United States
Environmental Protection
Agency

Office of Prevention, Pesticides
and Toxic Substances
(7501C)

Pesticide
Fact Sheet

Name of Chemical: Dinotefuran
Reason for Issuance: Conditional Registration
Year Issued: September 2004

Appendix I: Glossary of Terms and Acronyms
Appendix II: Bibliography

1. DESCRIPTION OF CHEMICAL

Generic Name:	Dinotefuran (N-methyl-N'-nitro-N"-[(tetrahydro-3-furanyl)methyl)]guanidine)
Common Name:	Dinotefuran
Trade Name:	Dinotefuran, MTI-446
EPA PC Code:	044312
Chemical Abstracts Service (CAS) Number:	165252-70-0
Year of Initial Registration:	2004
Pesticide Type:	Insecticide
Chemical Class:	Neo-nicotinoid
Registrant:	Mitsui Chemicals, Inc.

2. USE PATTERNS AND FORMULATIONS

Pests/Application Sites:	Controls insect pests such as aphids, whiteflies, thrips, leafhopper, leafminer, sawfly, mole cricket, white grubs, lacebugs, billbugs, beetles, mealybugs, sawfly larvae, and cockroaches in leafy vegetables, in residential and commercial buildings, outdoor uses for professional turf management, turf farms, professional ornamental

	production, golf courses, residential indoor, lawn and garden use
Types of Formulations:	Dinotefuran formulations include the technical product, formulation intermediates, soluble concentrates, granulars, soluble granules, baits, gels, and ready-to-use (RTU) sprays
Types and Methods:	Soil incorporation, foliar application, bait application, spot treatment. Foliar application can be made aerially or with tractor-mounted sprayers or spreaders, as well as, handheld equipment such as low-pressure handwand sprayers, backpack sprayers, turf guns, ready-to-use trigger sprayers, and hose-end sprayers. Bait applications can be made in bait stations or as spot treatment with the gel bait formulations
Application Rates:	Application rates vary with sites and pests Maximum application rate 0.54 lbs a.i./A/season
Carrier:	Water

3. SCIENCE FINDINGS

Dinotefuran is a broad-spectrum insecticide, which is proposed for food uses in/on leafy vegetables (except *Brassica*) (group 4), and for use in professional turf management, professional ornamental production, and in the residential indoor, pet, lawn and garden markets. Dinotefuran is a neonicotinoid in the nitroguanidine sub-class, same as another insecticide clothianidin. Available product chemistry, toxicology, ecological effects and environmental fate data supporting the proposed uses have been reviewed. The data and estimated risks to human health and the environment from its proposed uses are summarized below.

PHYSICAL AND CHEMICAL CHARACTERISTICS

Technical dinotefuran is an odorless white crystalline solid. It has a solubility of 39.83 g/L in water, and is highly soluble in dichloromethane, acetone, methanol, and ethyl acetate. Technical dinotefuran has a melting point of 107.5^{o} C, and a log P_{ow} of -0.549 at 25^{o} C. It is non-flammable, is not explosive to thermal, shock and frictional tests, and has a vapor pressure of $<1.7 \times 10^{-6}$ Pa at 25^{o} C.

HAZARD CHARACTERIZATION

Acute Toxicity

Technical dinotefuran has low acute toxicity by the oral (toxicity category IV), dermal (toxicity category IV), and inhalation (toxicity category IV) routes. It is not a dermal sensitizer, causes a low level of skin irritation (toxicity category IV) and moderate eye irritation (toxicity category II) (Table I).

Table 1. Acute Toxicity Profile of Dinotefuran

Guideline No.	Study Type	MRID #	Toxicity Category
81-1	Acute Oral – Rat	45639823	III
81-1	Acute Oral – Mouse	45639824	III
81-2	Acute Dermal – Rat	45639901	IV
81-3	Acute Inhalation – Rat	45639902	IV
81-4	Primary Eye Irritation – Rabbit	45639903	II
81-5	Primary Skin Irritation – Rabbit	45639904	IV
81-6	Dermal Sensitization (Guinea Pig Maximization test)	45639905	Not a sensitizer

Subchronic and Chronic Toxicity

The main target tissues are the nervous system and the immune system, with effects seen in several species. Nervous system toxicity is manifested as clinical signs and decreased motor activity seen after acute dosing (in both rats and rabbits) and increased motor activity seen after repeated dosing; these findings are consistent with effects on the nicotinic cholinergic nervous system. The results of subchronic, chronic, and other toxicity studies conducted on dinotefuran are summarized in Table 2.

Developmental and Reproductive Toxicity

No adverse effects in fetuses were seen in the developmental toxicity studies in rats or rabbits, at maternally toxic doses, and offspring (including decreased spleen and thymus weights, and decreased grip strength) effects in the reproduction study occurred at the same doses causing parental effects. There was a qualitative increase in sensitivity in rat pups in the reproductive toxicity study.

Immune System Toxicity

Immune system toxicity is manifested as decreases in spleen and thymus weights seen in multiple studies and species (including dogs, rats, and mice). There are also indications of endocrine-related toxicity, manifested in the reproductive toxicity study (in rats) as decreases in primordial follicles and altered cyclicity in females, abnormal sperm parameters in males; changes in testes or ovary weight were also seen in several species (mouse, dog, and rat).

Carcinogenicity

Dinotefuran has been classified as "Not likely to be carcinogenic to humans." This classification is based on the lack of evidence for carcinogenicity in mice and rats.

Mutagenicity

Submitted studies were found to be acceptable. There is no concern for mutagenicity resulting from exposure to dinotefuran.

Table 2. –Subchronic, Chronic, and Other Toxicity of Dinotefuran

Guideline No.	Study Type	MRID #	Results
870.3100	90-Day oral toxicity in rats	MRID: 45654205, 45654203 (range-finding)	NOAEL: 38/384 [M/F] mg/kg/day LOAEL: 384 [M] mg/kg/day based on adrenal histopathology; 1871 [F] mg/kg/day based on ↓ body weight/body weight gain, changes in hematology/clinical chemistry, changes in organ weights, and adrenal histopathology
870.3100	90-Day oral toxicity in mice	45654206, 45654204 (range-finding)	NOAEL: 4,442/5,414 [M/F] mg/kg/day LOAEL: 10,635/11,560 [M/F] mg/kg/day, based on ↓ body weight, body weight gain
870.3150	90-Day oral toxicity in dogs	45639906	NOAEL: 307/not determined [M/F] mg/kg/day LOAEL: 862 [M] mg/kg/day, based on ↓ body weight gain, hemorrhagic lymph nodes; <59 [F], based on ↓ body weight, body weight gain

Guideline No.	Study Type	MRID #	Results
870.3200	28-Day dermal toxicity (rats)	45639908, 45639937 (range-finding)	**Systemic**: NOAEL: 1,000 mg/kg/day LOAEL: not determined (no effects seen) **Dermal**: NOAEL: 1,000 [M], ≤200 [F] mg/kg/day LOAEL: not determined/≤1000 [M/F] mg/kg/day based on lack of effects in males, ↑ in acanthosis/ hyperkeratosis in high dose females (lower doses not evaluated histopathologically)
870.3465	28-Day inhalation toxicity (rat)	45639909, 46072401	NOAEL:<0.22 [M] mg/L, 0.22 [F] mg/L LOAEL: ↓ body weight gain, food consumption [M]; increased clinical signs (protruding eyes) [F]
870.3700a	Prenatal developmental toxicity study (rats)	45654207, 45639910 (range-finding)	**Maternal** NOAEL: 300 mg/kg/day LOAEL: 1,000 mg/kg/day based on ↓ body weight gain and food consumption **Developmental** NOAEL: 1,000 mg/kg/day LOAEL: not determined (no effects seen)
870.3700b	Prenatal developmental toxicity study (rabbits)	45654208, 45639911, 45639912 (range-finding)	**Maternal** NOAEL: 52 mg/kg/day LOAEL: 125 mg/kg/day based on ↓ body weight gains, food consumption, and necropsy findings **Developmental** NOAEL: 300 mg/kg/day LOAEL: >300 mg/kg/day (no effects seen)

Guideline No.	Study Type	MRID #	Results
870.3800	Reproduction and fertility effects (rats)	45639913, 45639914 (range-finding)	**Parental/systemic** NOAEL: 241/268[M/F] mg/kg/day LOAEL: 822/907[M/F] mg/kg/day, based on ↓ food consumption, weight gain in males, soft feces in females, and ↓ spleen weights in both sexes **Reproductive (tentative)** NOAEL: 241/268 [M/F] mg/kg/day LOAEL: 822/907 [M/F] mg/kg/day, based on ↓ uterine weights and microscopic alterations in the uterus and vagina of F_0 females, ↓ numbers of primordial follicles in F_1 females, altered estrous cyclicity in F_0 and F_1 females, ↑ in abnormal sperm morphology in F_0 and F_1 males, ↓ testicular sperm count in F_0 males, and ↓ in sperm motility in F_1 males **Developmental** NOAEL: 241/268 [M/F] mg/kg/day LOAEL: 822-935/907-1,005 [M/F] mg/kg/day based on ↓ body weights, body weight gains, and spleen weights in F_1 and F_2 males and females, ↓ thymus weights in F_2 males and females, and ↓ forelimb grip strength (F_1 males) or hindlimb grip strength (F_1 females)
870.4100a	Chronic toxicity (rats)	45640001	See 870.4300 Combined chronic toxicity/carcinogenicity (rats)
870.4100b	Chronic toxicity (dogs)	45654209	NOAEL: <20/22 [M/F] mg/kg/day LOAEL: 20/108 [M/F] mg/kg/day based on ↓ thymus weight, ↓ food efficiency, body weight, and body weight gain in females, ↓ thymus weight in males
870.4200a	Carcinogenicity (rats)	45640001	See 870.4300 Combined chronic toxicity/carcinogenicity (rats)

Guideline No.	Study Type	MRID #	Results
870.4200b	Carcinogenicity (mice)	45639917	NOAEL: <3 [M], <4 [F] mg/kg/day LOAEL: 3/4 [M/F] mg/kg/day based on ↓ spleen weights at week 79 terminal sacrifice in males and increased ovarian weights at week 53 in females
870.4300	Combined chronic toxicity/ carcinogenicity (rats)	45640001	NOAEL: 99.7/127.3 [M/F] mg/kg/day LOAEL: 991/1,332 [M/F] mg/kg/day based on ↓ body weight gain, food efficiency in females, ↑ incidences of kidney pelvic mineralization and ulceration in males
870.5100	Bacterial reverse mutation test	45640003	**Negative.** ± S9 up to 16,000 μg/plate
870.5100	Bacterial reverse mutation test	45654210	**Negative.** ± S9 up to limit dose of 5000 μg/plate
870.5300	*In vitro* mammalian cell gene mutation test	45640002	**Negative,** ± S9 up to 2,002 μg/mL (Mouse lymphoma L5178Y cells)
870.5375	*In vitro* mammalian chromosome aberration test	45654211	**Negative** for clastogenic/aneugenic activity up to 2,000 μg/mL (CHL/IU cells)
870.5395	*In vivo* mammalian cytogenics - micronucleus assay	45654212	**Negative** at oral doses up to 1,080 mg/kg/day for 2 days
870.6200a	Acute neurotoxicity screening battery	45640005	NOAEL: 750 [M], 325 [F] mg/kg/day LOAEL: 1,500 [M], 750 [F] mg/kg/day based on ↓ motor activity on day 1

Guideline No.	Study Type	MRID #	Results
870.6200b	Subchronic neurotoxicity screening battery	45640004	NOAEL: 33/40 [M/F] mg/kg/day LOAEL: 327/400 [M/F] mg/kg/day based on ↑ motor activity during week 2

Guideline No.	Study Type	MRID #	Results
870.7485	Metabolism and pharmacokinetics (rats)	45640006	Absorption was > 90% regardless of dose. The radiolabel was widely distributed through the body and was completely excreted within 168 hours of treatment. Urine was the primary elimination route, accounting for 88-99.8%. Excretion into the urine was rapid, being 84-99% complete within 24 hours of treatment. Absorption of the radioactivity was linear within the dose range of 50 and 1,000 mg/kg. Elimination of radioactivity was fast for all groups with a $T_{½}$ ranging from 3.64 to 15.2 hours for the low and high doses, respectively. Radioactivity was rapidly transferred from maternal blood to milk and widely distributed in the fetal tissues. The C_{max} for milk and fetal tissues was detected 0.5 hours after maternal treatment. The concentrations of radioactivity in fetal tissue and maternal milk declined quickly and were below detection limits 24 hours post-treatment. After IV or oral treatment, 75- 93% of the administered radiolabeled test material, or nearly 93-97% of total urinary radiolabel, was excreted unchanged in the urine. The parent compound was also the primary component in the plasma, milk, bile, feces, and most tissues collected 4-8 hours after treatment and at both dose levels. Less than 10% of the parent compound was metabolized into numerous minor metabolites that were not well resolved by HPLC or 2D-TLC. For all parameters measured in this study,

Guideline No.	Study Type	MRID #	Results
			no sex-related or dose-related differences or label position effects were found.
Special study	Neonatal rat metabolism study (12-day old rat pups)	45640007	After a single oral 50 mg/kg dose of [G-^{14}C] MTI-446 to 12-day-old rats, absorption was high (absorption could not be adequately determined but may have approached 80%) and the radiolabel was widely distributed within the body. Approximately 32-36% of the administered dose was excreted within 4 hours of treatment. Urine was the primary elimination route as indirectly evidenced by finding high radioactive areas in the kidneys and bladder by whole body autoradiography. No areas of tissue sequestration were found and no gender-related differences were identified. The test material was essentially not metabolized, the parent compound accounting for >97% of the radiolabel in the excreta, plasma, kidneys, and stomach, and nearly 61-83% in intestines (and contents), and liver.

DOSE RESPONSE ASSESSMENT AND FOOD QUALITY PROTECTION ACT (FQPA) CONSIDERATION

Dose Response Assessment

Based on submitted data, the Agency determination for the acute and chronic Reference Doses (RfDs), toxicological endpoint selections, and appropriate margins of exposure (MOEs) for use as appropriate in occupational/residential exposure risk assessments, is summarized below:

Acute Dietary Reference Dose (aRfD): For the general population, including infants and children, the dose and endpoint for establishing an aRfD is a NOAEL of 125 mg/kg/day from the developmental toxicity study in rabbits (MRID 45654208). No effects were seen on developing fetuses in the developmental toxicity studies (rat or rabbit), so a separate

endpoint for females 13-49 is not required. An uncertainty factor of 100 was selected (10x inter-species extrapolation and 10x intra-species variability), and therefore the aRfD is 1.25 mg/kg/day.

Chronic Dietary Reference Dose (cRfD): For all populations, the dose and endpoint for establishing an cRfD is a LOAEL of 20 mg/kg/day from the one year toxicity study in dogs (MRID 45654209). The NOAEL is 22 mg/kg/day in females; no NOAEL was determined for males (less than 20 mg/kg/day). The Agency determined that the available data does not support the reduction of the default 10X UF for the use of a LOAEL (i.e. lack of a NOAEL in the selected study). Therefore, an uncertainty factor of 1,000 was selected (10x inter-species extrapolation,10x intra-species variability, and10x for extrapolation from LOAEL to NOAEL), and the cRfD is 0.02 mg/kg/day.

Incidental Oral Short-Term (1-30 Days) Exposure: The dose and endpoint chosen is the NOAEL of 33 mg/kg/day, from the 90-day neurotoxicity study in rats (MRID 45640005). An MOE of 100 should be required (10x inter-species extrapolation and 10x intra-species variability).

Incidental Oral Intermediate-Term (1-6 Months) Exposure: The dose and endpoint chosen is the NOAEL of 22 mg/kg/day, from the one year toxicity study in dogs (MRID 45654209). An MOE of 100 should be required (10x inter-species extrapolation and 10x intra-species variability).

Dermal Absorption Factor: A dermal absorption factor of 30% was chosen by the Agency, after a comparison to structurally related chemicals (27% for thiamethoxam, and 30% for acetamiprid, based on dermal absorption studies for those chemicals). This is considered a conservative estimate, based on the inclusion of residues remaining in the skin, which may not be absorbed. A confirmatory dermal absorption study is required.

Dermal Short-Term (1-30 Days) Exposure: Quantification of short-term dermal risk is not required, because no effects were seen in an acceptable dermal toxicity study in rats (MRID 45639908) at doses up to the limit dose.

Dermal Intermediate-Term (1-6 Months) Exposure: The dose and endpoint chosen is the NOAEL of 22 mg/kg/day, from the one year toxicity study in dogs (MRID 45654209). An MOE of 100 should be required (10x inter-species extrapolation and 10x intra-species variability).

Dermal Long-Term (>6 Months) Exposure: The dose and endpoint chosen is the LOAEL of 20 mg/kg/day, from the one year toxicity study in dogs (MRID 45654209).

Inhalation Short- (1-30 Days) & Intermediate-Term (1-6 Months) Exposure: The dose and endpoint chosen is the LOAEL of 60 mg/kg/day (0.22 mg/L), from the 28-day inhalation toxicity study in rats (MRID 45639909). Although neurotoxicity was not evaluated in this study, use of this endpoint, along with an extra 10x uncertainty factor for extrapolation from LOAEL to NOAEL, will be protective of neurotoxic effects seen in rats and rabbits (NOAELs $\geq$33 mg/kg/day), for both short-term and intermediate-term

durations. An MOE of 100 should be required (10x inter-species extrapolation and 10x intra-species variability).

Inhalation Long-Term (>6 Months) Exposure: The dose and endpoint chosen is the LOAEL of 20 mg/kg/day, from the one year toxicity study in dogs (MRID 45654209. Absorption via inhalation is presumed to be equivalent to oral absorption.

Margins of Exposure: Table 3 Presents a summary of target Margins of Exposure (MOEs) for risk assessment.

