United States
Environmental Protection Agency

Office of Prevention, Pesticides and Toxic Substances (7505P)

Pesticide Fact Sheet

Name of Chemical: **Flubendiamide**
Reason for Issuance: **Conditional Registration**
Date Issued: **August 1, 2008**

DESCRIPTION OF CHEMICAL

Generic Name:	N^2-[1,1-Dimethyl-2-(methylsulfonyl)ethyl]-3-iodo-N^1-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide
Common Name:	Flubendiamide
EPA Chemical Code:	027602
Chemical Abstracts Service (CAS) Number:	272451-65-7
Pesticide Type:	Insecticide
Chemical Type:	Phthalic Acid Diamide
U.S. Producer:	Bayer CropScience LP 2 T.W. Alexander Drive Research Triangle Park, NC 27709-2014

USE PATTERNS AND FORMULATIONS

Application Sites: Flubendiamide is registered for use on corn, cotton, tobacco, pome and stone fruit, tree nut crops, grapes and vegetable crops (including cucurbit vegetables, fruiting vegetables and okra, leafy vegetables [except *Brassica*] and *Brassica* [cole] leafy vegetables).

Types of Formulations:
NNI-0001 Technical (manufacturing concentrate)
NNI-0001 24 WG Insecticide (water dispersible granule)
NNI-0001 480 SC Insecticide (soluble concentrate)

Application Methods and Rates: Flubendiamide acts against various lepidopterous insect pests such as armyworms, bollworms, corn borers, cutworms, diamondback moths, fruitworms and loopers. Foliar spray applications can be made by aerial, ground or chemigation application on all crops as needed for insect control. Single application rates range from 0.03 to 0.16 lb. a.i./A and can be applied 3-5 times per season. Seasonal application rates range from 0.09 to 0.47 lb. a.i./A. Pre-harvest intervals (PHIs) range from 1 to 28 days. The proposed reentry interval (REI) is 12 hours on both labels. NNI-0001 24 WG Insecticide is a 24% a.i. water dispersible granule. NNI-0001 480 SC Insecticide is a 39% a.i. soluble concentrate.

HUMAN HEALTH RISK ASSESSMENT

Hazard and risk assessments were conducted in relation to this registration application and tolerance petition for the use of flubendiamide on corn, cotton, tobacco, tree fruit, tree nuts, vine crops and vegetable crops and suggest that its use, consistent with the proposed labeling measures, will be protective of the public health and the environment.

Acute Toxicity: Flubendiamide has a low order of acute toxicity via the oral, dermal and inhalation routes (Category III). Though it is a slight irritant to the eye, flubendiamide is not a skin irritant and it is not a skin sensitizer. The acute toxicity findings for flubendiamide are summarized below:

Acute Oral Toxicity: III
Acute Dermal Toxicity: III
Acute Inhalation: III
Primary Eye Irritation: IV
Primary Dermal Irritation: IV
Dermal Sensitization: Negative

Other Toxicity: In the longer-term studies in the flubendiamide mammalian toxicology database, the primary target organs identified were the liver, thyroid, kidney and eyes. Liver effects reported in rats, mice and/or dogs include organ

weight increase, periportal fatty change, hypertrophy, and minimal foci of cellular alteration. Thyroid effects include organ weight increase, follicular cell hypertrophy and slight perturbations of triiodothyronine (T3) and thyroid stimulating hormone (TSH) in the rat and mouse. Kidney effects include increases in absolute and/or relative to body kidney weights and chronic nephropathy in the rat. Eye effects include eye enlargement, opacity, and exophthalmus with hemorrhage and appear only in rat pups. Other changes include mild microcytic anemia, decreased serum triglycerides and cholesterol in female rat, increased gamma glutamyl peptidase, alkaline phosphatase and shortened activated prothrombin time in dogs and adrenal weight increase and increase in adrenal cortical cell hypertrophy in dogs.

