropamide in an enclosed area. Both cases were considered probable with no more than moderate severity.

No recommendations are being made on napropamide incidents, based on the very limited data available for this pesticide.

## **B. Environmental Risk Assessment**

A summary of the Agency's environmental risk assessment for napropamide is presented below. More detailed information associated with the environmental risk from the use of napropamide can be found in the "*EFED Risk Assessment for the Napropamide Reregistration Eligibility Document*, dated August 15, 2005. In a memorandum entitled "*EFED RED Chapter for Napropamide Chronic Risk Recalculation for Mammals*" dated September 21, 2005, the Agency corrected a toxicity endpoint that resulted in lower chronic mammal RQs. However, this change had little impact on the ecological risk conclusion. This RED reflects the changes outlined in the memo. The complete environmental risk assessment and the memo mentioned above may be accessed in the OPP Public Docket OPP-2004-0162 and on the Agency's website at <http://www.epa.gov/pesticides/reregistration/status.htm>.

### **1. Environmental Exposure**

#### **a. Environmental Fate and Transport**

The environmental hazard and fate database is sufficient to characterize the environmental risks associated with napropamide use. However, EPA intends to issue a DCI following this RED to require submission of additional data for napropamide to address areas of uncertainty. These data are expected to confirm the conclusions of this environmental risk assessment and the Agency's reregistration eligibility decision.

Based on laboratory studies, it is expected that napropamide will be persistent in the terrestrial environment resulting in the potential for the chemical to reach the aquatic environment by runoff. Additionally, because laboratory metabolism studies demonstrate a half-life of approximately 446 days, there is a potential for napropamide to accumulate in the soil with repeated applications. However, field dissipation studies (where napropamide was soil incorporated in various countries) indicate much faster dissipation rates on the order of 17 to 24 days (US) 46 to 131 days (W. Germany), 15 to 51 days (Canada). Although napropamide can photodegrade in water, this route of degradation is expected to be slowed when soil incorporation occurs at time of application. In addition, any napropamide that reaches surface water will tend to partition to suspended soils and sediment, thereby reducing the amount available to undergo photolysis. Napropamide is not expected to be bioaccumulative. The major terminal degradate in terrestrial environments is carbon dioxide, but photodegradation in aquatic systems creates isomers of the parent compound.

Napropamide is expected to have moderate to low mobility in soil based upon batch equilibrium studies showing adsorption coefficient values between 3 to 15 ml/g. Adsorption of napropamide to soil increases with increasing clay content, organic carbon content, and pH. Napropamide is not expected to volatilize from dry soil surfaces based upon its vapor pressure of  $1.7 \times 10^{-7}$  mm Hg.

Napropamide photodegrades on soil with a half-life of 28 days. The major degradate is carbon dioxide. However, it is important to note that napropamide must be incorporated into the soil within one to 21 days of application in order to be efficacious; therefore, photodegradation on soil may not be a major route of dissipation.

In water, napropamide is expected to adsorb to suspended solids and sediment. Napropamide is stable to hydrolysis at pH 5, 7, and 9, but undergoes rapid direct photolysis in water with a half-life of 6.8 minutes for the parent compound napropamide. Identified degradates were Isomer I and Isomer II (propionamide). The two isomers also degrade rapidly, as the total residue (napropamide plus Isomers I and II) half-life in the photodegradation in water study was only 26 minutes. Because of light attenuation, aqueous photolysis will be an important pathway only in shallow, clear water bodies. Binding to suspended solids and sediment can also diminish the role photolysis plays in the degradation of napropamide. Neither volatilization from water nor bioconcentration are expected to be important fate processes.

#### **b. Aquatic Organism Exposure**

For exposure to aquatic fish and invertebrates, EPA considers surface water only, since most aquatic organisms are not found in ground water. Surface water models are used to estimate exposure to freshwater aquatic animals. The modeling results used in risk calculations for napropamide are detailed in the EFED chapter.

Unlike the drinking water assessment described in the human health risk assessment

section of this document, the ecological water resource assessment does not include the Index Reservoir (IR) and Percent-Crop Area (PCA) factor refinements. The IR and PCA factors represent a drinking water reservoir, not the variety of aquatic habitats, such as ponds adjacent to treated fields, relevant to a risk assessment for aquatic animals. Therefore, the EEC values used to assess exposure to aquatic animals are not the same as the values used to assess human dietary exposure from drinking water.

The Agency modeled surface water exposure using the Tier II Surface Water Computer model PRZM-EXAMS. Using PRZM-EXAMS, the Agency modeled a variety of crops where scenarios existed, use data were available, maximum application rates were highest, and geographical distribution of the crops were covered. Because the label does not specifically require soil incorporation at the time of application, EECs in the aquatic environment were determined assuming both soil incorporation and no soil incorporation at the time of application. The modeled surface water scenarios addressed the geographical distribution of specific crops in the US and the associated weather extremes. For example, citrus was modeled both in California and Florida, and apples were modeled in Oregon, North Carolina and Pennsylvania. Berries (e.g. blackberries and raspberries) were modeled in Oregon (Pacific Northwest). Pecans were modeled in Georgia, which created the highest estimates of water concentrations (See Table 8). EPA modeled cranberries based on a model designed to evaluate water concentrations for rice. See the EFED risk assessment for a complete listing of scenarios which were modeled. The resulting estimated environmental concentrations (EECs) from PRZM-EXAMS are presented in the table below

**Table 8: Estimated Environmental Concentrations (EECs) of Napropamide in Surface Water**

Crop/Scenario	EECs of Napropamide in Surface Water (ppb)		
	Peak	21-day Average	60-day Average
GA Pecan (6 lbs ai/A x1)	209.4	17.8	6.7
GA Pecan (4 lbs ai/A x 2)	156	12.1	4.7
GA Pecan (2 lbs ai/A x 1) Banded	69.7	5.9	1.6
GA Pecan (1 lbs ai/A x 2) Banded	52.3	4.0	1.6

**c. Terrestrial Organism Exposure**

The Agency assessed exposure to terrestrial organisms by first predicting the amount of napropamide residues found on animal food items and then by determining the amount of pesticide consumed by using information on typical food consumption by various species. Terrestrial wildlife exposure estimates are typically calculated for birds and mammals,



emphasizing a dietary exposure route for uptake of pesticide active ingredients. These exposures are considered as surrogates for terrestrial-phase amphibians as well as reptiles. For exposures to terrestrial organisms, such as birds and mammals, pesticide residues on food items are estimated based on the assumption that organisms are exposed to a single pesticide residue in a given exposure scenario. The application methods for napropamide are ground applications only (ground spray, chemigation, and granular broadcast). Because the label does not require immediate soil incorporation at the time of application (up to 3 weeks), EECs in the terrestrial organisms were determined assuming both soil incorporation and no soil incorporation at the time of application.

### Granular Applications

Napropamide is applied to crops in granular form. Birds may be exposed to granular pesticides by ingesting granules when foraging for food or grit. However, an avian risk assessment was not performed for napropamide because the avian toxicity profile showed that napropamide is not toxic to birds. Mammalian species may be exposed by walking on exposed granules or drinking water contaminated by granules. However, EPA does not currently assess chronic risks to mammals from granular applications because the Agency assumes that granular formulations disperse and disintegrate over a short period of time.

### Spray Applications and Residues

For napropamide spray applications, estimation of pesticide concentrations in wildlife food items focuses on quantifying possible dietary ingestion of residues on vegetative matter and insects. The residue estimates are based on a nomogram that relates food item residues to pesticide application rate. The estimated environmental concentrations (EECs) are generated from a spreadsheet-based model (T-REX) that calculates the decay of a chemical applied to foliar surfaces for single or multiple applications.

The terrestrial exposure assessment is based on the methods of Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994). Terrestrial EECs for liquid formulations were derived for representative major crops using current application rates and intervals between applications where applicable.

The EECs on food items may be compared directly with dietary toxicity data (as is the case for birds - acute and chronic RQ calculations; chronic RQ calculations for mammals) or converted to an oral dose (as is the case for and small mammals). The screening-level risk assessment for napropamide uses upper bound predicted residues as the measure of exposure. The predicted maximum residues of napropamide that may be expected to occur on selected avian or mammalian food items immediately following application are presented in table 9.

**Table 9: Upper Bound EECs of Napropamide on Mammalian Food Items**

Application rate	Estimated Environmental Concentration (EEC) (ppm)			
	Short grass	Tall grass	Broadleaf plants/small insects	Fruits/pods/large insects
6 lbs ai/A x 1 (broadcast)	1140	660	810	90
6 lbs ai/A x 1 (banded)	480	220	270	30
4 lbs ai/A x 2 (broadcast)	1253	574	705	78
4 lbs ai/A x 1 (broadcast)	960	440	540	60
3 lbs ai/A x 2 (broadcast)	939	431	528	59
2 lbs ai/A x 2 (broadcast)	480	220	270	30
2 lbs ai/A x 1 (banded)	160	73	90	10
1.33 lbs ai/A x 2 (banded) <sup>a</sup>	137	64	78	9
1 lbs ai/A x 1 (broadcast) <sup>b</sup>	240	110	135	15

<sup>a</sup> Application interval of 60 days

<sup>b</sup> Average napropamide use rate on tobacco

EECs for avian diets are not presented because napropamide is essentially non-toxic to birds.

#### **d. Non-target Terrestrial Plant Exposure**

Terrestrial plants in dry and semi-aquatic (wetland) areas may be exposed to pesticides from runoff and/or spray drift. EPA used the TERRPLANT model to estimate napropamide residues in areas adjacent to the treated field (sheet runoff), wetland areas (channelized runoff), and from spray drift.

Screening level TERRPLANT modeling uses the maximum single application rate of the different types of uses (orchards and vineyards at 6 lbs ai/A, vineyards at 6 lbs ai/A, and row crops at 2 and 4 lbs ai/A), as well as the lowest average napropamide use rate of 1 lb ai/A (tobacco). Napropamide products (both granular and liquid) specify incorporation by either wetting in or mechanical means. Consequently, the Agency modeled risk to terrestrial plants assuming incorporation of 2 to 4 inches of depth to bracket potential exposure. These depths are specified in labels as being minimum depths to incorporate applied napropamide. Incorporation to 4-inch depth resulted in slightly lowered EECs as compared to the 2-inch incorporation. Selected results are included in Table 10. For additional estimates, please see the environmental risk assessment.

**Table 10: Napropamide Terrestrial Plant EECs for Non-Target Vascular Plants**

Crop/ scenario	Form	Application	Adjacent Area Runoff	Wetland Area Runoff	Spray Drift
			ppb		
6 lbs ai./acre	Liquid	Ground Unincorp.	0.18	1.26	0.06
		Ground Incorp. (2 in.)	0.12	0.66	0.06
		Spray Chemigation	0.37	1.2	0.3
	Granular	Ground Unincorp	0.12	1.2	N/A
		Ground Incorp. (2 in.)	0.06	0.6	N/A
		Ground Incorp. (4 in.)	0.03	0.30	N/A
1.33 lbs ai./acre	Liquid	Ground Unincorp	0.04	0.28	0.01
		Ground Incorp. (2 in.)	0.03	0.15	0.01
		Spray Chemigation	0.08	0.23	0.07
	Granular	Ground Unincorp	0.03	0.30	N/A
		Ground Incorp. (2 in.)	0.013	0.13	N/A
		Ground Incorp. (4 in.)	0.007	0.07	N/A

**2. Environmental Effects (Toxicity)**

**a. Toxicity to Aquatic and Terrestrial Organisms**

Napropamide is classified as practically non-toxic to avian species on both an acute oral and subacute dietary basis; is practically non-toxic to mammalian species on an acute oral basis; is moderately toxic to freshwater fish; is slightly toxic to freshwater invertebrates; is slightly toxic to estuarine/marine fish; and is moderately toxic to estuarine/marine invertebrates.