Table 3. Summary of Margins of Exposure for Risk Assessment.

Route / Duration	Short-Term (1-30 Days)	Intermediate-Term (1 - 6 Months)	Long-Term (> 6 Months)
Occupational (Worker) Exposure			
Dermal	Not required	100	1,000
Inhalation	1,000	1,000	1,000
Residential (Non-Dietary) Exposure			
Oral	100	100	N/A
Dermal	Not required	100	1,000
Inhalation	1,000	1,000	1,000

The MOEs for occupational and residential exposures are based on the conventional uncertainty factor of 100X (10x inter-species extrapolation and 10x intra-species variability). An additional uncertainty factor of 10X (to extrapolate from a LOAEL to a NOAEL) is required for long term dermal and for inhalation exposure of all durations.

The doses and toxicological endpoints selected for the various exposure scenarios are summarized in Table 4.

Table 4. Summary of Toxicological Dose and Endpoints for Dinotefuran

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General population including infants and children)	NOAEL = **125** mg/kg/day UF = **100** **Acute RfD** = **1.25** mg/kg/day	FQPA SF = **1** **aPAD** = acute RfD / FQPA SF = **1.25** mg/kg/day	**Developmental Toxicity Study in Rabbits** LOAEL = **300** mg/kg/day based on **clinical signs in does (prone position, panting, tremor, erythema) seen following a single dose.**

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Chronic Dietary (All populations)	LOAEL= **20** mg/kg/day UF = **1,000** **Chronic RfD** = **0.02** mg/kg/day	FQPA SF = **1** **cPAD** = chronic RfD / FQPA SF = **0.02** mg/kg/day	**Chronic Toxicity Study in Dogs** LOAEL = **20** mg/kg/day based on **decreased thymus weight in males**
Short-Term Incidental Oral (1 to 30 days)	NOAEL= **33** mg/kg/day	**Residential** LOC for MOE = **100** **Occupational** = NA	**Subchronic Neurotoxicity study in rats** LOAEL = **327** mg/kg/day based on **increased motor activity during week 2**
Intermediate-Term Incidental Oral (1 to 6 months)	NOAEL= **22** mg/kg/day	**Residential** LOC for MOE =**100** **Occupational** = NA	**Chronic Toxicity Study in Dogs** LOAEL = **108** mg/kg/day based on **decreased body weight and body weight gain in females**
Short-Term Dermal (1 to 30 days)	No quantitation required.	**Residential** LOC for MOE = **NA** **Occupational** LOC for MOE = **NA**	No quantitation required. No systemic toxicity was seen at the limit dose in a 28-day dermal toxicity study in which neurotoxicity was evaluated. No developmental toxicity concerns.
Intermediate-Term Dermal (1 to 6 months)	Oral study NOAEL = **22** mg/kg/day (dermal absorption rate = **30**%)	**Residential** LOC for MOE =**100** **Occupational** LOC for MOE =**100**	**Chronic Toxicity Study in Dogs** LOAEL = **108** mg/kg/day based on **decreased body weight and body weight gain in females**
Long-Term Dermal (>6 months)	Oral study LOAEL= **20** mg/kg/day (dermal absorption rate = 30%)	**Residential** LOC for MOE = **1,000** **Occupational** LOC for MOE = **1,000**	**Chronic Toxicity Study in Dogs** LOAEL = **20** mg/kg/day based on **decreased thymus weight in males**
Short-Term Inhalation (1 to 30 days)	Inhalation study LOAEL= **60** mg/kg/day	**Residential** LOC for MOE = **1,000** **Occupational** LOC for MOE = **1,000**	**28-day Inhalation Toxicity Study in Rats** LOAEL = **60** mg/kg/day based on **decreased body weight gain in males**
Intermediate-Term Inhalation (1 to 6 months)	Inhalation study LOAEL= **60** mg/kg/day	**Residential** LOC for MOE =**1,000** **Occupational** LOC for MOE = **1,000**	**28-day Inhalation Toxicity Study in Rats** LOAEL = **60** mg/kg/day based on **decreased body weight gain in males**
Long-Term Inhalation (>6 months)	Oral study LOAEL= **20** mg/kg/day (inhalation absorption rate = 100%)	**Residential** LOC for MOE = **1,000** **Occupational** LOC for MOE = **1,000**	**Chronic Toxicity Study in Dogs** LOAEL = **20** mg/kg/day based on **decreased thymus weight in males**

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Cancer (oral, dermal, inhalation)			Not required; no evidence of carcinogenicity.

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

FQPA Decisions

The toxicology database for dinotefuran is adequate for FQPA assessment. Available studies include developmental toxicity studies in rats and rabbits, a reproductive toxicity study in rats, and acute and subchronic neurotoxicity studies in rats. Although there is generally low concern and no residual uncertainties for pre- and/or postnatal toxicity resulting from exposure to dinotefuran, some uncertainty is raised by a deficiency in the data (a lack of a NOAEL in the chronic dog study) and the need for a developmental immunotoxicity study (DIT).

The absence of a NOAEL for the chronic dog study and the need for a DIT study generate some uncertainty regarding the protectiveness of chronic regulatory endpoint and long-term level of concern. Accordingly, EPA does not have reliable data supporting adoption of a safety factor other than the default additional 10X factor as specified in FFDCA section 408(b)(2)(C). The chronic endpoint and long-term level of concern have therefore been generated using a overall safety/uncertainty factor of 1000 (representing 100X for inter-and intra-species variation and an additional 10X pursuant to FFDCA section 408(b)(2)(C).

The Agency does not have similar concerns regarding acute, short-term, and intermediate term risk assessments. First, the absence of a NOAEL only occurred in a chronic study. Second, reliable data show that the DIT is unlikely to result in a NOAEL for acute, short-term, or intermediate term effects that is lower than the NOAELs currently being used to assess the risk from such effects. EPA has required a Developmental Immunotoxicity Study (DIT) with dinotefuran based on the changes in the thymus weight in offspring in the reproduction study and in adult rats and dogs. There is, however, little evidence to support a direct effect of dinotefuran on immune function. This is because lymphoid organ weight changes can be secondary to generalized toxicity (e.g., reductions in body weight, body weight gain, and/or food efficiency). In the reproduction study, decreased thymus weights were seen in offspring in the presence of decreased body weight only at the Limit Dose (10,000 ppm). In the 1-year dog study, decrease in thymus weight was seen in the absence of other toxicity, however, no decrease in thymus weight was seen in the subchronic study in dogs which was conducted at higher doses (i.e., the results of the 1-year study was not supported by the results of the 90-day study).

Further, the only evidence on dinotefuran's potential immunological effect is found in studies with prolonged exposure. In the reproduction study, the effect of concern [i.e, decrease in thymus weight in only one generation (F2)] was seen only following approximately 13 weeks of exposure to the parental animals at close to the Limit Dose (1000 mg/kg). Similarly, thymus effects in the chronic dog study were only observable after long-term exposures, but were not seen in the 90-day dog study.

Finally, it is clear that DIT study, which is performed in the rat, will have to be conducted at high doses (close to the Limit Dose) to elicit a potential single dose effect and this will result in a potential NOAEL higher than that currently used for various risk assessments. As noted, in the rat reproduction study, effects only occurred at doses close to the Limit Dose (1000 mg/kg/day). The Limit Dose is the maximum dose recommended for testing in the Series 870 Health Effects Harmonized Test Guidelines; toxic effects occurring only at or near the Limit Dose are of less concern for human health since they may be specifically related to the high dose exposure and may not occur at the much lower doses to which humans are exposed. Additionally, in the acute neurotoxicity study in the rat, the LOAEL was 750 mg/kg/day in females and 1500 mg/kg/day in males based on reductions in motor activity indicating that high doses are required to elicit Dinotefuran-induced toxicity in rats.

The NOAELs in the critical studies selected for acute dietary (125 mg/kg/day), short term incidental oral (33 mg/kg/day), and intermediate term incidental oral and dermal (22 mg/kg/day) exposure scenarios are lower than the offspring NOAEL (241 mg/kg/day) in the reproduction study. Therefore, EPA is confident that the doses selected for these risk assessments will address the concerns for the thymus weight changes seen in the offspring in the reproduction study and will not underestimate the potential risk from exposure to dinotefuran.

The Agency believes there are reliable data showing that the regulatory endpoints are protective of children despite the need for a developmental neuorotoxicity study. Developmental neurotoxicity data received and reviewed for other compounds in this chemical class (neonicotinoids) including thiacloprid, clothianidin, and imidacloprid, indicate that the results of the required DNT study will not likely impact the regulatory doses selected for dinotefuran.

In addition, the acute and chronic dietary food exposure assessment utilized proposed tolerance level residues and 100% crop treated information for all commodities. By using these screening-level assessments, acute and chronic exposure/risks will not be underestimated. Furthermore, the dietary drinking water assessment (Tier 1 estimates) uses values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations. Finally, the residential assessment for children's postapplication exposures is based upon maximum application rates in conjunction with chemical-specific study data and are not expected to underestimate risk.

4. HUMAN HEALTH EXPOSURE AND RISK ASSESSMENT

Dinotefuran can be applied by the foliar route to leafy vegetables, and therefore, residues may be present in or on crops at harvest. Dinotefuran may also potentially be present in drinking water, given its high water solubility, high mobility in soils, and potential persistence in the environment. Therefore, exposures and risks from food and drinking water need to be assessed, as well as from residential uses. Risk assessments were conducted for acute and chronic dietary, intermediate-term oral and dermal, and short- and intermediate-term inhalation exposures.

Residue Profile

The submitted lettuce metabolism data are sufficient to support the proposed use on leafy vegetables. The total toxic residues requiring regulation include dinotefuran and its metabolites DN and UF in the tolerance expression and dinotefuran, DN (1-methyl-3-(tetrahydro-3-furylmethyl)guanidine), UF (1-methyl-3-(tetrahydro-3-furylmethyl)urea), and PHP (6-hydroxy-5-(2-hydroxyethyl)-methyl-1,3-diazinane-2-ylidene-N-nitroamine) for risk assessment purposes. However, the plant metabolism data indicated that PHP was found to be a major metabolite (>10% total radioactive residues) only in apples, but not in the other plants studied (lettuce, potato, rape, and rice), and hence the use of the recommended tolerance in/on leafy vegetables will not underestimate the exposure in the risk assessment; and therefore, the PHP metabolite was not included in the dietary risk assessment for leafy vegetables.

The residues of concern for ruminants and poultry tolerances are dinotefuran. The residues of concern for risk assessment are dinotefuran, UF and FNG (2-nitro-1-(tetrahydro-3-furylmethyl)guanidine) in ruminants, and dinotefuran and FNG in poultry. However, no methods and no tolerances for livestock commodities are needed for the use on leafy vegetables, since no significant livestock feedstuffs are associated with leafy vegetables.

Dietary Exposure and Risk

Acute and chronic dietary exposure analyses were conducted using the Dietary Exposure Evaluation Model-Food Consumption Intake Database (DEEM-FCID™, version1.3) program and the Lifeline™ model (version 2.0), which both incorporate consumption data from the United States Department of Agriculture's (USDA's) Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-96/1998. The dietary risk analyses incorporated tolerance level residues and assumed 100% of the leafy vegetables had been treated with dinotefuran. Nevertheless, the acute and chronic risk estimates are below the Agency's level of concern for the general U.S. population (<1% aPAD; <10% cPAD) and all population subgroups. A cancer dietary risk assessment for dinotefuran is not required. The dietary exposure and risk estimates for dinotefuran are summarized in Table 5 below.

Table 5. Summary of Dietary Exposure and Risk for Dinotefuran Using Both DEEM-FCID (Upper Row) and LifeLine (Lower Row) Software

Population Subgroup*	Acute Dietary (95 Percentile)		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% aPAD**	Dietary Exposure (mg/kg/day)	% cPAD**
General U.S. Population	0.0085	0.68	0.0017	8.6
	0.0089	0.7	0.0018	8.8
All Infants (< 1 year old)	0.0026	0.21	0.00089	4.4
	0.0025	0.2	0.00087	4.3
Children 1-2 years old	0.0076	0.61	0.0015	7.7

Population Subgroup*	Acute Dietary (95 Percentile)		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% aPAD**	Dietary Exposure (mg/kg/day)	% cPAD**
	0.0077	0.60	0.0014	7.0
Children 3-5 years old	0.0095	0.76	0.0017	8.6
	0.0092	0.70	0.0016	8.1
Children 6-12 years old	0.0086	0.69	0.0016	8.0
	0.0081	0.60	0.0014	7.1
Youth 13-19 years old	0.0075	0.60	0.0014	7.1
	0.0072	0.60	0.0014	6.9
Adults 20-49 years old	0.0088	0.71	0.0018	9.1
	0.0090	0.70	0.0018	9.1
Adults 50+ years old	0.0081	0.65	0.0018	8.8
	0.0093	0.70	0.0019	9.4
Females 13-49 years old	**0.0095**	**0.76**	**0.0019**	**9.4**
	0.010	**0.80**	**0.0019**	**9.7**

** The values for the highest exposed population for each type of risk assessment are bolded.*
*** %PADs are reported to 2 significant figures.*

A drinking water assessment for dinotefuran was conducted based on FIRST (FQPA Index Reservoir Screening Tool) was used to calculate the surface water EDWCs and the Screening Concentration in Ground Water (SCI-GROW) model was used to calculate the groundwater EDWC. All EDWCs values are less than the lowest drinking water level of comparison (DWLOC) values of 12,000 µg/L (all infants and children subgroups) and 180 µg/L (children 3-5 years old and children 6-12 years old) determined for the acute and chronic scenarios, respectively. Therefore, the EDWCs do not exceed Agency's level of concern.

Residential Exposure Estimates

There is a potential for exposure to homeowners in residential settings during the application of products containing dinotefuran. There is also a potential for exposure from entering areas previously treated with dinotefuran such as lawns where children might play, or golf courses, and home gardens that could lead to exposures for adults. As a result, risk assessments have been completed for both residential handler and postapplication scenarios.

The Agency combines risks resulting from exposures to individual chemicals when it is likely they can occur simultaneously based on the use pattern and the behavior associated with the exposed population. For this assessment, the Agency has added together risk values for adults applying dinotefuran to residential lawns and then being exposed to the treated lawn. For children,

dermal and incidental oral exposures from hugging treated pets were combined, and dermal and incidental oral exposures from activities on treated lawn were combined. These are considered to represent worst case scenarios for co-occurring residential exposures.

Combined Adults Residential Exposure

Residential handlers may be exposed dermally and by inhalation during mixing, loading and application of dinotefuran for short-term durations. However, a short-term dermal endpoint was not identified. For this reason, and because the short-and intermediate-term inhalation endpoints are the same, intermediate-term risks are assessed for residential handlers as a screen for their potential short-term exposures. Because common toxicity endpoints were identified for both dermal and inhalation routes, a combined risk from both routes of exposure is assessed. Combined risk was estimated by calculating an aggregate risk index (ARI) of combining risks was employed as follows:

$$ARI_{total} = 1/[1/ARI_{dermal\ for\ M/L/A} + 1/ARI_{dermal\ for\ postapp.} + 1/ARI_{inhal\ for\ M/L/A}]$$

All residential handler estimated exposures meet or exceed the Agency's target ARI of 1, and are therefore not of concern.

Residential postapplication exposures are assumed to be mostly of short-term duration (1 to 30 days); although intermediate-term (1 to 6 months) exposures are possible. Because there are numerous dinotefuran use products and scenarios, those scenarios assessed were chosen to cover the major residential use sites (i.e. turf, home garden, etc.) and highest use rates and exposures. The margins of exposure (MOEs) for postapplication exposure to dinotefuran are above the target MOE of 100, and therefore do not exceed Agency's level of concern for the following scenarios: 1) exposure to adults and children from turf products; 2) exposure to adults in vegetable gardens.

The risks from the combined exposures of adults applying dinotefuran to residential lawns and then being dermally exposed from post-application activities on the treated lawn are summarized in Table 6 below. Since the total ARI for adult's combined exposure is larger than the target ARI of 1, it does not exceed Agency's level of concern**.**

Table 6. Adult Residential Combined Risk

Scenario	Rate	Route	ARI	Total ARI
M/L/A Liquids to Lawn: hose-end sprayer	0.54 lb ai/A [Dinotefuran 10SL (10%); Dinotefuran 20% Turf & Ornamental]	Dermal	17	7
		Inhalation	970	
Postapplication on Treated Lawn	0.54 lb ai/A [Dinotefuran 10SL (10%); Dinotefuran 20% Turf & Ornamental]	Dermal	12	

Combined Children's Residential Exposures/Risks

Children's combined risks from hugging treated pets and activities on treated lawns are summarized in Table 7 below. Because the toxicity endpoint (i.e., NOAEL = 22 mg/kg/day, based on body weight gain) is the same for both dermal and incidental oral exposures, the total combined risk (i.e., total MOE) for children is calculated by adding the daily doses from all relevant exposure routes and activities and comparing this total to the common toxicity endpoint NOAEL. Since the total MOE for children's combined exposure from treated lawns exceeds the target MOE of 100, it does not exceed Agncy's level of concern

Table 7. Children's Residential Combined Risk From treated Turf

Scenario	Route	Daily Dose (mg/kg/day)	MOE	Total MOE
Activities on Turf	Dermal	0.002	700	590
Activities on Turf	HTM (Hand-to-Mouth)	0.000027	5800	
Activities on Turf	OTM (Object-to-Mouth)	0.0251	11,000	
Activities on Turf	SI (Soil Ingestion)	0.0178	800,000	

The Agency believes that the calculated risks represent conservative estimates of exposure because maximum application rates are used to define residue levels upon which the calculations are based. Estimates are thought to be conservative even when measures of central tendency (e.g., most transfer coefficients are thought to be central tendency) are used because values that would be considered to be in the lower percentile aspect of any input parameter have not been used in the calculations. Further, because a short-term dermal toxicity endpoint was not identified, the intermediate-term endpoint was used for all dermal risk estimates, even though residential exposure duration for both handlers and postapplication are believed to be short-term based on the use pattern and pesticide half-life. This is an additional high-end input to the risk estimates.