The hazard assessment indicated potential toxicity resulting from exposure to flubendiamide via different routes over different durations. The observed eye effects were selected as a critical effect for the acute dietary exposure scenario; whereas liver and thyroid effects were determined critical for the chronic dietary exposure scenario. Short- and intermediate-term dermal risks were also based on liver and thyroid effects, as well as blood effects. Short- and intermediate-term inhalation risks are based on liver toxicity, as well as adrenal weight increase and an increase in adrenal cortical cell hypertrophy.

Metabolism: Rat metabolism studies at low and high doses report fairly rapid absorption, with peak blood and plasma levels reached at approximately 6 to 12 hours post-dosing followed by a continuous decline. The NNI-0001 was fairly well distributed among blood and most of the organs and tissues, with some preference to the liver, adrenal glands, and fat. Generally, the liver and kidneys contained the greatest percentage of the administered dose. Excretion of NNI-0001 residues was rapid (majority of radioactivity recovered at the first 24-hour collection point), with feces being the predominant route of excretion. Renal excretion accounted for only 2% and <1% of the dose in male and female rats, respectively. Parent NNI-0001, NNI-0001-benzylalcohol (A-16) and NNI-0001-benzoic acid (A-18) were the major residues identified in the feces. Additionally, metabolite A-14 was identified in the fat of female rats at 1% of the administered dose.

In vitro metabolism and toxicokinetic studies in multiple mammalian species appear to confirm the findings reported in the *in vivo* rat metabolism study, that female rats appear to metabolize the parent compound differently from male rats and other species. Female rats do not show an ability to convert the parent compound to the metabolite A-16 due to the lack of β-NADPH that is required for metabolism, indicating there was no abiotic degradation of the test compound in the test systems. The lack of abiotic degradation and the longer terminal elimination half-life of the parent compound in the female rats, differentiate them from other test animals.

Endpoints

Acute: The 2-generation reproduction, 1-generation reproduction and DNT studies, as 3 co-critical studies, were selected for the acute reference dose (aRfD) of 0.995

mg/kg/day using 99.5 mg/kg/day from the DNT study (the highest NOAEL) and a LOAEL from the 1-generation reproduction study of 127 mg/kg/day (the lowest LOAEL) based on buphthalmia (enlargement of eyes), ocular opacity, retinal degeneration, hemorrhage, cataract and atrophy of the optic nerve. The NOAEL/LOAEL chosen result in a more refined yet health protective acute dietary risk assessment.

The weight of evidence from various studies suggest that the finding of enlarged eyeballs in rat offspring is a rat-specific phenomenon, resulting from exposure to higher steady-state concentrations of flubendiamide which may be due to the uniquely diminished capacity of the female rat to oxidize the parent compound. While human microsomes have been shown to be capable of approximately 4 times higher hydroxylation rates than female mouse microsomes and may be able to efficiently metabolize/excrete flubendiamide, preventing accumulation of the parent compound, it remains unclear whether this ability is the only requirement to avoid ocular toxicity. Due to the potential concern for increased susceptibility of human neonates vs. adults, this perinatal ocular effect is considered in the HED risk assessment.

Chronic: The 1-year chronic rat study, 1-year chronic dog study and the 24-month rat carcinogenicity study were selected as 3 co-critical studies for the chronic reference dose (cRfD) of 0.024 mg/kg/day with a NOAEL/LOAEL of 2.4/33.9 mg/kg/day (highest NOAEL of 2.4 mg/kg/day from 1-year chronic rat study and lowest LOAEL of 33.9 mg/kg/day from 24-month rat study. Although the 1-year dog study had NOAELs of 2.21/2.51 mg/kg/day, the lowest NOAELs from each study were considered when comparing NOAELs among the 3 studies, respectively, based on the consistent liver toxicity reported across multiple studies, different durations and multiple species. The NOAEL/LOAEL chosen are protective of effects seen in other long-term studies.