**Table 11: Summary of Napropamide Acute Aquatic Toxicity Data**

Species	Acute Toxicity		Chronic Toxicity	
	LC <sub>50</sub> or EC <sub>50</sub> (mg ai/L)	MRID	LOAEC/NOAEC (mg/L)	MRID
Rainbow Trout <i>Oncorhynchus mykiss</i>	6.4	115313	1.9/1.1	464591-09
Water Flea <i>Daphnia magna</i>	14.3	88064 57805	2.2/1.1	464787-04
Sheepshead Minnow <i>Cyprinodon variegatus</i>	14	416102-06	NO DATA	NO DATA
Eastern Oyster <i>Crassostrea virginica</i>	1.4	416671-01	NO DATA	NO DATA
Mysid Shrimp <i>Americamysis bahia</i>	4.2	416102-07	NO DATA	NO DATA

**Table 12: Summary of Napropamide Acute and Chronic Terrestrial Organism Toxicity Data**

Species	Acute Toxicity				Chronic Toxicity		
	Oral Toxicity LD <sub>50</sub> (mg ai/kg)	MRID	Subacute Dietary LC <sub>50</sub> (mg ai/kg)	MRID	NOAEC (mg ai/kg)	MRID	Affected Endpoints
Mallard Duck <i>Anas platyrhynchos</i>	>4640	229652	>5620	258393 113820 <sup>1</sup>	1000	79548 and 79555 <sup>1</sup>	NA <sup>2</sup>
Laboratory Rat <i>Rattus norvegicus</i>	>5000	230602	NA	NA	30	40362902	growth & reproduction
Honey Bee <i>(Apis mellifera)</i>	>113.5 ug ai/bee	464591- 15	NA	NA	NA	NA	NA

<sup>1</sup> Accession number<sup>2</sup> The effect demonstrated on body weight was deemed not related to the toxicant effects of napropamide.**Table 13: Summary of Napropamide Most Sensitive Plant Toxicity Endpoints**

Species	Toxicity		
	EC <sub>25</sub> / EC <sub>05</sub>	NOAEC (ppm)	Affected Endpoint (MRID)
Green alga <i>Selenastrum capricornutum</i> (TGAI)	3.4 (ppm)	NA	Cell Density (416102-10)
Blue-green alga <i>Anabaema sp.</i> (TGAI)	EC <sub>50</sub> = 3.4 EC <sub>50</sub> = 1.8 (ppm)	5.05	Cell Density (464591-12)
Aquatic Vascular Plant <i>Lemna Minor</i> (TGAI)	EC <sub>50</sub> = 0.35 EC <sub>50</sub> = 0.036 (ppm)	0.071	Biomass (464591-11)
Terrestrial plants	2.1- 0.095 (lbs ai/A)	< 0.017	Percent emergence and dry weight

**b. Ecological Risk Estimation (RQs)**

The Agency’s ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to non-target organisms from the use of napropamide products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the EEC to the most sensitive toxicity endpoint values, such as the median lethal dose (LD<sub>50</sub>) or the median lethal concentration (LC<sub>50</sub>). These RQ values are then compared to the Agency’s levels of concern (LOCs), given in Table 14, which indicate whether a pesticide, when used as directed, has the potential to cause adverse effects on non-target organisms. When the RQ exceeds the LOC for a particular category (e.g., endangered species), the Agency presumes a risk of concern to that category. These risks of concern may be addressed by further refinements of the risk assessment or mitigation. Use, toxicity, fate, and exposure are considered when characterizing the risk, as well as the levels of certainty and uncertainty in the assessment. EPA further characterizes ecological risk based on any reported incidents to non-target terrestrial or aquatic organisms in the field (e.g., fish or bird kills).

**Table 14: EPA’s Levels of Concern and Associated Risk Presumptions.**

If RQ > LOC value given below.....			Then EPA presumes .....
Terrestrial Organisms	Aquatic Organisms	Plants	Risk Presumption
0.5	0.5	1	<b>Acute Risk</b> - there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification.

If RQ > LOC value given below.....			Then EPA presumes .....
Terrestrial Organisms	Aquatic Organisms	Plants	Risk Presumption
0.2	0.1	N/A	<b>Acute Restricted Use</b> - there is potential for acute risk, but may be mitigated through restricted use classification.
0.1	0.05	1	<b>Acute Endangered Species</b> - endangered species may be adversely affected; regulatory action may be warranted.
1	1	N/A	<b>Chronic Risk</b> - there is potential for chronic risk; regulatory action may be warranted.

For a more detailed explanation of the ecological risks posed by the use of napropamide, refer to *EFED Risk Assessment for the Napropamide Reregistration Eligibility Document*, dated August 15, 2005.

## 1. Risk to Aquatic Organisms

### Fish and Aquatic Invertebrates

Acute RQ values for estuarine/marine invertebrates were all  $\leq 0.16$ . The highest RQs were estimated for Florida citrus and Georgia pecan scenarios. No LOCs were exceeded for chronic risks to aquatic organisms based on limited data. EPA has determined that additional chronic toxicity data should be submitted because of the potential environmental persistence of napropamide which may cause chronic exposure to aquatic organisms.

**Table 15: Acute Risk Quotients (RQ) for Estuarine/Marine Animals**

Crop Scenario	Application	Estuarine/Marine Invertebrates RQ
FL Citrus	4 lbs ai/A x 2 (broadcast)	0.16
GA Pecan	4 lbs ai/A x 2 (broadcast)	0.111
	6 lbs ai/A x 1 (broadcast)	0.15

### Aquatic Plants

RQs calculated for algae and non-listed aquatic vascular plants did not exceed EPA's level of concern for any uses of napropamide.

## 2. Risk to Non-target Terrestrial Organisms

## Birds

Toxicity data classify napropamide as practically nontoxic to birds. Therefore, avian environmental dietary exposure to napropamide is not expected to cause significant acute and chronic risks to birds.

## Mammals

Acute RQs for mammals were below the Agency's level of concern. Chronic RQs exceeded LOCs for mammals of all weights assessed. The majority of exceedences occurred for scenarios that evaluate mammals feeding on short grass, tall grass, and broadleaf plants/small insects. However, a few exceedences were estimated for mammals that feed on fruits/pods/large insects when the higher application rates are considered.

**Table 16: Mammalian Chronic RQ Values for Napropamide**

Application rate	Mammalian Chronic Risk Quotients			
	Short grass	Tall grass	Broadleaf plants/small insects	Fruits/pods/large insects
6 lbs ai/A x 1(broadcast)	<b>9.5 - 21</b>	<b>4.4 - 9.5</b>	<b>5.4 - 12</b>	0.6 - <b>1.3</b>
6 lbs ai/A x 1(banded)	<b>3.2 - 6.9</b>	<b>1.5 - 3.2</b>	<b>1.8 - 3.9</b>	0.2 - 0.4
4 lbs ai/A x 2 (broadcast)	<b>8.3 - 18</b>	<b>3.8 - 8.3</b>	<b>4.7 - 10</b>	0.5 - <b>1.1</b>
4 lbs ai/A x 1(broadcast)	<b>6.4 - 14</b>	<b>2.9 - 6.4</b>	<b>3.6 - 7.8</b>	0.4 - 0.9
3 lbs ai/A x 2 (broadcast)	<b>6.2 - 14</b>	<b>2.8 - 6.2</b>	<b>3.5 - 7.6</b>	0.4 - 0.8
2 lbs ai/A x 1(broadcast)	<b>3.2 - 6.9</b>	<b>1.5 - 3.2</b>	<b>1.8 - 3.9</b>	0.2 - 0.4
2 lbs ai/A x 1(banded)	<b>1.1 - 2.3</b>	0.5 - <b>1.1</b>	0.6 - <b>1.3</b>	0.07 - 0.1
1.33 lbs ai/A x 2 (banded)	0.9 - <b>2.0</b>	0.4 - 0.9	0.5 - <b>1.1</b>	0.06 - 0.1
1 lb ai/A x 1 <sup>3</sup> (broadcast)	<b>1.6 - 3.5</b>	0.7 - <b>1.6</b>	0.9 - <b>2.0</b>	0.1 - 0.22

<sup>1</sup>Lowest average use rate (tobacco)

**exceedances indicated in bold**

## Non-Target Insects

EPA currently does not routinely quantify risks to terrestrial non-target insects; therefore, risk quotients are not calculated for these organisms. Since napropamide is practically non-toxic to honey bees ( $LD_{50} > 113.5$  ug ai/bee) the potential for napropamide to have adverse effects on pollinators and other beneficial insects is low.

## Non-target Terrestrial Plants

Terrestrial plant risks were evaluated by RQ calculation for seedling emergence for non-endangered terrestrial and wetland/riparian plants (monocot and dicot) from sheet and channelized run-off. Vegetative vigor risks were evaluated for non-endangered terrestrial and wetland/riparian plant (monocot and dicot) from spray drift calculations. The Agency's plant LOC of 1.0 was exceeded at all application rates evaluated (6, 4, 2, 1 lb and 1.33 ai/A) with dicots generally showing more sensitivity than monocots. RQs for plants in areas adjacent to treated fields exceeded LOCs at all modeled application rates at different depths of incorporation with RQs ranging up to 12.

For endangered species, wetland plant risks were identified at all application rates and application methods modeled, with one exception (1 lb ai/A liquid application, incorporated to 4 inches). Plant risks were identified under all scenarios for the highest application rates modeled (6 lbs ai/A and 4 lbs ai/A), with the exception of monocots exposed to granular applications incorporated to 4 inches.

For a complete listing of other rates, please refer to *EFED Risk Assessment for the Napropamide Reregistration Eligibility Document*, dated August 15, 2005

### **3. Ecological Incidents**

EPA completed a review of the EIS database for ecological incidents involving napropamide. There were two reported incidents. The first incident involved adverse effects on fish (incident # 1000799-04). Napropamide and chlorpyrifos residues were identified in soil in the vicinity of a fish pond. The report deemed chlorpyrifos as a more probable reason for the incident than napropamide due to chlorpyrifos' high toxicity to fish. Napropamide is only slightly to moderately toxic to fish. The second incident report involved damage to seven acres of planted Douglas fir trees. The report concluded that napropamide was not likely the cause of the damage because it had only been applied once to the area. Oryzalin, which was used in the vicinity of the tree damage, was determined to be the likely cause of the damage; the oryzalin label specifically warns that it could damage Douglas fir trees.

### **4. Endangered Species Concerns**

EPA's ecological risk assessment concludes that RQs did not exceed an acute LOC for direct effects (no effect) from uses of napropamide to the following listed species: insects, birds, terrestrial phase amphibians, reptiles, freshwater fish, aquatic phase amphibians, freshwater crustaceans and marine/estuarine fish. Further, RQs did not exceed a chronic LOC for direct effects (no effect) for: insects, birds, terrestrial phase amphibians, reptiles, freshwater fish, aquatic phase amphibians, and freshwater crustaceans. Based on EPA's screening level assessment and as noted below, RQs for napropamide exceed acute levels of concern for direct effects to endangered species of mammals, mollusks, marine/estuarine crustaceans, aquatic vascular plants and terrestrial and semi-aquatic plants (both dicots and monocots). RQs were also exceeded for



chronic direct effects to mammals. While there are no chronic data on which to assess the potential for chronic effects to mollusks, marine/estuarine fish and marine/estuarine crustaceans, chronic NOAECs could be estimated for marine/estuarine fish and crustaceans using acute to chronic ratios derived using acute and chronic rainbow trout and daphnia toxicity results. These estimates would indicate the potential for 21-day EEC's to exceed LOC's for chronic concerns.