Aggregate Risk

As per FQPA, 1996, when there are potential residential exposures to the pesticide, aggregate risk assessment must consider exposures from three major sources: oral, dermal and inhalation exposures. The toxicity endpoints selected for these routes of exposure may be aggregated as follows:

For short-term aggregate exposure assessment, incidental oral and inhalation cannot be combined due to differences in the endpoint, i.e. neurotoxicity for incidental oral and decreases in body weight for inhalation. No quantification of dermal risk is required.

For intermediate-term aggregate exposure, incidental oral and dermal and inhalation endpoints can be aggregated because of the use of a common endpoint (decreased body weight gain).

For long-term aggregate exposure, incidental oral and dermal and inhalation endpoints can be aggregated because of the use of oral equivalents and a common endpoint (decreased thymus weight).

For the proposed uses, human health aggregate risk assessments have been conducted for acute aggregate exposure (food + drinking water), chronic aggregate exposure (food + drinking water), and residential intermediate-term exposure to children (from dermal and incidental oral exposures) and adults (from dermal and inhalation exposures). The intermediate-term aggregate risk assessment was performed as a screening level assessment, since a short-term aggregate risk assessment could not be performed. A cancer aggregate risk assessment was not performed because dinotefuran is not carcinogenic. All potential exposure pathways were assessed in the aggregate risk assessment. None of the aggregate exposure and risk estimates exceed Agency's level of concern.

Acute Aggregate Risk Assessment (Food and Drinking Water)

The acute aggregate risk assessment takes into account exposure estimates from dietary consumption of dinotefuran (food and drinking water). The results of the food only unrefined acute dietary exposure assessment (using tolerance level residues, not refined by percent crop treated, and processing factors for food) are all below Agency's level of concern. The DWLOCs were calculated from the difference between the food exposure and the aPAD. The EDWCs for surface and ground water EDWCs are several orders of magnitude less than the calculated DWLOCs for acute exposure to the combined residues of dinotefuran and its metabolites. Therefore, the acute aggregate risk associated with the proposed uses of dinotefuran do not exceed Agency's level of concern for the general U.S. population or any population subgroups. The acute dietary risks to four most sensitive population subgroups are summarized in Table 8 below.

Table 8.–Aggregate Risk Assessment for Acute Exposure to [dinotefuran]

Population Subgroup	aPAD (mg/kg/day)	% aPAD (Food)	Surface Water EDWC (ppb)	Ground Water EDWC (ppb)	Acute DWLOC (ppb)
U.S. Population	1.25	0.68	75.78	5.06	43,000
All infants (< 1 year old)	1.25	0.21	75.78	5.06	12,000
Children (3-5 years old)	1.25	0.76	75.78	5.06	12,000
Females (13-49 years old)	1.25	0.76	75.78	5.06	37,000

Chronic Aggregate Risk Assessment (Food and Drinking Water)

The chronic aggregate risk assessment takes into account exposure estimates from dietary consumption of dinotefuran (food and drinking water). The results of the food only

unrefined chronic dietary exposure assessment (using tolerance level residues, not refined by percent crop treated, and processing factors for food) are all below Agency's level of concern. The DWLOCs were calculated from the difference between the food exposure and the aPAD. The EDWCs for surface and ground water EDWCs are less than the calculated DWLOCs for chronic exposure to the combined residues of dinotefuran and its metabolites. Therefore, the chronic aggregate risk associated with the proposed uses of dinotefuran do not exceed Agency's level of concern for the general U.S. population or any population subgroups. The acute dietary risks to four most sensitive population subgroups are summarized in Table 9 below.

Table 9.–Aggregate Risk Assessment for Chronic (Non-Cancer) Exposure to dinotefuran

Population Subgroup	cPAD (mg/kg/day)	% cPAD (FOOD)	Surface Water EDWC (ppb)	Ground Water EDWC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.02	8.6	20.97	5.06	640
All infants (< 1 year old)	0.02	4.4	20.97	5.06	190
Children (3-5 years old)	0.02	8.6	20.97	5.06	180
Females (13-49 years old)	0.02	9.4	20.97	5.06	550

Short-term risk

For dinotefuran, short- and intermediate-term aggregate risk assessments based on exposure from oral, inhalation, and dermal routes were considered. However, for short-term aggregate exposure assessment, oral and inhalation risk estimates cannot be combined due to the different bases of their endpoints; i.e., neurotoxicity for oral and decrease in body weight for inhalation. Also, because no systemic toxicity was seen at the limit dose in a 28-day dermal toxicity study, no quantification of short-term dermal risk is required. Therefore, a short-term aggregate risk assessment cannot be performed for dinotefuran. However, an intermediate-term aggregate risk assessment was performed as a screening level assessment, which will apply to short-term aggregate risk.

Intermediate-term risk

Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term aggregate risk assessment was performed as a screening level assessment for adults and children.

The child subgroup with the highest estimated chronic dietary exposure (children 3-5 years old) was used to calculate the intermediate-term aggregate risk, including chronic dietary (food and drinking water) and residential dermal and oral exposures. All acceptable MOEs must be identical for all MOEs to be included in the intermediate-term risk assessment. Based on the toxicity endpoint information, all acceptable MOEs are 100, and an oral

endpoint for hand-to-mouth residential exposure was identified. In this case, the chronic dietary endpoint (NOAEL) was used to incorporate dietary (food and water), and residential exposures in the aggregate risk assessment. An intermediate-term residential exposure scenario was identified and includes dermal and oral exposure routes. To complete the aggregate intermediate-term exposure and risk assessment, chronic dietary (food and drinking water) and residential dermal and oral exposures must be included.

For children's combined exposure on turf, the total MOE was estimated to be 590. The average (chronic) dietary exposure for the highest exposed child subgroup (children 3-5 years old) was estimated to be 0.0017 mg/kg/day. The aggregate risk assessment for intermediate-term exposure to children is summarized in Table 10 below:

Table 10. Aggregate Risk Assessment for Intermediate-Term Exposure of Children to Dinotefuran.

Population	NOAEL mg/kg/day	Target MOE[1]	Max Exposure[2] mg/kg/day	Average Food Exposure mg/kg/day	Residential Exposure[3] mg/kg/day	Aggregate MOE (food & residential)[4]	Max Water Exposure[5] mg/kg/day	Ground Water EDWC[6] µg/L	Surface Water EDWC[6] µg/L	Intermediate-Term DWLOC[7] µg/L
Children 3-5 yrs old	22	100	0.22	0.0017	0.037227	565	0.181	20.97	5.06	1810

[1] The target MOE of 100 is based on the standard inter- and intra-species safety factors, 10x for intra -species variability and 10x for inter-species extrapolation.
[2] Maximum exposure (mg/kg/day) = NOAEL/Target MOE
[3] Residential exposure to children playing on treated lawns (combined dermal + oral hand-to-mouth + oral object-to-mouth + oral soil ingestion)
[4] Aggregate MOE = [NOAEL/(Avg. Food Exposure + Residential Exposure)]
[5] Maximum Water Exposure (mg/kg/day) = Target Maximum Exposure - (Food Exposure + Residential Exposure)
[6] The use site producing the highest level was used; i.e. turf.
[7] DWLOC (µg/L) = [Maximum water exposure (mg/kg/day) x body weight (10 kg)]/[Water exposure (1L) x 10^{-3} mg/µg]

Compared with the EDWCs, the aggregate intermediate-term DWLOC does not exceed Agency's level of concern for the subgroup population of children 3-5 years old.

For adults, the worst case intermediate-term aggregate risk assessment includes the following scenarios: 1) dermal and inhalation exposures to residential handlers (i.e. M/L/A of liquids to lawns by hose-end sprayers); 2) dermal postapplication exposures on treated lawns; and 3) oral dietary exposures (i.e. food + drinking water). Based on the toxicity endpoint information, the acceptable MOEs are not all identical. The intermediate-term inhalation endpoint has a UF/MOE of 1,000, because a NOAEL was not reached and a LOAEL was used instead, while the assessments for incorporating food, water and dermal exposures have UFs/MOEs of 100. In this case, the aggregate risk index (ARI) method was used to calculate DWLOC values for the adult aggregate intermediate-term risk assessment.

The highest estimated average (chronic) dietary exposure occurred with females 13-49 years old (i.e. 0.0019 mg/kg/day). The adult residential combined risks from dermal (ARI = 17) and inhalation (ARI = 970) exposures to residential handlers; and dermal

postapplication exposures (ARI = 12) on treated lawns were assessed and combined. The aggregate risk assessment for intermediate-term exposure to adults is summarized in Table 11 below.

Table 11. Aggregate Risk Assessment for Intermediate-Term Exposure of Adults to Dinotefuran.

Polulation	Target ARI[1]	ARI Food[2]	Residential ARIs[3]			Max Water Exposure ARI[4]	Ground Water EDWC[5] µg/L	Surface Water EDWC[5] µg/L	Intermediate-Term DWLOC[6] µg/L
			Applicators		Postapplication Dermal Exposure				
			Dermal Exposure	Inhalation Exposure					
Females 14-49 yrs old	1	116	17	970	12	1.18	20.97	5.06	5600

[1] ARI (Aggregate Risk Index) = $MOE_{Calculated}$ / $MOE_{Aceeptable}$
[2] ARI_{Food} = [22 / 0.0019] / 100 = 116
[3] $ARI_{dermal} = MOE_{calculated}/100$ and, $ARI_{inhal} = MOE_{inhal}/1{,}000$
[4] $ARI_{Water} = 1/[1/1- (1/ARI_{Residential\ aplicator\ dermal}) + (1/ARI_{Residential\ applicator\ inhalation}) + (1/ARI_{Postapplication\ dermal})]$
[5] The use site producing the highest level was used; i.e. turf.
[6] DWLOC (µg/L) = [Maximum water exposure (mg/kg/day) x body weight (60 kg)]/[Water exposure (2 L) x 10^{-3} mg/µg]; where Maximum water exposure = NOAEL (22) / [ARI_{Water} (1.18) x 100] = 0.1866 mg/kg/day

Compared with the EDWCs, the aggregate intermediate-term DWLOC does not exceed Agency's level of concern for the subgroup population of females 13-49 years old.

Occupational Exposure

The proposed uses of dinotefuran include numerous occupational use patterns, involving many different types of formulations and product packagings. There is potential for exposure from the mixing, loading, and applying of dinotefuran on both food and non-food use sites, and from entering areas previously treated with dinotefuran.

Occupational handlers may be exposed dermally and by inhalation during mixing, loading and application of dinotefuran for both short- and intermediate-term durations. A short-term dermal endpoint was not identified by the HIARC. For this reason, and because the short-and intermediate-term inhalation endpoints are the same, only intermediate-term baseline risks are assessed for handlers. Intermediate term risk estimates should cover short-term risks, as well. Further, because common toxicity endpoints were identified for both dermal and inhalation routes, a combined risk from both routes of exposure is assessed. Combined risk was estimated by calculating an aggregate risk index (ARI) because, while dermal and inhalation endpoint effects are the same, they occur at different dose levels and have different associated levels of concern for the MOE. The following formula is used to calculate the ARI:

$$ARI_{total} = 1/[(1/ARI_{dermal}) + (1/ARI_{inhal})]$$
where, $ARI_{dermal} = MOE_{calculated}/100$ and, $ARI_{inhal} = MOE_{inhal}/1{,}000$

Occupational handler exposure scenarios were organized and assessed according to the proposed dinotefuran product uses. The following handler scenarios were identified:

(1) mixing/loading/applying of liquids by high-pressure handwand;
(2) mixing/loading/applying of liquids by low-pressure handwand;
(3) mixing/loading/applying of liquids by backpack sprayer;
(4) open mixing/loading of liquids for groundboom, aerial and chemigation applications;
(5) applying liquids by groundboom in open cabs;
(6) applying liquids aerially in enclosed cockpits;
(7) flagging for aerially applied liquids;
(8) open mixing/loading of granulars for groundboom, aerial and chemigation applications;
(9) applying granulars by aerial;
(10) flagging for aerially applied granulars;
(11) open mixing/loading/applying granulars for application by belly grinder spreaders;
(12) open mixing/loading/applying granulars for application by push-type spreaders;
(13) applying granulars by tractor drawn spreaders;
(14) open pour hand application of granulars;
(15) mixing/loading/applying of liquids for application by handgun (lawn) sprayer;
(16) mixing/loading/applying of water-dispersible granules for application by handgun (lawn) sprayer;
(17) open mixing/loading/applying of granulars for application by sprinkler can;
(18) hand application of granular baits by spoon;
(19) hand placement of bait stations;
(20) hand application of gel baits by syringe; and
(21) hand application of ready-to-use (RTU) trigger-pump sprays

Handler exposure data from individual worker exposure studies, Pesticide Handlers Exposure Database (PHED), as well as Outdoor Residential Exposure Task Force (ORETF) with the use of gloves, the calculated ARIs for the following handler scenarios were greater than 1, and therefore, do not exceed Agency's level of concern

Occupational postapplication exposures and risks were assessed for the proposed food use on leafy vegetables and for the proposed non-food use scenarios of golf course maintenance, turf farm re-entry, and nursery and greenhouse ornamental production. Data from chemical-specific residue dissipation studies, as well as Outdoor Residential Exposure Task Force (ORETF) were used in calculating the risk estimates.

These proposed uses involve foliar applications to turf and ornamentals, and foliar and soil application to leafy vegetables. Therefore, there is a potential for short- and intermediate-term exposure to workers entering dinotefuran-treated areas to perform a variety of agricultural tasks, and a risk assessment is required. Long-term postapplication exposure is not expected for greenhouse workers engaged in the production of nursery ornamentals because of the infrequent application intervals, the relatively short half-life of dinotefuran and the concern for pest resistance from over-application.

Generally, inhalation exposure is expected to be negligible for most postapplication scenarios except for greenhouses, where, due to their enclosed nature, the airborne concentration of volatile or semi-volatile pesticides may result in concerns for greenhouse workers following application of such pesticides. However, because the vapor pressure of dinotefuran is very low (1.0×10^{-9} mm Hg @ 30 deg C), dinotefuran postapplication greenhouse inhalation risk is

considered to be negligible. In addition, because an estimate of inhalation exposure to applicators using greenhouse application methods (e.g., high-pressure handwand sprayers) and products did not exceed HED's level of concern, the potential postapplication exposure to any residual airborne concentration of dinotefuran also is not considered to be of concern.

Data from chemical-specific residue dissipation studies were submitted for use in completing the postapplication risk assessments for ornamental, turf and agricultural (leafy vegetable) applications. These studies were designed to determine the dissipation rate of dislodgeable foliar residues (DFR) following the application of dinotefuran. Aside from minor study limitations, each of these studies was found to be acceptable and the data deemed to be usable for risk assessment purposes. The highest estimated day zero residue values were used as a screen for estimated day zero residue exposure.

Using the intermediate-term dermal toxicity endpoint (a short-term endpoint was not identified by the HIARC) and data from the residue dissipation studies, the MOEs for all major postapplication activities reach the target MOE of 100 on the day of treatment (i.e., day 0) for all proposed uses (turf, ornamentals and leafy vegetables), and therefore, do not exceed Agency's level of concern.

Non-occupational Off-Target Exposure

Relative to post-application exposure, spray drift is often a potential source of exposure to residents nearby to agricultural spraying operations. This is particularly the case with aerial application, but, to a lesser extent, could also be a potential source of exposure from ground application methods. As indicated in this assessment, dinotefuran can be directly applied to residential turf. The rates of application to residential turf are equal to the agricultural rates of application. Application rates to turf are the highest rates for any use scenario. The resulting margins of exposure are not of concern to the Agency. Therefore, based on this assessment, the Agency believes that it is unlikely that there is higher potential for risk of exposure to spray drift from agricultural uses of this chemical than have been assessed for direct residential applications.

5. ENVIRONMENTAL EXPOSURE AND RISK

Dinotefuran has a moderate molecular weight, a very high water solubility, and a low octanol/water partition coefficient that suggest the potential for runoff and low bioaccumulation. The low vapor pressure and a very low Henry's Law Constant suggest that this compound is not expected to volatilize substantially from water or soils in natural environments. Dinotefuran's degradates, MNG and DN-phosphate, also have high solubility in water at 11,480 ppm and 619,400 ppm, respectively. A summary of selected physical and chemical properties for dinotefuran is presented in Table 11 below.

Table 11. Selected Physical/Chemical Properties for Dinotefuran

Parameter	Value
Molecular Weight	202.2 g/mol

Parameter	Value
Water Solubility (20°C)	39,830 ppm
Vapor Pressure (30°C)	$<1.275 \times 10^{-8}$ mm Hg
Henry's Law Constant	8.63×10^{-14} Atm •m^3/mol
Octanol/Water Partition Coefficient, K_{ow}	0.283
Log K_{OW}	-0.549

Environmental Fate Characteristics

The major route of dissipation for dinotefuran appears to be aqueous photolysis (half-life 1.8 days). However, dinotefuran is stable to hydrolysis in a range of pH's of 4-9 and appears to be relatively persistent to metabolism both in aerobic and anaerobic conditions (approximate half-lives 50-100 days). It is considered to be very highly mobile (K_{oc} = 6 - 45) in various soil types. This compound and its degradates (MNG, DN) are highly water soluble (11,480 - 619,400 ppm) and it has a low octanol/water partition coefficient (K_{ow} = 0.283) which suggests a low potential for fish bioaccumulation.