Carcinogenicity: Flubendiamide is considered to be "Not Likely to be Carcinogenic to Humans." There was no evidence of carcinogenicity in rats and mice up to the limit dose at 24- and 18-months, respectively. Flubendiamide was determined to be non-mutagenic in bacteria, negative in an *in vivo* mammalian cytogenetics assay and did not cause unscheduled DNA synthesis (repair of DNA damage) in mammalian cells *in vitro*. Overall, there was no clear evidence that flubendiamide was either mutagenic or clastogenic in either *in vivo* or *in vitro* assays. Quantification of cancer risk is; therefore, not needed for flubendiamide.

FQPA Safety Factor: EPA evaluated the quality of the toxicity/exposure data and has determined that the safety of infants and children would be adequately protected if the FQPA safety factor (SF) were reduced to 1x based on the following findings: (1) The toxicology database for flubendiamide is complete for purposes of risk assessment and the characterization of potential pre- and/or post-natal risks to infants and children. Although susceptibility was identified in the toxicological database (eye effects), the selected regulatory PODs (which are based on clear NOAELs) are protective of these effects; therefore, the human health risk assessment is protective;

(2) There are no treatment-related neurotoxic findings in the acute neurotoxicity and DNT studies in rats. Although eye effects were observed in the DNT study, the PODs employed in the HED risk assessment are protective of this effect; and (3) There are no residual uncertainties identified in the exposure databases and the exposure assessment is protective.

Dietary Exposure

Acute Risk: The acute dietary analysis assumed that 100% of crops with requested uses of flubendiamide are treated and that all treated crops contain residues at tolerance-level. In addition, tolerance-level residues for livestock commodities were included in these analyses to account for the potential transfer of plant residues to livestock tissues. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 12.93 ppb was used to assess the contribution to drinking water. These assumptions result in conservative, health-protective estimates of exposure which are well below the Agency's LOC (100% of the aPAD). **The maximum exposure estimate is less than 8% of the aPAD for the most highly exposed population subgroup, children 1-2 years old. These analyses indicate that there are no acute dietary exposure considerations that would preclude registration of flubendiamide for the requested uses.**

Chronic Risk: The chronic dietary analysis assumed that 100% of requested crops are treated and that all treated crops contain residues at the average residue levels found in the crop field trials and experimentally-determined processing factors where available. In addition, average-level residues for livestock commodities were also included in these analyses to account for the potential transfer of plant residues to livestock tissues. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration value of 11.95 ppb was used to assess the contribution to drinking water. These assumptions result in conservative, health-protective estimates of exposure which are well below the Agency's LOC (100% of the cPAD). **The maximum exposure estimate is less than 15% of the cPAD the most highly exposed population subgroup, children 1-2 years old. These analyses indicate that there are no chronic dietary exposure considerations that would preclude registration of flubendiamide for the requested uses.**

Aggregate Risk: The aggregate risk assessment considers dietary exposures from food and drinking water to flubendiamide consumed over the acute and chronic durations. **Acute and chronic dietary exposure is well below the Agency's LOC and there are no acute or chronic dietary exposure considerations that would preclude registration of flubendiamide for the requested uses.**

Residue Chemistry: The nature of the residue in plants, rotational crops and ruminants is adequately understood. For the purposes of tolerance establishment and

dietary/drinking water risk assessment, the residue of concern in plants, animals and rotational crops is the parent flubendiamide *per se*.