The screening level assessment for napropamide resulted in acute endangered species risks RQs above EPA's level of concern for marine/estuarine mollusks under several scenarios including Florida citrus, Oregon filbert, Pennsylvania apple, North Carolina apple, Georgia pecan, Florida tomato, and Florida pepper. Listed species RQs for aquatic invertebrates exceeded the LOC in only one scenario for marine/estuarine crustaceans (Florida citrus, 4 lbs ai/A applied twice). Also, the LOC is exceeded for endangered vascular aquatic plants under several scenarios. Chronic mammalian RQ values exceeded the LOC on grasses, broadleaf plants, and small insects at all modeled rates. Listed wetland plant risks were identified at all application rates and application methods modeled, with one exception (1 lb ai/A liquid application, incorporated to 4 inches). In addition, listed terrestrial plant risks were identified under all scenarios for the highest application rates modeled (6 lbs ai/A and 4 lbs ai/A), with the exception of monocots exposed to granular applications incorporated to 4 inches. At lower application rates (2, 1.33, and 1 lb ai/A), exceedances occurred for listed terrestrial plants under most scenarios. Additionally, there is a potential for indirect effects on any listed species that is either dependent upon mammals and /or dependent upon terrestrial and semi-aquatic plants, aquatic vascular plants, mollusks, and marine/estuarine crustaceans and occurs within areas where exposure is sufficient to produce adverse effects on these species mammals and/or terrestrial plants.

## **5. Risk Characterization**

The environmental risks for napropamide were based on a screening-level assessment to both terrestrial and aquatic environments from labeled uses of the chemical. The assessment was performed on geographic areas where the highest use rates and expected exposures are likely to occur. Results show some concerns for terrestrial and wetland/riparian plants (which are not unexpected due to the herbicidal nature of the compound), as well as some chronic risks to mammals. This is a screening-level assessment, and therefore, results should be considered conservative in nature. For example, upper-end risk values estimated in the assessment do not take into account some key cultural practices, such as banded applications, which greatly reduce the total amount of napropamide applied per acre. Also, this assessment does not account for the common technique of using plastic tarpaulins to cover the area directly below the crop to keep fruit and vegetables from contacting the soil. These tarpaulins likely reduce the extent of napropamide exposure to mammals following application of both granular and liquid formulations.

Additionally, where data were not available for evaluation, the Agency used conservative assumption values to calculate residue estimates for ecological assessment. Laboratory data indicated napropamide persistence, but field dissipation data from outside the United States,

indicated dissipation of approximately two months or less. Also, no foliar dissipation data were available, so a default half-life of 35 days was used to predict foliar residues for chronic risk calculations.

EPA modeled an application interval of 60 days for all scenarios with multiple applications. The use of 60 days is in accordance with labels for napropamide applied to turf and ornamentals. The Agency also believes that the 60-day interval is appropriate for the other crops with multiple applications.

The Agency recognizes that in many situations pre-emergence herbicides such as napropamide may be banded instead of broadcasted to an entire field. Therefore, EPA modeled potential exposure to plant and animals using both the maximum labeled rate(s) and “typical” banded rates (1.33 lbs ai/A). The 1.33 pound rate came from the 4 pound ai/A rate divided by 3 to account for banding treatment in the field.

The cranberry scenario resulted in exceedances of the Agency’s LOCs from peak estimates for aquatic animals and plants. However, the concentration of napropamide in water degrades within 1 hour. Therefore, flood water released into the surrounding aquatic habitats is not expected to pose a significant risk to aquatic organisms in these environments.

Avian risk assessments were not conducted for napropamide use because acute toxicity studies classified napropamide as practically nontoxic to birds. Furthermore, no chronic avian endpoint of concern was identified from available studies.

#### **IV. Risk Management, Reregistration, and Tolerance Reassessment Decision**

##### **A. Determination of Reregistration Eligibility**

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data to support reregistration of products containing napropamide as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing napropamide.

The Agency has completed its assessment of the dietary, residential, occupational, and ecological risk associated with the use of pesticide products containing the active ingredient napropamide from all sources. Based on a review of these data and on public comments on the Agency’s assessments for the active ingredient napropamide, the Agency has sufficient information on the human health and ecological effects of napropamide to make decisions as part of the tolerance reassessment process under FFDC and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that napropamide containing products are

eligible for reregistration provided that: (i) the risk mitigation measures outlined in this document are adopted; and (ii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of napropamide that are eligible for reregistration. Appendix B identifies the generic data requirements necessary as part of the Agency's determination of reregistration eligibility of napropamide, and lists the submitted studies that the Agency reviewed and found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of napropamide, the Agency has determined that napropamide products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA and FQPA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of napropamide. If all changes outlined in this document are incorporated into the product labels, then all current risks for napropamide will be adequately reduced for the purposes of this reregistration determination under FIFRA. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in section IV, number 4 below.

## **B. Public Comments**

Through the Agency's public participation process, EPA worked extensively with stakeholders and the public to reach its regulatory decisions for napropamide. During Phase 3 of the public comment period on the risk assessments, which closed on May 5, 2005, the Agency received comments from the registrant, grower groups and a private citizen. The comments pertained to the importance of particular uses and urged the Agency to consider how it regulated these commodities. For example, the Northern California Mint Growers submitted comments on the importance of napropamide for mint, and Walters Garden, Inc. outlined how it uses napropamide to reduce its need for the fumigant methyl bromide. These comments in their entirety, and the Agency's response, are available in the public docket (OPP-2004-0162) at <http://www.epa.gov/edockets>.

The RED and technical supporting documents for napropamide are available to the public through EPA's electronic public docket and comment system, EPA Dockets, under docket identification (ID) number OPP-2004-0162. The public may access EPA Dockets at <http://www.epa.gov/edockets>. In addition, the napropamide RED document may be downloaded or viewed through the Agency's website at <http://www.epa.gov/pesticides/reregistration/status.htm>.

## **C. Regulatory Position**

### **1. Food Quality Protection Act Findings**

#### **a. "Risk Cup" Determination**

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. EPA has determined that risk from dietary (food and water) exposure to napropamide is within its own “risk cup.” An aggregate assessment was conducted for exposures to napropamide through food, drinking water, and residential uses. The Agency has determined that the human health risks from these combined exposures to napropamide are within acceptable levels. In other words, EPA has concluded that the tolerances for napropamide meet FQPA safety standards.

**b. Determination of Safety to U.S. Population (including Infants and Children)**

The Agency has determined that the established tolerances for napropamide, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of napropamide. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of napropamide.

**c. Endocrine Disruptor Effects**

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 endocrine effects as the Administrator may designate.” Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the toxicity studies on napropamide, there was no estrogen, androgen, and/or thyroid mediated toxicity. When additional appropriate screening and/or testing protocols being considered under the Agency’s EDSP have been developed, napropamide may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

**d. Cumulative Risks**

Risks summarized in this document are those that result only from the use of napropamide. The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide’s residues and

other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for napropamide.

**D. Tolerance Reassessment Summary**

The napropamide tolerances listed under 40 CFR §180.328(a) and (b) are expressed in terms of N,N-diethyl-2-(1-naphthalenyloxy) propionamide. The tolerance expression is adequate. A summary of the tolerance reassessment and recommended modifications in commodity definitions for napropamide is presented in Table 18.

Although additional data are required to confirm the existing tolerance levels in/on the following commodities, the Agency has no dietary, drinking water or residential risk concerns associated with these tolerances and considers them reassessed: blackberry, blueberry, boysenberry, loganberry, raspberry, kiwi fruit, almonds, pecan, filbert, persimmon, and grape.

**Napropamide Table 18: Tolerance Reassessment Summary for Napropamide**

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ [Correct Commodity Definition]
<b>Tolerances Listed Under 40 CFR §180.328(a)</b>			
Almond, hulls	0.1 (N)*	0.1	
Artichoke, globe	0.1	Proposed Revocation	This use is being proposed for cancellation.
Asparagus	0.1	0.1	
Avocado	0.1	Proposed Revocation	This use is being proposed for cancellation by the registrant.
Basil	0.1	0.1	
Marjoram	0.1	0.1	
Rosemary	0.1	0.1	
Savory, summer	0.1	0.1	
Savory, winter	0.1	0.1	
Coffee bean	0.1 (N)	0.1	Although the registrant stated that they do not intend to support this use because there are no U.S. registration for coffee bean, EPA intends to maintain this tolerance for import uses only.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ [Correct Commodity Definition]
Fig	0.1 (N)	Proposed Revocation	This use is being proposed for cancellation.
Fruit, citrus	0.1 (N)	Proposed Revocation	[Fruit, citrus, group 10] These uses are being proposed for cancellation.
Fruit, pome	0.1 (N)	Proposed Revocation	These uses are being proposed for cancellation.
Fruit, small	0.1 (N)	TBD**	The established group tolerance on "fruit, small" is based on an obsolete crop grouping. EPA is now recommending that upon submission of additional field trial data, the tolerance for "fruit, small" be revoked concomitant with the establishment of a separate tolerance for Berry group 13, cranberry, grape, and strawberry. [Berry, group 13]
Fruit, stone	0.1 (N)	Proposed Revocation	These uses are being proposed for cancellation.
Kiwifruit	0.1	TBD	Additional residue field trial data are required.
Mint	0.1	0.1	[peppermint, tops and spearmint, tops]
Nut	0.1 (N)	TBD	Additional field trial data are required for almonds, pecans, and filbert. The remaining uses on nuts are being proposed for cancellation.***
Olive	0.1	Proposed Revocation	This use is being proposed for cancellation.
Persimmon	0.1	TBD	Additional data are required.
Pistachio	0.1	Proposed revocation	This use is being proposed for cancellation.
Rhubarb	0.1	0.1	
Sweet potato, roots	0.1	0.1	
Vegetable, brassica, leafy, group 5	0.1	0.1	
Vegetable, cucurbit, group 9	0.1	Revoke	There are presently no registered uses of napropamide on cucurbit vegetables. Unless the basic registrants or other interested parties support these uses and develop supporting data, the established tolerance will be revoked.
Vegetable, fruiting	0.1 (N)	0.1	[Vegetable, fruiting, group 8]
<b>Tolerances to be Established Under CFR §180.328(a)</b>			

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ [Correct Commodity Definition]
Berry, group 13	--	TBD	The established group tolerance on “fruit small” is based on an obsolete crop grouping. EPA is now recommending that the tolerance for “fruit, small” be revoked concomitant with the establishment of separate tolerances for cranberry and strawberry, and upon submission of additional field trial data, for Berry group 13 and grape.
Cranberry	--	0.1	
Grape	--	TBD	
Strawberry	--	0.1	
<b>Tolerances Listed Under 40 CFR §180.328(b)</b>			
Pomegranate	0.1	Proposed Revocation	This use is being proposed for cancellation.

\* Negligible Residues

\*\* TBD - To be determined following review of the data being required herein.

\*\*\* The use on walnut will be cancelled. Uses on almonds, pecan, and filbert will remain.

#### **a. Codex Harmonization**

No Codex or Canadian MRLs have been established for residues of napropamide.

### **E. Regulatory Rationale**

The following is a summary of the rationale for the mitigation measures necessary for reregistration eligibility and for managing risks associated with the use of napropamide. Where labeling revisions are warranted, specific language is set forth in the summary table of Section V (Table 20 of this RED document).

#### **1. Human Health Risk Management**

##### **a. Dietary (Food and Water) Risk Mitigation**

Acute dietary risk was not assessed because there were no toxicological endpoints attributable to a single exposure. Chronic dietary (food and water) exposure and risk from napropamide are below Agency’s level of concern; therefore, no additional mitigation is required.

##### **b. Residential Risk Mitigation**

Residential exposures do not pose a risk of concern. Therefore, no additional mitigation measures to address residential risks are required for napropamide.

##### **c. Aggregate Risk Mitigation**

Short term and chronic aggregate risks were below the Agency's level of concern. Therefore, no additional mitigation measures are required.

#### **d. Occupational Risk Mitigation**

Short- and intermediate-term inhalation risks to occupational handlers scenarios are below the Agency's level of concern (i.e., MOE  $\geq$ 100). Therefore, no additional mitigation is needed. EPA did not assess occupational postapplication risks to agricultural workers following treatments to agricultural crops with napropamide, since no dermal endpoint of concern was identified and because post application inhalation exposure is expected to be negligible once sprays and dusts have settled. Therefore, no mitigation measures are required. As a result, the general 12 hour REI, as established by the Worker Protection Standard, applies to all napropamide agricultural use products.