The high water solubility of dinotefuran, coupled with its very high mobility, and resistance to biodegradation shows that this compound has a strong potential to leach to the subsurface. Furthermore, there is the potential for exposure to adjacent bodies of water through spray drift and runoff events. Once in the rivers, ponds, or other bodies of water, the fate of dinotefuran is somewhat uncertain. Although aqueous photolysis appears to occur under laboratory tests conditions, this may not be an important degradation pathway in relatively deeper natural bodies of water (> 2m). The degradates of dinotefuran that are most likely to be observed in adjacent bodies of water are MNG, and DN. The photolysates UF, and DN-2-OH +DN-3-OH were not observed in metabolism studies.

Table 12. Environmental Fate Parameters for Dinotefuran and MNG

Parameter	Dinotefuran	MNG	MRID #
Water Solubility (25°C)	39,830 ppm	11,480 ppm	45640112 45639706
Hydrolysis Half-Life (pH 7)	stable	stable	45640102
Aerobic Soil Metabolism Half-Life (upper confidence bound value, 90th percentile, from 2 values)	138.4 days	459.3 (3x one value)	45640112
Aerobic Soil Metabolism Half-Life (mean)	81.5 days	153.1	45640111
Aerobic Aquatic Metabolism Half-life (upper confidence bound value, 90th percentile, from 2 values)	80.8 days	Calculated 2x459.3 = 918.6	45640117
Aqueous Photolysis Half-Life	1.8 days	2.4 days	45640105 45640107

Table 12. Environmental Fate Parameters for Dinotefuran and MNG

Parameter	Dinotefuran	MNG	MRID #
Adsorption/Desorption Coefficient (Lowest non-sand K_d)	0.22	0.16	45640114 45640116
Organic Carbon Adsorption/Desorption Coefficient (lowest non-sand K_{OC})	22 mL/g	16 mL/g	

Table 13. Environmental Fate Parameters for DN and DN-2-OH

Parameter	DN-2-OH	DN	MRID #
Water Solubility (25°C)	1,000,000 ppm (1)	619,400 ppm	45639707
Hydrolysis Half-Life (pH 7)	stable	stable	45640102
Aerobic Soil Metabolism Half-Life (3 times single value calculated by Biowin Program)	180	N/A	45640117.
Aerobic Soil Metabolism Half-Life	60 days	114 days (2)	
Aerobic Aquatic Metabolism Half-life (one value only)	342 days (N/A - (assumed same as DN)	114 days x 3 = 342 days	45640117
Aqueous Photolysis Half-Life	533.2 days (N/A - assumed same as DN)	533.2 days	45640108
Adsorption/Desorption Coefficient (Lowest non-sand K_d)	N/A	2.08	45640113
Organic Carbon Adsorption/Desorption Coefficient (lowest non-sand K_{OC})	10 mL/g	87 mL/g	

Table 14. Environmental Fate Parameters for UF

Parameter	Dinotefuran	UF	MRID #
Water Solubility (25°C)	39,830 ppm	4,171 ppm	45640112
Hydrolysis Half-Life (pH 7)	stable	stable	45640102
Aerobic Soil Metabolism Half-Life (upper confidence bound value, 90th percentile, from 2 values)	138.4 days	180 days	45640112
Aerobic Soil Metabolism Half-Life (mean)	81.5 days (2)	60 days	45640111
Aerobic Aquatic Metabolism Half-life	80.8 days	360 (2 x 180 days)	45640117

Table 14. Environmental Fate Parameters for UF

Parameter	Dinotefuran	UF	MRID #
Aqueous Photolysis Half-Life	1.8 days	Assumed Stable ~500 days	45640105
Adsorption/Desorption Coefficient (Lowest non-sand K_d)	0.22	Not available	45640114 45640113
Organic Carbon Adsorption/Desorption Coefficient (lowest non-sand K_{OC})	22 mL/g	10.48 mL/g	

Ecological Effects and Risk

Terrestrial Hazard

Dinotefuran was tested on various species of birds (bobwhite, Japanese quail, and mallard duck). The parent compound is practically nontoxic to Japanese quail on an acute basis (LD50 > 2,000 ppm) and slightly toxic to mallard duck (LC50 = 5,000 ppm) and Japanese quail (LC50 > 1,301 ppm) on a subacute dietary basis. Although there appeared to be no significant treatment-related effects on bobwhite quail reproductive parameters, chronic testing on mallard duck (NOAEC = 2,150 ppm) showed effects on several endpoints that included number of hatchlings/eggs laid, eggs set, and 14-day old survivors.

Dinotefuran is slightly to practically nontoxic on an acute basis to surrogate wild mammal species (laboratory rat) (LD50 = 1,000 - 3,000 mg/kg). Developmental test on the rat produced a NOAEC > 1,000 mg/kg bw/day and reproductive NOAEC at 3000 ppm. There were some affects in reproductive mammalian tests (such as slight decreases in testicular sperm counts in F_0 males and sperm mortality in F_1 males), however these affects did not change reproductive success of dose groups compared to the controls. These biological anomalies observed in rats are common in these laboratory studies and are not considered affects from endocrine disruption. The degradates MNG and DN were not tested on birds or surrogate mammals.

Dinotefuran is highly toxic to bees on an acute oral basis (LD50 = 0.023 ug ai/bee) and on an acute contact basis (LD50 = 0.047 ug ai /bee.

The Tier I seedling emergence and vegetative vigor studies showed that parent dinotefuran caused effects on plants below the statistical 25% level. Therefore, no EC_{25} endpoints were produced in those tests, so toxic affects on plants would be observed at levels higher than the maximum labeled application rate (0.536 lbs ai/Acre).

Aquatic Hazard

Submitted data indicate that dinotefuran is practically nontoxic on an acute basis to freshwater and estuarine/marine fish (LC50 > 99.3 ppm), as well as freshwater invertebrates (EC50 > 968.3 ppm). Chronic toxicity testing on freshwater invertebrates showed no treatment related effects and a NOAEC was calculated at > 95.3 ppm. However, dinotefuran appears to be highly toxic to the estuarine/marine invertebrates

(mysid shrimp EC50 = 0.79 ppm). Since an estuarine/marine chronic study was not submitted for this compound there is an uncertainty regarding chronic risk to estuarine invertebrates.

The degradates MNG and DN (in its stable form, DN-phosphate) were tested on aquatic plants; and MNG was tested on invertebrates (daphnids). Both degradates **do not appear** to be toxic to any of these organisms. None of the studies reviewed by EFED indicate any potential endocrine disruption effects on fish or invertebrates. Refer to Appendix V for hazard information on parent and degradate compounds.

Table 15. Ecological Toxicity Data Summary for Dinotefuran

A. Acute Toxicity to Japanese Quail

Species	*% ai*	*LD50 (mg/kg)*	*Toxicity Category*	*MRID No.*
Japanese quail *(Coturnix japonica)*	97.26	>2,000	Practically nontoxic	45639720

B. Subacute Toxicity to Mallard Duck

Species	*% ai*	*5-Day LC50 (ppm)*	*Toxicity Category*	*MRID No.*
Mallard duck *(Anas platyrhynchos)*	99.2	>5,000	Practically non-toxic	45639722

C. Subacute Toxicity to Japanese Quail

Species	*% ai*	*5-Day LC50 (ppm)*	*Toxicity Category*	*MRID No.*
Japanese quail *(Coturnix japonica)*	97.26	>1301	Slight- practically non toxic	45639721

D. Chronic Toxicity to Mallard Duck

Species	% ai	NOAEC (ppm)	LOAEC (ppm)	Endpoints affected	MRID No.
Mallard duck *(Anas platyrhynchos)*	99.3	2,150	5,270	Number of hatchlings/ eggs laid, number of hatchlings/ eggs set, and 14-day old survivors/eggs set	45639723

E. Chronic Toxicity to Bobwhite Quail					
Species	% ai	NOAEC (ppm)	LOAEC (ppm)	Endpoints Affected	MRID No.
Northern bobwhite quail *(Colinus virginianus)*	99.3	5,270	>5,270	None	45639724

F. Mammalian Acute and Chronic Toxicity				
Test Species	% ai	Toxicity Value	Affected Endpoints	MRID No. Author/ Year
laboratory rat *(Rattus norvegicus)*	99.1	LD_{50} = 2,804 mg/kg males, and 2,000 mg/kg for females	Morbidity	45639823 Glaza, Steven M./1997
laboratory rat *(Rattus norvegicus)*	98.9	Reproductive NOAEL = 3,000 ppm and LOAEL = 10, 000 ppm	Decreased uterine weights, miscroscopic alterations in uterus and vagina of F_0 females; decreased numbers of primordial follicles in F_1 females, altered estrous cyclicity in F_0females; slight increases in abnormal sperm morphology in F_0 and F_1 males, and slight deceases in testicular sperm count in F_0 males and sperm mortality in F_1 males.	45639913 45639914 Becker, H./ 2002
laboratory rat *(Rattus norvegicus)*	92.9	Developmental NOAEL $\geq$ 1,000 mg/kg bw/day LOAEL was not established	No statistically significant effects on developmental endpoints	45654207 45639910
Rabbit	92.9	Developmental NOAEL $\geq$ 300 mg/kg bw/day LOAEL was not established	No statistically significant effects on developmental endpoints	45654208 45639911 45639912

G. Nontarget Insect Toxicity				
Species	% ai	Endpoint/ Test type	Toxicity Category	MRID No.
Honeybee (*Apis mellifera*)	99.5	LD_{50} = 0.023 µg a.i./bee/ acute oral LD_{50} = 0.047 µg a.i./bee/ contact	Highly toxic	45639725
Honeybee (*Apis mellifera*)	21.4	LD_{50} = 0.032 µg a.i./bee/ acute oral LD_{50} = 0.061 µg a.i./bee/ contact	Highly toxic	45639726
Honeybee (*Apis mellifera*)	21.4	LD_{50} = 0.024 µg a.i./bee/ contact LD_{50} = 0.0076 µg a.i./bee/ acute oral	Highly toxic	45639727
Honeybee (*Apis mellifera*)	MTI-446 20% SG	48-hour RT_{25} = 90 (75-110) hour	N/A	45639728
Predacious mite (*Typhlodromus pyri Scheuten*)	21.09	LC_{50} = 30.1 g a.i./ha NOAEC = <15 g a.i./ha	N/A	45640120
Parasitoid wasp (*Aphidius rhopalosiphi*)	21.09	LC_{50} = 77.2 mg a.i./ha NOAEC = 7 mg a.i./ha	N/A	45640121
Predacious bug (*Orius laevigatus*)	21.09	LC_{50}= 13.3 mg a.i./ha NOAEC = <1.36 mg a.i./ha LOAEC = 8.8 mg a.i./ha	N/A	45640122

H. Freshwater Fish Acute Toxicity

Species/ Flow-through or Static	Test Material Purity	96-hour LC50 (mg/L)	Toxicity Category	MRID #
Rainbow trout (*Oncorhynchus mykiss*) Flow-through	MTI-446 97.26 %	>99.5	Practically nontoxic	45639714
Bluegill sunfish *(Leopmis macrochirus*) Flow-through	MTI-446 97.26 %	>99.3	Practically nontoxic	45639715
Carp (*Cyprinus carpio*)	MTI-446 97.26 %	>99.1	Practically nontoxic	45639716

I. Freshwater fish Chronic Toxicity

Species/Static or Flow-through	% ai	LOAEC (ppm)	NOAEC (ppm)	Effects	MRID No.
Rainbow Trout (*Oncorhynchus mykiss*) Flow-through	98.9	N/A	N/A	N/A	456397-19 INVALID STUDY

J. Freshwater Invertebrate Acute Toxicity

Species/Static or Flow-through	**Test Material Purity**	**48-hour LC_{50} or EC_{50} measured in mg/L**	**Toxicity Category**	**MRID No.**
Waterflea *(Daphnia magna)* Flow-Through	MTI-446 97.26 %	>968.3	Practically nontoxic	45639709
Waterflea *(Daphnia magna)* Flow-Through	DN Phosphate	>110.6	Practically nontoxic	45639710

K. Freshwater Invertebrate Chronic Toxicity

Species/Static or Flow-through	Test Material Purity	Study Type	Chronic Endpoints Affected	MRID No.
Waterflea *(Daphnia magna)*	MTI-446 97.26%	21-day chronic toxicity test	None NOAEC = 95.3 ppm; LOAEC >95.3 ppm	45639718

L. Estuarine/Marine Fish Acute Toxicity				
Species/Static or Flow-through	**% ai**	**96-hour LC50 (ppm)**	**Toxicity Category**	**MRID No.**
Sheepshead Minnow (*Cyprinodon variegatus*)	99.2	>109	Practically nontoxic	45639717

M. Estuarine/Marine Invertebrate Acute Toxicity				
Species/Static or Flow-through	**% ai.**	**96-hour LC50 or EC50 (ppm)**	**Toxicity Category**	**MRID No.**
Eastern oyster *(Crassostrea virginica)*	99.6	>141	Practically nontoxic	45639711
Mysid Shrimp (*Mysidopsis bahia)*	99.2	0.79	Highly toxic	45639713

N. Nontarget Aquatic Plant Toxicity (Tier I)					
Species	**Test Material Purity**	**Endpoints**	**EC_{50}/ IC_{50} (mg a.i. /L)**	**NOAEC (mg a.i. /L)**	**MRID No.**
Vascular Plants					
Duckweed (*Lemna Gibba*)	99.2% a.i.	Growth	>110	110	45639731
Nonvascular Plants					
Green Algae (*Pseudokirchneriella subcapitata*)	97.26% a.i.	Cell density	97.6	25	45639732
Green Algae (Selenastrum capricornutum)	MNG	Growth rate	>98.7	98.7	45639733
Green Algae (Selenastrum capricornutum)	DN Phoshpate	Growth rate	>100.4	100.4	45639734

Exposure and Risk to Terrestrial and Aquatic Organisms

In order to evaluate the potential risk to terrestrial and aquatic organisms from the use of dinotefuran, risk quotients (RQs) were calculated from the ratio of estimated environmental concentrations (EECs) to ecotoxicity values. The RQ values were calculated using the Tier I models, ELL-FATE and GENEEC,EECs, based on the maximum application rate of dinotefuran for the proposed uses. These RQs were then compared to the levels of concern (LOC) criteria used by EFED for determining potential risk to non-target organisms and the subsequent need for possible regulatory action. All risk quotients were less than the target LOC of 1. Therefore, the

proposed uses of dinotefuran do not trigger acute or chronic risks to non-endangered or endangered aquatic and terrestrial organisms (e.g., mammals, birds, fish, invertebrates, and plants). Although dinotefuran is potentially highly toxic to bees, the proposed uses of this compound are not associated with areas high in pollinating insects. Based upon ecotoxicological data on two of its degradates, DN was found to be nontoxic to freshwater invertebrates (daphnids) and aquatic plants (green algae) and MNG was found to be nontoxic to green algae.

Exposure of surface waters to dinotefuran is possible through surface water runoff, soil erosion, and off-target spray drift. Due to the low adsorption potential of dinotefuran (K_{OC}'s< 45), the exposure to surface and ground water is expected to be high.

Tier I Estimated Drinking Water Concentrations (EDWCs) for dinotefuran, and for its major transformation products - 1-methyl-2-nitroguanidine (MNG), 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine (DN), 1-methyl-3-(tetrahydro-3-furylmethyl)urea (UF), and DN-2-OH+DN-3-OH were calculated for use in the human health risk assessment.

The degradates UF and DN-2-OH are photolysates and are not likely to be formed in the leafy vegetable scenario that includes soil incorporation of the parent. The formation of these degradates would be a result of direct exposure of parent to surface waters through spray drift, followed by photolysis. The above estimated values for DN, UF, and DN-2-OH+DN-3-OH (Photolysates) are considered to be the upper bound estimates since these degradates are likely to form only in puddles or small water pockets in the field through photolysis. The combined peak concentration for the parent and the degradates is estimated at 52.06 ppb and the combined annual average surface water concentration is estimated at 9.64 ppb.

Based upon the aerobic soil metabolism and field dissipation studies, MNG is the only major degradate expected to be formed in soils. MNG contains the nitro guanidine structure and therefore is considered to posses similar toxicity as the parent. DN is also structurally similar to the parent and therefore considered to share similar toxicity as the parent. DN has been found to form under anaerobic conditions only. None of the degradates of dinotefuran are expected to have any higher toxicity than the parent.

Risk to nontarget insects

Dinotefuran parent is highly toxic to bees and since this chemical is an insecticide, protection of pollinators is a concern. The turf and leafy vegetable uses in this assessment are not expected to include areas highly associated with pollinating insects. Therefore potential kill events via direct spray or nontarget spray drift on pollinating insects in these areas appears to be minimal.

Risk to terrestrial plants

In the Tier I seedling emergence and vegetative vigor tests, no plant species showed at least a 25% detrimental effect on any parameter, when compared to the controls. Risk quotients could not be calculated since there was no EC_{25} data available for terrestrial plants. No Tier II terrestrial plant tests are required at this time.

Risk to endangered species

Risks to endangered species were evaluated for aquatic and terrestrial organisms. There were no LOCs which exceeded EFED's Tier I screen and no other concerns for endangered species have been identified for this risk assessment.

6. SUMMARY OF REGULATORY POSITION AND RATIONALE

Available data provide adequate information to support the conditional registration of dinotefuran technical and end-use products for use on leafy vegetables.

Labeling Restrictions

Manufacturing Use Products

Precautionary Statements/Environmental Hazards:

This pesticide is toxic to shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless it is in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the area

End-Use Products

1. Precautionary Statements/Environmental Hazards:

This pesticide is toxic to shrimp. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to aquatic organisms in water adjacent to treated areas. Do not dispose equipment washwaters or rinsate into a natural drain or water body.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

2. Since the field trial data submitted did not reflect the use of surfactants in the application sprays, the statements on the proposed label which state that control may be improved by the addition of a nonionic surfactant to the spray mixture must be deleted, until data depicting residues in the presence of a surfactant have been submitted and reviewed.

