Naptalam and Naptalam Sodium Reregistration

Ecological Risk Assessment

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I. EXECUTIVE SUMMARY

A. Potential Risks to Non-target Organisms

A Tier 1 screening level risk assessment focusing on maximum proposed uses of naptalam on curcubits (cucumber, watermelon, muskmelon, cantaloupe, honeydew melon, Persian melon, casaba) and ornamental woody plant stock suggests that concentrations of naptalam in the environment, when compared with minimum toxicity values, are unlikely to result in acute adverse effects to freshwater aquatic organisms. Insufficient toxicity data are available to characterize the risk of chronic adverse effects to freshwater organisms and no data are available to characterize the risk to estuarine/marine fish and invertebrates. Risks to terrestrial species may occur and are summarized below.

- The exposure to naptalam sodium salt on short grass, tall grass, broadleaf plants, and small insects from **curcubit application** exceeds the endangered species and acute restricted use levels of concern (LOC) for **maximum residue** conditions for 15 and 35 gram mammals. Additionally, the acute risk LOC is exceeded for 15g mammals that feed on short grass. The acute restricted use LOC is exceeded for **mean residue** conditions for 15 and 35 gram mammals that feed on short grass.

- The exposure to naptalam sodium salt on short grass, tall grass, broadleaf plants, and small insects resulting from **ornamental woody plant application** exceeds endangered species and acute restricted use levels of concern for **maximum residue** conditions for 15 and 35 gram mammals, and for 1000 gram mammals on short grass. Additionally, the acute LOC is exceeded for 15 and 35 gram mammals based on **maximum residues** on short grass, broadleaf plants, and small insects. Exposure to naptalam on short grass, broadleaf plants, and small insects for 15 and 35 gram mammals from ornamental woody plant application also exceeds the endangered species levels of concern for **mean residue** conditions.

- Chronic exposure to naptalam from **curcubit application** on short grass for **maximum residue** conditions poses a chronic risk to wild mammals (RQ = 1.74).

- Chronic exposure to naptalam from **ornamental woody plant** application exceeded the LOC based on **maximum residue** conditions on short grass, tall grass, broadleaf plants, and small insects. Additionally, the LOC is exceeded based on **mean residue** conditions on short grass.

The naptalam acid is practically non-toxic to mammalian species. Due to its environmental fate properties, it is assumed that most of the naptalam sodium salt will dissociate at environmental pH levels to form the non-toxic naptalam acid and sodium cations. It is therefore possible that the naptalam sodium salt acute endpoint (1,700 mg/kg bw) overestimates risk, due to the fact that very little of this chemical will persist in the environment long enough to lead to mammalian exposure.

1. Nature of Chemical Stressor

Naptalam (CAS number 132-66-1; 132-67-2 [naptalam sodium]) is a soil acting herbicide that controls broadleaf weeds at germination and early growth stage. It is absorbed by seeds and primary roots and interferes with normal growth. Naptalam exhibits minimal foliar activity and minimal activity on grassy weeds. This report focused on assessing and characterizing potential risks resulting from the agricultural uses of naptalam on cucumber, watermelon, honeydew, and cantaloupe.

2. Exposure Characterization Conclusions

The environmental fate and mobility of naptalam is pH dependent. Naptalam is formulated as a sodium salt and predominantly exists as an anion in the environment. Based on the pKa (4.6), naptalam sodium salt will dissociate under most environmental conditions and the predominant species will be the naptalam acid. Anions often possess high mobility in soils, tend to have significant leaching potential and will not volatilize from water or soil surfaces. The hydrolysis of naptalam appears to occur slowly under alkaline and neutral conditions but proceeds rapidly under acidic conditions with a half-life on the order of a few days. Biodegradation appears to be insignificant under anaerobic conditions, but may be an important environmental fate process in soil and water under aerobic conditions. A major degradation product of naptalam is 1-naphthylamine which has been classified as a carcinogen by the Occupational Safety and Health Administration (OSHA).

3. Effects Characterization Conclusions

Results of acute toxicity studies suggest that naptalam is practically non-toxic to freshwater fish and invertebrates. No chronic toxicity data were submitted for freshwater organisms and no acute or chronic testing of estuarine/marine fish or invertebrates was submitted.

Naptalam sodium salt is categorized as slightly toxic to small mammals on an acute oral basis and the potential for chronic reproductive effects appears to be low, whereas naptalam acid is practically non-toxic to mammalian species on an acute oral basis. Results of acute oral toxicity studies suggest that naptalam is practically non-toxic to birds. Results of reproductive studies of naptalam in birds are not available. Based on contact LD_{50} studies for the honey bee (*Apis mellifera*), naptalam is classified as practically non-toxic on an acute contact basis.

Because naptalam is an herbicide, it is anticipated that non-target plants may be particularly susceptible to adverse effects; however, no data were submitted to assess the toxicity of naptalam toward aquatic or terrestrial non-target plants.

II. PROBLEM FORMULATION

A. Stressor Source and Distribution

1. Chemical and Physical Properties

Naptalam is formulated as a sodium salt in order to increase its solubility. Based on the pKa (4.6), the salt will dissociate under most environmental conditions and the predominant species will be the naptalam acid. Therefore, naptalam will exist primarily as an anion in water and moist soils. Since the vapor pressure and Henry's law constant of anions are infinitesimally small, no volatilization from soil or water surfaces will occur. Anions tend to have much greater mobility in soils than neutral species or cations; therefore, it is expected that naptalam will be highly mobile and may have the potential to leach into groundwater. Hydrolysis occurs in a matter of a few days under acidic conditions, in distilled water, but metal ions that are ubiquitous in natural waters tend to retard the rate of hydrolysis. Photolysis and biodegradation under aerobic conditions also occur in a matter of days to a few weeks, however under anaerobic conditions naptalam appears to be stable.

The naptalam acid is practically non-toxic to mammalian species, and due to its environmental fate properties, it is assumed that most of the naptalam sodium salt will dissociate at environmental pH levels to form the non-toxic naptalam acid and sodium cations. It is therefore possible that the naptalam sodium salt acute endpoint (1,700 mg/kg bw) overestimates risk, due to the fact that very little of this chemical will persist in the environment long enough to lead to mammalian exposure.

2. Mode of Action

Naptalam is a selective herbicide absorbed predominantly by the roots, but also to some extent by the foliage, with accumulation in the meristematic tissue. It works by inhibiting seed germination and IAA transport.

3. Overview of Pesticide Usage

Naptalam use is largely limited to the eastern region of the United States with its highest use in the southeastern states particularly in Florida and Georgia. It is most frequently applied to cucumber and watermelon, but has also been used as a selective herbicide in honeydew and cantaloupe. It has additional uses on ornamental woody plant nursery stock.

B. Assessment Endpoints

Assessment endpoints are defined as "explicit expressions of the actual environmental value that is to be protected." Defining an assessment endpoint involves two steps: 1) identifying the valued attributes of the environment that are considered to be at risk; and 2) operationally defining the assessment endpoint in terms of an ecological entity (i.e., a community of fish and aquatic invertebrates) and its attributes (i.e., survival and reproduction). Therefore, selection of the assessment endpoints is based on valued entities (i.e., ecological receptors), the ecosystems potentially at risk, the migration pathways of pesticides, and the routes by which ecological receptors are exposed to pesticide-related contamination. The selection of clearly defined assessment endpoints is important because they provide direction and boundaries in the risk assessment for addressing risk management issues of concern.

1. Ecosystems Potentially at Risk

Ecosystems potentially at risk are expressed in terms of the selected assessment endpoints. The typical assessment endpoints for screening-level pesticide ecological risks are reduced survival, and reproductive and growth impairment for both aquatic and terrestrial animal species. Aquatic animal species of potential concern include freshwater fish and invertebrates, estuarine/marine fish and invertebrates, and amphibians. Terrestrial animal species of potential concern include birds, mammals, beneficial insects, and earthworms. For both aquatic and terrestrial animal species, direct acute and direct chronic exposures are considered. In order to protect threatened and endangered species, all assessment endpoints are measured at the individual level. Although all endpoints are measured at the individual level, they provide insight about risks at higher levels of biological organization (e.g. populations and communities). For example, pesticide effects on individual survivorship have important implications for both population rates of increase and habitat carrying capacity.

For terrestrial and semi-aquatic plants, the screening assessment endpoint is the perpetuation of populations of non-target species (crops and non-crop plant species). Existing testing requirements have the capacity to evaluate emergence of seedlings and vegetative vigor. Although it is recognized that the endpoints of seedling emergence and vegetative vigor may not address all terrestrial and semi-aquatic plant life cycle components, it is assumed that impacts at emergence and in active growth have the potential to impact individual competitive ability and reproductive success.

For aquatic plants, the assessment endpoint is the maintenance and growth of standing crop or biomass. Measurement endpoints for this assessment endpoint focus on algal and vascular plant (i.e., duckweed) growth rates and biomass measurements.

The ecological relevance of selecting the above-mentioned assessment endpoints is as follows: 1) complete exposure pathways exist for these receptors; 2) the receptors may be potentially sensitive to pesticides in affected media and in residues on plants, seeds, and insects; and 3) the receptors could potentially inhabit areas where pesticides are applied, or areas where runoff and/or spray drift may impact the sites because suitable habitat is available.

2. Ecological Effects

Table 1 gives examples of taxonomic groups and test species evaluated for ecological effects in screening level risk assessments.

Table 1. Taxonomic groups and test species evaluated for ecological effects in screening level risk assessments.

Taxonomic group	Example(s) of representative species
Birds[a]	Mallard duck (*Anus playtrhynchos*) Bobwhite quail (*Colinus virginianus*)
Mammals	Laboratory rat
Freshwater fish[b]	Bluegill sunfish (*Lopomis macrochirus*) Rainbow trout (*Oncorhynchus mykiss*)
Freshwater invertebrates	Water flea (*Daphnia magna*)
Estuarine/marine fish	Sheepshead minnow (*Cypridodon variegatus*)
Estuarine/marine invertebrates	Eastern Oyster (*Crassostrea virginica*) Mysid Shrimp (*Americamysis bahia*)
Terrestrial plants[c]	Monocots – corn (*Zea mays*) Dicots – soybean (*Glycine max*)
Aquatic plants and algae	Duckweed (*Lemna gibba*) Green algae (*Selenastrum capricornutum*)

[a]Birds may be surrogates for amphibians (terrestrial phase) and reptiles.
[b]Freshwater fish may be surrogates for amphibians (aquatic phase).
[c]Four species of two families of monocots, of which one is corn; six species of at least four dicot families, of which one is soybeans.

Within each of these very broad taxonomic groups, an acute and/or chronic endpoint is selected from the available test data. Additional ecological effects data for naptalam are available for honey bees (*Apis mellifera*) and have been incorporated into the risk characterization as an additional line of evidence. Studies on acute toxicity to plants that were classified as invalid were not included in the risk characterization.

A complete discussion of all toxicity data available for this risk assessment and the resulting measurement endpoints selected for each taxonomic group are included in **Appendix E**. A summary of the assessment and measurement endpoints selected to characterize potential ecological risks associated with exposure to naptalam is provided in **Table 2**.

Table 2. Summary of assessment and measurement endpoints.

Assessment Endpoint	Measurement Endpoint
1. Abundance (i.e., survival, reproduction, and growth) of individuals and populations of birds.	1a. Bobwhite quail acute oral LD_{50}. 1b. Bobwhite quail and mallard duck subacute dietary LD_{50}. 1c. Bobwhite quail and mallard duck chronic reproduction NOAEC and LOAEC.
2. Abundance (i.e., survival, reproduction, and growth) of individuals and populations of mammals.	2a. Laboratory rat acute oral LD_{50}. 2b. Laboratory rat developmental and chronic NOAEC and LOAEC.
3. Survival and reproduction of individuals and communities of freshwater fish and invertebrates.	3a. Rainbow trout and bluegill sunfish acute LC_{50}. 3b. Rainbow trout chronic (early-life) NOAEC and LOAEC. 3c. Water flea (and other freshwater invertebrates) acute EC_{50}. 3d. Water flea chronic (life-cycle) NOAEC and LOAEC.
4. Survival and reproduction of individuals and communities of estuarine/marine fish and invertebrates.	4a. Sheepshead minnow acute LC_{50}. 4b. Estimated chronic NOAEC and LOAEC values based on the acute-to-chronic ratio for freshwater fish. 4c. Eastern oyster and mysid shrimp acute LC_{50}. 4d. Mysid shrimp chronic (life-cycle) NOAEC and LOAEC. 4e. Estimated NOAEC and LOAEC values for mollusks based on the acute-to-chronic ratio for mysids.
5. Perpetuation of individuals and populations of non-target terrestrial and semi-aquatic species (crops and non-crop plant species).	5a. Monocot and dicot seedling emergence and vegetative vigor EC_{25} values.
6. Survival of beneficial insect populations.	6a. Honeybee acute contact LD_{50}.
7. Abundance (i.e., survival, reproduction, and growth) of earthworm populations.	7a. Acute and subchronic earthworm LC_{50} values.
8. Maintenance and growth of individuals and populations of aquatic plants from standing crop or biomass.	8a. Algal and vascular plant (i.e., duckweed) EC_{50} values for growth rate and biomass measurements.

LD_{50} = Lethal dose to 50% of the test population.
NOAEC = No-observed-adverse-effect level.
LOAEC = Lowest-observed-adverse-effect level.
LC_{50} = Lethal concentration to 50% of the test population.
EC_{50}/EC_{25} = Effect concentration to 50/25% of the test population.

C. Conceptual Model

1. Risk Hypotheses

In order for a chemical to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a contaminant moves in the environment from a source to an ecological receptor. For an ecological exposure pathway to be complete, it must have a source, a release mechanism, an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure. In addition, the potential mechanisms of transformation (i.e., which degradates may form in the environment, in which media, and how much) must be known, especially for a chemical whose metabolites/degradates are of greater toxicological concern. The assessment of ecological exposure pathways, therefore, includes an examination of the source and potential migration pathways for constituents, and the determination of potential exposure routes (e.g., ingestion, inhalation, dermal absorption).

Ecological receptors that may potentially be exposed to naptalam and its degradates include terrestrial and semi-aquatic wildlife (i.e., mammals, birds, and reptiles), terrestrial and semi-aquatic plants, and soil invertebrates. In addition to terrestrial ecological receptors, aquatic receptors (e.g., freshwater and estuarine/marine fish and invertebrates, and amphibians) may also be exposed to potential migration of pesticides from the site of application to various watersheds and other aquatic environments via runoff and spray drift.

2. Diagram

The conceptual site model shown in **Figure 1** generically depicts the potential source of naptalam, release mechanisms, abiotic receiving media, biological receptor types, and effects endpoints of potential concern.

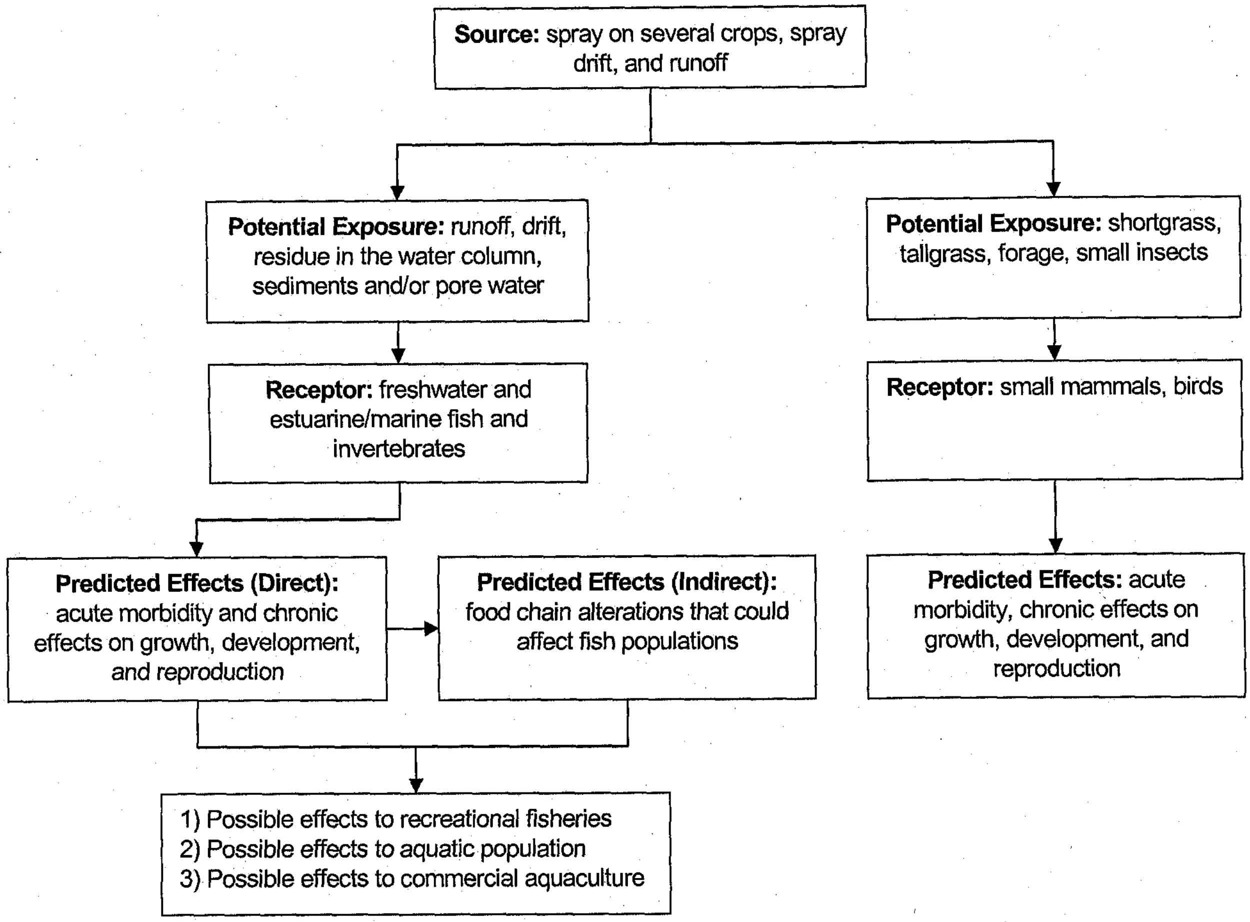


Figure 1. General conceptual model for a screening level ecological risk assessment.