Tolerances have been established in 40 CFR §180.639 in or on the following food commodities: almond, hulls (9.0 ppm); apple, wet pomace (2.0 ppm); *brassica*, head and stem, subgroup 5A (0.60 ppm); *brassica*, leafy greens, subgroup 5B (5.0 ppm); cattle, fat (0.30 ppm); cattle, kidney (0.30 ppm); cattle, liver (0.30 ppm); cattle, muscle (0.05 ppm); corn, field, forage (8.0 ppm); corn, field, grain (0.02 ppm); corn, field, stover (15 ppm); corn, pop, grain (0.02 ppm); corn, pop, stover (15 ppm); corn, sweet, forage (9.0 ppm); corn, sweet, kernel plus cob with husks removed (0.01 ppm); corn, sweet, stover (25 ppm); cotton gin byproducts (60 ppm); cotton, undelinted seed (0.90 ppm); egg (0.01 ppm); fruit, pome, group 11 (0.70 ppm); fruit, stone, group 12 (1.6 ppm); goat, fat (0.30 ppm); goat, kidney (0.30 ppm); goat, liver (0.30 ppm); goat, muscle (0.05 ppm); grain, aspirated fractions (5.0 ppm); grape (1.4 ppm); horse, fat (0.30 ppm); horse, kidney (0.30 ppm); horse, liver (0.30 ppm); horse, muscle (0.05 ppm); milk (0.04 ppm); milk, fat (0.30 ppm); nut, tree, group 14 (0.06 ppm); okra (0.30 ppm); poultry, fat (0.02 ppm); poultry, liver (0.01 ppm); poultry, muscle (0.01 ppm); sheep, fat (0.30 ppm); sheep, kidney (0.30 ppm); sheep, liver (0.30 ppm); sheep, muscle (0.05 ppm); vegetable, cucurbit, group 9 (0.20 ppm); vegetable, fruiting, group 8 (0.60 ppm) and vegetable, leafy, except *brassica,* group 4 (11 ppm); and in or on the following raw agricultural commodities: alfalfa, forage (0.15 ppm); alfalfa, hay (0.04 ppm); barley, hay (0.04 ppm); barley, straw (0.07 ppm); buckwheat (0.07 ppm); clover, forage (0.15 ppm); clover, hay (0.04 ppm); grass, forage (0.15 ppm); grass, hay (0.04 ppm); millet, pearl, forage (0.15 ppm); millet, pearl, hay (0.04 ppm); millet, proso, forage (0.15 ppm); millet, proso, hay (0.04 ppm); millet, proso, straw (0.07 ppm); oats, forage (0.15 ppm); oats, hay (0.04 ppm); oats, straw (0.07 ppm); rye, forage (0.15 ppm); rye, straw (0.07 ppm); sorghum, grain, forage (0.03 ppm); sorghum, grain, stover (0.06 ppm); soybean, forage (0.02 ppm); soybean, hay (0.04 ppm); teosinte, forage (0.15 ppm); teosinte, hay (0.04 ppm); teosinte, straw (0.07 ppm); triticale, forage (0.15 ppm); triticale, hay (0.04 ppm); triticale, straw (0.07 ppm); wheat, forage (0.15 ppm); wheat, hay (0.03 ppm) and wheat, straw (0.03 ppm).

At this time, there are currently no established CODEX, Canadian or Mexican MRLs established for residues of flubendiamide *per se* in crop or livestock commodities.

Occupational: No chemical-specific data for assessing human exposures during pesticide handling activities were submitted in support of the registration of flubendiamide. EPA used surrogate data from the PHED Version 1.1 (PHED Surrogate Exposure Guide, August 1998) to assess exposures. The level of concern is a Margin of Exposure (MOE) of less than 100. **All occupational handler MOEs for flubendiamide are estimated to be greater than 100 at some level of risk mitigation for the proposed uses.** Combined dermal plus inhalation risks are not a concern, provided that: (1) Baseline attire (long-sleeved shirt and long pants and shoes plus socks) is worn by all occupational handlers; (2) Handlers mixing and loading liquid concentrates to support aerial and chemigation applications wear

chemical-resistant gloves such as barrier laminate, butyl rubber, nitrile rubber or viton; and (3) Pilots use enclosed cockpits.

There is the possibility for agricultural workers to have post-application exposure to flubendiamide following its proposed agricultural crop uses. Therefore, occupational post-application exposures and risks were assessed using data from flubendiamide-specific DFR studies and using EPA's default assumptions that 20% of the initial application is available for transfer on day 0 (*i.e.*, 12 hours after application) and that the residue dissipates at a rate of 10% per day following treatment.