3. Specify a 120-day plantback interval for all crops other than leafy vegetables.

7. SUMMARY OF CONFIRMATORY DATA REQUIREMENTS

Residue Chemistry

1. Additional storage stability data in/on lettuce may be required pending review of MRID Numbers 45891614 and 45915401.

2. Confined Accumulation in Rotational Crops:

   a. The dates of sample extraction and analysis must be submitted.. If samples from the confined rotational crop study were stored >6 months from harvest to final analysis, storage stability data may be required to support the sample storage intervals.

   b. A new confined rotational crop study, reflecting a 1x application rate, will be required, if any plantback interval less than 120 days is sought.

Toxicology

1. A confirmatory dermal absorption study in the rat is required.

2. A developmental neurotoxicity study in the rat is required.

3. A developmental immunotoxicity study in the rat with comparative measures between pups and the parents is required. The protocol for this testing should be developed following discussion with OPP/HED scientists.

Environmental Fate

1. Photodegradation in Soil. The aqueous photolysis study shows that photolysis/photodegradation is a major degradation pathway for dinotefuran. However, the Agency requires a valid soil photolysis study in order to better evaluate this route of dissipation.

2. Aerobic Soil Metabolism

3. Anaerobic Aquatic/Soil Metabolism. This study needs to be repeated to assess any future aquatic uses.

4. Aerobic Aquatic Metabolism. This study needs to be repeated to assess any future aquatic uses.

Ecological Effects

1. Fish Early Life Stage Toxicity Test

2. Avian Acute Oral Test

3. Aquatic Invertebrate Life Cycle Test. This study will be needed to assess any future aquatic uses.

9. CONTACT PERSON AT EPA

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DISCLAIMER: The information presented in this Pesticide Fact Sheet is for informational purposes only and may not be used to fulfill data requirements for pesticide registration and reregistration.

Appendix I

GLOSSARY OF TERMS AND ABBREVIATIONS

ADNT	Acute delayed neurotoxicity
a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
ARI	Aggregate Risk Index
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
ChE	Cholinesterase
ChEI	Cholinesterase inhibition
cPAD	Chronic Population Adjusted Dose
%CT	Percent crop treated
DAT	Days after treatment
DEEM-FCID	Dietary Exposure Evaluation Model - Food Consumption Intake Database
DNA	Deoxyribonucleic acid
DNT	Developmental neurotoxicity
DIT	Developmental Immunotoxicity
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EPA	U.S. Environmental Protection Agency
FQPA	Food Quality Protection Act
GLC	Gas Liquid Chromatography
GLN	Guideline Number
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEL	Lowest Observed Adverse Effect Level
LOAEC	Lowest Observed Adverse Effect Concentration
LOC	Level of Concern
LOD	Limit of Detection
LOQ	Limit of quantitation
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number), EPA's system of recording and tracking studies submitted
MTD	Maximum tolerated dose
NA	Not Applicable
NOEC	No Observable Effect Concentration

GLOSSARY OF TERMS AND ABBREVIATIONS (Continued)

NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NOAEC	No Observed Adverse Effect Concentration
NPDES	National Pollutant Discharge Elimination System
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/ EXAMS	Tier II Surface Water Computer Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
TGAI	Technical Grade Active Ingredient
UF	Uncertainty Factor
µg	micrograms
µg/L	Micrograms Per Liter
µL/g	Microliter per gram
USDA	United States Department of Agriculture
WPS	Worker Protection Standard

Appendix II

Citations Considered to be Part of the Data Base Supporting the Registration of Dinotefuran

MRID	Citation
45636500	Sumitomo Chemical Company (2002) Submission of Product Chemistry, Toxicity and Efficacy Data in Shuriken Cockroach Gel Bait. Transmittal of 16 Studies.
45636501	Todd, R. (2002) Product Identity and Composition of Shuriken Cockroach Gel Bait. Unpublished study prepared by Insect Control & Research, Inc. 8 p. {OPPTS 830.1550}
45636502	Todd, R. (2002) Description of Materials Used to Produce Shuriken Cockroach Gel Bait. Unpublished study prepared by Insect Control & Research, Inc. 30 p. {OPPTS 830.1600}
45636503	Kawada, H. (2002) Description of Manufacturing Process of Shuriken Cockroach Gel Bait: Lab Project Number: SH1650. Unpublished study prepared by Sumitomo Chemicals Company, Ltd. 9 p. {OPPTS 830.1650}
45636504	Todd, R. (2002) Discussion of the Formation of Impurities in the Shuriken Cockroach Gel Bait. Unpublished study prepared by Insect Control & Research, Inc. 7 p. {OPPTS 830.1670}
45636505	Todd, R. (2002) Certified Limits of Shuriken Cockroach Gel Bait. Unpublished study prepared by Insect Control & Research, Inc. 7 p. {OPPTS 830.1750}
45636506	Evans, A.; Mullee, D. (2002) S-1638 Gel Bait: Determination of General Physico-Chemical Properties: Lab Project Number: SZF-0001: 483/038. Unpublished study prepared by Safepharm Laboratories Limited. 15 p. {OPPTS 830.6315, 830.7000, 830.7300}
45636507	Whittington, J. (2002) Shelf Life Storage Stability Characteristics of S-1638 Gel Bait: (One Month Interim Report): Lab Project Number: V-01-22483A: VAM-24A-001: VL-006-05. Unpublished study prepared by Valent USA Corporation. 55 p. {OPPTS 830.6317}
45636508	Whittington, J. (2002) Corrosion Characteristics of S-1638 Gel Bait: (One Month Interim Report): Lab Project Number: V-01-22483B: SZF-0003: V-24483B. Unpublished study prepared by Valent USA Corporation. 43 p. {OPPTS 830.6320}
45636509	Kunimatsu, T. (2002) Acute Oral Toxicity Study of S-1638 Gel Bait in Rats: Final Report: Lab Project Number: 3696. Unpublished study prepared by Sumitomo Chemical Company. 26 p. {OPPTS 870.1100}

45636510 Kunimatsu, T. (2002) Acute Dermal Toxicity Study of S-1638 Gel Bait in Rats: Final Report: Lab Project Number: 3699. Unpublished study prepared by Sumitomo Chemical Company. 25 p. {OPPTS 870.1200}

45636511 Nakamura, Y. (2002) Primary Skin and Eye Irritation Test of S-1638 Gel Bait in Rats: Lab Project Number: 3683. Unpublished study prepared by Sumitomo Chemical Company. 18 p. {OPPTS 870.2500, 870.2400}

45636512 Nomura, N. (2002) A Skin Sensitization Study of S-1638 Gel Bait in Guinea Pigs: Lab Project Number: I-1778. Unpublished study prepared by Bozo Research Center Inc. 39 p. {OPPTS 870.2600}

45636513 Gaynor, W. (2002) Efficacy of Two Cockroach Baits Against German Cockroaches: (Shuriken Cockroach Bait): Lab Project Number: G0171201001A098: 1201-017-0084. Unpublished study prepared by Insect Control & Research, Inc. 103 p.

45636514 Gaynor, W. (2002) Efficacy of Two Cockroach Baits Against American Cockroaches: (Shuriken Cockroach Gel Bait): Lab Project Number: G0171201002A098: 1201-017-0085. Unpublished study prepared by Insect Control & Research, Inc. 103 p.

45636515 Gaynor, W. (2002) Efficacy of Two Cockroach Baits Against German Cockroaches: (Shuriken Cockroach Gel Bait): Lab Project Number: G0171201001A086: 1201-017-0086. Unpublished study prepared by Insect Control & Research, Inc. 59 p.

45636516 Gaynor, W. (2002) Efficacy of Two Cockroach Baits Against American Cockroaches: (Shuriken Cockroach Gel Bait): Lab Project Number: G0171201002A086: 1201-017-0087. Unpublished study prepared by Insect Control & Research, Inc. 98 p.

45639100 Mitsui Chemicals, Inc. (2002) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Dinotefuran 20% SG and the Petition for Tolerance of Dinotefuran on Leafy Vegetables and Cotton Seed Undelinated/Gin Byproducts. Transmittal of 14 Studies.

45639101 Ebihara, K.; Harnish, W. (2002) Dinotefuran 20% SG: Product Identity and Disclosure of Ingredients, Including Manufacturing Process and Discussion of Formation of Impurities. Unpublished study prepared by Mitsui Chemicals, Inc. 60 p. {OPPTS 830.1550, 830.1600, 830.1620, 830.1650, 830.1670}

45639102 Landis, W. (2002) Dinotefuran (MTI-446) 20% SG: Physical and Chemical Properties. Unpublished study prepared by Mitsui Chemicals, Inc. 37 p.

45639103 Wolf, S. (2001) Validation of An Analytical Method for the Determination of MTI-446 (Active Ingredient) in MTI-446 20% SG: Lab Project Number: 806837. Unpublished study prepared by RCC Ltd. 45 p. {OPPTS 830.1800}

45639104 Wolf, S. (2001) Determination of MTI-446 (Active Ingredient) in a Batch of MTI-446 20% SG: Lab Project Number: 818278. Unpublished study prepared by RCC Ltd. 36 p. {OPPTS 830.1800}

45639105 Tognucci, A. (2002) Determination of the Oxidation/Reduction of MTI-446 20% SG with Certain Agents: Lab Project Number: 796230. Unpublished study prepared by RCC Ltd. 28 p. {OPPTS 830.6314}

45639106 Muller-Kafer, R. (2002) Determination of the Storage Stability and Corrosion Stability of MTI-446 20% SG (Shelf Life at Room Temperature): Lab Project Number: 796285. Unpublished study prepared by RCC Ltd. 43 p. {OPPTS 830.6317 and 830.6320}

45639107 Tognucci, A. (2002) pH-Determination of an Aqueous Dispersion of MTI-446 20% SG: Lab Project Number: 796263. Unpublished study prepared by RCC Ltd. 26 p. {OPPTS 830.7000}

45639108 Tognucci, A. (2002) Determination of the Bulk Density of MTI-446 20% SG: Lab Project Number: 796274. Unpublished study prepared by RCC Ltd. 27 p. {OPPTS 830.7300}

45639109 Oda, S. (2001) Acute Oral Toxicity Study of MTI-446 20% SG in Rats: Lab Project Number: B-4831. Unpublished study prepared by Bozo Research Center, Inc. 37 p. {OPPTS 870.1100}

45639110 Oda, S. (2001) Acute Dermal Toxicity Study of MTI-446 20% SG in Rats: Lab Project Number: B-4832. Unpublished study prepared by Bozo Research Center, Inc. 37 p. {OPPTS 870.1200}

45639111 Decker, U. (2002) MTI-446 20% SG: 4-Hour Acute Inhalation Study in Rats: Lab Project Number: 838743. Unpublished study prepared by RCC Ltd. 86 p.

45639112 Ukon, Y. (2002) Eye Irritation Study of MTI-446 20% in Rabbits: Lab Project Number: I-1727. Unpublished study prepared by Bozo Research Center, Inc. 30 p. (OPPTS 870.2400}

45639113 Ukon, Y. (2002) Skin Irritation Study of MTI-446 20% in Rabbits: Lab Project Number: I-1728. Unpublished study prepared by Bozo Research Center, Inc. 24 p. {OPPTS 870.2500}

45639114 Ukon, Y. (2002) Skin Sensitization Study of MTI-446 20% in Guinea Pigs (Buehler Test): Lab Project Number: I-1729. Unpublished study prepared by Bozo Research Center, Inc. 29 p. {OPPTS 870.2600}

45639200 Mitsui Chemicals, Inc. (2002) Submission of Product Chemistry Data in Support of the Application for Registration of Dinotefuran TK. Transmittal of 2 Studies.

45639201 Ebihara, K.; Harnish, W. (2002) Dinotefuran TK: Product Identity and Disclosure of Ingredients, Including Manufacturing Process and Discussion of Formation of Impurities. Unpublished study prepared by Mitsui Chemicals, Inc. 28 p. {OPPTS 830.1550, 830.1600, 830.1620, 830.1650, 830.1670}

45639202 Landis, W. (2002) Dinotefuran TK: Physical and Chemical Properties. Unpublished study prepared by Mitsui Chemicals, Inc. 58 p.

45639600 Mitsui Chemicals, Inc. (2002) Submission of Product Chemistry, Toxicity and Efficacy Data in Support of the Application for Registration of Dinotefuran Ready To Use. Transmittal of 12 Studies.

45639601 Ebihara, K.; Renfroe, J. (2002) Dinotefuran Ready To Use Product Identity and Disclosure of Ingredients, Including Manufacturing Process and Discussion of Formation of Impurities. Unpublished study prepared by Mitsui Chemicals, Inc. 51 p. {OPPTS 830.1550, 830.1600, 830.1620, 830.1650, 830.1670}

45639602 Washburn, K. (2002) Dinotefuran Ready To Use Pump 0.5%: Product Chemistry: End-Use Product: Final Report: Lab Project Number: 6685-01. Unpublished study prepared by Stillmeadow, Inc. 14 p. {OPPTS 830.6302, 830.6303, 830.6304, 830.6314, 830.7000, 830.7100, 830.7300}

45639603 Anderson, W. (2002) Dinotefuran Ready To Use: Storage Stability with Corrosion Characteristics: Lab Project Number: 6686-01. Unpublished study prepared by Stillmeadow, Inc. 9 p. {OPPTS 830.6317 and 830.6320}

45639604 Kuhn, J. (2001) Dinotefuran Ready To Use Pump 0.5%: Acute Oral Toxicity Study in Rats: Final Report: Lab Project Number: 6679-01. Unpublished study prepared by Stillmeadow, Inc. 10 p. {OPPTS 870.1100}

45639605 Kuhn, J. (2001) Dinotefuran Ready To Use Pump 0.5%: Acute Dermal Toxicity Study in Rabbits: Final Report: Lab Project Number: 6680-01. Unpublished study prepared by Stillmeadow, Inc. 12 p. {OPPTS 870.1200}

45639606 Carter, L. (2002) Dinotefuran Ready To Use Pump 0.5%: Acute Inhalation Toxicity Study in Rats: Final Report: Lab Project Number: 6681-01. Unpublished study prepared by Stillmeadow, Inc. 20 p. {OPPTS 870.1300}

45639607 Kuhn, J. (2001) Dinotefuran Ready To Use Pump 0.5%: Acute Eye Irritation Study in Rabbits: Final Report: Lab Project Number: 6682-01. Unpublished study prepared by Stillmeadow, Inc. 17 p. {OPPTS 870.2400}

45639608 Kuhn, J. (2001) Dinotefuran Ready To Use Pump 0.5%: Acute Dermal Irritation Study in Rabbits: Final Report: Lab Project Number: 6683-01. Unpublished study prepared by Stillmeadow, Inc. 12 p. {OPPTS 870.2500}

45639609 Kuhn, J. (2002) Dinotefuran Ready To Use Pump 0.5%: Skin Sensitization Study in Guinea Pigs: Final Report: Lab Project Number: 6684-01. Unpublished study prepared by Stillmeadow, Inc. 17 p. {OPPTS 870.2600}

45639610 Kirkland, R. (2002) Efficacy of Dinotefuran Ready To Use as a Pump Spray in the Control of Cockroaches: Lab Project Number: BIO 330-01. Unpublished study prepared by Bio Research. 34 p. {OPPTS 810.3500}

45639611 Kirkland, R. (2002) Efficacy of Dinotefuran Ready To Use as a Pump Spray in the Residual Control of Household Pests: Lab Project Number: BIO 332-01. Unpublished study prepared by Bio Research. 54 p. {OPPTS 810.3500}

45639612 Donahue, L. (2002) In vitro Efficacy Evaluations of Dinotefuran (MTI-446) Ready To Use Formulation Against Selected Arthropod Pest Species: Final Report: Lab Project Number: LND01-1. Unpublished study prepared by Sierra Research Laboratories (SRL). 20 p. {OPPTS 810.3500}

45639700 Mitsui Chemicals, Inc. (2002) Submission of Product Chemistry, Toxicity, Residue and Environmental Fate Data in Support of the Application for Registration of Dinotefuran Technical and the Petition for Tolerance of Dinotefuran on Leafy Vegetables and Cottonseed Undelinted/Gin Byproducts. Transmittal of 35 Studies.