D. Analysis Plan

1. Key Uncertainties and Data Gaps

The adequacy of the submitted data was evaluated relative to Agency guidelines. The following identified data gaps for environmental fate and toxicity endpoints result in a degree of uncertainty in evaluating the ecological risk of naptalam.

- Hydrolysis half-lives are not available at neutral and alkaline pH levels. However, no degradation was observed in the dark control for the aqueous photolysis study conducted at pH 7. Therefore, stability to hydrolysis is assumed at neutral pH.

- No data are available to assess the acute or chronic risk of naptalam to estuarine/marine fish and invertebrates.

- No data are available to assess the chronic risk of naptalam to freshwater fish and invertebrates and aquatic and terrestrial plants.

- No data are available on the potential for naptalam to bioaccumulate in fish. Given the very high log K_{ow}, we expect that naptalam, once dissociated, will accumulate in fish tissue.

2. Measures of Exposure

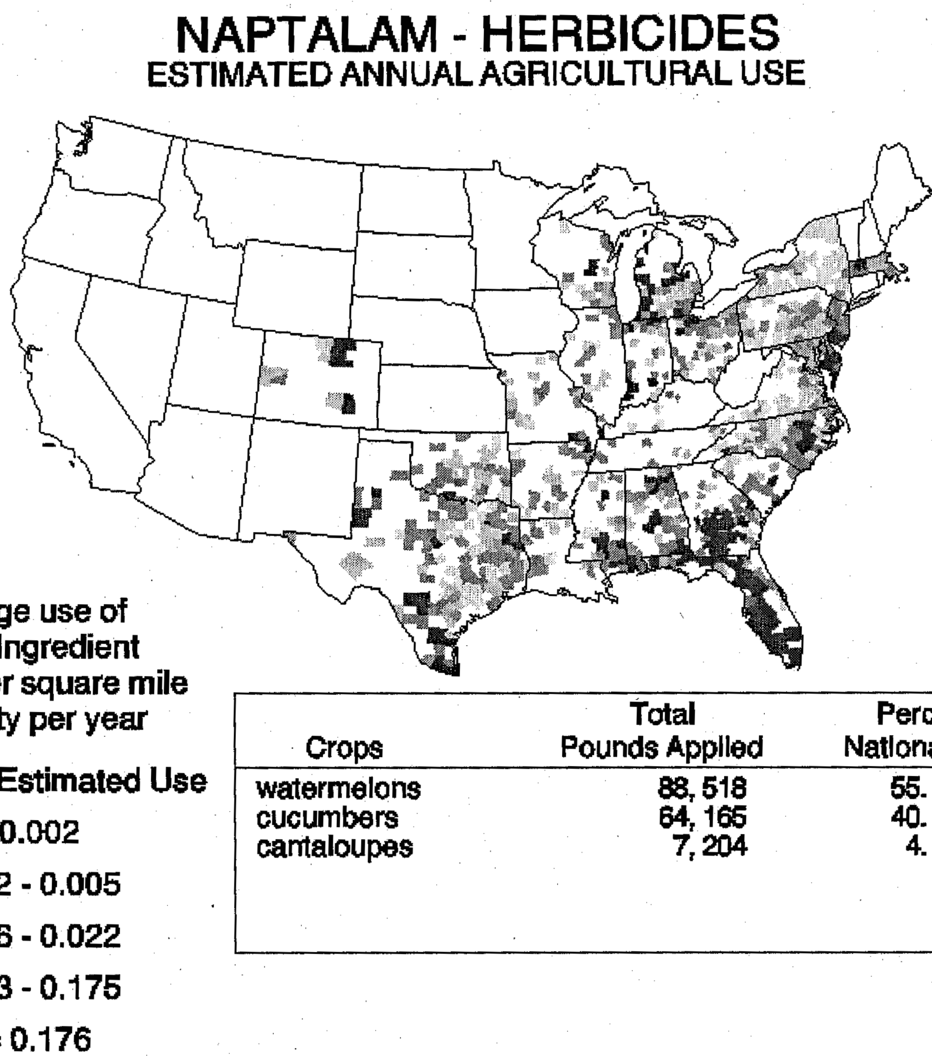
Exposure concentrations for aquatic ecosystems assessments were estimated based on EFED's aquatic Tier I model GENEEC Version 2.0 (GENEEC2, 2001). This program uses the soil/water partition coefficient and degradation kinetic data to estimate runoff from a ten hectare field into a one hectare by two meter deep 'standard' pond. This Tier I model was designed as a screen and estimates protective pesticide concentrations in surface water from a few basic chemical parameters and pesticide label use and application information. Residues in potential dietary sources for mammals and birds (e.g., vegetation, insects) were estimated using the conceptual approach given in the Tier 1 model ELL-FATE Version 1.4 (ELL-FATE, 2004).

3. Measures of Effect

Measures of effect are generally based on the results of a toxicity study, although monitoring data may also be used to provide supporting lines of evidence for the risk characterization. A complete summary of the measures of effect based on toxicity studies for different ecological receptors and effect endpoints (acute/chronic) is given in **Table 2.** Examples of measures of acute effects (e.g., lethality) include an oral LD_{50} for mammals and LC_{50} for fish and invertebrates. Examples of measures of chronic effects include a NOAEL for birds or mammals based on reproduction or developmental endpoints, and an EC_{50} for plants based on growth rate or biomass measurements.

4. Measures of Ecosystem and Receptor Characteristics

For the Tier 1 assessment using GENEEC2 and ELL-FATE, the ecosystems that are modeled are intended to be generally representative of any aquatic or terrestrial ecosystem associated with areas where naptalam is used. The receptors addressed by the aquatic and terrestrial risk assessments are summarized in **Figure 2**. For aquatic assessments, generally fish and aquatic invertebrates in both freshwater and estuarine/marine environments are represented. For terrestrial assessments, three different size classes of small mammals are represented, along with four potential foraging categories (see **Appendix E** for a detailed description).



Crops	Total Pounds Applied	Percent National Use
watermelons	88, 518	55. 36
cucumbers	64, 165	40. 13
cantaloupes	7, 204	4. 51

Figure 2. Agricultural uses of naptalam in 1992 (USGS, 2004).

III. ANALYSIS PHASE

A. Use Characterization

The agricultural uses of naptalam in the United States are for watermelon, cucumber, cantaloupe, and honeydew crops. The total amount of naptalam increased from 1992 to 1997 according to data supplied by the National Center for Food and Agricultural Policy Pesticide Use Database and the USGS National Pesticide Use Synthesis project illustrated in **Table 3** and **Figure 2**. The total weight of naptalam applied to watermelon, the crop with the highest naptalam application, increased in 1992 from approximately 88,000 to 97,000 pounds in 1997. Naptalam use is limited to the eastern region of the United States with the highest use in the southeastern states, particularly in Florida and Georgia. Information provided by the registrant (EFED, 2004), Crompton, describes the highest single application rate of naptalam as 4 lb a.i./A with a maximum of two applications per season. Applications may occur 2 to 6 weeks between treatments. The highest sales of naptalam in 2003 were in Texas, North Carolina, and Georgia for use on watermelon, cucumber, cantaloupe, and honeydew crops. The average area that is treated with naptalam per season is 23,400 acres, based on registrant data for 2000–2003. Naptalam is also currently approved for use on woody ornamental nursery stock.

Table 3. Agricultural uses of naptalam in 1997 (NCFAP, 2004).

Crop	State (Top 3)	Pounds of naptalam applied per state	Total pounds of naptalam applied
Watermelon	Florida	37910.0	97133.2
	Georgia	25011.3	
	Texas	8387.7	
Cucumber	Florida	19981.2	78895.0
	Georgia	13812.0	
	Michigan	10398.7	
Cantaloupe	Indiana	2235.3	8387.3
	Colorado	2055.0	
	Maryland	1194.0	
Honeydew	Texas	960.9	960.9

B. Exposure Characterization

1. Environmental Fate and Transport Characterization

Environmental fate properties of naptalam are shown in **Table 4**.

Table 4. Physical and chemical properties of naptalam.

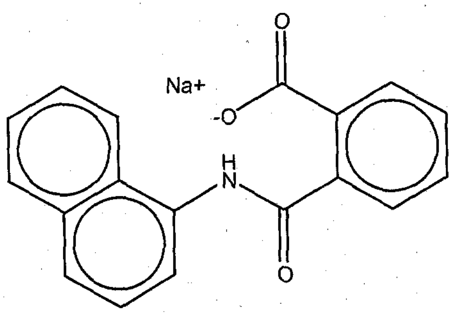
Property	Value	Reference
Structure (sodium salt)		
CAS number	132-66-1 132-67-2 (sodium salt)	
Pesticide classification	Herbicide	
SMILES notation	OC(=O)c1ccccc1C(=O)Nc2cccc3ccccc23 (naptalam) [Na]OC(=O)c1ccccc1C(=O)Nc2cccc3ccccc23 (sodium salt)	
Molecular weight	291.3 g/mol (naptalam) 313.3 g/mol (sodium salt)	Tomlin, 1997 Tomlin, 1997
Molecular formula	$C_{18}H_{13}NO_3$ (naptalam) $C_{18}H_{12}NO_3Na$ (sodium salt)	Tomlin, 1997 Tomlin, 1997
Water solubility (20 °C)	200 mg/L (naptalam) 300,000 mg/L (sodium salt) 249,000 mg/L at 25 °C (sodium salt)	Tomlin, 1997 Tomlin, 1997 Weed Science Society of America, 1994
Dissociation constant (pK_a)	4.6	Tomlin, 1997
Vapor pressure (25 °C)	9.1×10^{-11} mm Hg	EPIWIN
Henry's law constant	2.4×10^{-15} atm-m^3/mol	EPIWIN
log K_{ow}	5.42 (naptalam) -0.39 (sodium salt)	Tomlin, 1997 EPIWIN
Hydrolysis half-life		MRID 43647701
pH 5	2.9 days	
pH 7	No data	
pH 9	No data	

Table 4. Physical and chemical properties of naptalam.

Property	Value	Reference
Aqueous photolysis half-life	6.2–6.9 days 10.3 days	MRID 41385401 MRID 41385401
Soil photolysis half-life	15.9 days	MRID 41385402
Aerobic soil metabolism half-life	36.7 days	MRID 41427201
Anaerobic soil half-life	246 days	MRID 41427202
Adsorption coefficient (K_{oc})	20	Weber, 1994

At pH 7, naptalam appears to be stable to chemical hydrolysis based on information from the dark control in the aqueous photolysis study; however, at pH 5 naptalam hydrolyzed with a half-life of approximately 3 days. Experiments have shown that metal ions such as copper and zinc may inhibit the rate of hydrolysis, therefore, this reaction may occur more slowly in natural waters and soils than under laboratory conditions using distilled, deionized water. Three degradation products have been observed during the degradation of naptalam : 1-naphthylamine, N-(1-naphthyl)phthalimide, and phthalic acid. Photolysis of naptalam may be an important environmental fate process based on aqueous photolysis half-lives in the range of 6.2 to 10.3 days, and a soil photolysis half-life of 15.9 days. 1-Naphthylamine and N-(1-naphthyl)phthalimide were observed as degradation products in both aqueous and soil photolysis experiment. Naptalam degraded with a half-life of 36.7 days in a sandy loam soil under aerobic conditions. Two non-volatile degradates were identified (N-1-naphthylphtalimide and 1-naphthylamine). Under anaerobic conditions the half-life of naptalam is considerably longer (246 days).

Naptalam is formulated as a sodium salt in order to increase its solubility. Based on the pKa (4.6), the salt will dissociate under most environmental conditions and the predominant species will be the naptalam acid. Therefore, naptalam will exist primarily as an anion in water and moist soils. The high solubility of the sodium salt and a reported K_{oc} value of 20 from the open literature indicates that naptalam may leach into groundwater. Field dissipation experiments submitted to EFED do not satisfy the data requirements of Guideline 164-1 and the results of the submitted experiments have been deemed of uncertain value due to experimental deficiencies.

2. Aquatic Resource Exposure Assessment

a. Aquatic Organism Exposure Modeling

To determine ecological risks associated with agricultural uses of naptalam, estimated environmental concentrations (EECs) in surface water were modeled using the Tier I model Generic Estimated Environmental Concentrations (GENEEC, Version 2.0, dated August 1, 2001). Input parameter values are based on the data presented in **Table 5.** The product label for 'Alanap' describes an aerial and ground application. Of these two application methods, aerial applications are more likely to yield higher EECs due to the potential for spray drift. Therefore, GENEEC2 was run for aerial applications of naptalam. The peak (24-hour), 21-day and 60-day surface water EECs for curcubit application of naptalam are 452.4, 442.2, and 423.1 ppb, respectively. The peak (24-hour), 21-day and 60-day surface water EECs for ornamental woody plant application of naptalam are 470.7, 460.1, and 440.2 ppb, respectively. **Table 6** shows the output of the model.

Table 5. Input parameters for naptalam used in GENEEC2.

Parameter	Value	Source
Crop	Cucurbits[a] Ornamental woody plants	Master label
Water solubility (mg/L at 25 °C)	249,000	Weed Science Society of America, 1994
Hydrolysis half-life (days)	stable (at pH 7)	MRID 41385401
Aerobic soil metabolism half-life (days)	110[b]	36.7 days x 3 (MRID 41427201) USEPA, 2002
Aerobic aquatic metabolism half-life (days)	220	No study; value calculated as 2 x aerobic soil $t_{1/2}$ (USEPA, 2002)
Aqueous photolysis half-life (days)	6.2	MRID 41385401
Adsorption coefficient (K_{oc})[c]	20	Weber, 1994
Pesticide is wetted-in	Yes	Master label
Application method (for maximum application rate)	Aerial	Master label
Application rate (lb a.i./A)	Cucurbits[a]: 4 Ornamental woody plants: 8	Master label
Maximum number of applications per year	Cucurbits[a]: 2 Ornamental woody plants: 1	Master label
Application interval (days)	14	Master label
Depth of incorporation (cm)	0	Master label

[a]Cucumber, watermelon, muskmelon, cantaloupe, honeydew melon, Persian melon, casaba.
[b]MRID 00145416 (1978) not used in this calculation because of analytical issues and extraction problems.
[c]No study available on the adsorption/desorption coefficient (lowest non-sand K_d).

Table 6. Summary of crop application scenario and estimated environmental concentrations (EECs) of naptalam obtained from GENEEC2.

Crop	Application rate (lb a.i./A)	Maximum # of applications	EEC (ppb)		
			Peak	21 day	60 day
Cucurbits[a]	4	2	452.4	442.2	423.1
Ornamental woody plants	8	1	470.7	460.1	440.2

[a]Cucumber, watermelon, muskmelon, cantaloupe, honeydew melon, Persian melon, casaba

b. Aquatic Organism Exposure Monitoring (Field Data)

No data were identified to provide information on aquatic organism monitoring.

3. Terrestrial Organism Exposure

The EFED terrestrial exposure model, ELL-FATE (ELL-FATE, Version 1.4, dated April 7, 2004), is used to estimate exposures and risks to avian and mammalian species. Input values on avian and mammalian toxicity as well as chemical application and foliar half-time data are required to run the model. The model provides estimates of both exposure concentrations and risk quotients (RQs). Specifically, the model provides estimates of concentrations (maximum and average) of chemical residues on the surface of different types of foliage that may be sources of exposure to avian, mammalian, reptilian, or terrestrial-phase amphibian receptors. The surface residue concentration (ppm) is estimated by multiplying the application rate (pounds active ingredient per acre) by a value specific to each food item. These values (termed the Hoerger-Kenaga estimates) along with a more detailed discussion of the methodology implemented by ELL-FATE, are presented in **Appendix C** (ELL-Fate Model and Results).

For multiple applications, the EEC is determined by adding the mass on the surface immediately following the application to the mass of the chemical still present on the surfaces on the day of application (determined based on first order kinetics using the foliar half-life as the rate constant). It should be noted that because the EEC represents the concentration immediately following a direct application, the foliar half-life variable is only influential for scenarios involving multiple applications. The following table describes the input values used for estimating avian and mammalian exposure risks to naptalam.