### **2. Environmental Risk Mitigation**

No risks of concern (acute or chronic) are predicted for aquatic organisms; however, chronic toxicity data are limited and will be required as a follow-up to this RED. Napropamide is essentially non-toxic to birds. There were no exceedences for acute risk to mammals. However, the Agency has determined that napropamide may pose risks to mammals and plants. The Agency's screening level risk assessment on napropamide shows chronic risk to mammals feeding on short grass, tall grass, broadleaf plants, small insects, fruits, pods, and large insects. At all modeled application rates, terrestrial and wetland/riparian plants exceed the Agency's level of concern. The following mitigation will reduce ecological risks:

- *Cancellation of the following uses: pistachio, walnut, grapefruit, lemon, nectarine, orange, tangerine, tangelo, apricot, cherry, peach, plum, prune, apple, pear, fig, avocado, pomegranate, artichoke, and olive.*
- *Limitation of the number of applications permitted to once per year for all remaining uses (except ornamentals).*
- *A decrease in the maximum application rate for almonds (8 to 4 lbs per year), pecans (8 to 4 lbs per year), cranberries (15 to 9 lbs per year), grapes (8 to 4 lbs per year), kiwi fruit (8 to 4 lbs per year), persimmons (8 to 4 lbs per year) , and turf (6 to 2 lbs per year).*

Table 19 identifies all remaining uses that will be permitted after the mitigation measures are put in place:

**Table 19: Napropamide: Remaining Uses and Application Rates**



<b>Site</b>	<b>New Maximum Rate (lb ai/A)</b>	<b>No App/year</b>	<b>Max Load/Year (lb ai/A)</b>
<b>Tree Nuts</b>			
<i>Almond</i>	4	1	4
<i>Pecan</i>	4	1	4
Filbert	4	1	4
<b>Brassica Crops</b>			
Broccoli	2	1	2
Brussels sprouts	2	1	2
Cabbage	2	1	2
Cauliflower	2	1	2
Asparagus	2	1	2
<b>Berries</b>			
Blackberry	4	1	4
Blueberry	4	1	4
Boysenberry	4	1	4
Loganberry	4	1	4
Raspberry	4	1	4
Strawberry	4	1	4
<i>Cranberry</i>	9	1	9
<b>Tropical Fruits</b>			
<i>Kiwi Fruit</i>	4	1	4
<i>Persimmon</i>	4	1	4
<b>Fruiting Vegetables</b>			
Eggplant	2	1	2
Pepper	2	1	2
Tomato	2	1	2
<b>Additional Crops</b>			
<i>Grapes</i>	4	1	4

Site	New Maximum Rate (lb ai/A)	No App/year	Max Load/Year (lb ai/A)
Sweet Potato	4	1	4
Tobacco	2	1	2
Basil	4	1	4
Marjoram	4	1	4
Mint	4	1	4
Rosemary	4	1	4
Savory	4	1	4
<b>Ornamentals</b>			
Ornamentals*	6	2	12
<i>Turf</i>	2	1	2

Italicized crops denote changes in use rates

\* Includes shade trees/ornamental trees(field and container grown), ground cover, herbaceous plants, woody shrubs, vines, dichondra at seeding

### 3. Significance of Napropamide Use

Napropamide is an important herbicide with key uses in several agricultural sectors. For ornamentals, it is significantly important in the Pacific Northwest. Although napropamide is only used on 1 percent of ornamentals nationally, in Washington it is used on 97 percent of the nursery-grown rhododendron and azalea crop. It also provides a critical niche for tomatoes and peppers since many alternatives are not labeled for pre-plant incorporated treatments that are needed for these production activities. It provides a niche for eggplant and tobacco to control weeds where other alternatives do not give adequate control. In addition, for a number of crops, napropamide is important to growers as they transition away from methyl bromide.

As already discussed in this RED document, the environmental risks for napropamide were based on a screening-level assessment for both terrestrial and aquatic environments. Results indicate some concerns for acute risks to terrestrial and wetland/riparian plants (which are not unexpected due to the herbicidal nature of the compound), as well as some chronic risks to mammals. In order to address these ecological risks, the Agency will require napropamide registrants to reduce the total napropamide used while still preserving many of the important uses of this chemical. Reduction of use, and subsequent reduction of ecological exposure, will result from a combination of voluntary cancellations, lowering the use rate of several crops and limiting the number of applications per year for most crops (See Table 19 for specifics on the new uses and use rates). As a result of these mitigation measures, the amount of napropamide exposure to

plant, animal, and water resources is lowered therefore, limiting the amount that is released into the environment.

#### **4. Endangered Species Considerations**

Based on EPA's screening level assessment, RQs for napropamide exceed acute levels of concern for direct effects to endangered species of mammals, mollusks, marine/estuarine crustaceans, aquatic vascular plants and terrestrial and semi-aquatic plants (both dicots and monocots). RQs were also exceeded for chronic direct effects to mammals. Further, based on screening level assessments of potential direct effects to these taxa, the potential for indirect effects to all taxa of listed species can not be precluded at this time. These findings are based solely on EPA's screening level assessment and do not constitute "may affect" finding under the Endangered Species Act.

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 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 to affect any particular species, EPA puts basic toxicity and exposure data developed for reregistration eligibility decisions into context for individual listed species and their locations by evaluating important ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations and biological requirements and behavioural aspects of the particular species. When conducted, this analysis will consider regulatory changes recommended in this RED that are being implemented at that time. A determination that there is a likelihood of potential impact to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service or National Marine Fisheries Service as necessary. If the Agency determines use of napropamide "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

EPA is not requiring specific napropamide label language at the present time relative to threatened and endangered species. If in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program. Until that species specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to napropamide at levels of concern.

#### **F. Other Labeling Requirements**

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing napropamide. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

## **1. Spray Drift Management**

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, EPA will continue to work with all interested parties on this important issue.

From its assessment of napropamide, as summarized in this document, the Agency concludes that no additional drift mitigation measures are needed for napropamide. In the future, napropamide product labels may need to be revised to include additional or different drift label statements.

### **V. What Registrants Need to Do**

The Agency has determined that napropamide is eligible for reregistration provided that: (i) additional data are submitted to confirm this decision; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants will be required to amend their product labeling to incorporate the label statements set forth in the Label Summary Table in Section C below. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring label amendments, product specific data and additional 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 eight months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Below are additional generic data and label amendments that the Agency intends to require for napropamide.

#### **A. Manufacturing-Use Products**

##### **1. Generic Data Requirements**

The generic data base supporting the reregistration of napropamide for the above eligible uses has been reviewed and determined to be substantially complete. However, the data listed below are necessary to confirm the reregistration eligibility decision documented in this RED.

- 860.1340      Residue Analytical Method - Plants.
- 860.1500      Crop Field Trials are required for the following commodities: berries, tree nuts, grape, kiwi fruit, and persimmon.
- 860.1520      Magnitude of Residue in Processed Food/Feed (Coffee and Mint).

830.1550	Product Identity and Disclosure of Ingredients (composition and chemical identity)
830.1600	Starting Materials & Manufacturing Process (Description of Beginning Materials Used to Produce the Product)
830.1620	Description of the Production Process
830.1700	Preliminary Analysis
830.1750	Certified Limits (Certification of Limits)
830.1800	Enforcement Analytical Method (Analytical methods to verify certified limits)
830.6313	Stability to Normal and Elevated Temperatures, Metals and Metal Ions (stability)
850.1300	Daphnid Chronic Toxicity Test (early life stage in fish)
850.1350	Mysid (Shrimp) Chronic Toxicity Test (life cycle in aquatic invertebrates)
850.1500	Fish Life Cycle Study
850.4400	Aquatic Plant Toxicity Test Using the Following Species: <i>Lemna gibba</i> , <i>Skeletonema costatum</i> , <i>Anabaena flos-aquae</i> , and a freshwater diatom such as <i>Navicula pelliculosa</i> .

## **2. Labeling for Manufacturing-Use Products**

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 20.

### **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 the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that 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 Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements.

## **2. Labeling for End-Use Products**

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 22. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

### **D. Labeling 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 (Table 20) describes how language on the labels should be amended.

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.

### Labeling 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.

<b>Table 11: Summary of Labeling Changes for Napropamide</b>		
<b>Description</b>	<b>Amended Labeling Language</b>	<b>Placement on Label</b>
Manufacturing Use Products		
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 group	“Only for formulation into a dry flowable, granular, and liquid herbicide for the following use(s) [fill blank only with those uses that are being supported by MP registrant].”	Directions for Use
	<p>“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).”</p> <p>“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).”</p>	Directions for Use

**Table 11: Summary of Labeling Changes for Napropamide**

<b>Description</b>	<b>Amended Labeling Language</b>	<b>Placement on Label</b>
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



**Table 11: Summary of Labeling Changes for Napropamide**

Description	Amended Labeling Language	Placement on Label
End Use Products Intended for Occupational Use		
PPE Requirements Established by the RED <sup>1</sup> for products	<p>“Personal Protective Equipment (PPE)”</p> <p>“Mixers, loaders, applicators, and other handlers must wear:                      Long-sleeved shirt and long pants                      Chemical Resistant Gloves                      Shoes plus socks.”</p>	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Engineering Controls for Aerial Applicators	Pilots must use an enclosed cockpit that meets the requirements in the Worker Protection Standard	
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.”	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE Requirements.)
User Safety Recommendations	<p>User Safety Recommendations</p> <p>Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>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.”</p>	Precautionary Statements immediately following User Safety Requirements  (Must be placed in a box.)

**Table 11: Summary of Labeling Changes for Napropamide**

<b>Description</b>	<b>Amended Labeling Language</b>	<b>Placement on Label</b>
Environmental Hazards	“Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.”  Note: May need to be modified based on toxicity and use.	Precautionary Statements immediately following the User Safety Recommendations

**Table 11: Summary of Labeling Changes for Napropamide**

<b>Description</b>	<b>Amended Labeling Language</b>	<b>Placement on Label</b>
Restricted-Entry Interval	“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24”	Directions for Use, Agricultural Use Requirements Box
Early Re-entry Personal Protective Equipment established by the RED.	“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 * Eye wear	
Spray Drift		Directions for Use
General Precautions and 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.”	Directions for Use

**Table 11: Summary of Labeling Changes for Napropamide**

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p>End use product labels must be revised to delete all references to and use directions for the following cancelled uses: pistachio, walnut, grapefruit, lemon, nectarine, orange, tangerine, tangelo, apricot, cherry, peach, plum, prune, apple, pear, fig, avocado, pomegranate, artichoke, and olive.</p> <p>The following risk mitigation measures must be reflected in the Directions for Use:</p> <p><u>Almonds</u>                      “Maximum application rate per crop cycle: 4 pounds active ingredient per acre.”                      “Apply a maximum of one application per year.”</p> <p><u>Pecans</u>                      “Maximum application rate per crop cycle: 4 pounds active ingredient per acre.”                      “Apply a maximum of one application per year.”</p> <p><u>Cranberries</u>                      “Maximum application rate per crop cycle: 9 pounds active ingredient per acre.”                      “Apply a maximum of one application per year.”</p> <p><u>Grapes</u>                      “Maximum application rate per crop cycle: 4 pounds active ingredient per acre.”                      “Apply a maximum of one application per year.”</p> <p><u>Kiwi Fruit</u>                      “Maximum application rate per crop cycle: 4 pounds active ingredient per acre.”                      “Apply a maximum of one application per year.”</p> <p><u>Persimmons</u>                      “Maximum application rate per crop cycle: 4 pounds active ingredient per acre.”                      “Apply a maximum of one application per year.”</p>	Place in the Directions for Use under Application Instructions for Each Crop

**Table 11: Summary of Labeling Changes for Napropamide**

Description	Amended Labeling Language	Placement on Label
End Use Products Intended Primarily for Use by Homeowners		
Application Restrictions	“Do not apply this product in a way that will contact ay person, pet, either directly or through drift. Keep people and pets out of the area during application.”	Directions for Use under General Precautions and Restrictions
Entry Restriction	Liquid:  “Do not allow people or pets to enter the treated area until sprays have dried.”  Dry:  “Do not allow people or pets to enter the treated area until dusts have settled. [If watering-in is required after the application, do not enter or allow others to enter the treated areas (except those involved in the watering) until the watering-in is complete and the surface is dry.”	Directions for Use under General Precautions and Restrictions
Application Equipment Restrictions	For turf, the maximum application rate per application: 2 pounds active ingredient per acre. Can only apply a maximum of one application per year.	Directions for Use under General Precautions and Restrictions

Instructions in the Labeling section appearing in quotations represent the exact language that should appear on the label.