45639701 Ebihara, K.; Harnish, W. (2002) Dinotefuran Technical: Product Identity and Disclosure of Ingredients, Including Manufacturing Process and Discussion of Formation of Impurities. Unpublished study prepared by Mitsui Chemicals, Inc. 82 p. {OPPTS 830.1550, 830.1600, 830.1620, 830.1650, 830.1670}

45639702 Malinski, M. (2000) MTI-446 Product Chemistry: Lab Project Number: 011098-1: MTI-446: 011098-0. Unpublished study prepared by Ricerca, LLC. 193 p. {OPPTS 830}

45639703 Ramsay, N.; Craig, W. (2001) Dinotefuran 5-Batch Analysis of Dinotefuran to Fulfill the Requirements of OPPTS Guidelines 830.1700 and 830.1800 and EC Council Directive 94/37/EEC Article 1.9 to 1.11: Lab Project Number: 20426: 341084: 4108A. Unpublished study prepared by Inveresk Research. 90 p. {OPPTS 830.1700, 830.1800}

45639704 Macdonald, E.; Graham, P. (2001) Physico-Chemical Testing with MNG: Partition Coefficient: Lab Project Number: 19350: 281675: 8169. Unpublished study prepared by Inveresk Research. 20 p. {OPPTS 830.7550}

45639705 Macdonald, E.; Graham, P. (2001) Physico-Chemical Testing with DN Phosphate: Partition Coefficient: Lab Project Number: 19352: 281680: 8169. Unpublished study prepared by Inveresk Research. 6 p. {OPPTS 830.7550}

45639706 Macdonald, E.; Graham, P. (2001) Physico-Chemical Testing with MNG: Water Solubility: Lab Project Number: 19349: 281633: 8169. Unpublished study prepared by Inveresk Research. 18 p. {OPPTS 830.7840}

45639707 Macdonald, E.; Graham, P. (2001) Physico-Chemical Testing with DN Phosphate: Water Solubility: Lab Project Number: 19351: 281649: 8169. Unpublished study prepared by Inveresk Research. 6 p. {OPPTS 830.7840}

45639708 Hewitt, A. (2002) Atomization Droplet Size Spectra for MTI-446 Insecticide: Lab Project Number: L02-001. Unpublished study prepared by Stewart Agricultural Research Services, Inc. 20 p. {OPPTS 840.1100}

45639709 Peither, A. (2000) Acute Toxicity of MTI-446 to Daphnia Magna in a 48-Hour Immobilization Test: Lab Project Number: 740968: MTI-446: 740970. Unpublished study prepared by RCC Ltd. 32 p. {OPPTS 850.1010}

45639710 Kelly, C.; Murphy, C.; Allan, J. (2002) DN Phosphate Determination of Acute Toxicity to Daphnia (48 h, Static): Lab Project Number: 20122: 800141. Unpublished study prepared by Inveresk Research. 24 p. {OPPTS 850.1010}

45639711 Drottar, K.; Kendall, T.; Krueger, H. (2001) MTI-446 Technical: A 96-Hour Shell Deposition Test with the Eastern Oyster (Crassostrea virginica): Final Report: Lab Project Number: 236A-106A. Unpublished study prepared by Wildlife International, Ltd. 38 p. {OPPTS 850.1025}

45639712 Kendall, T.; Nixon, W. (2001) Analytical Method Verification for the Determination of MTI-446 Technical in Saltwater: Lab Project Number: 236C-102. Unpublished study prepared by Wildlife International, Ltd. 28 p. {OPPTS 850.1035}

45639713 Blankinship, A.; Drottar, K.; Kendall, T.; et al. (2001) MTI 446-Technical: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysid (Mysidopsis bahia): Final Report: Lab Project Number: 236A-104A. Unpublished study prepared by Wildlife International, Ltd. 38 p. {OPPTS 850.1035}

45639714 Peither, A. (1999) Acute Toxicity of MTI 446 to Rainbow Trout (Oncorhynchus mykiss) in a 96-Hour Static Test: Lab Project Number: 740924. Unpublished study prepared by RCC, Ltd. 33 p. {OPPTS 850.1075}

45639715 Peither, A. (2000) Acute Toxicity of MTI-446 to Bluegill Sunfish (Lepomis macrochirus) in a 96-Hour Static Test: Lab Project Number: 740946: 740957. Unpublished study prepared by RCC, Ltd. 33 p. {OPPTS 850.1075}

45639716 Peither, A. (2000) Acute Toxicity of MTI-446 to Common Carp (Cyprinus carpio) in a 96-Hour Static Test: Lab Project Number: 741003: 741014. Unpublished study prepared by RCC, Ltd. 33 p. {OPPTS 850.1075}

45639717 Blankinship, A.; Drottar, K.; Kendall, T.; et al. (2001) MTI-446 Technical: A 96 Hour Flow-Through Acute Toxicity Test with the Sheepshead Minnow (Cyprinodon variegatus): Final Report: Lab Project Number: 236A-105. Unpublished study prepared by Wildlife International, Ltd. 39 p. {OPPTS 850.1075}

45639718 Peither, A. (2000) Influence of MTI-446 on Survival and Reproduction of Daphnia magna in a Semistatic Test over Three Weeks: Lab Project Number: 752106: 752117. Unpublished study prepared by RCC, Ltd. 40 p. {OPPTS 850.1300}

45639719 Peither, A. (2001) Toxic Effects of MTI-446 to Rainbow Trout (Oncorhynchus mykiss) in an Early-Life Stage Toxicity Test: Lab Project Number: 794338: 794340. Unpublished study prepared by RCC, Ltd. 54 p. {OPPTS 850.1400}

45639720 Burri, R. (2000) MTI-446 Technical: Acute Oral Toxicity Test in the Japanese Quail: Lab Project Number: 746425. Unpublished study prepared by RCC, Ltd. 46 p.

45639721 Burri, R. (2000) MTI-446 Technical: Avian Dietary Toxicity Test in the Japanese Quail: Lab Project Number: 746436. Unpublished study prepared by RCC, Ltd. 47 p. {OPPTS 850.2200}

45639722 Burri, R. (2000) MTI-446 Technical: Avian Dietary Toxicity Test in the Mallard Duck: Lab Project Number: 793754: 904994. Unpublished study prepared by RCC, Ltd. 46 p. {OPPTS 850.2200}

45639723 Mitchell, L.; Martin, K.; Beavers, J.; et. al. (2002) MTI-446 Technical: A Reproduction Study with the Mallard: Final Report: Lab Project Number: 236-115. Unpublished study prepared by Wildlife International, Ltd. 157 p.

45639724 Mitchell, L.; Martin, K.; Beavers, J.; et al. (2002) MTI-446 Technical: A Reproduction Study with the Northern Bobwhite: Final Report: Lab Project Number: 236-114. Unpublished study prepared by Wildlife International, Ltd. 159 p.

45639725 Harnish, W. (2000) Acute Contact and Oral Toxicity of MTI-446, Active to Honey Bees: Lab Project Number: 41421F001. Unpublished study prepared by Landis International, Inc. 68 p. {OPPTS 850.3020}

45639726 Harnish, W. (2000) Acute Contact and Oral Toxicity of MTI-446, 20% WG to Honey Bees: Lab Project Number: 41421F002. Unpublished study prepared by Landis International, Inc. 62 p. {OPPTS 850.3020}

45639727 Thompson, H. (1998) A Formulation Containing MTI-446: Acute Contact and Oral Toxicity to Honey Bees (Apis mellifera): Lab Project Number: FP2400. Unpublished study prepared by Central Science Laboratory, National Bee Unit. 47 p.

45639728 Hummel, R. (2001) Evaluation of Toxicity of Residues of MTI-446 on Alfalfa to Honey Bees (Apis mellifera): Lab Project Number: 43421F001. Unpublished study prepared by Landis International, Inc. 46 p. {OPPTS 850.3030}

45639729 Porch, J.; Martin, K.; Krueger, H. (2001) MTI-446 20% SG: A Toxicity Test to Determine the Effects of the Test Substance on Seedling Emergence of Ten Species of Plants: Final Report: Lab Project Number: 236-116. Unpublished study prepared by Wildlife International, Ltd. 54 p. {OPPTS 850.4100}

45639730 Porch, J.; Brignole, A.; Krueger, H.; et al. (2001) MTI-446 20% SG: A Toxicity Test to Determine the Effects of the Test Substance on Vegetative Vigor of Ten Species of Plants: Final Report: Lab Project Number: 236-117. Unpublished study prepared by Wildlife International, Ltd. 74 p. {OPPTS 850.4150}

45639731 Batscher, R. (2002) Toxicity of MTI-446 to the Aquatic Higher Plant Lemna Gibba in a 7-Day Semistatic Growth Inhibition Test: Lab Project Number: 827752. Unpublished study prepared by RCC, Ltd. 55 p. {OPPTS 850.4400}

45639732 Seyfried, B. (2000) Toxicity of MTI-446 to Pseudokirchneriella subcapitata (Formerly Selenastrum capricornutum) in a 96-Hour Algal Growth Inhibition Test: Lab Project Number: 740981: 740992. Unpublished study prepared by RCC, Ltd. 37 p. {OPPTS 850.5400}

45639733 Kelly, C.; Ferguson, K. (2002) MNG Alga, Growth Inhibition Test (96 h): Lab Project Number: 19918: 800199. Unpublished study prepared by Inveresk Research. 29 p. {OPPTS 850.5400}

45639734 Kelly, C.; Ferguson, K. (2002) DN Phosphate Alga, Growth Inhibition Test (96 h): Lab Project Number: 19849: 800183: 8169. Unpublished study prepared by Inveresk Research. 28 p. {OPPTS 850.5400}

45639735 Volkel, W. (2002) (Carbon 14)-MTI-446: Plant Metabolism in Rape: Lab Project Number: 767880. Unpublished study prepared by RCC, Ltd. 110 p. {OPPTS 860.1300}

45639800 Mitsui Chemicals, Inc. (2002) Submission of Environmental Fate, Residue and Toxicity Data in Support of the Application for Registration of Dinotefuran Technical and the Petition for Tolerance of Dinotefuran on Leafy Vegetables and Cottonseed Undelinted/Gin Byproducts. Transmittal of 24 of 149 Studies.

45639801 Mamouni, A. (2002) (Carbon-14)-MTI-446 Oil Seed Rape Incurred Residues (Residue Method Efficiency): Lab Project Number: 842768. Unpublished study prepared by RCC Ltd. 25 p. {OPPTS 860.1300}

45639802 Mamouni, A. (2002) (Carbon-14)-MTI-446 Plant Metabolism in Potato: Lab Project Number: 734310. Unpublished study prepared by RCC Ltd. 116 p. {OPPTS 860.1300}

45639803 McClanahan, R.; Lentz, N.; Waller, R. (1999) Metabolic Fate of MTI-446 in Rice: Lab Project Number: 7466-98-0021-EF-001-001: 7466-98-0021-EF-000. Unpublished study prepared by Ricerca, Inc. 374 p. {OPPTS 860.1300}

45639804 Panthani, A.; Walsh, K.; Shah, J. (2002) Metabolism of (Carbon-14)-MTI-446 in Apples: Lab Project Number: 012786-1: R160101: 012786-0-1. Unpublished study prepared by Ricerca, LLC. 216 p. {OPPTS 860.1300}

45639805 Panthani, A.; Walsh, K.; Sandacz Herczog, K. (2002) Metabolism of (Carbon-14)-MTI-446 in Lettuce (Postemergent Spray Treatment): Lab Project Number: 012785-1: 012785-0-1: 012785-0. Unpublished study prepared by Ricerca, LLC. 204 p. {OPPTS 860.1300}

45639806 Hatzenbeler, C.; Lentz, N. (2002) Metabolism of (Carbon-14)-MTI-446 in Lactating Goats: Lab Project Number: 013346-1: 013346-0. Unpublished study prepared by Ricerca, LLC. 181 p. {OPPTS 860.1300}

45639807 Hatzenbeler, C.; Lentz, N. (2002) Metabolism of (Carbon-14)-MTI-446 in Laying Hens: Lab Project Number: 013347-1: 013347-0-1: 013347-0. Unpublished study prepared by Ricerca, LLC. 178 p. {OPPTS 860.1300}

45639808 Wais, A. (2001) Validation of the Residue Analytical Method for MTI-446 in Lettuce: Lab Project Number: 784945. Unpublished study prepared by RCC Ltd. 52 p. {OPPTS 860.1340}

45639809 Wolf, S. (2001) Development and Validation of Residue Analytical Method for the MTI-446 Metabolites DN and UF in Lettuce: Lab Project Number: 836111. Unpublished study prepared by RCC Ltd. 69 p. {OPPTS 860.1340}

45639813 MacGregor, J.; Van Hoven, R.; Nixon, W. (2002) Independent Laboratory Validation of Methods for the Analysis of MTI-446 and Its Metabolite MNG in Soil: Lab Project Number: 236C-106: 836100: 739923. Unpublished study prepared by Wildlife International Ltd. 134 p. {OPPTS 860.1340}

45639814 MacGregor, J.; Fischer, D.; Nixon, W. (2002) Independent Laboratory Validation of Methods for the Analysis of MTI-446 and Its Metabolites DN and UF in Lettuce: Lab Project Number: 236C-107: 836111: 784945. Unpublished study prepared by Wildlife International Ltd. 162 p. {OPPTS 860.1340}

45639815 Van Hoven, R.; Nixon, W. (2002) Assessment of Multiresidue Methodology as Presented in Pesticide Analytical Manual (PAM), Volume I, for the Determination of Dinotefuran in Nonfatty and Fatty Plant Substrates: Lab Project Number: 236C-103. Unpublished study prepared by Wildlife International Ltd. 48 p. {OPPTS 860.1360}

45639817 Wais, A. (2002) MTI-446: Storage Stability in Lettuce, Cotton, Apple, Tomato and Potato: Interim Report: Lab Project Number: 827537. Unpublished study prepared by RCC Ltd. 36 p. {OPPTS 860.1380}

45639818 Mamouni, A. (2002) DN, MNG, UF: Storage Stability in Lettuce: Interim Report: Lab Project Number: 834388. Unpublished study prepared by RCC Ltd. 32 p. {OPPTS 860.1380}

45639819 Hummel, R. (2002) Raw Agricultural Commodity (RAC) Residue Evaluation of MTI-446 20% Applied to Head Lettuce and Leaf Lettuce: Lab Project Number: 41409A005: 795306: 1714-01-414-01-09B-18. Unpublished study prepared by Landis International, Inc. 209 p. {OPPTS 860.1500}

45639820 Hummel, R. (2002) Raw Agricultural Commodity (RAC) Residue Evaluation of MTI-446 20% Applied to Celery and Spinach: Lab Project Number: 41409A006: 810055: 1714-01-414-01-09H-19. Unpublished study prepared by Landis International, Inc. 200 p. {OPPTS 860.1550}

45639822 Hattermann, D. (2002) Confined Accumulation of (Carbon-14) MTI-446 in Rotational Crops in California: Lab Project Number: 41429C008: 820901: 1651-01-414-01-29C-34. Unpublished study prepared by Landis International, Inc. 98 p. {OPPTS 860.1850}

45639823 Glaza, S. (1997) Acute Oral Toxicity Study of MTI-446 in Rats: Final Report: Lab Project Number: CHW 6648-118: TP6137. Unpublished study prepared by Corning Hazleton, Inc. 66 p.

45639824 Glaza, S. (1997) Acute Oral Toxicity Study of MTI-446 in Mice: Final Report: Lab Project Number: CHW 6648-119: TP6138. Unpublished study prepared by Corning Hazleton, Inc. 44 p.

45639900 Mitsui Chemicals, Inc. (2002) Submission of Toxicity Data in Support of the Application for Registration of Dinotefuran Technical and the Petition for Tolerance of Dinotefuran on Leafy Vegetables and Cottonseed Undelinted/Gin ByProducts. Transmittal of 17 of 148 Studies.

45639901 Glaza, S. (1997) Acute Dermal Toxicity Study of MTI-446 in Rats: Final Report: Lab Project Number: CHW 6648-120: TP6273. Unpublished study prepared by Corning Hazleton, Inc. 40 p.

45639902 Shepherd, N. (1999) MTI-446: Acute Inhalation (Nose-Only) Toxicity Study in the Rat: Lab Project Number: 1300/3-D6154: 1300/3. Unpublished study prepared by Covance. 64 p. {OPPTS 870.1300}

45639903 Glaza, S. (1998) Primary Eye Irritation Study of MTI-446 in Rabbits: Final Report: Lab Project Number: COVANCE 6648-122: TP6275. Unpublished study prepared by Covance Laboratories, Inc. 44 p.

45639904 Glaza, S. (1998) Primary Dermal Irritation Study of MTI-446 in Rabbits: Final Report: Lab Project Number: COVANCE 6648-121. Unpublished study prepared by Covance Laboratories, Inc. 34 p.

45639905 Glaza, S. (1997) Dermal Sensitization Study of MTI-446 in Guinea Pigs--Maximization Test: Final Report: Lab Project Number: COVANCE 6648-123: TP6276: 70300317. Unpublished study prepared by Covance Laboratories, Inc. 88 p.

45639906 Weiler, M. (1999) 13-Week Dietary Toxicity Study with MTI-446 in Dogs: Final Report: Lab Project Number: 6648-128. Unpublished study prepared by Covance Laboratories, Inc. 436 p.

45639907 Henwood, S. (2001) 14-Day Range-Finding Dermal Toxicity Study with MTI-446 in Rats: Final Report: Lab Project Number: 6648-150. Unpublished study prepared by Covance Laboratories, Inc. 120 p. {OPPTS 870.3200}

45639908 Henwood, S. (2001) 28-Day Dermal Toxicity Study with MTI-446 in Rats: Final Report: Lab Project Number: COVANCE 6648-149. Unpublished study prepared by Covance Laboratories, Inc. 424 p. {OPPTS 870.3200}

45639909 Mita, I. (2002) MTI-446: 28 Day Inhalation (Nose-Only) Toxicity Study in the Rat: Final Report: Lab Project Number: 719/16. Unpublished study prepared by Covance Laboratories, Ltd. 252 p. {OPPTS 870.3465}

45639910 Sakurai, T. (1998) A Dose-Finding Teratogenicity Study of MTI-446 Given Orally to Rats: Lab Project Number: H-97162: Unpublished study prepared by Nippon Experimental Medical Research Institute Co., Ltd. 52 p. (OPPTS 870.3700}

45639911 Sakurai, T. (1998) A Dose-Finding Teratogenicity Study of MTI-446 Given Orally to Rabbits: Lab Project Number: H-97165: Unpublished study prepared by Nippon Experimental Medical Research Institute Co., Ltd. 66 p. {OPPTS 870.3700}

45639912 Sakurai, T. (1998) A Single 2-Week Repeated Dose Preliminary Study of MTI-446 Given Orally to Rabbits: Lab Project Number: H-97164. Unpublished study prepared by Nippon Experimental Medical Research Institute Co., Ltd. 35 p. {OPPTS 870.3700}

45639913 Becker, H. (2002) MTI-446: Two-Generataion Reproduction Study in the Han Wistar Rat by Oral (Dietary) Administration: Lab Project Number: 775192. Unpublished study prepared by RCC, Ltd. 1521 p. {OPPTS 870.3800}

45639914 Edwards, J.; Knuppe, C.; Weber, K. (2001) MTI-446 Technical: Preliminary Two Generation Study in the Han Wistar Rat: Lab Project Number: 774990. Unpublished study prepared by RCC, Ltd. 358 p. {OPPTS 870.3800}

45639915 Teramoto, I. (1998) Repeated Dose Toxicity Test of MTI-446 Mixed in the Diet for One Week Using Dogs: Lab Project Number: H-97327. Unpublished study prepared by Jitsuiken Medical Research Institute, Inc. 43 p. {OPPTS 870.4100}

45639916 Teramoto, I. (1998) Repeated Dose Toxicity Test of MTI-446 by Forced Oral Administration for One Week Using Dogs: Lab Project Number: H-97326. Unpublished study prepared by Jitsuiken Medical Research Institute, Inc. 40 p. {OPPTS 870.4100}

45639917 Weiler, M. (2000) 78-Week Dietary Carcinogenicity Study with MTI-446 in Mice: Final Report: Lab Project Number: COVANCE 6648-130. Unpublished study prepared by Covance Laboratories, Inc. 2615 p.