A maximum single application rate of 8 lbs a.i./A was used (consistent with currently labeled uses on woody ornamentals), as well as a scenario involving an application rate of 4 lbs a.i./A, for a maximum of two applications per season with a minimum interval of 14 days for curcubit crops. Although no information was available on the foliar dissipation rate of naptalam, two values were identified from a study of dislodgable foliar residue. The upper 90% confidence interval of the mean of the two values is approximately 4 days. Given the uncertainty in using data from a dislodgable foliar residue study to estimate dissipation rates, two scenarios were considered to explore the plausible range of concentrations. Scenarios were run with a foliar half life of 4 days.

A summary of the input parameters used in ELL-FATE for each scenario is presented in **Table 7**. Naptalam concentrations on foliar surfaces ranged from 65–1,920 ppm for conditions of maximum residues and 30–680 ppm for conditions of mean residues. Naptalam concentrations are highest on the surfaces of short grass and lowest on the surfaces of fruits, pods, and large insects. **Table 8** shows the EECs of naptalam applied to cucurbits and **Table 9** shows the output for ornamental woody crops. A thorough description of the ELL-FATE model is provided in **Appendix C.**

Table 7. Input parameters used in ELL-FATE v1.4 to determine terrestrial EECs for naptalam.

Input variable	Parameter value	Source
Maximum application rate	Cucurbits[a]: 4 lbs a.i./A Ornamental woody plants: 8 lbs a.i./A	Product label
Maximum number of applications per year	Cucurbits[a]: 2 Ornamental woody plants: 1	Product label
Frequency of application[b]	14 days	Product label
Foliar half-life	35 days 4 days (for cucurbits only)[c]	Default (ELL-FATE, 2004) MRID 44972501, 90% UCL

[a]Cucumber, watermelon, muskmelon, cantaloupe, honeydew melon, Persian melon, casaba
[b]Interpreted as the interval (days) between successive applications. For single application scenarios, this variable is set to 0.
[c]90% UCL = 90% upper confidence limit on the mean: $\overline{t_{1/2}} + \frac{(t_{90,n-1}s)}{\sqrt{n}} = \frac{(1.66 + 2.88)}{2} + \frac{(3.078 \times 0.8267)}{\sqrt{2}} = 4.15$

Table 8. Acute, 24-hour average terrestrial EECs for naptalam applied to CUCURBITS[a] estimated using Kenaga values[b].

Foliage type	Maximum residues (ppm)	Mean residues (ppm)
Short grass	1,045	370
Tall grass	479	157
Broadleaf plants and small insects	588	196
Fruits/pods/large insects	65	30

[a]Cucumber, watermelon, muskmelon, cantaloupe, honeydew melon, Persian melon, and casaba.
[b]Application rate = 4 lbs a.i./A, 2 applications, 14 day inverva; half-life = 4 days

Table 9. Acute, 24-hour average terrestrial EECs for naptalam applied to ORNAMENTAL WOODY CROPS estimated using Kenaga values[a].

Foliage type	Maximum Residues (ppm)	Mean Residues (ppm)
Short grass	1,920	680
Tall grass	880	288
Broadleaf plants and small insects	1,080	360
Fruits/pods/large insects	120	56

[a]Application rate = 8 lbs a.i./A, 1 application; half-life = 35 days

4. Non-target Plant Exposures

Due to the lack of acceptable studies on plant toxicity, exposure modeling was not conducted for non-target terrestrial plants.

C. Ecological Effects Characterization

In screening-level ecological risk assessments, effects characterization describes the types of effects a pesticide can produce in an aquatic or terrestrial organism. This characterization is based on registrant-submitted studies that describe acute and chronic effects toxicity information for various aquatic and terrestrial animals and plants. Appendix E summarizes the results of the registrant-submitted toxicity studies used to characterize effects for this risk assessment. Toxicity testing reported in this section does not represent all species of birds, mammals, or aquatic organisms. Only a few surrogate species for both freshwater fish and birds are used to represent all freshwater fish (2000+) and bird (680+) species in the United States. For mammals, acute studies are usually limited to Norway rat or the house mouse. Estuarine/marine testing is usually limited to a crustacean, a mollusk, and a fish. Also, neither reptiles nor amphibians are tested. The risk assessment assumes that avian and reptilian toxicities are similar. The same assumption is used for fish and amphibians.

In general, categories of acute toxicity ranging from "practically nontoxic" to "very highly toxic" have been established for aquatic organisms (based on LC_{50} values), terrestrial organisms (based on LD_{50} values), avian species (based on LC_{50} values), and non-target insects (based on LD_{50} values for honey bees) (EPA 2001). These categories are presented in **Appendix E**.

1. Aquatic Effects

The most sensitive acute and chronic toxicity reference values associated with naptalam exposure to freshwater and estuarine/marine species are summarized in **Table 10.** A more detailed summary of the aquatic toxicity data available to characterize risks associated naptalam applications is given in **Appendix E** (Ecological Effects Data).

a. Aquatic Animals

The acute toxicity of naptalam to freshwater fish was evaluated in two species, with 96-hour LC_{50} values of 76.1 mg/L for rainbow trout (*Oncorhynchus mykiss*) and 118.5 mg/L for bluegill sunfish (*Lepomis macrochirus*). The acute toxicity of naptalam to freshwater invertebrates was evaluated in the daphnid (*Daphnia magna*), with a 48-hour LC_{50} value of 118.5 mg/L. Based on the acute toxicity classifications established by EPA (2001) (see **Appendix E**), these results suggest that naptalam is slightly toxic to fish and practically nontoxic to aquatic invertebrates.

No data were submitted on the chronic toxicity of naptalam to freshwater fish or invertebrates. In addition, no data were submitted on the acute or chronic toxicity of naptalam to marine/estuarine fish or invertebrates.

b. Aquatic Plants

No data were submitted on the toxicity of naptalam to non-target aquatic plants.

Table 10. Naptalam toxicity reference values (TRVs) for aquatic organisms.[a]

Exposure scenario	Species	Exposure duration	Toxicity reference value (mg/L)	Reference
Freshwater fish				
Acute	Rainbow trout *(Oncorhynchus mykiss)*	96 hour	76.1	MRID 00070193 Core
Chronic	No test data submitted			
Freshwater invertebrates				
Acute	Daphnia (*Daphnia magna*)	48 hour	118.5	MRID 00082971 Core
Chronic	No test data submitted			
Estuarine/marine fish				
No test data submitted				
Estuarine/marine invertebrates				
No test data submitted				
Aquatic plants				
No test data submitted				

[a]A more detailed summary of the aquatic toxicity data available to characterize risks associated with naptalam applications is given in Appendix E.

2. *Terrestrial Effects*

a. Terrestrial Animals

The most sensitive acute and chronic toxicity references values associated with naptalam exposure to terrestrial organisms are summarized in **Table 11.** A more detailed summary of these studies, along with additional toxicity data on terrestrial species exposed to naptalam, is given in **Appendix E** (Ecological Effects Data).

Table 11. Naptalam toxicity reference values (TRVs) for terrestrial organisms.

Effects Endpoint	Species	Exposure Duration	Toxicity Reference Value	Reference
Mammals				
Acute	Rat (*Rattus norvegicus*)	Single dose SODIUM SALT	LD_{50} = 1,700 mg/kg bw	MRID 29172
Acute	Rat	Single dose ACID	LD_{50} = >8,192 mg/kg bw	MRID 76205
Chronic	Rat (*Rattus norvegicus*)	Multigeneration reproduction and fertility effects	NOAEL = 30 mg/kg bw-day LOAEL = 150 mg/kg bw-day based on reduced mean pup body weights.	MRID 00031684 Core
Birds				
Acute	Mallard duck (*Anas platyrhynchos)*	96 hours	LD_{50} = >4,640 mg/kg bw	MRID GS-0183-01 Core
Acute	Mallard duck (*Anas platyrhynchos)*	5 days	LC_{50} = >10,000 mg/kg diet	MRID 00108853 Core
Chronic	No test data submitted			
Non-target insects				
Acute	Honeybee (*Apis mellifera)*	Acute contact	LD_{50} = 113.2 µg/bee	MRID 00028772 Core
Terrestrial plants				
No test data submitted				

Mammalian Species

Both an acute oral toxicity study in the rat (*Rattus norvegicus*) and a multigeneration reproduction study in the rat (*Rattus norvegicus*) are available for naptalam. The acute toxicity of naptalam sodium salt (MRID 29172) as well as naptalam acid (MRID 76205) were examined. The chronic study was classified as a core (acceptable) study. Based on the acute toxicity categories established by EPA (2001) (**Appendix E**), the oral LD_{50} is 1,700 mg/kg body weight.

Based on the results in **Table 11,** naptalam sodium salt is categorized as slightly toxic to small mammals on an acute oral basis (LD_{50} = 1,700 mg/kg bw), naptalam acid is practically non-toxic (LD_{50} >8,192), and the potential for chronic reproductive effects appears to be low. In a multigeneration reproduction study in the rat (*Rattus norvegicus*) possible systemic toxicity was observed in the offspring in the form of a statistically significant reduction in the mean pup body weights in the high-dose group (3,000 mg/kg in the diet or 150 mg/kg bw). This is equal to the lowest-observed-adverse-effect level (LOAEL). The no-observed-adverse-effect level (NOAEL) for naptalam for reproductive effects was 600 mg/kg diet or 30 mg/kg bw (MRID 00031684). Results of this study along with others are presented in **Appendix B, Table B-3**. The value of 1,700 mg/kg bw is used as the toxicity value for assessing acute risks to mammals from exposure to naptalam sodium salt. RQ values were not calculated for naptalam acid because there were no deaths in the study. The systemic NOAEL of 30 mg/kg bw is used as the toxicity value for assessing chronic risks.

Avian Species

For avian species, acute toxicity studies have been conducted in two species, as summarized in **Appendix B, Tables B1 to B2**. For the mallard (*Anas platyrhynchos*), the acute oral LD_{50} value is >4,640 mg/kg bw. The acute dietary LC_{50} values for the mallard and the bobwhite quail (*Colinus virginianus*) are greater than 10,000 mg/kg diet. These values suggest that naptalam is practically non-toxic to birds. Results of reproductive studies of naptalam in birds (Guideline 71-4) are not available.

Non-target Insects

Based on the contact LD_{50} value of 113.2 µg/bee for the honey bee (*Apis mellifera*), naptalam is classified as practically non-toxic on an acute contact. Currently, EFED does not assess risk to non-target insects. Results of acceptable studies are used for recommending appropriate label precautions. Based on the results of this study in honey bees, the concern for acute toxicity to non-target insects is very low.

b. Terrestrial Plants

Toxicity data for terrestrial plants was not submitted by the registrant.

IV. RISK CHARACTERIZATION

A. Risk Estimation – Integration of Exposure and Effects Data

Results of the exposure and toxicity effects data are used to evaluate the likelihood of adverse ecological effects on non-target species. For the assessment of naptalam risks, the risk quotient (RQ) method is used to compare exposure and measured toxicity values (see **Appendix F**). Estimated environmental concentrations (EECs) are divided by acute and chronic toxicity values. The RQs are then compared to the Agency's levels of concern (LOCs). These LOCs, summarized in Appendix F, are the Agency's interpretive policy and are used to analyze potential risk to non-target organisms and the need to consider regulatory action. For non-target aquatic animals (i.e., fish and invertebrates), surface water EECs were obtained from the Tier I GENEEC2 model (see **Table 6**). For non-target terrestrial animals (i.e., birds and mammals), the EECs were obtained from ELL-FATE (see **Table 8 and Table 9**). Toxicity reference values for aquatic and terrestrial organisms exposed to naptalam are summarized in **Table 10** and **Table 11**, respectively.

1. Non-target Aquatic Animals and Plants

All acute RQ values for freshwater fish and aquatic invertebrates are well below the level of concern for acute high risk (LOC 0.5), acute restricted risk (LOC 0.1), or acute endangered risk (LOC 0.05). Detailed tabular summaries of the RQ calculations for each crop use scenario, receptor, and effects endpoint, are given in **Appendix F**.

Toxicity data are either inadequate or unavailable to calculate RQs based on the following measurement endpoints (e.g., acute or chronic toxicity reference values) and receptors:

- chronic (early-life) NOAEC or LOAEC for freshwater fish;
- chronic (life-cycle) NOAEC or LOAEC for freshwater invertebrates;
- acute LC_{50} for estuarine/marine fish or invertebrates;
- chronic (early-life) NOAEC or LOAEC for estuarine/marine fish;
- chronic (life-cycle) NOAEC or LOAEC for estuarine/marine invertebrates;
- algal and vascular plant EC_{50} values for growth rate and biomass measurements.

2. Non-target Terrestrial Animals

RQs for birds and mammals were calculated by comparing toxicity values with EECs representing multiple exposure scenarios for naptalam sodium salt:

- two different crop uses (cucurbits, with 4 lbs a.i./A, 2 applications, and 14 day interval; woody ornamentals, with 8 lbs a.i./A, 1 application);
- foliar dissipation half-life of 4 days for curcubits (90% UCL from two values reported from dislodgable residue studies);
- default half-life of 35 days for ornamental woody plant application (ELL-FATE);
- maximum and mean residue levels; and
- four different foliage types representing potential food/habitat categories (short grass; tall grass; broadleaf plants and small insects; and fruits/pods/large insects).

Terrestrial mammal acute RQ values were not calculated for naptalam acid because there were no deaths in the study at concentrations as high as 8,192 mg/kg.

3. *Avian Species*

Avian acute toxicity studies indicate that the LC_{50} is >10,000 mg/kg diet, and no deaths were observed in the study. Therefore, naptalam is classified as practically non-toxic and RQ values were not calculated based on the results of the acute toxicity studies.

4. Non-target Terrestrial and Semi-aquatic Plants

Results of the exposure and toxicity effects data are used to evaluate the likelihood of adverse ecological effects on non-target species. For the assessment of naptalam risks, the risk quotient (RQ) method is used to compare exposure and measured toxicity values. Estimated environmental concentrations (EECs) are divided by acute and chronic toxicity values. The RQs are compared to the Agency's levels of concern (LOCs). These LOCs are the Agency's interpretive policy and are used to analyze potential risk to non-target organisms and the need to consider regulatory action. The surface water EECs were obtained from the Tier I GENEEC2 model (see **Table 6)** and the EECs for calculating avian and mammalian RQ values were obtained from ELL-FATE (see **Table 8 and Table 9**).

5. Freshwater Fish and Invertebrates

Acute RQ values for freshwater fish and aquatic invertebrates are well below the level of concern for acute high risk (LOC 0.5), acute restricted risk (LOC 0.1), or acute endangered risk (LOC 0.05). These data are summarized in **Tables 12 and 13.**

Table 12. Acute RQs for evaluating toxic risk of naptalam exposure to freshwater fish. RQs are based on the rainbow trout (Oncorhynchus mykiss) LC_{50} = 76.1 ppm. EEC values are generated from GENEEC2.

Crop Application Rate	Organism	LC/EC_{50} (ppm)	EEC Peak (ppm)	Acute RQ (EEC/LC_{50})
Cucurbits[a] (4 lbs a.i./A) x 2 (14d int)	Freshwater fish (*Oncorhynchus mykiss*)	76.1	0.452	0.01
Ornamental woody plants (8 lbs a.i./A) x 1	Freshwater fish (*Oncorhynchus mykiss*)	76.1	0.471	0.01

[a]Cucumber, watermelon, muskmelon, cantaloupe, honeydew melon, Persian melon, casaba.
96-hour LC_{50} for rainbow trout: 76.1 mg/L.

Table 13. Acute RQs for evaluating toxic risk of naptalam exposure to freshwater invertebrates. RQs are based on waterflea (Daphnia magna) LC_{50} = 118.5 ppm. EEC values (ppm) are generated from GENEEC2.

Crop Application Rate	Organism	LC_{50} (ppm)	EEC Peak (ppm)	Acute RQ[2]
Cucurbits[a] (4 lbs a.i./A) x 2 (14d int)	Freshwater invertebrates (*Daphnia magna*)	118.5	0.452	0.004
Ornamental woody plants (8 lbs a.i./A) x 1	Freshwater invertebrates (*Daphnia magna*)	118.5	0.471	0.004

[a]Cucumber, watermelon, muskmelon, cantaloupe, honeydew melon, Persian melon, casaba.
48-hour LC_{50} for Daphnia magna: 118.5 mg/L.

6. Mammals

The RQs for mammalian acute toxicity are provided in **Tables 14 and 15.** An acute LD_{50} value of 1,700 mg/kg for rats was used to calculate acute mammalian RQs for naptalam sodium salt. The RQs based on maximum residues range from 0.001 to 0.42 while the RQs based on mean residues range from 0.0004 to 0.15. The exposure to naptalam sodium salt on short grass, tall grass, and broadleaf plants and small insects appear to pose risks to endangered species and to pose acute restricted use risk for maximum residue conditions for 15 and 35 gram mammals. Exposure to naptalam sodium salt on short grass for 15 and 35 gram mammals poses acute risk to endangered species for mean residue conditions. RQ values were not calculated for naptalam acid because no mortality occurred in the study (>8,192 mg/kg bw).

Table 14. Acute RQs for mammalian toxicity to naptalam sodium salt applications to CURCUBITS[ab] using a foliar half-life value of 4 days[c]. RQs estimated using ELL-FATE Version 1.4 with an acute LC_{50} value of 1,700 mg/kg body weight.