Instructions in the Labeling section not in quotes represents actions that the registrant should take to amend their labels or product registrations.

<sup>1</sup> 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.

<sup>2</sup> If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” designation must be dropped. **[This footnote is not needed if a respirator is not required]**

\* Text “Wash the outside of gloves before removing” in User Safety Recommendations may not be needed if gloves are not required.

**Appendix A: Use Patterns Eligible for Reregistration**

Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/Comments
Almond						
Chemigation, Band Treatment, Irrigation Incorporation, Directed Spray	50% DF [70506-36 ]	4	4	35	12	
Asparagus						
Chemigation, Band Treatment, Soil Incorporation, Directed Spray	50% DF [70506-36 ]	2	2	35	12	Two applications are allowed per year for asparagus.
Basil						
Band Treatment, Broadcast, Chemigation Soil Incorporation	50% DF	4	4		12	There is currently no registered uses of napropamide on basil. The registrant (United Phosphorus Inc.) has indicated that they will propose the inclusion of basil on the product label for the 50% DF formulation (70506-36).
Blackberry						
Chemigation, Band Treatment, Irrigation Incorporation, Directed Spray	50% DF [70506-36 ]	4	4	90	12	
Blueberry						

Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/Comments
Chemigation, Band Treatment, Irrigation Incorporation, Directed Spray	50% DF [70506-36 ]	4	4	90	12	
Boysenberry						
Chemigation, Band Treatment, Irrigation Incorporation, Directed Spray	50% DF [70506-36 ]	4	4	90	12	
Broccoli						
Chemigation, Band Treatment, Soil Incorporation, Directed Spray	50% DF [70506-36 ]	2	2	90	12	Two applications are allowed per year for broccoli.
Brussels sprouts						
Chemigation, Band Treatment, Soil Incorporation, Directed Spray	50% DF [70506-36 ]	2	2	90	12	Two applications are allowed per year for Brussels Sprouts.
Cabbage						
Chemigation, Band Treatment, Soil Incorporation, Directed Spray	50% DF [70506-36 ]	2	2	90	12	Two applications are allowed per year for cabbage.
Cauliflower						



Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/Comments
Chemigation, Band Treatment, Soil Incorporation, Directed Spray	50% DF [70506-36 ]	2	2	90	12	Two applications are allowed per year for cauliflower.
Cranberry						
Aerial, Ground Spray	10% G [70506-34 ]	9	9	90	12	
Eggplant						
Chemigation, Band Treatment, Irrigation Incorporation, Directed Spray	50% DF [70506-36 ]	2	2	90	12	Two applications are allowed per year for eggplant.
Filbert						
Broadcast, Chemigation	50%	4	4	35	12	
Grape						
Chemigation, Band Treatment, Irrigation Incorporation, Directed Spray	50% DF [70506-36 ]	4	4	35	12	
Kiwi Fruit						
Chemigation, Band Treatment, Irrigation Incorporation, Directed Spray	50% DF [70506-36 ]	4	4	35	12	
Loganberry						

Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/Comments
Chemigation, Band Treatment, Irrigation Incorporation, Directed Spray	50% DF [70506-36 ]	4	4	90	12	
Majoram						
Band Treatment, Broadcast, Chemigation Soil Incorporation	50% DF	4	4	90	12	There is currently no registered uses of napropamide on marjoram. The registrant (United Phosphorus Inc.) has indicated that they will propose the inclusion of marjoram on the product label for the 50% DF formulation (70506-36).
Ornamentals (Trees-field & Container, Herbaceous Plants, Woody Shrubs, Vines)						
Band Treatment, Directed Spray, Ground Spray	50% DF [70506-38 ]	6	6	N/A	12	
Pecan						
Chemigation, Band Treatment, Irrigation Incorporation, Directed Spray	50% DF [70506-36 ]	4	4	35	12	
Pepper						
Chemigation, Band Treatment, Soil Incorporated, Incorporation, Directed Spray	50% DF [70506-36 ]	2	2	90	12	Two applications are allowed per year for pepper.
Persimmon						

Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/Comments
Chemigation, Band Treatment, Irrigation Incorporation, Directed Spray	50% DF [70506-36 ]	4	4	180	12	
Raspberry						
Chemigation, Band Treatment, Irrigation Incorporation, Directed Spray	50% DF [70506-36 ]	4	4	90	12	
Rhubarb						
Chemigation, Band Treatment, Soil Incorporation, Broadcast	50% DF [70506-36 ]	4	4	90	12	
Rosemary						
Band Treatment, Broadcast, Chemigation Soil Incorporation	50%	4	4	90	12	There is currently no registered uses of napropamide on rosemary. The registrant (United Phosphorus Inc.) has indicated that they will propose the inclusion of rosemary on the product label for the 50% DF formulation (70506-36).
Savory						
Band Treatment, Broadcast, Chemigation Soil Incorporation	50%	4	4	90	12	There is currently no registered uses of napropamide on savory. The registrant (United Phosphorus Inc.) has indicated that they will propose the inclusion of savory on the product label for the 50% DF formulation (70506-36).
Strawberry						

Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ai/A)	Seasonal Max (lbs ai/A/Yr)	PHI (days)	REI (Hours)	Restrictions/Comments
Chemigation, Band Treatment, Irrigation Incorporation, Directed Spray	50% DF [70506-36 ]	4	4	35	12	
Sweet Potato						
Broadcast, Band Treatment, Soil Incorporation,	50% DF [70506-36 ]	2	2	90	12	Two applications are allowed per year for sweet potato.
Tobacco						
Broadcast, Band Treatment, Soil Incorporation	50% DF [70506-36 ]	2	2	N/A	12	
Tomato						
Chemigation, Band Treatment, Soil Incorporation, Directed Spray	50% DF [70506-36 ]	2	2	90	12	Two applications are allowed per year for tomato.
Turf						
Band Treatment, Directed Spray, Ground Spray	50% DF [70506-38 ]	2	2	N/A	12	

# APPENDIX B

## Data Supporting Guideline Requirements for the Reregistration of Napropamide

REQUIREMENT		USE PATTERN	CITATION(S)
<b><u>PRODUCT CHEMISTRY</u></b>			
New Guideline Number	Old Guideline Number		
830.1550	61-1	Product Identity and Composition	All 41222501, 41222502, 43160601
830.1600	61-2A	Start. Mat. & Mnfg. Process	All 41222501, 42013001
830.1670	61-2B	Formation of Impurities	All 40491301, 41222501, 42013001
830.1700	62-1	Preliminary Analysis	All 40924701, 41222502, 43160601, 43160602
830.1750	62-2	Certification of limits	All 41222502
830.1800	62-3	Analytical Method	All 41222502, 42013002, 42275201, 42679201, 43160601
830.6302	63-2	Color	All 41222503
830.6303	63-3	Physical State	All 41222503
830.6304	63-4	Odor	All 41222503
830.7200	63-5	Melting Point	All 41222503
830.7300	63-7	Density	All 41222503
830.7840 830.7860	63-8	Solubility	All 41222503
830.7950	63-9	Vapor Pressure	All 41222503
830.7550	63-11	Octanol/Water Partition Coefficient	All 41222503
830.7000	63-12	pH	All 41222503
830.6313	63-13	Stability	All 41222503
830.6317	63-17	Storage Stability	All 41222503, 42013003, 4207801
830.6320	63-20	Corrosion characteristics	All 41222503, 42013003
<b><u>ECOLOGICAL EFFECTS</u></b>			
850.2100	71-1A	Avian Acute Oral Toxicity	B, C, K 00160000
850.2200	71-2A	Avian Dietary Toxicity - Quail	B, C, K 00022923
850.2200	71-2B	Avian Dietary Toxicity - Duck	B, C, K 00022923
850.1075	72-1A	Fish Toxicity Bluegill	B, C, K 40098001
850.1075	72-1C	Fish Toxicity Rainbow Trout	40098001

### Data Supporting Guideline Requirements for the Reregistration of Napropamide

REQUIREMENT			USE PATTERN	CITATION(S)
850.1010	72-2A	Invertebrate Toxicity	B, C, K	41257101
None	72-3A	Estuarine/Marine Toxicity - Fish		40228401
850.1025	72-3B	Estuarine/Marine Toxicity - Mollusk		40228401
850.1035	72-3C	Estuarine/Marine Toxicity - Shrimp		40228401
850.3020	141-1	Honey Bee Acute Contact		00036935
850.3030	141-2	Honey Bee Residue on Foliage		05000837

### **TOXICOLOGY**

870.1100	81-1	Acute Oral Toxicity-Rat	ALL	41222504
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	ALL	41222505
870.1300	81-3	Acute Inhalation Toxicity-Rat	ALL	00138933
870.2400	81-4	Primary Eye Irritation-Rabbit	ALL	41222506
870.2500	81-5	Primary Skin Irritation	ALL	41222507
870.2600	81-6	Dermal Sensitization	ALL	41377902, 42981001
870.6100	81-7	Acute Delayed Neurotoxicity - Hen		00079791, 41905901
870.6200	81-8	Acute Neurotoxicity Screen		42912501
870.3100	82-1A	Subchronic Oral Toxicity Test (90-Day Feeding - Rodent)	B, L	43371201
870.3250	82-3	90-day Subchronic Dermal Toxicity Test, Rat		41342001
870.4100	83-1A	Chronic Feeding Toxicity - Rodent	B, L	00112525, 42980901
870.4100	83-1B	Chronic Feeding Toxicity -Non-Rodent	B, L	00077819, 42679401
870.4200	83-2A	Oncogenicity - Rat	B, L	00117443, 42980901
870.4200	83-2B	Oncogenicity - Mouse	B, L	00117443, 00126039
870.3700	83-3A	Developmental Toxicity - Rat	B, L	40152701, 4250101
870.3700	83-3B	Developmental Toxicity - Rabbit	B, L	00127831
870.3800	83-4	2-Generation Reproduction - Rat	B, L	00077802, 42054301
870.5140	84-2A	Gene Mutation (Ames Test)	B, C, K, L, M	41222508
870.5375	84-2B	Structural Chromosomal Aberration	B, C, K, L, M	41312901
None	84-4	Other Genotoxic Effects	B, C, K, L, M	42156401
870.7485	85-1	General Metabolism	B, L	41988401
870.7600	85-2	Dermal Penetration		42111501

**Data Supporting Guideline Requirements for the Reregistration of Napropamide**

REQUIREMENT			USE PATTERN	CITATION(S)
870.7200	86-1	Domestic (Companion) Animal Safety		40436601, 41810101, 41810102
<b><u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u></b>				
875.1200	233	Estimation of Dermal Exposure, Indoor Sites		45519601, 45528801
875.1400	234	Estimation of Inhalation Exposure, Indoor Sites		45519601, 45528801
875.2400	133-3	Dermal Passive Dosimetry Exposure		42622301, 45485501
875.2500	133-4	Inhalation Passive Dosimetry Exposure		42622301
<b><u>ENVIRONMENTAL FATE</u></b>				
None	160-5	Chemical Identity	ALL	41222501, 41222502, 43160601
835.2120	161-1	Hydrolysis	ALL	41929101
835.4100	162-1	Aerobic Soil Metabolism	B, C, K	00077821, 42082401
835.1240	163-1	Leaching/Adsorption/Desorption	B, C, K	41681301
None	164-A-SS	Dissipation of Residues in Excrement		42848501
<b><u>RESIDUE CHEMISTRY</u></b>				
860.1300	171-4B	Nature of Residue - Livestock	B	00116020, 00117354, 00120147, 00120204, 42828801, 42828802, 42828803
860.1340	171-4C	Residue Analytical Method - Plants	B	00038458, 00077812, 00077814, 00077816, 00115939, 00116020, 00116553, 00117329, 00117340, 00117351, 00117354, 00117389, 00118265, 00120147, 00120200, 00120205, 00120206, 00120229, 00130705, 00133913, 05004211