45640000 Mitsui Chemicals, Inc. (2002) Submission of Toxicity and Environmental Fate Data in Support of the Application for Registration of Dinotefuran Technical and the Petition for Tolerance of Dinotefurn on Leafy Vegetables and Cottonseed on Undelinted/Gin Byproducts. Transmittal of 10 of 148 Studies.

45640001 Weiler, M. (2000) 104-Week Dietary Combined Chronic Toxicity and Carcinogenicity Study with MTI-446 in Rats: Final Report: Lab Project Number: 6648-131. Unpublished study prepared by Covance Laboratories Inc. 5209 p.

45640002 Lloyd, M. (2002) MTI-446 Technical Material: Mutation at the Thymidine Kinase (tk) Locus of Mouse Lymphoma L5178Y Cells (MLA) using the Microtitre(R) Fluctuation Technique: Final Report: Lab Project Number: 719/15: 719/15-D6173. Unpublished study prepared by Covance Laboratories Inc. 61 p. {OPPTS 870.5300}

45640003 Oguma, Y. (1996) A DNA Repair Assay of Bacillus subtilis on MTI-446: Lab Project Number: 4731. Unpublished study prepared by BML, Inc. 16 p. (OPPTS 870.5500}

45640004 Weiler, M. (2001) 13-Week Dietary Neurotoxicity Study with MTI-446 in Rats: Final Report: Lab Project Number: 6648-148. Unpublished study prepared by Covance Laboratories Inc. 962 p. {OPPTS 870.6200}

45640005 Weiler, M. (2001) Acute Oral Gavage Neurotoxicity Study with MTI-446 in Rats: Final Report: Lab Project Number: 6648-147. Unpublished study prepared by Covance Laboratories Inc. 721 p. {OPPTS 870.6200}

45640006 Cheng, T. (2000) Metabolism of (Carbon 14) MTI-446 in Rats: Lab Project Number: 6648-136. Unpublished study prepared by Covance Laboratories Inc. 519 p.

45640007 Cheng, T.; Howard, S. (2000) Absorption, Distribution, Metabolism and Excretion of G-(Carbon 14) MTI-446 Following Administration of a Single Dose to Neonatal Rats: Lab Project Number: 6648-141. Unpublished study prepared by Covance Laboratories Inc. 76 p.

45640008 Hummel, R. (2002) Dissipation of Dislodgeable Foliar Residues on Leafy Vegetables Following Application of MTI-446: Final Report: Lab Project Number: 41409A004: 795295. Unpublished study prepared by RCC, Ltd and Landis International, Inc. 137 p. {OPPTS 875.2100}

45640009 Hattermann, D. (2002) Dissipation of Dislodgeable Foliar Residues on Ornamentals Following Application of MTI-446 20% SG: Final Report: Lab Project Number: 43422A007: 832353. Unpublished study prepared by RCC Ltd. 134 p. {OPPTS 875.2100}

45640010 Hattermann, D. (2002) Determination of Transferable Turf Residues on Turf Treated with MTI-446 20% SG: Final Report: Lab Project Number: 42424A006. Unpublished study prepared by RCC Ltd. 190 p. {OPPTS 875.2100}

45640100 Mitsui Chemicals, Inc. (20020 Submission of Toxicity, Residue, Risk, Exposure and Environmental Fate Data in Support of the Application for the Registration of Dinotefuran Technical and the Petition for Tolerance of Dinotefuran on Leafy Vegetables and Cottonseed Undelinted/Gin Byproducts. Transmittal of 25 of 148 Studies.

45640101 Sydney, P. (1998) MTI-446: Determination of Hydrolysis as a Function of pH: Final Report: Lab Project Number: MTO/098: 95/MTO098/1216. Unpublished study prepared by Huntingdon Life Sciences. 47 p.

45640102 Ishii, M. (2000) Hydrolysis Study of MTI-446: Lab Project Number: GH9901. Unpublished study prepared by Japan Analytical Chemistry Consultants Co., Ltd. 111 p.

45640103 Mamouni, A. (2001) (Carbon-14)-MNG: Hydrolysis at Three Different pH Values: Lab Project Number: 731215. Unpublished study prepared by RCC Ltd. 45 p. {OPPTS 835.2110}

45640104 Mamouni, A. (2001) (Carbon-14)-DN Phosphate: Hydrolysis at Three Different pH Values: Lab Project Number: 731237. Unpublished study prepared by RCC Ltd. 31 p. {OPPTS 835.2110}

45640105 van der Gaauw, A. (2002) Aqueous Photolysis of (Carbon-14)-MTI-446 Under Laboratory Conditions and Determination of Quantum Yield: Lab Project Number: 729011. Unpublished study prepared by RCC Ltd. 104 p. {OPPTS 835.2210}

45640106 Ishii, M. (2000) Aqueous Photodegradation of MTI-446: Lab Project Number: GP9901. Unpublished study prepared by Japan Analytical Chemistry Consultants Co., Ltd. 197 p.

45640107 Burgener, A. (2001) Aqueous Photolysis of (Carbon-14)-MNG Under Laboratory Conditions and Determination of Quantum Yield: Lab Project Number: 731248. Unpublished study prepared by RCC Ltd. 69 p. {OPPTS 835.2210}

45640109 Shah, J.; Hatzenbeler, C. (2001) Photodegradation of (Carbon-14)-MTI-446 on Soil: Lab Project Number: 012788-1. Unpublished study prepared by Ricerca, LLC. 99 p.

45640110 van der Gaauw, A. (2000) Estimation of the Degradation of MTI-446 by Photo-Oxidation in Air: Lab Project Number: 731160. Unpublished study prepared by RCC Ltd. 18 p.

45640111 Lentz, N. (2001) Aerobic Degradation of MTI-446 in Soil--Preliminary Study: Lab Project Number: 012561-1. Unpublished study prepared by Ricerca, Inc. 73 p.

45640112 Lentz, N. (2001) Aerobic Soil Metabolism of MTI-446: Lab Project Number: 013184-1. Unpublished study prepared by Ricerca, LLC. 80 p.

45640113 Volkel, W. (2001) Adsorption/Desorption of (Carbon-14)-DN Phosphate on Soils: Lab Project Number: 729066. Unpublished study prepared by RCC Ltd. 76 p.

45640114 Volkel, W. (2001) Adsorption/Desorption of (Carbon-14)-MTI-446 on Soils: Lab Project Number: 728998. Unpublished study prepared by RCC Ltd. 102 p.

45640115 Ishii, M. (2000) Soil Adsorption of MTI-446: Lab Project Number: GA9901. Unpublished study prepared by Japan Analytical Chemistry Consultants Co., Ltd. 50 p.

45640116 Volkel, W. (2001) Adsorption/Desorption of (Carbon-14)-MNG on Soils: Lab Project Number: 729055. Unpublished study prepared by RCC Ltd. 72 p.

45640117 Volkel, W. (2000) (Carbon-14)-MTI-446 Degradation and Metabolism in Aquatic Systems: Lab Project Number: 709604. Unpublished study prepared by RCC Ltd. 139 p.

45640118 Hummel, R. (2002) Terrestrial Field Dissipation of Residues Following Application of MTI-446 to Bare Soil in California, Georgia, and New York: Lab Project Number: 41421A007. Unpublished study prepared by RCC Ltd. 227 p.

45640119 Wais, A. (2001) Validation of the Residue Analytical Method for MTI-446 in Soil: Lab Project Number: 739923. Unpublished study prepared by RCC Ltd. 77 p.

45640120 Aldershof, S. (2000) A Laboratory Dose-Response Study to Evaluate the Effects of MTI-446 20% SG on Survival and Reproduction of the Predaceous Mite Typhlodromus pyri Scheuten (Acari:Phytoseiidae): Lab Project Number: RCC011TPL: 756268. Unpublished study prepared by MITOX Stichting Bevordering Duurzame Plaagbestrijding. 27 p.

45640121 Aldershof, S. (2000) A Laboratory Dose-Response Study to Evaluate the Effects of MTI-446 20% SG on Survival and Reproduction of the Parasitoid Wasp Aphidius rhopalosiphi (DeStephani-Perez) (Hymenoptera: Braconidae): Lab Project Number: RCC012ARL: 756270. Unpublished study prepared by MITOX Stichting Bevordering Duurzame Plaagbestrijding. 24 p.

45640122 Aldershof, S. (2000) A Laboratory Dose-Response Study to Evaluate the Effects of MTI-446 20% SG on Survival and Reproduction of the Predacious Bug Orius laevigatus (Fleber) (Hemiptera, Anthocoridae): Lab Project Number: 756281: RCC013OLL. Unpublished study prepared by MITOX Stichting Bevordering Duurzame Plaagbestrijding. 25 p.

45640123 Wolf, S. (2001) Development and Validation of a Residue Analytical Method for the MTI-446 Metabolite MNG in Soil: Lab Project Number: 836100. Unpublished study prepared by RCC Ltd. 47 p.

45640124 Wais, A. (2002) MTI-446: Storage Stability in Soil: Interim Report: Lab Project Number: 827572. Unpublished study prepared by RCC Ltd. 31 p. {OPPTS 860.1380}

45640125 White, S.; Williams, M. (2002) Dinotefuran Technical: Food Quality Protection Act (FQPA) Supplemental Information Document. Unpublished study prepared by Mitsui Chemicals, Inc. 13 p.

45641800 Hartz Mountain Corporation (2002) Submission of Efficacy Data in Support of the FIFRA 6(a)(2) Data Requirements for Dinotefuran. Transmittal of 1 Study.

45641801 Sharp, M. (2002) In Vivo Activity of Flea Dermal Treatments against the Cat Flea (Ctenocephalides felis) on Cats: Lab Project Number: 1589. Unpublished study prepared by Sharp Veterinary Research. 33 p.

45644300 Sunimoto CHemical Company, Ltd. (2002) Submission of Product Chemistry Data in Support of the Application for Registration of Shuriken Coackroach Gel Bait. Transmittal of 1 Study.

45644301 Whittington, J. (2002) Quantitation of S-1638 in S-1638 Gel Bait by High Performance Liquid Chromatography: Lab Project Number: V-01-24483M1: VAM-24A-001: V-24483M1. Unpublished study prepared by Valent USA Corporation. 32 p. {OPPTS 830.1800}

45653600 Mitsui Chemicals, Inc. (2002) Submission of Toxicity Data in Support of the Application for Registration of Dinotefuran Cat Spot-On. Transmittal of 2 Studies.

45654200 Mitsui Chemicals, Inc. (2002) Submission of Product Chemistry, Residue and Toxicity Data in Support of the Petition for Tolerance of Dinotefuran on Leafy Vegetables and Cottonseed Undelinted/Gyn Byproducts and the Application for Registration Dinotefuran Technical. Transmittal of 12 Studies.

45654201 Landis, W. (2002) Dinotefuran (MTI-446) Technical: Physical and Chemical Properties. Unpublished study prepared by Mitsui Chemicals, Inc. 59 p.

45654203 Weiler, M. (1997) 4-Week Dietary Toxicity Study with MTI-446 in Rats: Final Report: Lab Project Number: CHW 6648-125. Unpublished study prepared by Corning Hazleton Inc. 254 p. {OPPTS 870.3050}

45654204 Weiler, M. (1997) 4-Week Dietary Toxicity Study with MTI-446 in Mice: Final Report: Lab Project Number: CHW 6648-124. Unpublished study prepared by Corning Hazleton Inc. 313 p. {OPPTS 870.3050}

45654205 Weiler, M. (1997) 13-Week Dietary Toxicity Study with MTI-446 in Rats: Final Report: Lab Project Number: CHW 6648-127. Unpublished study prepared by Corning Hazleton Inc. 488 p.

45654206 Weiler, M. (1997) 13-Week Dietary Toxicity Study with MTI-446 in Mice: Final Report: Lab Project Number: CHW 6648-126. Unpublished study prepared by Corning Hazleton Inc. 455 p.

45654207 Sakurai, T. (2002) Teratogenicity Study of MTI-446 Given Orally to Rats: Lab Project Number: H-97163. Unpublished study prepared by Nippon Experimental Medical Research Institute Co., Ltd. 112 p. {OPPTS 870.3700}

45654208 Sakurai, T. (1998) Teratogenicity Study of MTI-446 Given Orally to Rabbits: Lab Project Number: H-97166. Unpublished study prepared by Nippon Experimental Medical Research Institute Co., Ltd. 119 p. {OPPTS 870.3700}

45654209 Weiler, M. (1999) 52-Week Dietary Chronic Toxicity Study with MTI-446 in Dogs: Final Report: Lab Project Number: 6648-129. Unpublished study prepared by Covance Laboratories Inc. 467 p.

45654210 Takeda, C. (1996) MTI-446: Microbial Reverse Mutation Assay: Lab Project Number: CRC3113. Unpublished study prepared by Chromosome Research Center (CRC). 15 p. {OPPTS 870.5100, 870.5265}

45654211 Takeda, C. (1996) MTI-446: In vitro Mammalian Cytogenetics Test: Lab Project Number: CRC0076. Unpublished study prepared by Chromosome Research Center (CRC). 15 p. {OPPTS 870.5375}

45654212 Nakajima, M. (1995) Micronucleus Test of EXP-316 with Mice: Lab Project Number: 2498. Unpublished study prepared by An-Pyo Center. 33 p. {OPPTS 870.5395}

45890400 Mitsui Chemicals, Inc. (2003) Submission of Product Chemistry, Toxicity and Efficacy Data in Support of the Application for Registration of Dinotefuran 10% Spot-On For Cats and the Petition for Tolerance of Dinotefuran on Numerous RACs. Transmittal of 8 Studies.

45890500 Mitsui Chemicals, Inc. (2003) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Dinotefuran 10SL and the Petition for Tolerance of Dinotefuran for Use on Numerous RACs. Transmittal of 8 Studies.

45890501 Fumoto, K.; Harnish, W. (2003) Dinotefuran 10% SL: Product Identity and Disclosure of Ingredients, Including Manufacturing Process and Discussion of Formation of Impurities. Unpublished study prepared by Mitsui Chemicals, Inc. 36 p. {OPPTS 830.1550, 830.1660, 830.1650, 830.1670}

45890502 Washburn, K. (2003) Product Chemistry: End-Use Product: MTI-446 10% SL: Final Report: Lab Project Number: 7333-02. Unpublished study prepared by Stillmeadow, Inc. 16 p. {OPPTS 830.6302, 830.6303, 830.6304, 830.6314, 830.6315, 830.6316, 830.7000, 830.7100, 830.7300}

45890503 Oda, S. (2003) Acute Oral Toxicity Study of MTI-446 10% SL in Rats: Lab Project Number: B-5041. Unpublished study prepared by Bozo Research Center, Inc. 32 p. {OPPTS 870.1100}

45890504 Oda, S. (2003) Acute Dermal Toxicity Study of MTI-446 10% SL in Rats: Lab Project Number: B-5042. Unpublished study prepared by Bozo Research Center, Inc. 37 p. {OPPTS 870.1200}

45890505 Mulier, B. (2003) MTI-446 10%SL: A 4-Hour Acute Inhalation Toxicity Study in the Rat: Lab Project Number: 846222. Unpublished study prepared by RCC Ltd. 82 p. {OPPTS 870.1300}

45890506 Nomura, N. (2003) An Eye Irritation Study of MTI-446 10% SL in Rabbits: Lab Project Number: I-1929. Unpublished study prepared by Bozo Research Center, Inc. 31 p. {OPPTS 870.2400}

45890507 Nomura, N. (2003) A Skin Irritation Study of MTI-446 10% SL in Rabbits: Lab Project Number: I-1930. Unpublished study prepared by Bozo Research Center, Inc. 24 p. {OPPTS 870.2500}

45890508 Nomura, N. (2003) A Skin Sensitization Study of MTI-446 10% SL in Guinea Pigs (Buehler Test): Lab Project Number: I-1931. Unpublished study prepared by Bozo Research Center, Inc. 32 p. {OPPTS 870.2600}

45890700 Mitsui Chemicals, Inc. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of Dinotefuran 0.5% Ornamental and Vegetable RTU and the Petition for Tolerance of Dinotefuran on Numerous RACs. Transmittal of 1 Study.

45890701 Fumoto, K.; Harnish, W. (2002) Dinotefuran 0.5% Ornamental and Vegetable RTU: Product Identity and Disclosure of Ingredients, Including Manufacturing Process and Discussion of Formation of Impurities. Unpublished study prepared by Mitsui Chemicals, Inc. 51 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670}

45890800 Mitsui Chemicals, Inc. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of Dinotefuran 20SG. Transmittal of 1 Study.

45890801 Taylor, E. (2003) Dinotefuran 20% SG: Product Identity, Composition, and Analysis: Lab Project Number: 2003-MTI446-001. Unpublished study prepared by Valent U.S.A. Corporation. 153 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1750, 830.1800}

45890900 Mitsui Chemicals, Inc. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of Dinotefuran 0.2% Lawn Granule and the Petition for Tolerance of Dinotefuran on Numerous RACs. Transmittal of 1 Study.