	RQs based on maximum residues[d]			RQs based on mean residues		
Foliage Type	**15 g**	**35 g**	**1,000 g**	**15 g**	**35 g**	**1,000 g**
Short grass	**0.58**	**0.41**	0.09	**0.21**	**0.14**	0.03
Tall grass	**0.27**	**0.19**	0.04	0.09	0.06	0.01
Broadleaf plants and small insects	**0.33**	**0.23**	0.05	**0.11**	0.08	0.02
Fruits/pods/large insects	0.04	0.03	0.006	0.02	0.01	0.003
Seeds (granivores)	0.01	0.006	0.001	0.004	0.003	0.0005

[a]Cucumber, watermelon, muskmelon, cantaloupe, honeydew melon, Persian melon, casaba.
[b]Curcubit application = 4 lbs a.i./A, 2 applications, 14 day interval.
[c]90% UCL = 90% upper confidence limit on the mean:
[d]The latest version of ELL-FATE, Version 1.4, estimates EEC's and RQs based on maximum and mean residues. The distinction is made by using different Kenaga values for maximum and mean residues. The Kenaga values are lower for the mean residues than the maximum residues. A table of the Kenaga values is included in Appendix E.
exceedances are indicated in bold type

Table 15. Acute RQs for mammalian toxicity to naptalam sodium salt applications to ORNAMENTAL WOODY PLANTS[a] using a foliar half-life value of 35 days[b]. RQs estimated using ELL-FATE Version 1.4 with an acute LC_{50} value of 1,700 mg/kg body weight.

	RQs based on maximum residues[c]			RQs based on mean residues		
Foliage Type	**15 g**	**35 g**	**1,000 g**	**15 g**	**35 g**	**1,000 g**
Short grass	**1.07**	**0.75**	**0.17**	**0.38**	**0.26**	0.06
Tall grass	**0.49**	**0.34**	0.08	**0.16**	**0.11**	0.03
Broadleaf plants and small insects	**0.60**	**0.42**	0.10	**0.20**	**0.14**	0.03
Fruits/pods/large insects	0.07	0.05	0.01	0.03	0.02	0.00
Seeds (granivores)	0.01	0.01	0.00	0.01	0.00	0.00

[a]Ornamental woody plant application = 8 lbs a.i./A, 1 application; half-life = 35 days
[b]ELL-FATE default half-life
[c]The latest version of ELL-FATE, Version 1.4, estimates EEC's and RQs based on maximum and mean residues. The distinction is made by using different Kenaga values for maximum and mean residues. The Kenaga values are lower for the mean residues than the maximum residues. A table of the Kenaga values is included in Appendix E.
exceedances are indicated in bold type

The RQs for naptalam mammalian chronic toxicity are provided in **Tables 16 and 17.** A chronic NOAEL, representing reproduction and fertility effects, of 30 mg/kg/day or 600 ppm for rats was used to calculate the chronic mammalian RQs for naptalam. The RQs based on maximum residues for curcubit application range from 0.11–1.74 while the RQs based on mean residues range from 0.05–0.62. The RQs based on maximum residues for ornamental woody plant application range from 0.20–3.20 while the RQs based on mean residues range from 0.09–1.13.

Table 16. Chronic RQs for mammalian toxicity to naptalam applications to CUCURBITS[ab]. RQs estimated using ELL-FATE Version 1.4 with an acute LC_{50} value of 600 ppm.

Foliage Type	**RQs based on maximum residues[c]**	**RQs based on mean residues**
Short grass	**1.74**	0.62
Tall grass	0.80	0.26
Broadleaf plants and small insects	0.98	0.33
Fruits/pods/large insects	0.11	0.05

[a]Cucumber, watermelon, muskmelon, cantaloupe, honeydew melon, Persian melon, casaba.
[b]Curcubit application = 4 lbs a.i./A, 2 applications, 14 day interval
[c]The latest version of ELL-FATE, Version 1.4, estimates EEC's and RQs based on maximum and mean residues. The distinction is made by using different Kenaga values for maximum and mean residues. The Kenaga values are lower for the mean residues than the maximum residues. A table of the Kenaga values is included in Appendix E.
exceedances are indicated in bold type

Table 17. Chronic RQs for mammalian toxicity to naptalam applications to ORNAMENTAL WOODY PLANTS[a]. RQs estimated using ELL-FATE Version 1.4 with an acute LC_{50} value of 600ppm.

Foliage Type	RQs based on maximum residues[b]	RQs based on mean residues
Short grass	**3.20**	**1.13**
Tall grass	**1.47**	0.48
Broadleaf plants and small insects	**1.80**	0.60
Fruits/pods/large insects	0.20	0.09

[a]Ornamental woody plant application = 8 lbs a.i./A, 1 application; half-life = 35 days
[b]The latest version of ELL-FATE, Version 1.4, estimates EEC's and RQs based on maximum and mean residues. The distinction is made by using different Kenaga values for maximum and mean residues. The Kenaga values are lower for the mean residues than the maximum residues. A table of the Kenaga values is included in Appendix E.
exceedances are indicated in bold type

B. Risk Description – Interpretation of Direct Effects

1. Risks to Aquatic Organisms

Naptalam is used as an herbicide on cucumber and watermelon crops, particularly in states such as Florida, Georgia and Texas (see Section 3(a), Use Characterization); therefore, exposure to this herbicide will primarily occur in the southern regions of the United States where these crops are frequently grown. Addionally, naptalam is applied to ornamental woody plant nursery stock. Following the application of naptalam, spray drift or field runoff may contaminate adjacent ponds, streams, or lakes. Naptalam degrades fairly readily (half-life on the order of a few days) at low pH, but may be more persistent at neutral or alkaline conditions. Naptalam has also been shown to undergo direct photolysis with half-lives on the order of several days. However, photolysis in water will be an important degradation pathway only in clear shallow water bodies. In soil, photolysis is only important if the chemical is near the surface. Since naptalam is watered-in, photolysis is not expected to play a significant role in its degradation. The environmental persistence of naptalam is expected to be a few weeks to months under most environmental conditions with photolysis, hydrolysis and aerobic biodegradation contributing to its removal from soil and water. Volatilization from soil and water surfaces is not expected to be an important fate process since naptalam exists as an anion in the environment. Naptalam is expected to possess high mobility in soils and leaching to groundwater is a possibility.

Freshwater fish and aquatic invertebrates do not appear to be at acute risk from exposure to naptalam (risk quotients were orders of magnitude less than the levels of concern). No chronic toxicity data are available for freshwater species and no acute or chronic data are available for estuarine/marine fish or invertebrates and aquatic plants.

2. Risks to Terrestrial Organisms

Naptalam is classified as practically non-toxic to birds. RQ values were not calculated based on the results of the acute toxicity studies. The RQs for mammals based on maximum residue EECs calculated with ELL-FATE for naptalam application to curcubits range from 0.001 to 0.58 while the RQs based on mean residues range from 0.0005 to 0.21. The exposure to naptalam sodium salt on short grass, tall grass, broadleaf plants, and small insects resulting from curcubit application exceeds endangered species and acute restricted use levels of concern for maximum residue conditions for 15 and 35 gram mammals, and the LOC for acute risk is exceeded for 15g mammals that feed on short grass based on maximum residues. Exposure to naptalam sodium salt on short grass, broadleaf plants, and small insects for 15 and 35 gram mammals also exceeds the endangered species levels of concern for mean residue conditions.

The exposure to naptalam sodium salt on short grass, tall grass, broadleaf plants, and small insects resulting from ornamental woody plant application exceeds endangered species and acute restricted use levels of concern for maximum residue conditions for 15 and 35 gram mammals, and for 1000 gram mammals on short grass. Additionally, the acute LOC is exceeded for 15 and 35 gram mammals based on maximum residues on short grass, broadleaf plants, and small insects. Exposure to naptalam on short grass, broadleaf plants, and small insects for 15 and 35 gram mammals from ornamental woody plant application also exceeds the endangered species levels of concern for mean residue conditions.

Chronic RQ values from naptalam curcubit application based on maximum residues range from 0.11–1.74, while the RQs based on mean residues range from 0.05–0.62. Chronic mammalian RQs from naptalam ornamental woody plant application based on maximum residues range from 0.2 - 3.2 and 0.09 - 1.13 for maximum and mean residues, respectively.

Chronic LOCs are exceeded for naptalam application to curcubits for mammals that feed on short grass based on maximum residue values. Additionally mammalian chronic LOCs are exceeded for naptalam application to ornamental woody plants at maximum residue conditions on short grass, tall grass, broadleaf plants, and small insects. Mean residue values generate an LOC exceedance for mammals that feed on short grass.

This risk may be overestimated because naptalam acid is practically non-toxic to mammalian species. Due to its environmental fate properties, it is assumed the most of the naptalam sodium salt will dissociate at environmental pH levels to form the non-toxic naptalam acid and sodium cations. It is therefore possible that the naptalam sodium salt acute endpoint (1,700 mg/kg bw) overestimates risk, due to the fact that very little of this chemical will persist in the environment long enough to lead to mammalian exposure.

3. Review of Incident Data

There have been no incidents related to naptalam reported to the Environmental Incident Information System (EIIS) database (reported to the Agency from 1991 to 2003).

4. Endocrine Effects

Due to the lack of available data, it cannot be determined whether naptalam exhibits endocrine toxicity in aquatic organisms. Studies on the effects of naptalam on avian reproduction were not submitted to the Agency; thus, no conclusion can be made regarding the potential for naptalam to cause endocrine disruption in avian species. In a multigeneration reproduction study in the rat (*Rattus norvegicus*) possible systemic toxicity was observed in the offspring in the form of statistically significant reduction in the mean pup body weights in the high-dose group (3,000 mg/kg in the diet or 150 mg/kg bw) (MRID 00031684).

Under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), EPA is required to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was 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). When the appropriate screening and or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, naptalam may be subjected to additional screening and or testing to better characterize effects related to endocrine disruption.

5. *Threatened and Endangered Species Concerns*

a. Taxonomic Groups Potentially at Risk

The registrant must provide information on the proximity of Federally listed endangered species to the naptalam use sites. This requirement may be satisfied in one of three ways: 1) having membership in the FIFRA Endangered Species Task Force (Pesticide Registration Notice 2000-2); 2) citing FIFRA Endangered Species Task Force data; or 3) independently producing these data, provided the information is of sufficient quality to meet FIFRA requirements. The information will be used by the OPP Endangered Species Protection Program to develop recommendations to avoid adverse effects to listed species.

Curcubit Applications

The Agency's acute levels of concern (LOC) for endangered/threatened species are exceeded for 15g and 35g mammals that feed on short grass, tall grass, broadleaf plants, and small insects in or near curcubit fields based on maxiumum naptalam residues. Mean naptalam residue values lead to endangered species acute LOC exceedances for 15g and 35g mammals that feed on short grass, and maximum residue levels lead to endangered species LOC exceedances for 15g and 35g mammals that feed on short grass, long grass, broadleaf plants, and small insects.

The chronic endangered species LOC is exceeded for mammals that feed on short grass in or near curcubit fields based on maximum naptalam residue values.

Ornamental Woody Plant Applications

The Agency's acute levels of concern (LOC) for endangered/threatened species are exceeded for 15g and 35g mammals that feed on short grass, tall grass, broadleaf plants, and small insects where ornamental woody plants are grown based on maxiumum and mean naptalam residues. Large (1000g) mammal LOC exceedances occur for animals that feed on short grass, broadleaf plants, and small insects based on maximum naptalam residues.

The chronic endangered species LOC is exceeded for endangered/threatened mammals that feed on short grass, tall grass, broadleaf plants, and small insects where ornamental woody plants are grown based on maximum naptalam residue values. The chronic LOC is also exceeded for mammals that feed on short grass based on mean naptalam residue values.

Listed species
Fifty-six endangered or threatened mammal species inhabit states where naptalam is used. However, many of these listed species are not at risk through naptalam exposure based on size, food items, and habitat. The entire list of listed endangered/threatened mammalian species can be found in **Appendix G.**

Those species whose size and feeding habits lead to possible acute naptalam exposure include the following (25 species):

- Ferret, Black-Footed
- Kangaroo Rat (Fresno, Giant, Morro Bay, San Bernardino, Stephens', and Tipton)
- Mouse (Alabama Beach, Choctawhatchee Beach, Pacific Pocket, Perdido Key Beach, Preble's Meadow Jumping, Salt Marsh Harvest, and Southeastern Beach)
- Prarie Dog, Utah
- Rabbit (Pygmy and Riparian Brush)
- Shrew, Buena Vista
- Squirrel (Carolina Northern Flying, Delmarvia Peninsula Fox, Mount Graham Red, and Virginia Northern Flying)
- Vole (Amargosa and Florida Salt Marsh)
- Woodrat, Riparian

b. Probit Slope Analysis

The probit slope response relationship is evaluated to calculate the chance of an individual event corresponding to the listed species acute LOCs. If information is unavailable to estimate a slope for a particular study, a default slope assumption of 4.5 is used as per original Agency assumptions of typical slope cited in Urban and Cook (1986). Analysis of raw data from the rat naptalam acute toxicity study (MRID 29172) estimate a slope of 7.94 (95% C.I. 3.9 - 11.9). Based on this slope, the corresponding estimate chance of individual mortality of mammals following naptalam exposure is 1 in 1×10^{15}. To explore possible bounds to such estimates, the upper and lower values for the mean slope estimate (3.9 - 11.9) can be used to calculate upper and lower estimates of the effects probability associated with the listed species LOC. These values are 1 in 20,800 and 1 in 1×10^{16}. RQ exceedances only occur for 15g and 35g mammals, with RQ values ranging from 1.07 to the LOC (0.1). The estimated individual mortality associated with the calculated RQ values (0.1 to 1.07) range from 1 in 1×10^{15} to 1 in 1 (100%), respectively.

c. Critical Habitat

In the evaluation of pesticide effects on designated critical habitat, consideration is given to the physical and biological features (constituent elements) of a critical habitat identified by the U.S Fish and Wildlife and National Marine Fisheries Services as essential to the conservation of a listed species and which may require special management considerations or protection. The evaluation of impacts for a screening level pesticide risk assessment focuses on the biological features that are constituent elements and is accomplished using the screening-level taxonomic analysis (risk quotients, RQs) and listed species levels of concern (LOCs) that are used to evaluate direct and indirect effects to listed organisms.

The screening-level risk assessment has identified potential concerns for indirect effects on listed species for those organisms dependant upon small (15g) and medium (35g) sized mammals. In light of the potential for indirect effects, the next step for EPA and the Service(s) is to identify which listed species and critical habitat are potentially implicated. Analytically, the identification of such species and critical habitat can occur in either of two ways. First, the agencies could determine whether the action area overlaps critical habitat or the occupied range of any listed species. If so, EPA would examine whether the pesticide's potential impacts on non-endangered species would affect the listed species indirectly or directly affect a constituent element of the critical habitat. Alternatively, the agencies could determine which listed species depend on biological resources, or have constiuent elements that fall into, the taxa that may be directly or indirectly impacted by the pesticide. Then EPA would determine whether use of the pesticide overlaps the critical habitat or the occupied range of those listed species. At present, the information reviewed by EPA does not permit use of either analytical approach to make a definitive identification of species that are potentially impacted indirectly or critical habitats that is potentially impacted directly by the use of the pesticide. EPA and the Service(s) are working together to conduct the necessary analysis.

This screening-level risk assessment for critical habitat provides a listing of potential biological features that, if they are constituent elements of one or more critical habitats, would be of potential concern. These correspond to the taxa identified above as being of potential concern for indirect effects and include small and medium sized mammals. This list should serve as an initial step in problem formulation for further assessment of critical habitat impacts outlined above, should additional work be necessary"

d. Indirect Effect Analysis

The Agency acknowledges that pesticides have the potential to exert indirect effects upon the listed organisms by, for example, perturbing forage or prey availability, altering the extent of nesting habitat, creating gaps in the food chain, etc.

In conducting a screen for indirect effects, direct effect LOCs for each taxonomic group are used to make inferences concerning the potential for indirect effects upon listed species that rely upon non-endangered organisms in these taxonomic groups as resources critical to their life cycle.

Because screening-level acute RQs for mammals exceed the endangered species acute LOCs, the Agency uses the dose response relationship from the toxicity study used for calculating the RQ to estimate the probability of acute effects associated with an exposure equivalent to the EEC. This information serves as a guide to establish the need for and extent of additional analysis that may be performed using Services-provided "species profiles" as well as evaluations of the geographical and temporal nature of the exposure to ascertain if a "not likely to adversely affect" determination can be made. The degree to which additional analyses are performed is commensurate with the predicted probability of adverse effects from the comparison of the dose response information with the EECs. The greater the probability that exposures will produce effects on a taxa, the greater the concern for potential indirect effects for listed species dependent upon that taxa, and therefore, the more intensive the analysis on the potential listed species of concern, their locations relative to the use site, and information regarding the use scenario (e.g., timing, frequency, and geographical extent of pesticide application).