**Data Supporting Guideline Requirements for the Reregistration of Napropamide**

REQUIREMENT			USE PATTERN	CITATION(S)
860.1340	171-4D	Residue Analytical Method - Animals	B	00038458, 00077812, 00077814, 00077816, 00115939, 00116020, 00116553, 00117329, 00117340, 00117351, 00117354, 00117389, 00118265, 00120147, 00120200, 00120205, 00120206, 00120229, 00130705, 00133913, 05004211
860.1380	171-4E	Storage Stability	B	00117329, 00117354, 00117361, 00117389, 00133913
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	B	00038458, 00084189, 00115939, 00117298, 00117298, 00117339, 00117340, 00117354, 00117389, 00118265, 00120200, 00120206, 00120225, 00120227, 05006630



## **Appendix C. TECHNICAL SUPPORT DOCUMENTS**

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The docket initially contained preliminary risk assessments and related documents as of August 10, 1998. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on June 16, 1999.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

[www.epa.gov/pesticides/op](http://www.epa.gov/pesticides/op)

These documents include:

### **HED Documents:**

- Napropamide: REVISED HED Chapter of the Reregistration Eligibility Decision Document (RED). 2/23/05 Stanton, Susan
- Napropamide. Chronic Dietary Exposure Assessments for the Reregistration Eligibility Decision. 10/29/04. Stanton, Susan
- Napropamide: Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document. 2/20/05. Tadayon, Nadar

- Revised Product Chemistry Considerations. 2/15/05. Drew, Danette
- Napropamide. Revised Residue Chemistry Considerations for Reregistration Eligibility Decision. 2/18/05. Drew, Danette
- Review of Napropamide Incident Reports. 11/4/04. Blondell, Jerome
- Outcome of the 3/16/93 Meeting of HED Metabolism Committee. 4/7/93. Knizner, Steven
- Napropamide: Final HED Chapter of the Reregistration Eligibility Decision (RED) Document. 7/7/05. Stanton, Susan

**EFED Documents:**

1. EFED Risk Assessment for Napropamide Registration Eligibility Document. 3/1/05. Breithaupt, James & Jenkins, Fred
2. Drinking Water Assessment for Napropamide for Terrestrial Uses 8/17/04. Breithaupt, James
3. Drinking Water Assessment for Napropamide. 11/12/04. Breithaupt, James
4. Guidance for selecting Input parameters in Modeling the Environmental Fate & Transport of Pesticides. 2/28/02. US EPA (Office of Pesticide Programs (OPP) Environmental Fate and Effects Division.
5. EFED Risk Assessment for the Napropamide Reregistration Eligibility Document. 8/15/05. Borges, Shannon & Breithaupt, James.
6. EFED Response to “Error Only” and Public Comments for the Napropamide RED. 8/16/05. Breithaupt, James
7. EFED RED Chapter for Napropamide Chronic Risk Recalculations for Mammals. 9/22/05. Randall, Donna

8. EFED RED Chapter for Napropamide Chronic Risk Recalculation Spreadsheet Supporting Documentation for Mammals. 9/22/05 Randall, Donna

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- 16213 Yu Farina, L. (1986) Characterization of Devrinol  
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- 43928 Smith, J. (1996) Product Chemistry for Napropamide-  
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- 44409 Crowther, H. (1997) Napropamide: Product Identity,  
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United Phosphorus at Sandbach UK: Lab Project  
Number: RAD1822. Unpublished study prepared by  
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- 44409 Kennedy, D.; Robson, C. (1997) Napropamide:  
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Methods of Analysis to Verify Certified Limits for  
Napropamide Technical (TGAI) Produced by United  
Phosphorus at Sandbach UK: Lab Project Number:  
702371: CGR10/97: WRC-88-76. Unpublished study  
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### **61-2 Description of Beginning Materials and Manufacturing Proces**

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- 40135 Stauffer Chemical Company (1971) The Name, Chemical Identity and Composition of the  
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CDL:095554-B)

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- 44409301 Crowther, H. (1997) Napropamide: Product Identity, Description of Beginning Materials and Manufacturing Process and Discussion of the Formation of Impurities for Napropamide Technical (TGAI) Produced by United Phosphorus at Sandbach UK: Lab Project Number: RAD1822. Unpublished study prepared by Zeneca Ag Products. 93 p.
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## **62-1 Preliminary Analysis**

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## **63-2 Color**

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### **63-3 Physical State**

**MRID**

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### **63-6 Boiling Point**

**MRID**

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### **63-7 Density**

**MRID**

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### **63-9 Vapor Pressure**

**MRID**

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### **63-10 Dissociation Constant**

**MRID**

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### **63-12 pH**

**MRID**

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### **63-14 Oxidizing/Reducing Action**

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**63-16 Explodability****MRID**

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**63-19 Miscibility****MRID**

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### **63-21 Dielectric breakdown voltage**

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## **81-2 Acute dermal toxicity in rabbits or rats**

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## 81-4 Primary eye irritation in rabbits

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- 49481 Murphy, J.J.; Didriksen, J.; Gray, R.A. (1970?) Metabolism of Radioactive 2-(alpha-Naphthoxy)-N,N-diethyl propionamide (R- 7465) in Plants and Animals. (Unpublished study received May 5, 1972 under 2F1194; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091006-C)
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## **122-1 Seed Germination/Seedling Emergence and Vegetable Vigor**

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43175301 Ericson, J. (1994) Addendum to MRID 41575301 (WRC 88-80): Aqueous Photolysis of Napropamide: Lab Project Number: WRC 88-80. Unpublished study prepared by Zeneca Inc. 19 p.

### **161-3 Photodegradation-soil**

#### **MRID**

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41863202 Lee, K. (1989) Soil Photolysis of Napropamide: Lab Project Number: WRC 88-79: ENV-003. Unpublished study prepared by ICI Americas Inc. 30 p.

## **162-1 Aerobic soil metabolism**

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- 41901801 Lay, M. (1989) Aerobic Metabolism of Napropamide in Soil: Supplemental Information: Lab Project Number: WRC 89-38. Unpublished Study prepared by ICI Americas Inc. 11 p.
- 45074202 Graham, D. (2000) Determination of Napropamide Residues in Soil by Capillary Gas Chromatography: Lab Project Number: RR-90-005B. Unpublished study prepared by Zeneca Ag Products. 19 p.
- 92125016 Calderbank, A. (1990) ICI Americas Inc. Phase 3 Summary of MRID 41105901. Aerobic Metabolism of Napropamide in Soil: Report No. WRC 89-38; Study No. PMS-267. Prepared by ICI AMERICAS INC./WESTERN RESEARCH. 17 p.

## **162-2 Anaerobic soil metabolism**

### **MRID**

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## **162-3 Anaerobic aquatic metab.**

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## **162-4 Aerobic aquatic metab.**

### **MRID**

- 45074201 Graham, D. (2000) Napropamide Determination at ppb Concentrations in Water: Lab Project Number: RRC-88-09. Unpublished study prepared by Zeneca Ag Products. 14 p.

## **163-1 Leach/adsorp/desorption**

### **MRID**

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- 49490 Miller, W.W.; Gray, R.A. (1969?) Behavior and Persistence of 2- (alpha-Naphthoxy)-N,N-diethyl propionamide (R-7465) in Soils and Water. (Unpublished study received May 5, 1972 under 2F1194; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091006-L)
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- 110744 Fisher, J.; Callan, E. (1979) Goal and Devrinol Soil Residue Decline Study: Technical Report No. 34H-79-4. (Unpublished study received Mar 12, 1979 under 707-EX-142; submitted by Rohm & Haas Co., Philadelphia, PA; CDL:098213-B)
- 113815 Thomas, V. (1973) Leaching Study on Devrinol Degradation Products. (Unpublished study received Nov 6, 1973 under 476-2108; submitted by Stauffer Chemical Co., Richmond, CA; CDL:180005-A)
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- 41575302 Spillner, C. (1987) Adsorption and Desorption of Napropamide in Four Soils: Lab Project Number: PMS-270: MRC-87-29. Unpublished study prepared by ICI Americas Inc. 45 p.
- 42707201 Spillner, C. (1993) Addendum to MRID 41575302 Adsorption and Desorption of Napropamide in Four Soils: Lab Project Number: PMS-270: MRC 87-29. Unpublished study prepared by Zeneca Inc. 10 p.
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## **164-1 Terrestrial field dissipation**

### **MRID**

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- 49495 Riggs, R.L.; Humphreys, R.; MacLaren, G.; et al. (1971) Waylay (R-7465) Run-Off Study: Soil, Water, Silt, Fish Residues. (Unpublished study including FSDS nos. B-1066, B-1067, B-1083..., received May 5, 1972 under 2F1194; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091006-Q)
- 163272 Stauffer Chemical Co. (1986) Field Dissipation Study with Devrinol 2E and 10G: California Field Research Station. Unpublished compilation. 13 p.
- 163273 Stauffer Chemical Co. (1986) Field Dissipation Study with Devrinol 2E and 10G: Florida Field Research Station. Unpublished compilation. 37 p.
- 41575303 Pearson, F. (1989) Devrinol 10G Field Dissipation Study for Terrestrial Food Crop Uses: Napropamide (Calif. 1989): Lab Project Number: DEVR-88-SD-01: USO2-88-122. Unpublished study prepared by ICI Americas Inc. 157 p.

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- 43742401 Meyers, T. (1995) Devrinol: Terrestrial Soil Dissipation for Napropamide, Mississippi, 1993-1994: Lab Project Number: NAPR-93-SD-01: RR 95-009B. Unpublished study prepared by Zeneca Ag Products. 77 p.
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## **164-2 Aquatic field dissipation**

### **MRID**

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## **165-1 Confined rotational crop**

### **MRID**

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- 43419901 French, D. (1993) Addendum to MRID 42794501: Napropamide: Uptake and Metabolism in Rotational Crops: Lab Project Number: RJ1348B. Unpublished study prepared by Zeneca Agrochemicals. 36 p.

## **165-4 Bioaccumulation in fish**

### **MRID**

- 92125019 Calderbank, A. (1990) ICI Americas Inc. Phase 3 Summary of MRID 00039774. Exposure of Fish



to Carbon 14-labelled Devrinol: Accumulation, Distribution and Elimination of Residues: Report No. T-2224. Prepared by BIONOMICS, INC. 15 p.

## **171-11 Tobacco Uses: Total Residues and Pyrolysis Products**

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- 2760 Stauffer Chemical Company (1975) Tillam 6-E Residue Data on Wisconsin Cigar Binder Tobacco (Types 54 and 55). (Unpublished study received Jul 19, 1976 under 476-1615; CDL:225188-A)
- 27323 Thompson, L.; Worsham, A.D.; Newman, R.C. (1975) Residue Studies Summary: Devrinol on Tobacco. (Unpublished study received Sep 7, 1976 under 476-2108; prepared in cooperation with Univ. of Kentucky and others, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:225547-F)
- 41575306 McKay, J. (1990) Napropamide: Storage Stability Study (Validation): Tobacco: Lab Project Number: RR 89-061. Unpublished study prepared by ICI Americas Inc. 37 p.
- 92125059 Adelson, B.; McKay, J. (1990) ICI Americas Inc. Phase 3 Summary of MRID 00120304 and Related MRIDs 00025882. Devrinol Magnitude of the Residue Applied Lay-by on Tobacco: Lab. Study ID No. RR 90-095B. Prepared by ICI Americas. 8 p.