45890901 Fumoto, K.; Harnish, W. (2003) Dinotefuran 0.2% Lawn Granule: Product Identity and Disclosure of Ingredients, Including Manufacturing Process and Discussion of Formation of Impurities. Unpublished study prepared by Mitsui Chemicals, Inc. 27 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670}

45891000 Mitsui Chemicals, Inc. (2003) Submission of Product Chemistry and Efficacy Data in Support of the Application for Registration of Dinotefuran Fire Ant Bait 0.005% and the Petition for Tolerance of Dinotefuran on Numerous RACs. Transmittal of 2 Studies.

45891100 Mitsui Chemicals, Inc. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of Dinotefuran 0.5% Cockroach Gel Bait Professional and the Petition for Tolerance of Dinotefuran on Numerous RACs. Transmittal of 1 Study.

45891101 Fumoto, K.; Harnish, W. (2003) Dinotefuran 0.5% Cockroach Gel Bait Professional: Product Identity and Disclosure of Ingredients, Including Manufacturing Process and Discussion of Formation of Impurities. Unpublished study prepared by Mitsui Chemicals, Inc. 40 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670}

45891200 Mitsui Chemicals, Inc. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of Dinotefuran 0.5% Roach Bait Stations and the Petition for Tolerance of Dinotefuran on Numerous RACs. Transmittal of 1 Study.

45891201 Fumoto, K.; Harnish, W. (2003) Dinotefuran 0.5% Roach Bait Stations: Product Identity and Disclosure of Ingredients, Including Manufacturing Process and Discussion of Formation of Impurities. Unpublished study prepared by Mitsui Chemicals, Inc. 40 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670}

45891300 Mitsui Chemicals, Inc. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of Dinotefuran 0.4% Lawn Granule and the Petition for Tolerance of Dinotefuran on Numerous RACs. Transmittal of 2 Studies.

45891301 Fumoto, K.; Harnish, W. (2003) Dinotefuran 0.4% Lawn Granule: Product Identity and Disclosure of Ingredients, Including Manufacturing Process and Discussion of Formation of Impurities. Unpublished study prepared by Mitsui Chemicals, Inc. 27 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670}

45891302 Washburn, K. (2003) Dinotefuran 0.4% Granule: Product Chemistry: End-Use Product: Final Report: Lab Project Number: 7376-03. Unpublished study prepared by Stillmeadow, Inc. 13 p. {OPPTS 830.6302, 830.6303, 830.6304, 830.6314, 830.7000, 830.7300}

45891400 Mitsui Chemicals, Inc. (2003) Submission of Product Chemistry and Efficacy Data in Support of the Application for Registration of Dinotefuran 0.2% Roach Bait Stations and the Petition for Tolerance of Dinotefuran on Numerous RACs. Transmittal of 3 Studies.

45891401 Fumoto, K.; Harnish, W. (2003) Dinotefuran 0.2% Roach Bait Stations: Product Identity and Disclosure of Ingredients, Including Manufacturing Process and Discussion of Formation of Impurities. Unpublished study prepared by Mitsui Chemicals, Inc. 40 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670}

45891402 Gaynor, W.; Basit, A.; Kilbourn, R.; et. al. (2003) Efficacy of 0.2% w/w Shuriken and Pre-Empt Cockroach Baits Against German and Oriental Cockroaches (No Choice Box Method): Lab Project Number: N3261102001A086: 326-0035. Unpublished study prepared by Insect Control and Research, Inc. 157 p. {OPPTS 810.3500}

45891403 Gaynor, W.; Basit, A.; Kilbourn, R.; et. al. (2003) Efficacy of 0.2% w/w Shuriken and Pre-Empt Cockroach Baits Against German and Oriental Cockroaches (Choice Box Method): Lab Project Number: N3261102001A098: 326-0036. Unpublished study prepared by Insect Control and Research, Inc. 155 p. {OPPTS 810.3500}

45891500 Mitsui Chemicals, Inc. (2003) Submission of Product Chemistry and Efficacy Data in Support of the Application for Registration of Dinotefuran 0.5% Multi-Purpose RTU and the Petition for Tolerance of Dinotefuran on Numerous RACs. Transmittal of 3 Studies.

45891501 Fumoto, K.; Renfroe, J. (2003) Dinotefuran 0.5% Multi-Purpose RTU: Product Identity and Disclosure of Ingredients, Including Manufacturing Process and Discussion of Formation of Impurities. Unpublished study prepared by Mitsui Chemicals, Inc. 51 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670}

45891502 Foard, T.; Spero, N.; Zgidou, F.; et. al. (2003) Initial and Residual Efficacy of a 0.5% Shuriken Spray Formulation Compared to RID (a 0.5% Permethrin Aerosol) Against Body Lice on an Inanimate Surface: Lab Project Number: 326-0038: N3260200001A992. Unpublished study prepared by Insect Control and Research, Inc. 30 p. {OPPTS 810.3500}

45891503 Spero, N.; Basit, A.; Bertsch, M.; et. al. (2003) Evaluation of the Initial and Residual Efficacy of a 0.5% w/w Shuriken Spray Against Cockroaches, Ants, Mosquitoes and Fleas: Lab Project Number: 326-0037: N3211002003A260. Unpublished study prepared by Insect Control and Research, Inc. 286 p. {OPPTS 810.3500}

45891600 Mitsui Chemicals, Inc. (2003) Submission of Product Chemistry, Residue and Environmental Fate Data in Support of the Application for Registration of Dinotefuran Technical. Transmittal of 19 Studies.

45891601 Hattermann, D. (2003) Raw Agricultural Commodity (RAC) Residue Evaluation of MTI-446 20% Applied to Tomato and Pepper: Lab Project Number: 43415A010: 714-02-434-01-15B-34: 714-02-434-01-15B-35. Unpublished study prepared by Landis International, Inc. 369 p. {OPPTS 860.1500}

45891602 Hummel, R. (2003) Raw Agricultural Commodity (RAC) Residue Evaluation of MTI-446 Applied to Cucurbit Vegetables: Final Report: Lab Project Number: 43413A014: 714-02-434-01-13A-98: 714-02-434-01-13A-99. Unpublished study prepared by Landis International, Inc. 359 p. {OPPTS 860.1500}

45891603 Hummel, R. (2003) Raw Agricultural Commodity (RAC) Residue Evaluation of MTI-446 Applied To Head and Stem Brassica: Lab Project Number: 43414A013: 714-02-434-01-14D-75: 714-02-434-01-14D-76. Unpublished study prepared by Landis International, Inc. 308 p. {OPPTS 860.1500}

45891604 Hattermann, D. (2003) Raw Agricultural Commodity (RAC) Residue Evaluation of MTI-446 Applied to Grapes: Lab Project Number: 43403A018: 14-02-434-01-03B-140: 14-02-434-01-03B-141. Unpublished study prepared by Landis International, Inc. 179 p. {OPPTS 860.1500}

45891605 Hummel, R. (2003) Raw Agricultural Commodity (RAC) Residue Evaluation of MTI-446 Applied to Potato: Final Report: Lab Project Number: 14-02-434-01-08D-125: 14-02-434-01-08D-126: 14-02-434-01-08D-127. Unpublished study prepared by Landis International, Inc. 182 p. {OPPTS 860.1500}

45891606 Hummel, R. (2003) Comparison of MTI-446 Residues Detected on Leafy Vegetable Raw Agricultural Commodity (RAC): Foliar Application Versus Soil Application: Lab Project Number: 43409A015: 14-02-434-01-09B-121: 14-02-434-01-09B-122. Unpublished study prepared by Landis International, Inc. 160 p. {OPPTS 860.1500}

45891607 Hattermann, D. (2003) Processed Commodity (PC) Residue Evaluation of MTI-446 Applied to Grape: Lab Project Number: 43403A019: 14-02-434-01-03B-148: 14-02-434-01-03B-149. Unpublished study prepared by Landis International, Inc. 227 p. {OPPTS 860.1520}

45891608 Hattermann, D. (2003) Processed Commodity (PC) Residue Evaluation of MTI-446 Applied to Tomato: Lab Project Number: 43415A011: 714-02-434-01-15B-62: 714-02-434-01-15B-63. Unpublished study prepared by Landis International, Inc. 204 p. {OPPTS 860.1520}

45891609 Hattermann, D. (2003) Processed Commodity (PC) Residue Evaluation of MTI-446 Applied to Potato: Lab Project Number: 43408A017: 14-02-434-01-08D-138: 14-02-434-01-08D-139. Unpublished study prepared by Landis International, Inc. 174 p. {OPPTS 860.1520}

45891610 Hummel, R. (2003) Terrestrial Field Dissipation of Residues Following Application of MTI-446 to Bare Soil in California, Georgia, and New York: Amended Final Report: Lab Project Number: 41421A007: 795284: 641-01-414-01-21E-31. Unpublished study prepared by Landis International, Inc. and RCC LTD. 19 p.

45891611 Hummel, R. (2003) Raw Agricultural Commodity (RAC) Residue Evaluation of MTI-446 20% Applied to Celery and Spinach: Amended Final Report: Lab Project Number: 41490A006: 714-01-414-01-09C-26: 714-01-414-01-09C-29. Unpublished study prepared by Landis International, Inc. 16 p. {OPPTS 860.1500}

45891612 Hummel, R. (2003) Raw Agricultural Commodity (RAC) Residue Evaluation of MTI-446 20% Applied to Head Lettuce and Leaf Lettuce: Amended Final Report: Lab Project Number: 41409A005: 714-01-414-01-09B-07: 714-01-414-01-09B-08. Unpublished study prepared by Landis International, Inc. 16 p. {OPPTS 860.1500}

45891613 Ross, V. (2003) Residues of MTI-446 and its Metabolites DN and UF in Milk and Tissues of Dairy Cows: Lab Project Number: 02/46: 261/024360. Unpublished study prepared by Huntingdon Life Sciences Ltd. 206 p. {OPPTS 860.1480}

45891614 Wais, A. (2002) Storage Stability in Lettuce, Cotton, Apple, Tomato and Potato: MTI-446: Lab Project Number: 827537. Unpublished study prepared by RCC Ltd. 53 p. {OPPTS 860.1380}

45891615 Wais, A. (2002) Storage Stability in Soil: MTI-446: Lab Project Number: 827572. Unpublished study prepared by RCC Ltd. 31 p.

45891616 Volkl, S. (2003) Anaerobic Soil Degradation and Metabolism: (Carbon 14)-MTI-446: Lab Project Number: 841703. Unpublished study prepared by RCC Ltd. 121 p.

45891617 Hug, R. (2002) Determination of the Storage Stability and Corrosion Stability of MTI-446 20% SG (Shelf Life at Room Temperature): Interim Report: Lab Project Number: 796285. Unpublished study prepared by RCC Ltd. 49 p. {OPPTS 830.6317 and 830.6320}

45891618 Stearns, J. (2003) Magnitude of the Residues of V-10112 in Potatoes: Lab Project Number: V-02-24871: 236C-124: V-24871. Unpublished study prepared by Valent U.S.A. Corporation. 249 p. {OPPTS 860.1500}

45891619 Stearns, J. (2003) Magnitude of the Residues of V-10112 in Grapes: Lab Project Number: V-02-24862: 236C-123: V-24862. Unpublished study prepared by Valent U.S.A. Corporation. 241 p. {OPPTS 860.1500}

45900200 Mitsui Chemicals, Inc. (2003) Submission of Toxicity and Exposure and Risk Data in Support of the Petition for Tolerance of Dinotefuran in/on Leafy Vegetables, Cotten Seed Undelinted/gin Byproducts. Transmittal of 1 Study.

45900201 White, S.; Williams, M. (2003) Food Quality Protection Act (FQPA) Supplemental Information Document: Dinotefuran Technical. 13 p.

45912200 Mitsui Chemicals, Inc. (2003) Submission of Reduced-Risk Rationale Data in Support of the Application for Registration of Dinotefuran. Transmittal of 1 Study.

45912201 Gale, E.; Harnish, W.; Kane, D.; et al. (2003) Reduced-Risk Pesticide Rationale for Dinotefuran. Unpublished Study. 271 p.

45915400 Mitsui Chemicals, Inc. (2003) Submission of Residue Data in Support of the Application for Registration of Dinotefuran Technical. Transmittal of 1 Study.

45915401 Mamouni, A. (2002) DN, MNG, UF: Storage Stability in Lettuce: Lab Project Number: 834388. Unpublished study prepared by RCC Ltd. 64 p. {OPPTS 860.1380}

46072400 Mitsui Chemicals, Inc. (2003) Submission of Toxicity Data in Support of the Application for Registration of Dinotefuran Technical. Transmittal of 1 Study.

46072401 Gale, E. (2003) MTI-446 28-Day Inhalation (Nose Only) Toxicity Study in the Rat: Response to USEPA. Project Number: 719/16. Unpublished study prepared by Covance Laboratories, Ltd. 8 p.

46132900 Mitsui Chemicals, Inc. (2003) Submission of Residue Data in Support of the Application for Registration of Dinotefuran Technical. Transmittal of 1 Study.

46132901 Airs, D. (2003) Validation of the Methods of Analysis for Determining Concentrations of MTI-446 and Its Two Metabolites, DN and UF, in Bovine Tissues and Milk and Eggs From Hens. Project Number: MTU/250, MTU/250/024447, 2002054. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 154 p.

46133500 MItsui Chemical, Inc. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of Dinotefuran TK. Transmittal of 1 Study.

46133501 Tognucci, A. (2003) Determination of the Storage Stability and Corrosion Stability of MTI-446 Technical Concentrate (Shelf Life at Room Temperature). Project Number: 832285. Unpublished study prepared by RCC Ltd. 53 p.

46133600 Mitsui Chemicals, Inc. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of Dinotefuran Technical. Transmittal of 1 Study.

46133601 Tognucci, A. (2003) Determination of the Storage Stability and Corrosion Stability of MTI-446 Technical Material (Shelf Life at Room Temperature). Project Number: 828865. Unpublished study prepared by RCC Umweltchemie Ag. 53 p.

46254100 Mitsui Chemicals Inc. (2004) Submission of Efficacy Data in Support of the Applications for Registration of Shuriken Cockroach Gel Bait, Dinotefuran 0.2% Roach Bait Station and Dinotefuran 0.5% Roach Bait Station. Transmittal of 5 Studies.

46254101 Miller, P.; Peters, B. (2003) Tray Study to Determine the Efficacy of Sumitomo S-1638 Cockroach Gel and Bayer Premise Cockroach Gel Against the German Cockroach. Project Number: C02/68/004, R03/1641. Unpublished study prepared by University of Technology. 12 p.

46254102 Miller, P.; Peters, B. (2003) Field Study to Determine the Efficacy of Sumitomo S-1638 Cockroach Gel and Bayer Premise Cockroach Gel Against the German Cockroach. Project Number: C02/68/004, R03/1650. Unpublished study prepared by University of Technology. 15 p.

46254103 Sembo, S. (2004) Field Test Results of a 0.25% Dinotefuran (Shuriken) Gel Bait Against Cockroaches. Project Number: HPTR/20040006. Unpublished study prepared by Sumitomo Chemical Co. 7 p.

46254104 Sembo, S. (2003) Field Test Results of a 0.5% Shuriken (Dinotefuran) Gel Bait Against Cockroaches. Project Number: HPTR/20030034. Unpublished study prepared by Sumitomo Chemical Co. 7 p.

46254105 Sembo, S. (2004) Laboratory Tests to Compare the Efficacy of Shuriken (Dinotefuran) Gel Bait and Blattanex Bait Against Cockroaches. Project Number: HPTR/20040007. Unpublished study prepared by Sumitomo Chemical Co. 7 p.

46254200 Mitsui Chemicals, Inc. (2004) Submission of Efficacy Data in Support of the Application for Registration of Dinotefuran Fly Bait. Transmittal of 1 Study.

46254201 Sembo, S. (2003) Oral Efficacy of Shuriken (Dinotefuran) and Imidacloprid Against Houseflies. Project Number: HPTR/20030033. Unpublished study prepared by Sumitomo Chemical Co. 6 p.

46254500 Mitsui Chemicals, Inc. (2004) Submission of Efficacy Data in Support of the Application for Registration of Dinotefuran 20% PCO. Transmittal of 1 Study.

46254501 Sembo, S. (2004) Residual Activity of Solvent-Based Liquid Shuriken (Dinotefuran) Formulations Against German Cockroaches. Project Number: HPTR/20040010. Unpublished study prepared by Sumitomo Chemical Co. 6 p.

46254600 Mitsui Chemicals, Inc. (2004) Submission of Efficacy Data in Support of the Application of Registration of Dinotefuran Total Release Fogger. Transmittal of 1 Study.

46254601 Sembo, S. (2004) Insecticidal Efficacy of Shuriken (Dinotefuran) Total-Release Aerosol Formulations Against Cockroaches. Project Number: HPTR/20040008. Unpublished study prepared by Sumitomo Chemical Co. 8 p.

46270900 Mitsui Chemicals, Inc. (2004) Submission of Residue Data in Support of the Application for Registration of Dinotefuran Technical. Transmittal of 1 Study.

46270901 MacGregor, J.; Van Hoven, R.; Nixon, W. (2002) Laboratory Validation of Method(s) for the Analysis of MTI-446 and its Metabolites DN and UF in Multiple Crop Substrates. Project Number: 236C/113. Unpublished study prepared by Wildlife International, Ltd. 122 p.

46301600 Landis International (2004) Submission of Toxicity Data in Support of the Application for Registration of Dinotefuran Technical. Transmittal of 1 Study.

46301601 Kuhn, J. (2004) Acute Eye Irritation Study in Rabbits: (Dinotefuran Technical). Project Number: 8394/04. Unpublished study prepared by Stillmeadow, Inc. 18 p.