Screening-level chronic RQs for mammals that feed on short grass exceed the LOC; therefore, there may be a potential concern for indirect effects. The Agency considers this to be indicative of a potential for adverse effects to those listed species that rely either on a specific plant species (plant species obligate) or multiple plant species (plant dependent) for some important aspect of their life cycle. The Agency may determine if listed organisms for which plants are a critical component of their resource needs are within the pesticide use area. This is accomplished through a comparison of Service-provided "species profiles" and listed species location data. If no listed organisms that are either plant species obligates or plant dependent reside within the pesticide use area, a no effect determination on listed species is made. If plant species obligate or dependent organism may reside within the pesticide use area, the Agency may consider temporal and geographical nature of exposure, and the scope of the effects data, to determine if any potential effects can be determined to not likely adversely affect a plant species obligate or dependent listed organism.

Indirect effects to terrestrial animals may result from reduced food items to animals, behavior modifications from reduced or a modified habitat, and from alterations of habitats. Alterations of habitats can affect the reproductive capacity of some terrestrial animals.

C. Description of Assumptions, Uncertainties, Strengths, and Limitations

Data Gaps

There are several environmental fate data gaps that lead to uncertainties with regards to exposure and predicted environmental concentrations. Information on the hydrolysis of naptalam under neutral and alkaline conditions is lacking. Also missing are batch equilibrium studies on naptalam and its major degradates. Therefore, assumptions were made, based upon information in the open literature, about the mobility of naptalam in soil. There are also no studies available on the potential for naptalam to accumulate in fish. Based on the very high octanol-water partition coefficient, it is assumed that naptalam will bioaccumulate. Accumulation in fish studies, which provide bioconcentration factors, would reduce the uncertainties in this area. Finally, scientifically valid terrestrial field dissipation studies have not been submitted. As a result, we have no information on the fate and transport of naptalam and its degradates under actual field conditions. While the laboratory studies are designed to address one dissipation process at a time, terrestrial field dissipation studies address pesticide loss as a combined result of chemical and biological processes (e.g., hydrolysis, photolysis, microbial transformation) and physical migration (e.g., volatilization, leaching, plant uptake). Pesticide dissipation may proceed at different rates under field conditions and may result in formation of degradates at levels different from those observed in laboratory studies. Data from these studies can reduce potential overestimation of exposure and risk and can confirm assumptions of low levels of toxic degradates.

Ecotoxicity data for terrestrial and aquatic animals are limited by the number of species tested. Species variability in toxicity to chemicals can, at times, be quite high. Additionally, using only one species to characterize risk for all animals in a species category may result in the underestimation of risks for a particularly sensitive animal while overestimating the risks of others. In addition, use of laboratory rats as surrogates for wild animals has inherent uncertainties because laboratory animals are generally bred to minimize genetic variability and to be sensitive to chemical exposures (i.e., likely to exhibit responses at lower doses). In these cases, toxicity may be overstated. Although it appears that naptalam is relatively non-toxic to freshwater aquatic organisms, chronic risk from naptalam exposure and risk to estuarine/marine animals cannot be assessed due to a lack of data.

The screening level assessment strongly suggests that risks to freshwater aquatic organisms are well below levels of concern for acute or chronic effects. Even though naptalam may not degrade rapidly in water (hydrolysis is pH dependent), the toxicity data suggest naptalam may be slightly toxic to fish and is non-toxic to aquatic invertebrates.

The screening level assessment for mammals suggests that there are several scenarios in which both acute and chronic LOCs are exceeded. The greatest source of uncertainty in the assessment of acute mammalian risks stems from the single reported acute oral LD_{50} value of the naptalam sodium salt (1,700 mg/kg body weight), and the study needs to be more closely evaluated to confirm that it can be classified as acceptable for use in quantitative risk assessment. The naptalam acid is practically non-toxic to mammalian species, and due to its environmental fate properties, it is assumed the most of the naptalam sodium salt will dissociate at normal environmental pH levels to form the non-toxic naptalam acid and sodium cations. It is therefore possible that the naptalam sodium salt acute endpoint (1,700 mg/kg bw) overestimates risk, due to the fact that very little of this chemical will persist in the environment long enough to lead to mammalian exposure. Other sources of uncertainty related to the protective assumptions inherent in the use of ELL-FATE as screening level model (e.g., maximum residues, first order kinetics, etc.). This model is intended to yield high-end estimates of exposure, and the marginal exceedance of the LOCs (i.e., < 2X) suggest that a more refined assessment of exposure may yield a more refined estimate of the acute and chronic risks.

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APPENDIX A. Environmental Fate Studies

Hydrolysis 161-1 (MRID 43647701)

Non-radiolabeled naptalam and naphthalene ring-labeled [^{14}C]naptalam, at a nominal concentration of 51.9 ppm, degraded with a reviewer-calculated half-life of 2.9 days in sterilized pH 5 aqueous buffer solution incubated in darkness at 25 °C for up to 21 days. The registrant-calculated half-life was approximately 1 day. The parent compound initially present (mean of duplicate) at 96.6% of the applied radioactivity, decreased to 48.5% by 1 day, 25% by 4 days, and 5.0% by 8 days, and was 1.1% (one replicate) at 21-days post-treatment. Three main degradates were observed. The major degradate 1-naphthylamine was a maximum (mean of duplicate) of 86.9% of the applied radioactivity at 21-days post-treatment. The major degradate N-(1-naphthyl)phthalimide was a maximum of 13.5% of the applied radioactivity at 2 days post-treatment and was 3.4% at 21 days. The major degradate (non-radiolabeled) phthalic acid was a maximum (mean of duplicate) of 20.4 ppm at 21-days post-treatment. This study is considered supplemental since no data were provided at pH 7 and 9.

Huang and Stone (1999) demonstrated that dissolved metal ions (Cu^{2+} and Zn^{2+}) inhibit the rate of hydrolysis for naptalam when compared to metal free solutions. The hydrolysis half-life of naptalam in pH 5 solution containing 1 mM (millimolar) $CuCl_2$ was over 200 hours, while the half-life in metal free solution was about 100 hours. The pH dependence of naptalam hydrolysis was also investigated and it was concluded that hydrolysis is an acid catalyzed reaction, which occurs much more rapidly under acidic conditions as compared to neutral or alkaline pH. Over the course of a 14-day incubation period, the hydrolysis of naptalam was considered negligible at pH 7.5, but increased dramatically as the pH was lowered to 4. At pH 4 approximately 90% of the initially applied amount of naptalam was converted to its main degradate 1-naphthylamine in about a day in metal free solutions. In solutions containing either 1 mM $ZnCl_2$ or $CuCl_2$, only about 80% conversion was observed in the same time frame. It was also noted that as the levels of $ZnCl_2$ and $CuCl_2$ were increased from 1 to 4 mM, the amount of hydrolysis to 1-naphthylamine decreased.

The mechanism and rate of hydrolysis of naptalam was studied at pH range 0.9 to 5. At pH 5 the hydrolysis half-life was calculated as 29 hours, while at lowest pH (pH 0.9) the half-life was about 46 minutes (Granados et al., 1995).

Aqueous Photolysis 161-2 (MRID 41385401)

Naptalam photodegraded with half-lives in the range of 6.2–6.9 days in sterile aqueous pH 7 buffered 0.001 M and 0.01 M phosphate solutions and 10.3 days in 0.1 M phosphate solutions that were continuously irradiated with a xenon arc lamp (890 W/m^2). Naptalam did not degrade in dark control samples. At 15 days post-treatment naptalam comprised 18.6–21.3% of the applied radioactivity. The major degradation product observed was 1-naphthylamine comprising 47.5–49.8% of the applied radioactivity 15 days post-treatment. N-(1-naphthyl)phthalimide was also observed, comprising 7.3–7.5% of the applied radioactivity post-treatment. The study was considered supplemental since not all the radioactivity was accounted for in the test samples.

Soil Photolysis 161-3 (MRID 41385402)

Naptalam degraded with an observed half-life of 15.9 days in a sandy loam soil (63% sand, 31% silt, 6% clay, 4.7% organic matter, pH 6.8) that was continuously irradiated with a xenon arc lamp (700–750 W/m^2). In a dark control the degradation half-life was 22.4 days; therefore, it was concluded that biodegradation had occurred even though the soil samples had been autoclaved. The degradates 1-naphthylamine and N-(1-naphthyl)phthalimide were detected in both the irradiated samples and dark control at levels less than 7% of the initially applied amount. The study was considered supplemental since not all the radioactivity was accounted for in the test samples.

Aerobic Soil Metabolism 162-1 (MRID 41427201)

Naptalam degraded with a half-life of 36.7 days in a sandy loam soil (62% sand, 28% silt, 10% clay, 5% organic matter, pH 6.5) that was incubated in the dark at moisture content of 75% field capacity. ^{14}C labeled naptalam degraded from 93% (5.98 ppm) of the applied radioactivity at day 0 to 39.4% (2.53 ppm) at 41 days post-application, to 3.6% (0.23 ppm) at 135 days post-application. Two non-volatile degradates were identified: N-(1-naphthyl)phthalimide which was a maximum of 6.1% of the applied radioactivity at day 41 and 1-naphthylamine, which reached a maximum of 2.2% of the applied radioactivity slightly after application. At 135 days post-application $^{14}CO_2$ accounted for 39.5% of the initially applied radioactivity.

Anaerobic Soil Metabolism 162-2 (MRID 41427202)

Naptalam degraded with a half-life of 246 days in a sandy loam soil (62% sand, 28% silt, 10% clay, 5% organic matter, pH 6.5) that was incubated anaerobically in the dark following 30 days of aerobic incubation. Naptalam declined from 5.98 ppm (immediately following application) to 4.14 ppm 30 days post-application (just prior to establishing anaerobic conditions). The concentration declined over the following 60 days under anaerobic conditions to 3.48 ppm. Two non-volatile degradates were identified, N-1-naphthylphtalimide and 1-naphthylamine, which reached maximum levels of 0.42 and 0.12 ppm, respectively, after 31 days of anaerobic incubation.

Adsorption/Desorption 163-1

No data were submitted regarding the adsorption/desorption of naptalam from soil surfaces. Although no experimental details were provided a soil K_{oc} value of 20 has been reported (Weber, 1994), which indicates naptalam will have very high mobility in soils. It is noted that naptalam exists as an anion in water and moist soil surfaces and anionic species tend to have very high mobility in soils.

Terrestrial Field Dissipation 164-1 (41385403; 40488901)

MRID 40488901

Naptalam (Alanap-L, formulation not further identified) was sprayed at 4 lb ai/A as a tank-mix with bensulide (Prefar, formulation and source unidentified, 6 lb ai/A) to a field plot (75 x 200 feet) of silty clay loam soil (8.8 % sand, 55.6% silt, 35.6 % clay, 1.43% organic matter, pH 6.2) planted to honeydew (type and growth stage unspecified) and located in Lafayette, Indiana; the application occurred on May 20, 1985. Immediately following treatment, the soil was cultivated to a 2-inch depth to incorporate the herbicides plus a soil conditioner (undescribed). An untreated plot (size and location unspecified) was maintained as a control. Ten to fifteen soil cores (diameter unspecified; 0- to 6- and 6- to 12-inch depths) were taken from the treated plot prior to treatment and at 0, 3, 7, 14, 30, and 60 days post-treatment. Soil samples were stored (storage conditions were not adequately described) approximately 520 days prior to analysis. Total naptalam residues dissipated in the 0–6 inch soil core with half-lives of 3–7 days. This study was deemed unacceptable since sampling intervals were inadequate to accurately establish the half-life and the analytical method did not distinguish between naptalam and its degradation products.

MRID 413854031

Naptalam (Alanap-L, 2 lb/gallon SC/L, Uniroyal Chemical) was surface-applied twice at a rate of 4 lb ai/A/application to two field plots (50 x 50 feet) located near Kerman, California. The first plot was sandy loam soil (69% sand, 21% silt, 10% clay, 0.66% organic matter, pH 6.1, CEC 4.1 meq/100 g) and was treated on June 28, 1988. The second field plot was loamy sand soil (83.6% sand, 10.0% silt, 6.4% clay, 0.3% organic matter, pH 6.3, CEC 3.5 meq/100 g) and was treated on July 6, 1988. The plots were harrowed prior to treatment; immediately following the applications, the plots were cultivated (weasel) to a 2-inch depth and hand-planted watermelon. The second application was made to each plot post-emergence (26–27 days post-planting); the first plot was treated on July 25, 1988, and the second plot was treated on August 1, 1988. Following the second application, the plots were cultivated to a 2-inch depth. Total naptalam residues dissipated in the 0–6 inch soil core with a half-life of 37.4 days in the California sandy loam and dissipated in the 0–6 inch soil core of the California loamy sand with a half-life of 10.6 days. These studies were deemed unacceptable for several reasons including sampling intervals that were inadequate to accurately establish the half-life and the analytical method did not distinguish between naptalam and its degradation products.

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APPENDIX B. Aquatic Exposure Model (FIRST, SCI-GROW, and GENEEC2) – Inputs, Results, Output

1. Surface Water Modeling

a. Background Information on FIRST Version 1.0

FIRST Version 1.0 (2001) was used to estimate concentrations that may occur in vulnerable surface waters. FIRST is a screening model designed to estimate the pesticide concentrations found in water for use in human health drinking water assessments. It provides high-end estimates of the concentrations that might be found in a small drinking water reservoir due to the use of pesticide. Like GENEEC2, the model previously used for Tier I screening level assessments, FIRST is a single-event model (one run-off event). It can also account for spray drift from multiple applications. FIRST takes into consideration the so-called Index Drinking Water Reservoir (see below) by representing a larger field and pond than the standard GENEEC2 scenario. The FIRST scenario includes a 427-acre field immediately adjacent to a 13-acre reservoir, 9-feet deep, with continuous flow (two turnovers per year). The pond receives a spray drift event from each application plus one runoff event. The runoff event moves a maximum of 8% of the applied pesticide into the pond. This amount can be reduced due to degradation on the field and the effect of binding to soil. Spray drift is equal to 6.4% of the applied concentration from the ground spray application and 16% for aerial applications.

FIRST also makes adjustments for the percent crop area (PCA). While FIRST assumes that the entire watershed would not be treated, the use of a PCA is still a screen because it represents the highest percentage of crop cover of any large watershed in the United States, and it assumes that the entire crop is being treated. Various other protective assumptions of FIRST include the use of a small drinking water reservoir surrounded by a runoff-prone watershed, the use of the maximum application rate, no buffer zone, and a single large rainfall.

I. Index Reservoir

The index reservoir represents potential drinking water exposure from a specific area (Illinois) with known cropping patterns, weather, soils, and other factors. One source of uncertainty is the extent to which this index reservoir is representative of areas with different climates, crops, pesticides used, sources of water (e.g., rivers instead of reservoirs, etc.), and hydrogeology. In general, because the index reservoir represents a fairly vulnerable watershed, the concentration estimated with the index reservoir will likely be higher than the actual concentration for most drinking water sources. However, the index reservoir is not a worst-case scenario. Communities that derive their drinking water from smaller bodies of water with minimal outflow, or with more runoff prone soils, would likely receive higher drinking water exposures. Areas with a more humid climate that use a similar reservoir and cropping patterns may also receive higher exposures in their drinking water than predicted using this scenario.

A single steady flow has been used to represent the flow through the reservoir. Discharge from the reservoir also removes chemicals so this assumption will underestimate removal from the reservoir during wet periods and overestimate removal during dry periods. This assumption can both underestimate or overestimate the concentration in the pond depending upon the annual precipitation pattern at the site.

The index reservoir scenario uses the characteristics of a single soil to represent the soil in the basin. In fact, soils can vary substantially across even small areas, and this variation is not reflected in these simulations.

The index reservoir scenario does not consider tile drainage. Areas that are prone to substantial runoff are often tile drained. Portions of the cotton growing regions of Mississippi are known to have tile drains. Tile drainage contributes additional water and in some cases, additional pesticide loading to the reservoir. This may cause either an increase or decrease in the pesticide concentration in the reservoir. Tile drainage also causes the surface soil to dry out faster. This will reduce runoff of the pesticide into the reservoir. The watershed used as the model for the index reservoir (Shipman City Lake) does not have tile drainage in the cropped areas.

ii. Percent Crop Area

The PCA is a watershed-based modification to the results of the index reservoir. Implicit in its application is the assumption that field-scale models currently in use reflect basin-scale processes consistently for all pesticides and uses. In other words, we assume that the large field simulated by FIRST are reasonable approximations of pesticide fate and transport within a watershed that contains a drinking water reservoir. If the models fail to capture pertinent basin-scale fate and transport processes consistently for all pesticides and all uses, the application of a factor that reduces the estimated concentrations predicted by modeling could, in some instances, result in inadvertently passing a chemical through the screen that may actually pose a risk. A preliminary survey of water assessments which compared screening model estimates to readily available monitoring data suggest uneven model results. In some instances, the screening model estimates are more than an order of magnitude greater than the highest concentrations reported in available monitoring data; in other instances, the model estimates are less than monitoring concentrations. Because of these concerns, the Scientific Advisory Panel recommended using the PCA only for 'major' crops in the Midwest. For other crops, development of PCAs will depend on the availability of relevant monitoring data that could be used to evaluate the result of the PCA adjustment.