## **171-4B Residue Analytical Methods**

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- 32355 MacLaren, G.E.; Patchett, G.G. (1973) Determination of Residues of Devrinol(R) in Crops, Animal Tissues, and Soils. Method no. WRC 73-56 dated Nov 20, 1973. (Unpublished study received on unknown date under 4F1447; CDL:093855-B)
- 32356 Patchett, G.G. (1972) Determination of Residues of Devrinol(TM) Metabolites R-25541 and R-25124 in Crops. Method WRC 72-27 dated Jun 19, 1972. (Unpublished study received on unknown date under 4F1447; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:093855-C)
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- 49485 Stauffer Chemical Company (1971) Crop Residue Report: ?R-7465 50W|: FSDS No. B-0685. (Reports by various sources; unpublished study including FSDS nos. B-1787, B-0686, B-0683..., received May 5, 1972 under 2F1194; CDL:091006-G)
- 49486 Stauffer Chemical Company (1971) Crop Residue Report: ?R-7465 50W|: FSDS No. B-0190. (Reports by various sources; unpublished study including FSDS nos. B-0189, B-1858, B-1860..., received May 5, 1972 under 2F1194; CDL:091006-H)
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- 65363 MacLaren, G.E.; Patchett, G.G. (1973) Determination of Residues of Devrinol<sup>(R)</sup>I in Crops, Animal Tissues, and Soils. Method no. WRC 73-56 dated Nov 20, 1973. (Unpublished study received Mar 28, 1977 under 476-2184; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:229227-B)
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### **171-4C Magnitude of the Residue [by commodity]**

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- 23235 Parker, R.; Solether, N.; Gay, A.D.; et al. (1974) Crop Residue Studies Summary for Devrinol 50- WP 4-6 Lbs. a.i./A on Grapefruit and Oranges in Texas. (Unpublished study received Dec 17, 1974 under 476-2108; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:101112-G)
- 23883 Thompson, R.; Jensen, ?; Elmore, C.; et al. (1974) Crop Residue Studies Summary for Devrinol 50-WP (4 Lbs. A.I./A) Tank Mixed with Simazine 80-WP (0.5-1 Lb.A.I./A) and/or Paraquat (1 Lb.A.I./A) in California/Arizona. (Unpublished study re- ceived Dec 17, 1974 under 476-2150; prepared in cooperation with Kern County Land Company and others, submitted by Stauffer Chem- ical Co., Richmond, Calif.; CDL:028423-J)

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- 25885 Dewey, M.L.; Doty, C.; Griffin, M.; et al. (1976) Devrinol 50-WP: Summary of Crop Residue on Avocados. (Unpublished study received Jan 29, 1980 under 476-2108; prepared in cooperation with Morse Laboratories, Inc. and Lemoniera Co., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:099218-G)
- 25886 Sullivan, R.E.; De Guzman, D.; Dorman, D.C.; et al. (1979) Devrinol(R) Selective Herbicide: Summary of Crop Residue Data on Cucurbits. (Unpublished study received Jan 29, 1980 under 476- 2108; prepared in cooperation with Morse Laboratory, Inc. and others, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:099218-H)
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- 25888 DeGuzman, D.; Dorman, D.C.; Agamalian, H.; et al. (1979) Devri- nol^(R)I Selective Herbicide: Summary of Crop Residue Data on Leafy Vegetables. (Unpublished study received Jan 29, 1980 un- der 476-2108; prepared in cooperation with Oregon State Univ. and others, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:099218-J)
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- 25890 Tootilian, G.; Apkarian, V. (1975) Devrinol 50-WP: Summary of Crop Residue on Persimmons. (Unpublished study received Jan 29, 1980 under 476-2108; prepared in cooperation with Sadoian Brothers and others, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:099218-M)
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- 113804 Bleiberg, M.; Woodard, G. (1970) Evaluation of Acute Pharmacodynamic Properties of R-7465. (Unpublished study received Jun 2, 1972 under 2F1194; prepared by Woodard Research Corp., submitted by Stauffer Chemical Co., Richmond, CA; CDL:091008-D)
- 113805 Stauffer Chemical Co. (1969) ?Toxicity of R-7465 to Rabbits; Toxicology Lab Report T-1389. (Compilation; unpublished study received Jun 2, 1972 under 2F1194; CDL:091008-E)
- 113812 Brookman, D.; Ja, B. (1973) Analysis of 50W and 2E Formulations of Devrinol: WRC 73-25. (Unpublished study received on unknown date under 4F1447; submitted by Stauffer Chemical Co., Richmond, CA; CDL:093858-A)
- 113813 Meyding, G. (1973) Letter sent to C. Smith dated Apr 3, 1973: Devrinol 50-WP. (Unpublished study received on unknown date under 4F1447; submitted by Stauffer Chemical Co., Richmond, CA; CDL:093858-B)
- 113816 Stauffer Chemical Co. (1975) ?Study: Specific Herbicide Residues on Tobacco|. (Compilation; unpublished study received on unknown date under unknown admin. no.; CDL:223372-A)
- 5004454 Holt, H.A.; Wickham, S.H.; Wichman, J.R. (1976) Forest nursery weed control results. Pages 175-177, ~In~Proceedings, North Central Weed Control Conference. Vol. 31. Lincoln, Nebr.: North Central Weed Control Conference.
- 40251600 Stauffer Chemical Co. (1987) Submission of Toxicology Data as Part of Generic Data Base for Devrinol. Transmittal of 1 study.
- 40362900 Stauffer Chemical Co. (1987) Submission of Product Chemistry and Toxicological Data for the Chemical, Devrinol Technical. Transmittal of 4 studies.
- 40838600 ICI Americas Inc. (1988) Submission of Fate Data in Support of Registration of Devrinol Technical Selective Herbicide (EPA Reg.No. 10182-255). Transmittal of 1 study.
- 41067800 ICI Agricultural Products Group (1989) Submission of Data To Support Registration of Devrinol Technical Selective Herbicide: Product Chemistry Data. Transmittal of 1 study.
- 41105900 ICI Americas Inc. (1989) Submission of Data To Support Registration of Devrinol Technical Selective Herbicide: Aerobic Soil Metabolism Study. Transmittal of 1 study.
- 41156600 ICI Americas Inc. (1989) Submission of Data To Support Registration of Devrinol Technical Selective Herbicide: Toxicology Data. Transmittal of 2 studies.
- 41453400 ICI Americas, Inc. (1990) Submission of Toxicological Data to Support the Amended Registration for Devrinol 50-DF Selective Herbicide. Transmittal of 1 study.
- 41462000 Rohm and Haas Co. (1990) Submission of data in support of reregistration of Pronamide: Confined rotation crop study. Transmittal of 1 study.
- 41575300 ICI Americas Inc. (1990) Submission of residue data to support the registration of Napropamide for agricultural use. Transmittal of 10 studies.
- 41582200 ICI Americas Inc. (1990) Submission of Toxicity Data in Support of Technical Napropamide Registration. Transmittal of 1 study.
- 41610200 ICI Americas Inc. (1990) Submission of Product Chemistry Data and Toxicity Data to Support the Napropamide FIFRA 88 Accelerated Reregistration. Transmittal of 10 Studies.

41667100 ICI Americas, Inc. (1990) Submission of toxicity data to support the registration of Napropamide. Transmittal of 1 study.

41863200 ICI Americas Inc. (1991) Submission of Environmental Fate Data to Support the Reregistration of Napropamide. Transmittal of 2 Studies.

41901800 ICI Americas Inc. (1991) Submission of Data to Support the Reregistration of Napropamide: Environmental Fate Data. Transmittal of 1 Study.

41943300 ICI Americas, Inc. (1991) Submission of supplemental product chemistry information for Devrinol herbicide. Transmittal of 1 study.

42006700 ICI Americas Inc. (1991) Submission of toxicity data in support of reregistration of napromamide. Transmittal of 4 studies.

42027700 ICI Americas Inc. (1991) Submission of toxicity data in support of reregistration of napropamide. Transmittal of 3 studies.

42081300 ICI Americas, Inc. (1991) Submission of toxicity data in support of registration of napromamide. Transmittal of 1 study.

42181000 ICI Ag. Products (1992) Submission of toxicity data to support the registration of Devrinol 50 DF (Napropamide). Transmittal of 1 study.

42189100 ICI Americas, Inc. (1992) Submission of toxicity data in support of reregistration of Napropamide. Transmittal of 2 studies.

42231500 ICI Americas Inc. (1992) Submission of FIFRA 88 Phase 3 Committed Data To Support Accelerated Reregistration of Napropamide: Toxicology Study. Transmittal of 1 study.

42256500 Interregional Research Project No. 4 (1992) Submission of residue data in support of proposed tolerance for Napropamide. Transmittal of 1 study.

42349800 ICI Americas, Inc. (1992) Submission of residue data in support of the reregistration of Napropamide. Transmittal of 2 studies.

42393900 ICI Agricultural Products (1992) Submission of residue data in support of the reregistration of Napropamide. Transmittal of 1 study.

42656200 Zeneca (1993) Submission of toxicity and environmental data in support of the reregistration for Napropamide. Transmittal of 2 studies.

42657400 Zeneca (1993) Submission of toxicity data in support of the reregistration for napropamide. Transmittal of 1 study.

42699700 Zeneca Inc. (1993) Submission of environmental fate data in support of the Phase 4 requirement for Napropamide. Transmittal of 1 study.

42707200 Zeneca Inc. (1993) Submission of environmental fate data in support of the napropamide reregistration. Transmittal of 1 study.

42758900 Zeneca Inc. (1993) Submission of metabolism data in support of the reregistration for napropamide. Transmittal of 3 studies.



- 42764200 Zeneca Inc. (1993) Submission of supplemental environmental fate data in support of reregistration for Napropamide. Transmittal of 1 study.
- 42775800 Zeneca Ag Products (1993) Submission of residue (animal metabolism) data to support Phase 3 reregistration requirements for Napropamide. Transmittal of 2 studies.
- 42794500 Zeneca Inc. (1993) Submission of environmental fate data in support of the phase 3 data for napropamide. Transmittal of 1 study.
- 42845900 Zeneca Ag Products (1993) Submission of supplemental residue data in support of reregistration for napropamide. Transmittal of 1 study.
- 43068800 Zeneca Inc. (1993) Submission of Supplemental Toxicology Data in Support of Napropamide Reregistration. Transmittal of 1 Study.
- 43175300 Zeneca Inc. (1994) Submittal of Environmental Fate Data in Support of Reregistration of Napropamide. Transmittal of 1 study.
- 43182400 Zeneca Ag Products (1994) Submittal of Additional Comments on Avian Toxicity Study in Support of Reregistration for Napropamide. Transmittal of 1 study.
- 43249400 ZENECA Inc. (1994) Submission of Residue Chemistry Data for Napropamide in Support of Reregistration. Transmittal of 5 studies.
- 43345100 Zenaca Ag Products (1994) Submission of Residue Data in Support of Napropamide Reregistration. Transmittal of 9 Studies.
- 43419900 Zeneca Inc. (1993) Submittal of Environmental Fate Data in Support of Napropamide Reregistration. Transmittal of 1 study.
- 43506700 Zeneca Ag Products (1994) Submission of Toxicity Data in Support of the Reregistration of Napropamide. Transmittal of 1 Study.
- 43514400 Zeneca Ag Products (1995) Submission of Environmental Fate Data in Support of Napropamide Reregistration. Transmittal of 1 Study.
- 43659500 Ciba-Geigy Corp. (1995) Submission of Pesticide Residues in the Environment Data in Support of FIFRA 6(a)(2) Requirements for over 20 Organic Pesticides. Transmittal of 2 Studies.
- 43659501 MacCoy, D.; Crepeau, K.; Kuivila, K. (1995) Dissolved Pesticide Data for the San Joaquin River at Vernalis and the Sacramento River at Sacramento, California, 1991-94: Open File Report 95-110. Prepared by U.S. Geological Survey in cooperation with the U.S. EPA and the California Regional Water Quality Control Board; available from U.S. Government Printing Office. 31 p.
- 43659502 Crepeau, K.; Domagaiski, J.; Kuivila, K. (1994) Methods of Analysis and Quality-Assurance Practices of the U.S. Geological Survey Organic Laboratory, Sacramento, California-- Determination of Pesticides in Water by Solid-Phase Extraction and Capillary-Column Gas Chromatography/Mass Spectrometry: Open File Report 94-362. Prepared by the U.S. Geological Survey; available from U.S. Government Printing Office. 21 p.
- 43742400 Zeneca Ag Products (1995) Submission of Environmental Fate Data in Support of Napropamide Reregistration. Transmittal of 2 Studies.
- 43843400 Interregional Research Project No. 4 (1995) Submission of Residue Chemistry Data in Support of