The spatial data used for the PCA came from readily-available sources and have a number of inherent limitations related to the size of the watershed, the distance between the treated fields and the water body is not addressed, and data from the 1992 Census of Agriculture was used. The PCA adjustment is only applicable to pesticides applied to agricultural crops. Contributions to surface waters from non-agricultural uses such as urban environments are not well modeled. Currently, non-agricultural uses are not included in the screening model assessments for drinking water.

b. Model Inputs and Results

FIRST was run for row crops using the proposed label application rate (4lb a.i./A). An aerial application was chosen in accordance with the product label and the default setting for the depth of incorporation of 0 inches was used. According to the Agency's guidelines for selecting inputs for Tier 1 models (EPA, 2002a), the default PCA of 0.87 was used. Table B-1 shows the input parameters used in the FIRST and GENEEC2 models (see Aquatic Exposure Assessment for GENEEC2 results).

The peak, 24-hour expected EEC generated from FIRST is 685.5 ppb and the annual average is 250.7 ppb (see Table B-2). The 24-hour peak, 21-day and 60-day EECs estimated from GENEEC2 are 452.4, 442.2, and 423.1 ppb, respectively.

Table B-1. Input parameters for naptalam used in GENEEC2 and FIRST.

Parameter	Value	Source
Crop	Cucurbits[a] Ornamental woody plants	Master label
Water solubility (mg/L at 25 °C)	249,000	Weed Science Society of America, 1994
Hydrolysis half-life (days)	stable (at pH 7)	MRID 41385401
Aerobic soil metabolism half-life (days)	110	36.7 days x 3 (MRID 41427201) EPA, 2002a
Aerobic aquatic metabolism half-life (days)	220	No study; value calculated as 2 x aerobic soil $t_{1/2}$ (EPA, 2002a)
Aqueous photolysis half-life (days)	6.2	MRID 41385401
Adsorption coefficient (K_{oc})[c]	20	Weber, 1994
Pesticide is wetted-in	Yes	Master label
Application method (for maximum application rate)	Aerial	Master label
Application rate (lb a.i./A)	Cucurbits[a]: 4 Ornamental woody plants: 8	Master label
Maximum number of applications per year	Cucurbits[a]: 2 Ornamental woody plants: 1	Master label
Application interval (days)	14	Master label
Depth of incorporation (cm)	0	Master label

[a]Cucumber, watermelon, muskmelon, cantaloupe, honeydew melon, Persian melon, casaba
[b]No study available on the adsorption/desorption coefficient (lowest non-sand K_d).

Table B-2. Surface water environmental concentrations (EECs) for drinking water risk assessment for naptalam generated from FIRST.

Crop	Surface water concentrations (ppb)	
	Peak, 24 hour	Annual average
Cucurbits[a]	685.5	250.7
Ornamental woody plants	716.7	262

[a]Cucumber, watermelon, muskmelon, cantaloupe, honeydew melon, Persian melon, casaba.

Table B-3. Summary of crop application scenario and EECs of naptalam obtained from GENEEC2.

Crop	Application rate (lb a.i./A)	Maximum # of applications	EEC (ppb)		
			Peak	21 day	60 day
Cucurbits[a]	4	2	452.4	442.2	423.1
Ornamental woody plants	8	1	470.7	460.1	440.2

[a]Cucumber, watermelon, muskmelon, cantaloupe, honeydew melon, Persian melon, casaba.

2. Groundwater Modeling

a. Background Information on SCI-GROW Version 2.3

Groundwater concentrations were estimated using the Tier 1 model SCI-GROW Version 2.3. SCI-GROW provides a groundwater screening exposure value to be used in determining the potential risk to human health from drinking water contaminated with the pesticide. Since the SCI-GROW concentrations are likely to be approached in only highly vulnerable aquifers, which constitute a very small percentage of drinking water sources, it is not appropriate to use SCI-GROW for national or regional exposure estimates.

SCI-GROW estimates likely groundwater concentrations if the pesticide is used at the maximum allowable rate in areas where groundwater is exceptionally vulnerable to contamination. In most cases, a large majority of the use area will have groundwater that is less vulnerable to contamination than the areas used to derive the SCI-GROW estimate.

b. Model Inputs and Results

SCI-GROW was run for naptalam for row crops. Input values for naptalam are presented in Table B-4. The modeling results of naptalam by SCI-GROW are summarized in Table B-5. The peak 24-hour concentration is 3.3 ppb.

Table B-4. Input parameters used in SCI-GROW.

Input variable	Parameter value	Comment
Application rate (lbs a.i./A)	Curcurbits[a]: 4 Ornamental woody plants: 8	Proposed label
Maximum applications per year	Curcurbits[a]: 2 Ornamental woody plants: 1	Proposed label
K_{oc} (mL/g)	20	Weber, 1994
Aerobic soil metabolism half-life (days)	36.7	MRID 41427201

[a]Cucumber, watermelon, muskmelon, cantaloupe, honeydew melon, Persian melon, casaba

Table B-5. Ground-water concentrations of naptalam estimated using SCI-GROW v.2.3.

Crop	Peak 24-hour Concentration (ppb)
Cucurbits[a] (4 lbs a.i./A, 2 applications, 14 day interval)	11.1
Ornamental woody plants (8 lbs a.i./A, 1 application)	11.1

[a]Cucumber, watermelon, muskmelon, cantaloupe, honeydew melon, Persian melon, casaba

FIRST v. 1.0 Model Output

RUN No. 1 FOR naptalam sodium ON cucurbits * INPUT VALUES *

RATE (#/AC) ONE(MULT)	No.APPS & INTERVAL	SOIL Koc	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	%CROPPED AREA	INCORP (IN)
4.000(7.662)	2 14	20.0	*******	AERIAL(16.0)	87.0	.0

FIELD AND RESERVOIR HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (RESERVOIR)	PHOTOLYSIS (RES.-EFF)	METABOLIC (RESER.)	COMBINED (RESER.)
110.00	0	N/A	6.20- 768.80	220.00	171.05

UNTREATED WATER CONC (MICROGRAMS/LITER (PPB)) Ver 1.0 AUG 1, 2001

PEAK DAY (ACUTE) CONCENTRATION	ANNUAL AVERAGE (CHRONIC) CONCENTRATION
685.548	250.739

SCI-GROW Version 2.3 Model Output

```
                         SCIGROW
                       VERSION 2.3
           ENVIRONMENTAL FATE AND EFFECTS DIVISION
                OFFICE OF PESTICIDE PROGRAMS
            U.S. ENVIRONMENTAL PROTECTION AGENCY
                      SCREENING MODEL
              FOR AQUATIC PESTICIDE EXPOSURE

SciGrow version 2.3
chemical:naptalam sodium
time is  9/30/2004  10:25:46
-----------------------------------------------------------------------
 Application      Number of       Total Use    Koc      Soil Aerobic
 rate (lb/acre)  applications   (lb/acre/yr)  (ml/g)  metabolism (days)
-----------------------------------------------------------------------
     4.000           2.0            8.000     2.00E+01        36.7
-----------------------------------------------------------------------
groundwater screening cond (ppb) =   1.11E+01
***********************************************************************
```

GENEEC2 Model Output

```
RUN No.  34 FOR naptalam          ON    curcubits       * INPUT VALUES *
--------------------------------------------------------------------
 RATE (#/AC)    No.APPS &   SOIL  SOLUBIL   APPL TYPE NO-SPRAY INCORP
  ONE(MULT)     INTERVAL    Koc   (PPM )    (%DRIFT)   (FT)     (IN)
--------------------------------------------------------------------
4.000(  7.662)   2  14      20.0*******   AERL_B( 13.0)      .0    .0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)
--------------------------------------------------------------------
METABOLIC  DAYS UNTIL  HYDROLYSIS   PHOTOLYSIS   METABOLIC  COMBINED
 (FIELD)   RAIN/RUNOFF   (POND)     (POND-EFF)    (POND)     (POND)
--------------------------------------------------------------------
 110.00        0          N/A      6.20-  768.80   220.00    171.05

GENERIC EECs (IN MICROGRAMS/LITER (PPB))      Version 2.0 Aug 1, 2001
--------------------------------------------------------------------
   PEAK       MAX 4 DAY     MAX 21 DAY    MAX 60 DAY    MAX 90 DAY
   GEEC       AVG GEEC       AVG GEEC      AVG GEEC      AVG GEEC
--------------------------------------------------------------------
  452.40       450.94        442.24        423.08        409.11
```

APPENDIX C. Terrestrial Exposure Model (ELL-FATE) – Inputs, Results, Output

The model output from ELL-FATE for naptalam is in the attached Microsoft Excel spreadsheet Naptalam ELLFATE Version 1.4.

Kenaga Estimates and ELL-FATE Model – Explanation

Hoerger and Kenaga estimates (1972) as modified by Fletcher, Nellessen, and Pfleeger (1994) were used to approximate the residues on plants and insects. Hoerger-Kenaga categories represent preferred foods of various terrestrial vertebrates: fruits and bud and shoot tips of leafy crops are preferred by upland game birds; leaves and stems of leafy crops are consumed by hares and hoofed mammals; seeds, seed pods and grasses are consumed by rodents; and insects are consumed by various birds, mammals, reptiles and terrestrial-phase amphibians. Terrestrial vertebrates also may be exposed to pesticides applied to soil by ingesting pesticide granules and/or pesticide-laden soil when foraging. Rich in minerals, soil comprises 5 to 30% of dietary intake by many wildlife species (Beyer and Conner, 1994).

Hoerger-Kenaga pesticide environmental concentration estimates (EECs) were based on residue data correlated from more than 20 pesticides on more than 60 crops. Representative of many geographic regions (seven states) and a wide array of cultural practices, Hoerger-Kenaga estimates also considered differences in vegetative yield, surface/mass ratio, and interception factors. In 1994, Fletcher, Nellessen, and Pfleeger reexamined the Hoerger-Kenaga simple linear model ($y=B^1x$, where x=application rate and y=pesticide residue in ppm) to determine whether the terrestrial EECs were accurate. They compiled a data set of pesticide day-0 and residue-decay data involving 121 pesticides (85 insecticides, 27 herbicides, and 9 fungicides from 17 different chemical classes) on 118 species of plants. They found that Hoerger-Kenaga estimates needed only minor modifications to elevate the predictive values for forage and fruit categories from 58 to 135 ppm and from 7 to 15 ppm, respectively. Otherwise, the Hoerger-Kenaga estimates were accurate in predicting the maximum residue values after a 1 lb ai/A application. Mean values represent the arithmetic mean of values from samples collected the day of pesticide treatment. These values, summarized in Table C-1, are the predicted 0-day maximum and mean residues of a pesticide that may be expected to occur on selected avian, mammalian, reptilian, or terrestrial-phase amphibian food items immediately following a direct single application at a 1 lb ai/A application rate. For pesticides applied as a non-granular product (e.g., liquid, dust), the EECs on food items following product application are compared to LC_{50} values to assess risk.

Spreadsheet-based Terrestrial Exposure Values

A first order decay assumption is used to determine the concentration at each day after initial application based on the concentration resulting from the initial and additional applications. The decay is calculated from the standard first order rate equation:

$$\mathbf{C_T = C_i e^{-kT}}$$

or in integrated form:

$$\mathbf{\ln (C_T/C_i) = -kT}$$

Where:

$\mathbf{C_T}$ = concentration at time T on day zero.

C_i = concentration in parts per million (ppm) present initially (on day zero) on the surfaces.

C_i = is calculated based on Kenaga and Fletcher by multiplying the application rate, in pounds active ingredient per acre, by 240 for short grass, 110 for tall grass, 135 for broad-leaf plants/insects, and 15 for seeds. A similar approach is used to calculate mean residues (see Table C-1). Additional applications are converted from pounds active ingredient per acre to ppm on the plant surface and the additional mass is added to the mass of the chemical still present on the surfaces on the day of application.

k = degradation rate constant determined from studies of hydrolysis, photolysis, microbial degradation, etc. Since degradation rate is generally reported in terms of half-life, the rate constant is calculated from the input half-life ($k = \ln 2/T_{1/2}$) instead of being input directly. Choosing which process controls the degradation rate and which half-life to use in terrestrial exposure calculations is open for debate and should be done by a qualified scientist.

T = time, in days, since the start of the simulation. The initial application is on day 0. The simulation is set to run for 365 days.

ELL-FATE calculates the maximum and mean residue concentrations on each type of surface on a daily interval for one year.

Table C-1. Kenaga values used in ELL-FATE (2004) Version 1.4.

Foliage type	Maximum residues	Mean residues
Short grass	240	85
Tall grass	110	36
Broadleaf plants and small insects	135	45
Fruits/pods/large insects	15	7

Literature Cited

Beyer and Conner. 1994

ELL-FATE. 2004. Terrestrial Exposure and Risk Model Version 1.4. April 7, 2004. Environmental Fate and Effects Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, D.C.

Fletcher, JS; Nellessen, JE; Pfleeger, TG. 1994. Literature review and evaluation of the EPA food-chain (Kenaga) Nomogram, an instrument for estimating pesticide residues on plants. Environ Toxicol Chem 13(9):1383–1391.

Hoerger F; Kenaga, EE. 1972. Pesticide Residues on Plants: Correlation of Representative Data as a Basis for Estimation of Their Magnitude in the Environment. Agricultural Department, Dow Chemical Corporation, Midland, MI. 18 pgs.

APPENDIX D. TerrPlant Model – Inputs, Results, Output

No plant toxicity data was submitted, therefore, TerrPlant was not run.

APPENDIX E. Ecological Effects Data

I. Toxicity to Terrestrial Animals

a. Birds, Acute and Subacute

One acute oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the toxicity of naptalam to birds. The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). Results of these studies are tabulated in Table E-1.

Table E-1. Avian acute oral toxicity.

Species	% a.i.	LD_{50} (mg/kg bw)	Toxicity Category	MRID Number	Study Classification[a]
Mallard duck *(Anas platyrhynchos)*	94	>4,640	Practically non-toxic	GS-0183-01	Core

[a]Core: study satisfies guideline; Supplemental: study is scientifically sound, but does not satisfy guideline

The data that were submitted show that the LD_{50} values fall in the range of >2,000 mg/kg, therefore, naptalam is categorized as practically non-toxic to avian species on an acute oral basis, therefore, Guideline 71-1 is fulfilled.

Two subacute dietary studies using the TGAI are required to establish the toxicity of naptalam to birds. The preferred test species are mallard duck and bobwhite quail. Results of these tests are tabulated in Table E-2.

Table E-2. Avian subacute dietary toxicity.

Species	% a.i.	LC_{50} (mg/kg diet)[a]	Toxicity Category	MRID Number	Study Classification[b]
Northern bobwhite quail *(Colinus virginianus)*	94	>10,000	Practically non-toxic	00082969	Core
Mallard duck *(Anas platyrhynchos)*	94	>10,000	Practically non-toxic	00108853	Core

[a]5-day dietary exposure followed by additional 3-day observation period.
[b]Core: study satisfies guideline; Supplemental: study is scientifically sound, but does not satisfy guideline.

The data that were submitted show that the LC_{50} values fall in the range of >5,000 ppm, therefore, naptalam is categorized as practically non-toxic to avian species on a subacute dietary basis. Therefore, Guideline 71-2 is fulfilled.

b. Birds, Chronic

Avian reproduction studies using the TGAI are required for naptalam because the following conditions are met: (1) birds may be subject to repeated or continuous exposure to the pesticide, especially preceding or during the mating season; (2) the pesticide is stable in the environment to the extent that potentially toxic amounts may persist in animal feed; and (3) the pesticide is stored or accumulated in plant or animal tissues. The preferred test species are mallard duck and bobwhite quail.

c. Mammals, Acute and Chronic

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. The toxicity values for mammalian oral, dermal, and inhalation toxicity tests are reported in Table E-3.

Table E-3. Mammalian toxicity.

Species	Study Type/Doses	Results	MRID No.
Rat (*Rattus norvegicus*)	Acute oral	LD_{50} = 1,700 mg/kg/day (salt) LD_{50} >8,192 mg/kg/day (acid)	29172 76205
Rat (*Rattus norvegicus*)	Acute dermal – rat	LD_{50} >2 g/kg	00068402
Rat (*Rattus norvegicus*)	Acute inhalation – rat	LC_{50} >2.0 mg/L	43936401
Rabbit	Acute eye irritation – rabbit	Slight irritation	00078530
Rabbit	Acute dermal irritation – rabbit	Non-irritant	00060403
Guinea pig (*Cavia porcellus*)	Skin sensitization – Guinea pig	Dermal sensitizer	00015185
Rat (*Rattus norvegicus*)	90-Day oral toxicity rat; 0, 25, 50, 250 mg/kg/day	NOAEL = 1,000 ppm (50 mg/kg/day) LOAEL = 5,000 ppm (250 mg/kg/day) based on reduced body weight gain, reduced food efficiency, and decreased organ weights.	00106276

Table E-3. Mammalian toxicity.