- the Petition for Tolerance for Napropamide on Oriental Radish. Transmittal of 1 Study.
- 43875000 Zeneca Ag Products (1995) Submission of Toxicity Data in Support of the Reregistration of Napropamide. Transmittal of 1 Study.
- 43928600 Platte Chemical Co. (1996) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Napropamide-Oxadiazon 4-2 Granules. Transmittal of 7 Studies.
- 44006500 Zeneca Ag Products (1996) Submission of Product Chemistry Data in Support of Registration Amendment of DEVRINOL Technical. Transmittal of 2 Studies.
- 44020100 Zeneca Ag Products (1996) Submission of Residue Data in Support of the Reregistration of Napropamide. Transmittal of 2 Studies.
- 44152200 Platte Chemical Co. (1996) Submission of Product Chemistry Data in Support of the Registration of Napropamide-Oxadiazon 4-2 Granules. Transmittal of 1 Study.
- 44409300 Zeneca Ag Products (1997) Submission of Product Chemistry Data in Support of the Registration of Devrinol Technical Selective Herbicide. Transmittal of 2 Studies.
- 45074200 Zeneca Ag Products (2000) Submission of Environmental Fate Data in Support of Registration of Napropamide. Transmittal of 2 Studies.
- 46105000 Gharda USA Inc. (2003) Submission of Product Chemistry and Toxicity Data in Support of the Application for the Registration of Gharda Napropamide Technical. Transmittal of 3 Studies.
- 46142700 United Phosphorus, Inc. (2003) Submission of Product Chemistry Data in Support of the Amended Registrations of Devrinol 2-EC Selective Herbicide and Devrinol 2-EC Ornamental Herbicide. Transmittal of 1 Study.
- 46285600 United Phosphorus, Inc. (2004) Submission of Product Chemistry Data in Support of the Registrations of Devrinol 2EC Ornamental Herbicide and Devrinol 2EC Selective Herbicide. Transmittal of 1 Study.
- 46302200 United Phosphorus, Inc. (2004) Submission of Toxicity Data in Support of the Amended Registrations of Devrinol 2-EC Selective Herbicide and Devrinol 2-EC Ornamental Herbicide. Transmittal of 2 studies.
- 46308700 United Phosphorus, Inc. (2004) Submission of Product Chemistry Data in Support of the Amended Registrations of Devrinol 2-EC Selective Herbicide and Devrinol 2-EC Ornamental Herbicide. Transmittal of 1 Study.
- 46308701 Tillman, A. (2004) Devrinol 2-EC Selective Herbicide, Devrinol 2-EC Ornamental Herbicide: Justification for Change in Hazard Classification. Project Number: UPI/2004/02. Unpublished study prepared by United Phosphorus Inc. 37 p.
- 46338600 Gharda USA, Inc. (2004) Submission of Product Chemistry Data in Support of the Application for Registration of Gharda Napropamide Technical. Transmittal of 1 Study.
- 46427000 Gharda USA, Inc. (2004) Submission of Product Chemistry Data in Support of the Application for Registration of Napropamide Technical. Transmittal of 3 Studies.
- 46427001 Sonawane, K. (2004) Physical and Chemical Characteristics of Napropamide Technical: UV-VIS Absorption Spectra. Project Number: C/NAAO/019, GLP/PC/0401, GLP/PC/01. Unpublished

- study prepared by Gharda Chemicals Ltd. 22 p.
- 46427002 Sonawane, K. (2004) Physical and Chemical Characteristics of Napropamide Technical: Dissociation Constant. Project Number: C/NAO/020, GLP/PC/0401, GLP/PC/02. Unpublished study prepared by Gharda Chemicals Ltd. 30 p.
- 46427003 Sonawane, K. (2004) Physical and Chemical Characteristics of Napropamide Technical: Accelerated Storage Stability. Project Number: C/NAO/021, GLP/PC/03, GPLP/PC/0401. Unpublished study prepared by Gharda Chemicals Ltd. 31 p.
- 46459100 United Phosphorus, Inc. (2005) Submission of Product Chemistry, Residue, Environmental Fate and Toxicity Data in Support of the Reregistration of Napropamide. Transmittal of 12 Studies.
- 46459102 White, G. (2003) Spectral Examination of Napropamide: Final Report. Project Number: J/14368, FOR/02/024. Unpublished study prepared by: G.C. Laboratories, Ltd. 34 p.
- 46459103 Lurvey, E. (1993) Napropamide: Magnitude of Residue on Basil. Project Number: 03439, 90/FLR/050, 90/FL/045. Unpublished study prepared by Interregional Research Project No. 4, University of Florida and Zeneca Inc. 147 p.
- 46459104 Shaw, D. (2001) Napropamide: Aerobic Soil Route and Rate of Degradation. Project Number: UPH/027, UPH/027/013239. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 75 p.
- 46459106 McKay, J. (1989) Devrinol 50-WP Field Dissipation Study: Simcoe, Ontario, Canada: Final Report. Project Number: WRC/89/50, WRC/73/56. Unpublished study prepared by ICI Americas Inc. 139 p.
- 46459109 Tapp, J.; Sankey, S.; Caunter, J.; et. al. (1989) Napropamide: Determination of the 28 Day LC50 to Rainbow Trout (*Salmo gairdneri*). Project Number: BL/B/3624, S051/A. Unpublished study prepared by Imperial Chemical Industries, Ltd. 24 p.
- 46459111 Jenkins, C. (2002) Napropamide Higher Plant (*Lemna minor*) Growth Inhibition Test. Project Number: UPH022/013214. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 39 p.
- 46459112 Jenkins, C. (2002) Napropamide: Algal Growth Inhibition Assay (*Anabaena*). Project Number: UPH021/013213. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 34 p.
- 46459113 Balluff, M. (2003) Seedling Emergence Dose Response Test for Non-Target Plants Following Multiple Rate Application of Devrinol 45FL in the Greenhouse Under Controlled Climactic Conditions in Spain, 2002. Project Number: 20023053/S1/FNTP. Unpublished study prepared by Arbeitsgemeinschaft GAB Biotechnologie. 64 p.
- 46459114 Balluff, M. (2003) Seedling Emergence Dose Response Test for Non-Target Plants Following Multiple Rate Application with Soil Incorporation of Devrinol 45FL in the Greenhouse Under Controlled Climactic Conditions in Spain, 2003. Project Number: 20023053/S3/FNTP. Unpublished study prepared by Arbeitsgemeinschaft GAB Biotechnologie. 57 p.
- 46459115 Schmitzer, S. (2003) Laboratory Testing for Toxicity (Acute Contact and Oral) of Devrinol 450 SC on Honey Bees (*Apis mellifera* L.): Final Report. Project Number: 17073035. Unpublished study prepared by Institut fuer Biologische Analytik und Consulting IBACON. 43 p.
- 46459116 Gough, H.; Pilling, E. (1995) Napropamide: Acute Contact Toxicity to Honey Bees (*Apis mellifera*) of a 50% Wettable Powder Formulation. Project Number: TMJ3457B. Unpublished study prepared by Jealott's Hill Res. Station. 11 p.

- 46462000 United Phosphorus, Inc. (2005) Submission of Risk Data in Support of the Reregistration of Napropamide. Transmittal of 1 Study.
- 46462001 Tillman, A. (2005) Registrant's Error Comments on EPA's Preliminary Risk Assessments for the Reregistration Eligibility Decision for Napropamide. Project Number: UPI/2005/01. Unpublished study prepared by United Phosphorus Inc. 34 p.
- 46478700 United Phosphorus, Inc. (2005) Submission of Environmental Fate and Toxicity Data in Support of the Reregistration of Napropamide. Transmittal of 4 Studies.
- 46478701 McKay, J. (1989) Devrinol 50-WP Field Dissipation Study: Rodney, Ontario, Canada: Final Report. Project Number: WRC/89/55, 006031. Unpublished study prepared by ICI Americas, Inc. 163 p.
- 46478702 Simmons, N. (1990) Napropamide: Soil Dissipation Studies (West Germany 1988-89). Project Number: RJ0860B. Unpublished study prepared by ICI Agrochemicals. 119 p.
- 46478703 Long, K.; Roberts, G. (1995) Napropamide: Degradation of 14-(Carbon)-Labelled Material in Natural Sediment-Water Systems. Project Number: AA0900/A, BL5425/B. Unpublished study prepared by Jealott's Hill Res. Station. 62 p.
- 46494900 Gharda Chemical Ltd. (2005) Submission of Toxicity Data in Support of the Application for Registration of Gharda Napropamide Technical. Transmittal of 2 Studies.
- 46553300 United Phosphorus, Inc. (2005) Submission of Toxicity Data in Support of the FIFRA 6(a)(2) Data Requirements for Devrinol 2-EC Selective Herbicide and Devrinol 2-EC Ornamental Herbicide. Transmittal of 1 Study.
- 46574100 United Phosphorus, Inc. (2005) Submission of Toxicity Data in Support of the Amended Registrations of Devrinol 2-EC Selective Herbicide and Devrinol 2-EC Ornamental Herbicide. Transmittal of 3 Studies.
- 92125000 ICI Americas Inc. (1990) Reregistration Phase 3 Response: Diethyl-2-(1-naphthalenyloxy)propanamide.
- 92125999 ICI Americas Inc. (1990) Reregistration Phase 3 Response: Diethyl-2-(1-naphthalenyloxy)propanamide. Correspondence and Supporting Material.

## Appendix E. Generic Data Call-In

The Generic Data Call-In will be posted at a later date. See Chapter V of the napropamide RED for a list of studies.

**Appendix F. Product Specific Data Call-In**

A Product Specific Data-Call-In will be posted at a later date.

**Appendix G. EPA's Batching of Napropamide products for meeting acute toxicity data requirements for reregistration.**

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing NAPROPAMIDE as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among:

Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Thirteen products were found which contain Napropamide as the active ingredient. These products have been placed five batches and a no batch group in accordance with the active and inert ingredients and type of formulation.

Batching Instructions:

No Batch: Each product in this Batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch 1	EPA Reg. No.	Percent Active Ingredient
	33658-22	97
	70506-35	95.7

Batch 2	EPA Reg. No.	Percent Active Ingredient
	70506-36	50
	70506-38	50

Batch 3	EPA Reg. No.	Percent Active Ingredient
	70506-31	43.2
	70506-37	43.2



Batch 4	EPA Reg. No.	Percent Active Ingredient
	70506-63	24.1
	70506-64	24.1

Batch 5	EPA Reg. No.	Percent Active Ingredient
	70506-33	2
	70506-39	2

No Batch	EPA Reg. No.	Percent Active Ingredient
	34704-771	Napropamide: 4.0 Oxadiazon: 2.0
	70506-27	21.8
	70506-34	10

**Appendix H. List of Registrants Sent this Data Call-In**

A list of registrants sent this data call-in will be posted at a later date.