Species	Study Type/Doses	Results	MRID No.
Rat (*Rattus norvegicus*)	90-Day oral toxicity dog; Males: 0, 11.4, 29.7, 124.7 mg/kg/day Females: 0, 9.7, 29.9, 123.6 mg/kg/day	NOAEL = 1,000 ppm (29.7–29.9 mg/kg/day) LOAEL = 3,000 ppm (123.6–124.7 mg/kg/day) based on reduced body weight gains, reduced food efficiency, and increased absolute and relative liver weights.	00106277
Dog (*Canis familiarus*)	90-Day oral toxicity; 0, 5.3, 25.8, 121 mg/kg/day	NOAEL = 200 ppm (5.3 mg/kg/day) LOAEL = females: 1,000 ppm (25.8 mg/kg/day); males 5,000 ppm (121 mg/kg/day) based on liver weights, increased enzyme activity and bilirubin.	41057501
Rat (*Rattus norvegicus*)	Teratology study in the rat; 0, 15, 115, 500 mg/kg/day	Maternal NOAEL = 15 mg/kg/day LOAEL = 115 mg/kg/day based on reduced body weight gain (minimal and not supported by other observations). **Developmental** NOAEL = 115 mg/kg/day LOAEL = 500 mg/kg/day based on reduced fetal weights, increased skeletal observations.	000106320
Rabbit	Teratology study in rabbits	**Maternal** NOAEL = 200 mg/kg/day LOAEL = 650 mg/kg/day based on reduced body weight gain, mortality, and clinical observations. **Developmental** NOAEL = 200 mg/kg/day LOAEL = 650 mg/kg/day based on increased skeletal observations.	00157186

Table E-3. Mammalian toxicity.

Species	Study Type/Doses	Results	MRID No.
Rat (*Rattus norvegicus*)	Multigeneration reproduction and fertility study in the rat; 0, 6, 30, 150 mg/kg/day	**Parental/Systemic** NOAEL = 600 ppm (30 mg/kg/day) LOAEL = 3,000 ppm (150 mg/kg/day) based on reduced body weights. **Reproductive** NOAEL >3,000 ppm (150 mg/kg/day) LOAEL >3,000 ppm (150 mg/kg/day) **Offspring** NOAEL = 600 ppm (30 mg/kg/day) LOAEL = 3,000 ppm (150 mg/kg/day) based on reduced mean pup body weights.	00031684
Rat (*Rattus norvegicus*)	104-Week chronic toxicity in the rat; 0, 5.6, 27, 140 mg/kg/day	NOAEL >140 mg/kg/day LOAEL >140 mg/kg/day.	00077053
Dog (*Canis familiaris*)	12-Month oral chronic toxicity study in the dog; 0, 5.3, 25.8, 121 mg/kg/day	NOAEL = 1,000 ppm (25.8 mg/kg/day) LOAEL = 5,000 ppm (121 mg/kg/day) based on increased liver weights, increased levels of alkaline phosphatase and bilirubin.	41057501
Rat (*Rattus norvegicus*)	Metabolism and pharmacokinetics – rat	^{14}C naptalam was rapidly absorbed, distributed and excreted with 7-day recovery of 85%	40274502

[1]Core: study satisfies guideline; Supplemental: study is scientifically sound, but does not satisfy guideline; NA: not available

Based on these results naptalam is categorized as slightly toxic to small mammals on an acute oral basis (LD_{50} = 1,700 mg/kg bw) and the potential for chronic reproductive effects appears to be low. In a multigeneration reproduction study in the rat (*Rattus norvegicus*) possible systemic toxicity was observed in the offspring in the form of statistically significant reduction in the mean pup body weights in the high-dose group (3,000 mg/kg in the diet or 150 mg/kg bw). This is equal to the lowest-observed-adverse-effect level (LOAEL). The no-observed-adverse-effect level (NOAEL) for naptalam for reproductive effects was 600 mg/kg diet or 30 mg/kg bw (MRID 00031684).

d. Terrestrial Insects, Honeybee Acute

A honey bee acute contact study using the TGAI is required for naptalam because its use on crops will result in honey bee exposure. The acute contact LD_{50}, using the honey bee (*Apis mellifera*) is an acute contact, single-dose laboratory study designed to estimate the quantity of toxicant required to cause 50% mortality in a test population. The TGAI is administered by one of two methods: whole body exposure to technical pesticide in a non-toxic dust diluent; or topical exposure to technical pesticide via micro-applicator. The median lethal dose (LD_{50}) is expressed in micrograms of active ingredient per bee (μg a.i./bee). Results of this test are tabulated below (Table E-4). Toxicity category descriptions for honey bee acute contact toxicity are from Atkins (1981):

The following toxicity category descriptions were developed by Atkins (1981) and have been used by EFED to characterize honey bee acute contact toxicity values (EPA, 2004):

LD_{50} (μg a.i./bee)	Toxicity Category
<2	Highly toxic
2–<11	Moderately toxic
>11	Practically nontoxic

Table E-4. Honey bee acute contact toxicity.

Species	% a.i.	48-hour LD_{50} (μg/bee)	Category	MRID Number	Study Classification[a]
Honey bee *(Apis mellifera)*	Technical	113.2	Practically non-toxic	00028772	Core

[a]Core: study satisfies guideline; Supplemental: study is scientifically sound, but does not satisfy guideline.

The data that were submitted show that the LD_{50} for the honey bee falls in the range of >11 μg/bee, therefore, naptalam is categorized as practically non-toxic to the honeybee on an acute contact basis. Therefore, Guideline 141-1 is fulfilled. Further acute oral toxicity testing and foliar residue toxicity testing with the honeybee were not required. A honey bee foliar residue toxicity study is required on an end-use product for any pesticide intended for outdoor application when the proposed use pattern indicates that honey bees may be exposed to the pesticide and when the formulation contains one or more active ingredients having an acute contact honey bee LD_{50} which falls in the moderately toxic or highly toxic range.

II. Toxicity to Freshwater Animals

a. Freshwater Fish, Acute

Two freshwater fish toxicity studies using the TGAI are required to establish the acute toxicity of naptalam to fish. The preferred test species are rainbow trout (*Oncorhynchus mykiss*) (a coldwater fish) and bluegill sunfish (*Lepomis macrochirus*) (a warmwater fish). Results of these tests are tabulated below in Table E-5.

Table E-5. Freshwater fish acute toxicity.

Species	% a.i.	96-Hour LC_{50} (mg/L)	Toxicity Category	MRID Number	Study Classification[a]
Bluegill sunfish *(Lepomis macrochirus)*	94	354.4	Practically non-toxic	00070193	Core
Rainbow trout *(Oncorhynchus mykiss)*	94	76.1	Practically non-toxic	00070193	Core
Bluegill sunfish *(Lepomis macrochirus)*	95	>180[b]	Practically non-toxic	00024161	Supplemental

[a]Core: study satisfies guideline; Supplemental: study is scientifically sound, but does not satisfy guideline.
[b]72-hour LC_{50}

The acute studies that were submitted show that naptalam is classified as practically non-toxic to freshwater fish. Therefore, Guideline 72-1 is fulfilled.

b. Freshwater Fish, Chronic

An freshwater fish early life stage toxicity test using the TGAI is required for naptalam because the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity. Toxicity testing data for freshwater fish to chronic exposures of naptalam were not available from the registrant submitted data. The Guideline 72-4 (a) has not been fulfilled.

c. Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test (Guideline 72-2) using the TGAI is required to establish the toxicity of naptalam to aquatic invertebrates. The preferred test species is the water flea (*Daphnia magna*). Submitted results of acute toxicity tests with freshwater invertebrates are tabulated in Table E-6.

Table E-6. Freshwater invertebrate acute toxicity.

Species	% a.i.	48-Hour LC_{50} (mg/L)	Toxicity Category	MRID Number	Study Classification[a]
Waterflea (*Daphnia magna*)	94	118.5	Practically non-toxic	00082971	Core

[a]Core: study satisfies guideline

The data that were submitted show that naptalam is classified as practically non-toxic to freshwater invertebrates (i.e., daphnids) with an acute LC_{50} value of 118.5 mg/L. Therefore, Guideline 72-2 requirements for acute invertebrate toxicity are fulfilled.

d. Freshwater Invertebrate, Chronic

A freshwater aquatic invertebrate life-cycle test (Guideline 72-4) using the TGAI is required if the end-use product may be transported to water from the intended use site, and the presence in water is likely to be continuous or recurrent. Toxicity testing data for freshwater invertebrates to chronic exposures of naptalam were not available from the registrant submitted data. This data requirement has not been met.

III. Toxicity to Estuarine/Marine Animals

a. Estuarine/Marine Fish, Acute

Acute toxicity testing with estuarine/marine fish using the TGAI is required for naptalam because the end-use product is expected to reach this environment because of its use in coastal counties (i.e., crops). The preferred test species is the sheepshead minnow (*Cyprinodon variegatus*). Toxicity testing data for estuarine/marine fish to acute exposures of naptalam were not available from the registrant submitted data. Therefore, Guideline 72-3a is not fulfilled.

b. Estuarine/Marine Fish, Chronic

An estuarine/marine fish early life stage toxicity test using the TGAI is required for naptalam because the end-use product is expected to be transported to an estuarine/marine environment and the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity. The preferred test species is the sheepshead minnow (*C. variegatus*). Toxicity testing data for freshwater fish to chronic exposures of naptalam were not available from the registrant submitted data. Therefore, Guideline 72-4 (a) has not been fulfilled.

c. Estuarine/Marine Invertebrates, Acute

Acute toxicity testing with estuarine/marine invertebrates using the TGAI is required for naptalam because the end-use product is expected to reach this environment because of its use in coastal counties (i.e., crops). The preferred test species are mysid shrimp (*Mysidopsis bahia*) and eastern oyster (*Crassostrea virginica*). Toxicity testing data for estuarine/marine invertebrates to acute exposures of naptalam were not available from the registrant submitted data. The Guidelines 72-3 (b) and 72-3 ©) are not fulfilled.

d. Estuarine/Marine Invertebrates, Chronic

An estuarine/marine invertebrate early life stage life-cycle toxicity test using the TGAI is required for naptalam because the end-use product is expected to be transported to an estuarine/marine environment and the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity. The preferred test species is mysid shrimp (*M. bahia*). Toxicity testing data for estuarine/marine invertebrates to chronic exposures of naptalam were not available from the registrant submitted data. Therefore, Guideline 72-4 (b) has not been fulfilled.

IV. Toxicity to Plants

a. Terrestrial Plants

Terrestrial plant toxicity testing is required for naptalam as it is an herbicide (Guideline 122-1 (a) and (b). Toxicity testing data for terrestrial plants and naptalam was not available from the registrant submitted data. The guideline is not fulfilled.

b. Aquatic Plants

Aquatic plant testing (Guideline 122-2 [Tier I]) is required for naptalam as it has outdoor non-residential terrestrial uses and may move off-site by run-off (solubility >10 ppm in water) or may move by drift (aerial). Toxicity testing data for aquatic plants and naptalam was not available from the registrant submitted data. The guideline is not fulfilled.

V. Open Literature Search

A search of the open literature for toxicity information on naptalam was completed by searching the EPA's Ecotoxicology database (ECOTOX) as well as TOXLINE and PubMed. ECOTOX is a publicly available database summarizing the ecological effects of single chemicals to aquatic and terrestrial plants and animals (http://www.epa.gov/ecotox).

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APPENDIX F. The Risk Quotient Method and Levels of Concern

The risks to terrestrial and aquatic organisms are determined based on a method by which risk quotients (RQs) are compared with levels of concern (LOCs). This method provides an indication of a chemical's potential to cause an effect in the field from effects observed in laboratory studies, when used as directed. Risk quotients are expressed as the ratio of the estimated environmental concentration (EEC) to the species-specific toxicity reference value (TRV):

$$RQ = \frac{EEC}{TRV}$$

Units for EEC and TRV should be the same (e.g., μg/L or ppb). The RQ is compared to the LOC as part of a risk characterization. Acute and chronic LOCs for terrestrial and aquatic organisms are given in recent Agency guidance (EPA, 2004) and summarized in Table F-1 below.

Table F-1. Level of concern (LOC) by risk presumption category (EPA, 2004).

Risk Presumption	RQ	LOC
	Mammals and Birds	
Acute Risk[a]	EEC[b]/LC_{50} or LD_{50}/sqft[c] or LD_{50}/day[d]	0.5
Acute Restricted Use[e]	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day (or LD_{50} <50 mg/kg)	0.2
Acute Endangered Species[f]	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.1
Chronic Risk	EEC/NOEC	1
	Aquatic Animals	
Acute Risk	EEC[g]/LC_{50} or EC_{50}	0.5
Acute Restricted Use	EEC/LC_{50} or EC_{50}	0.1
Acute Endangered Species	EEC/LC_{50} or EC_{50}	0.05
Chronic Risk	EEC/NOEC	1
	Terrestrial and Semi-aquatic Plants	
Acute Risk	EEC/EC_{25}	1
Acute Endangered Species	EEC/EC_{05} or NOEC	1

Table F-1. Level of concern (LOC) by risk presumption category (EPA, 2004).

Risk Presumption	RQ	LOC
	Aquatic Plants	
Acute Risk	EEC^h/EC_{50}	1
Acute Endangered Species	EEC^g/EC_{05} or NOEC	1

[a]Potential for acute toxicity for receptor species if RQ > LOC (EPA, 2004).
[b]Estimated environmental concentration (ppm) on avian/mammalian food items
[c]mg/ft^2
[d]mg of toxicant consumed per day
[e]Potential for acute toxicity for receptor species, even considering restricted use classification, if RQ > LOC (EPA, 2004).
[f]Potential for acute toxicity for endangered species of receptor species if RQ > LOC (EPA, 2004).
[g]EEC = ppb or ppm in water
[h]EEC = lbs a.i./A

For acute exposure to terrestrial and aquatic plants, an LOC of 1 is used. Currently the Agency does not perform assessments for chronic risk to plants or acute/chronic risks to non-target insects.

For this Tier I assessment of naptalam, acute exposure to aquatic organisms is represented by the maximum 24-hour EEC value calculated using GENEEC2. EECs used to assess acute and chronic risk to avian and mammalian species were calculated using ELL-FATE.

The Agency has developed an Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register notice. The Agency is not imposing label modifications at this time. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

Limitations in the use of naptalam may be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. The Agency will notify the registrants if any label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

Literature Cited

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APPENDIX G. Summary of Threatened and Endangered Species

Species Detail by State for Preliminary Assessment
Cucurbits, all (306)

Minimum of 1 Acre.

Alabama (4)

BAT, GRAY *Family:* Vespertilionidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal
BAT, INDIANA *Family:* Vespertilionidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal
MOUSE, ALABAMA BEACH *Family:* Cricetidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal
MOUSE, PERDIDO KEY BEACH *Family:* Cricetidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal

Arizona (7)

BAT, LESSER (=SANBORN'S) LONG-NOSED *Family:* Phyllostomidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal
JAGUAR *Family:* Felidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal
Jaguarundi, Sinaloan *Family:* Felidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal
OCELOT *Family:* Felidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal
PRONGHORN, SONORAN *Family:* Antilocapridae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal
SQUIRREL, MOUNT GRAHAM RED *Family:* Sciuridae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal

Minimum of 1 Acre.

WOLF, GRAY		Threatened	Critical Habitat	Mammal
Family: Canidae	*Medium:*		*Diet:* *Habitat:*	

Arkansas (2)

BAT, GRAY		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	
BAT, OZARK BIG-EARED		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	

California (21)

FOX, SAN JOAQUIN KIT		Endangered	Critical Habitat	Mammal
Family: Canidae	*Medium:*		*Diet:* *Habitat:*	
FOX, SAN MIGUEL ISLAND		Endangered	Critical Habitat	Mammal
Family: Canidae	*Medium:*		*Diet:* *Habitat:*	
FOX, SANTA CATALINA ISLAND		Endangered	Critical Habitat	Mammal
Family: Canidae	*Medium:*		*Diet:* *Habitat:*	
FOX, SANTA CRUZ ISLAND		Endangered	Critical Habitat	Mammal
Family: Canidae	*Medium:*		*Diet:* *Habitat:*	
FOX, SANTA ROSA ISLAND		Endangered	Critical Habitat	Mammal
Family: Canidae	*Medium:*		*Diet:* *Habitat:*	
KANGAROO RAT, FRESNO		Endangered	Critical Habitat	Mammal
Family: Heteromyidae	*Medium:*		*Diet:* *Habitat:*	
KANGAROO RAT, GIANT		Endangered	Critical Habitat	Mammal
Family: Heteromyidae	*Medium:*		*Diet:* *Habitat:*	

Minimum of 1 Acre.

KANGAROO RAT, MORRO BAY		Endangered	Critical Habitat	Mammal
Family: Heteromyidae	*Medium:*		*Diet:* *Habitat:*	
KANGAROO RAT, SAN BERNARDINO		Endangered	Critical Habitat	Mammal
Family: Heteromyidae	*Medium:*		*Diet:* *Habitat:*	
KANGAROO RAT, STEPHENS'		Threatened	Critical Habitat	Mammal
Family: Heteromyidae	*Medium:*		*Diet:* *Habitat:*	
KANGAROO RAT, TIPTON		Endangered	Critical Habitat	Mammal
Family: Heteromyidae	*Medium:*		*Diet:* *Habitat:*	
MOUNTAIN BEAVER, POINT ARENA		Endangered	Critical Habitat	Mammal
Family: Aplodontidae	*Medium:*		*Diet:* *Habitat:*	
MOUSE, PACIFIC POCKET		Endangered	Critical Habitat	Mammal
Family: Heteromyidae	*Medium:*		*Diet:* *Habitat:*	
MOUSE, SALT MARSH HARVEST		Endangered	Critical Habitat	Mammal
Family: Cricetidae	*Medium:*		*Diet:* *Habitat:*	
OTTER, SOUTHERN SEA		Threatened	Critical Habitat	Mammal
Family: Mustelidae	*Medium:*		*Diet:* *Habitat:*	
RABBIT, RIPARIAN BRUSH		Endangered	Critical Habitat	Mammal
Family: Leporidae	*Medium:*		*Diet:* *Habitat:*	
SEAL, GUADALUPE FUR		Threatened	Critical Habitat	Mammal
Family: Phocidae	*Medium:*		*Diet:* *Habitat:*	
SHEEP, PENINSULAR BIGHORN		Threatened	Critical Habitat	Mammal
Family: Bovidae	*Medium:*		*Diet:* *Habitat:*	

Minimum of 1 Acre.

SHREW, BUENA VISTA		Endangered	Critical Habitat		Mammal
Family: Soricidae	*Medium:*		*Diet:*		
			Habitat:		
VOLE, AMARGOSA		Endangered	Critical Habitat		Mammal
Family: Cricetidae	*Medium:*		*Diet:*		
			Habitat:		
WOODRAT, RIPARIAN		Endangered	Critical Habitat		Mammal
Family: Cricetidae	*Medium:*		*Diet:*		
			Habitat:		

Colorado (2)

FERRET, BLACK-FOOTED		Endangered	Critical Habitat		Mammal
Family: Mustelidae	*Medium:*		*Diet:*		
			Habitat:		
MOUSE, PREBLE'S MEADOW JUMPING		Threatened	Critical Habitat		Mammal
Family: Zapodidae	*Medium:*		*Diet:*	invertivore	
			Habitat:	Terrestrial	

Connecticut (2)

BAT, INDIANA		Endangered	Critical Habitat		Mammal
Family: Vespertilionidae	*Medium:*		*Diet:*		
			Habitat:		
WHALE, NORTHERN RIGHT		Endangered	Critical Habitat		Mammal
Family: Balaenidae	*Medium:*		*Diet:*		
			Habitat:		

Delaware (2)

SQUIRREL, DELMARVA PENINSULA FOX		Endangered	Critical Habitat		Mammal
Family: Sciuridae	*Medium:*		*Diet:*		
			Habitat:		
WHALE, NORTHERN RIGHT		Endangered	Critical Habitat		Mammal
Family: Balaenidae	*Medium:*		*Diet:*		
			Habitat:		

Florida (8)

Minimum of 1 Acre.

BAT, GRAY		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	
BAT, INDIANA		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	
MANATEE, WEST INDIAN (FLORIDA)		Endangered	Critical Habitat	Mammal
Family: Trichechidae	*Medium:*		*Diet:* *Habitat:* Marine	
MOUSE, CHOCTAWHATCHEE BEACH		Endangered	Critical Habitat	Mammal
Family: Cricetidae	*Medium:*		*Diet:* *Habitat:*	
MOUSE, SOUTHEASTERN BEACH		Threatened	Critical Habitat	Mammal
Family: Cricetidae	*Medium:*		*Diet:* *Habitat:*	
PANTHER, FLORIDA		Endangered	Critical Habitat	Mammal
Family: Felidae	*Medium:*		*Diet:* *Habitat:*	
VOLE, FLORIDA SALT MARSH		Endangered	Critical Habitat	Mammal
Family: Cricetidae	*Medium:*		*Diet:* *Habitat:*	
WHALE, NORTHERN RIGHT		Endangered	Critical Habitat	Mammal
Family: Balaenidae	*Medium:*		*Diet:* *Habitat:*	

Georgia (3)

BAT, GRAY		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	
BAT, INDIANA		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	

Minimum of 1 Acre.

MANATEE, WEST INDIAN (FLORIDA) — Endangered — Critical Habitat — Mammal
Family: Trichechidae — *Medium:* — *Diet:* — *Habitat:* Marine

Hawaii (2)

BAT, HAWAIIAN HOARY — Endangered — Critical Habitat — Mammal
Family: Vespertilionidae — *Medium:* — *Diet:* — *Habitat:*

SEAL, HAWAIIAN MONK — Endangered — Critical Habitat — Mammal
Family: Phocidae — *Medium:* — *Diet:* — *Habitat:*

Illinois (1)

BAT, INDIANA — Endangered — Critical Habitat — Mammal
Family: Vespertilionidae — *Medium:* — *Diet:* — *Habitat:*

Indiana (2)

BAT, GRAY — Endangered — Critical Habitat — Mammal
Family: Vespertilionidae — *Medium:* — *Diet:* — *Habitat:*

BAT, INDIANA — Endangered — Critical Habitat — Mammal
Family: Vespertilionidae — *Medium:* — *Diet:* — *Habitat:*

Iowa (1)

BAT, INDIANA — Endangered — Critical Habitat — Mammal
Family: Vespertilionidae — *Medium:* — *Diet:* — *Habitat:*

Kansas (1)

FERRET, BLACK-FOOTED — Endangered — Critical Habitat — Mammal
Family: Mustelidae — *Medium:* — *Diet:* — *Habitat:*

Kentucky (2)

Minimum of 1 Acre.

BAT, GRAY — Endangered — Critical Habitat — Mammal
Family: Vespertilionidae — *Medium:* — *Diet:* — *Habitat:*

BAT, INDIANA — Endangered — Critical Habitat — Mammal
Family: Vespertilionidae — *Medium:* — *Diet:* — *Habitat:*

Louisiana (1)

BEAR, LOUISIANA BLACK — Threatened — Critical Habitat — Mammal
Family: Ursidae — *Medium:* — *Diet:* — *Habitat:*

Maine (2)

LYNX, CANADA — Threatened — Critical Habitat — Mammal
Family: Felidae — *Medium:* — *Diet:* — *Habitat:*

WHALE, NORTHERN RIGHT — Endangered — Critical Habitat — Mammal
Family: Balaenidae — *Medium:* — *Diet:* — *Habitat:*

Maryland (3)

BAT, INDIANA — Endangered — Critical Habitat — Mammal
Family: Vespertilionidae — *Medium:* — *Diet:* — *Habitat:*

SQUIRREL, DELMARVA PENINSULA FOX — Endangered — Critical Habitat — Mammal
Family: Sciuridae — *Medium:* — *Diet:* — *Habitat:*

WHALE, NORTHERN RIGHT — Endangered — Critical Habitat — Mammal
Family: Balaenidae — *Medium:* — *Diet:* — *Habitat:*

Massachusetts (2)

BAT, INDIANA — Endangered — Critical Habitat — Mammal
Family: Vespertilionidae — *Medium:* — *Diet:* — *Habitat:*

Minimum of 1 Acre.

WHALE, NORTHERN RIGHT *Family:* Balaenidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal

Michigan (1)

BAT, INDIANA *Family:* Vespertilionidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal

Minnesota (1)

WOLF, GRAY *Family:* Canidae	*Medium:*	Threatened	Critical Habitat *Diet:* *Habitat:*	Mammal

Mississippi (1)

BEAR, LOUISIANA BLACK *Family:* Ursidae	*Medium:*	Threatened	Critical Habitat *Diet:* *Habitat:*	Mammal

Missouri (2)

BAT, GRAY *Family:* Vespertilionidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal
BAT, INDIANA *Family:* Vespertilionidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal

Montana (2)

BEAR, GRIZZLY *Family:* Ursidae	*Medium:*	Threatened	Critical Habitat *Diet:* *Habitat:*	Mammal
WOLF, GRAY *Family:* Canidae	*Medium:*	Threatened	Critical Habitat *Diet:* *Habitat:*	Mammal

New Hampshire (1)

Minimum of 1 Acre.

BAT, INDIANA		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	

New Jersey (2)

BAT, INDIANA		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	
WHALE, NORTHERN RIGHT		Endangered	Critical Habitat	Mammal
Family: Balaenidae	*Medium:*		*Diet:* *Habitat:*	

New Mexico (5)

BAT, LESSER (=SANBORN'S) LONG-NOSED		Endangered	Critical Habitat	Mammal
Family: Phyllostomidae	*Medium:*		*Diet:* *Habitat:*	
BAT, MEXICAN LONG-NOSED		Endangered	Critical Habitat	Mammal
Family: Phyllostomidae	*Medium:*		*Diet:* *Habitat:*	
FERRET, BLACK-FOOTED		Endangered	Critical Habitat	Mammal
Family: Mustelidae	*Medium:*		*Diet:* *Habitat:*	
JAGUAR		Endangered	Critical Habitat	Mammal
Family: Felidae	*Medium:*		*Diet:* *Habitat:*	
WOLF, GRAY		Threatened	Critical Habitat	Mammal
Family: Canidae	*Medium:*		*Diet:* *Habitat:*	

New York (2)

BAT, INDIANA		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	

Minimum of 1 Acre.

WHALE, NORTHERN RIGHT		Endangered	Critical Habitat	Mammal
Family: Balaenidae	*Medium:*		*Diet:* *Habitat:*	

North Carolina (5)

BAT, INDIANA		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	
MANATEE, WEST INDIAN (FLORIDA)		Endangered	Critical Habitat	Mammal
Family: Trichechidae	*Medium:*		*Diet:* *Habitat:* Marine	
SQUIRREL, CAROLINA NORTHERN FLYING		Endangered	Critical Habitat	Mammal
Family: Sciuridae	*Medium:*		*Diet:* *Habitat:*	
WHALE, NORTHERN RIGHT		Endangered	Critical Habitat	Mammal
Family: Balaenidae	*Medium:*		*Diet:* *Habitat:*	
WOLF, RED		Endangered	Critical Habitat	Mammal
Family: Canidae	*Medium:*		*Diet:* *Habitat:*	

Ohio (1)

BAT, INDIANA		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	

Oklahoma (3)

BAT, GRAY		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	
BAT, INDIANA		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	

Minimum of 1 Acre.

BAT, OZARK BIG-EARED *Family:* Vespertilionidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal

Oregon (1)

DEER, COLUMBIAN WHITE-TAILED *Family:* Cervidae	*Medium:*	Endangered	Critical Habitat *Diet:* herbivore *Habitat:* Terrestrial	Mammal

Pennsylvania (2)

BAT, INDIANA *Family:* Vespertilionidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal
SQUIRREL, DELMARVA PENINSULA FOX *Family:* Sciuridae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal

Rhode Island (2)

BAT, INDIANA *Family:* Vespertilionidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal
WHALE, NORTHERN RIGHT *Family:* Balaenidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal

South Carolina (3)

MANATEE, WEST INDIAN (FLORIDA) *Family:* Trichechidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:* Marine	Mammal
WHALE, NORTHERN RIGHT *Family:* Balaenidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal
WOLF, RED *Family:* Canidae	*Medium:*	Endangered	Critical Habitat *Diet:* *Habitat:*	Mammal

Minimum of 1 Acre.

South Dakota (1)

FERRET, BLACK-FOOTED		Endangered	Critical Habitat	Mammal
Family: Mustelidae	*Medium:*		*Diet:* *Habitat:*	

Tennessee (4)

BAT, GRAY		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	
BAT, INDIANA		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	
SQUIRREL, CAROLINA NORTHERN FLYING		Endangered	Critical Habitat	Mammal
Family: Sciuridae	*Medium:*		*Diet:* *Habitat:*	
WOLF, RED		Endangered	Critical Habitat	Mammal
Family: Canidae	*Medium:*		*Diet:* *Habitat:*	

Texas (3)

BEAR, LOUISIANA BLACK		Threatened	Critical Habitat	Mammal
Family: Ursidae	*Medium:*		*Diet:* *Habitat:*	
JAGUARUNDI, Gulf Coast		Endangered	Critical Habitat	Mammal
Family: Felidae	*Medium:*		*Diet:* *Habitat:*	
OCELOT		Endangered	Critical Habitat	Mammal
Family: Felidae	*Medium:*		*Diet:* *Habitat:*	

Utah (2)

FERRET, BLACK-FOOTED		Endangered	Critical Habitat	Mammal
Family: Mustelidae	*Medium:*		*Diet:* *Habitat:*	

Minimum of 1 Acre.

PRAIRIE DOG, UTAH		Threatened	Critical Habitat	Mammal
Family: Sciuridae	*Medium:*		*Diet:* *Habitat:*	

Vermont (1)

BAT, INDIANA		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	

Virginia (6)

BAT, GRAY		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	
BAT, INDIANA		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	
BAT, VIRGINIA BIG-EARED		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	
SQUIRREL, DELMARVA PENINSULA FOX		Endangered	Critical Habitat	Mammal
Family: Sciuridae	*Medium:*		*Diet:* *Habitat:*	
SQUIRREL, VIRGINIA NORTHERN FLYING		Endangered	Critical Habitat	Mammal
Family: Sciuridae	*Medium:*		*Diet:* *Habitat:*	
WHALE, NORTHERN RIGHT		Endangered	Critical Habitat	Mammal
Family: Balaenidae	*Medium:*		*Diet:* *Habitat:*	

Washington (4)

BEAR, GRIZZLY		Threatened	Critical Habitat	Mammal
Family: Ursidae	*Medium:*		*Diet:* *Habitat:*	

Species Detail by State for Preliminary Assessment
Cucurbits, all (306)

Minimum of 1 Acre.

DEER, COLUMBIAN WHITE-TAILED		Endangered	Critical Habitat	Mammal
Family: Cervidae	*Medium:*		*Diet:* herbivore *Habitat:* Terrestrial	
RABBIT, PYGMY		Endangered	Critical Habitat	Mammal
Family: Leporidae	*Medium:*		*Diet:* herbivore *Habitat:* Terrestrial	
WOLF, GRAY		Threatened	Critical Habitat	Mammal
Family: Canidae	*Medium:*		*Diet:* *Habitat:*	

West virginia (1)

BAT, INDIANA		Endangered	Critical Habitat	Mammal
Family: Vespertilionidae	*Medium:*		*Diet:* *Habitat:*	

Wisconsin (1)

WOLF, GRAY		Threatened	Critical Habitat	Mammal
Family: Canidae	*Medium:*		*Diet:* *Habitat:*	

APPENDIX H. Data Requirements Tables – Environmental Fate and Effects

Ecological Effects Data Requirements Table for Naptalam

Table H-1. Ecological effects data requirements for naptalam.

Guideline Number	Data Requirement	Is Data Requirement Satisfied?	Study ID #'s	Study Classification[a]
71-1(a)	Avian Oral LD_{50}	Yes	GS-0183-01	Core
71-2 (a)	Avian Dietary LC_{50} Quail	Yes	00082969	Core
71-2 (b)	Avian Dietary LC_{50} Mallard	Yes	00108853	Core
71-4	Avian Reproduction	No		
72-1 (a)	Freshwater Fish LC_{50} Bluegill	Yes	0070193	Core
72-1 (b)	Freshwater Fish LC_{50} Rainbow trout	Yes	0070193	Core Supplemental
72-2	Freshwater Invertebrate Acute LC_{50}	Yes	00082971	Core
72-3(a)	Estuarine/Marine Fish LC_{50}	No		
72-3(b)	Estuarine/Marine Mollusk LC_{50}	No		
72-3(c)	Estuarine/Marine Shrimp LC_{50}	No		
72-4(a)	Freshwater Fish Early Life-Stage	No		
72-4(b)	Aquatic Invertebrate Life-Cycle	No		
72-5	Freshwater Fish Full Life-Cycle	No		
81-1	Acute Oral LD_{50} Rat			
82-1(a)	90-day Subchronic Oral LD_{50} Rat			
82-1(b)	Subchronic Oral LD50 Non-rodent			
83-3	Chronic (Teratology) NOAEL Rat			
83-4	Chronic (Multgeneration) NOAEL Rat			
122-1(a)	Seedling Emergence	No		
122-1 (b)	Vegetative Vigor	No		
122-2	Aquatic Plant Growth	No		
123-1(a)	Seed Germ./Seedling Emergence (Tier II)	No		
123-1(b)	Vegetative Vigor (Tier II)	No		
123-2	Aquatic Plant Growth	No		
144-1	Honey Bee Acute Contact LD_{50}	Yes	00028772	Core

Table H-1. Ecological effects data requirements for naptalam.

Guideline Number	Data Requirement	Is Data Requirement Satisfied?	Study ID #'s	Study Classification[a]
141-2	Honey Bee Residue on Foliage	Not Required		

[a]Core: study satisfies guideline; Supplemental: study is scientifically sound, but does not satisfy guideline

Table H-2. Environmental fate data requirements for naptalam.

Guideline Number	Data Requirement	MRID #'s	Study Classification
161-1	Hydrolysis	43647701	Supplemental
161-2	Photodegradation in Water	41385401	Supplemental
161-3	Photodegradation on Soil	41385402	Supplemental
161-4	Photodegradation in Air	–	–
162-1	Aerobic Soil Metabolism	41427201	Acceptable
162-2	Anaerobic Soil Metabolism	41427202	Acceptable
162-3	Anaerobic Aquatic Metabolism	–	–
162-4	Aerobic Aquatic Metabolism	–	–
163-1	Leaching-Adsorption/ Desorption	–	–
163-2	Laboratory Volatility	–	–
163-3	Field Volatility	–	–
164-1	Terrestrial Field Dissipation	41385403 40488901	Unacceptable Unacceptable
164-2	Aquatic Field Dissipation	–	–
164-3	Forestry Dissipation	–	–
165-4	Accumulation in Fish	–	–