For flubendiamide, the exposure durations for non-cancer post-application risk assessment were short- (1 to 30 days) and intermediate-term (>30 days and up to several months). However, since the dermal toxicological endpoint of concern is the same for short- and intermediate-term exposures, the short- and intermediate-term post-application risks are numerically identical. **Inhalation exposures are thought to be negligible in outdoor post-application scenarios, since flubendiamide has a relatively low vapor pressure (7.5×10^{-7} mm Hg).**

It should be noted that the grape and corn flubendiamide-specific DFR data indicate that flubendiamide does not dissipate characteristically in a steady state. Rather, there is evident fluctuation up and then down, though the ultimate trend is downwards. In fact, the highest residue value detected in the entire study was detected on corn on the 2nd day after the last treatment. That observation (0.390 $\mu g/cm^2$) is higher than the residue value calculated for corn using EPA default assumptions (0.21 $\mu g/cm^2$) by a factor of 1.86 (0.390/0.21 = 1.86). To ensure that the post-application assessments, using default DFRs are protective, EPA conducted a highly conservative assessment assuming that all the default DFRs would be 1.86x higher if flubendiamide-specific data were generated on each of those crops (an assumption that is not likely, since in the case of grapes, the DFR residues were less than the default assumptions). **Therefore, even when assuming an extraordinarily worse-case scenario, post-application exposure to flubendiamide does not pose a risk to occupational workers.**

Flubendiamide is classified in acute toxicity category III for acute dermal toxicity and category IV for primary eye irritation and primary skin irritation. It is not a dermal sensitizer. **A restricted entry interval (REI) of 12 hours is appropriate and meets the requirements of the Worker Protection Standard for Agricultural Pesticides (WPS).**

ENVIRONMENTAL RISK ASSESSMENT

Ecological Effects

The Agency has determined, based on the proposed uses, that there is no potential risk to freshwater and marine fish, marine crustaceans, marine mollusks and aquatic plants at the limit of solubility for parent flubendiamide. In addition, there is no

potential acute risk or reproductive effects to birds and mammals, earthworms, beneficial insects including honey bees and natural Lepidoptera predators, and terrestrial plants for all of the proposed uses.

There is a potential risk to freshwater benthic invertebrates exposed to flubendiamide and its degradate des-iodo. EPA has compared the body of toxicological data for the parent compound and des-iodo. With the possible exception of chronic testing with chironomid midges, there is no apparent difference in toxicity evident from the available data. In the case of the chironomid data, conversion of effect endpoints to pore water units results in an estimated NOAEC for the parent compound of approximately 1 μg/L. The corresponding NOAEC for des-iodo is 0.28 μg/L. Because of the estimated nature of the parent compound NOAEC (the value is estimated from the relationship between nominal and pore water measurements at other dose levels because actual measurements of pore water concentrations were not made at the NOAEC level) and because NOAEC comparisons are usually confounded by the dose selections at study design onset, EPA concluded that there was insufficient data to demonstrate a significant difference in toxicity between the parent and degradate. However, for the purposes of risk assessment and in consideration of the use of data as prescribed in the Agency's Risk Assessment Overview Document, risk calculations are based on the chronic endpoints established for each chemical, specifically.

Using these NOAEC values, RQs for parent flubendiamide would range from 0.94 to 21.3. Considering only the accumulation within the first 30 years of use for all of the crop scenarios, RQs for the des-iodo degradate would range from 0.03 to 6.9 in the 1st year, 2.9 to 64 in the 10th year, 4.9 to 127 in the 20th year and 12 to 190 in the 30th year. Uncertainties in the model results make longer term estimates of accumulation and risk unreliable. However, due to the persistence of both the parent and degradate, there is a concern for potential accumulation in aquatic sediments over time.

Testing of the formulated products 480 SC and 24 WG resulted in RQs ranging up to 0.1 for freshwater invertebrates. Results of a mesocosm study conducted with the formulated products also did not identify any serious risk concerns for water column invertebrates.

Adult ladybird beetles are potentially at risk due to ingestion of food items (aphids and pollen) containing flubendiamide residues. In addition, there is a potential direct risk to non-target lepidopterous species, including endangered species. Lepidoptera may occur in areas adjacent to treated fields, where they may be exposed to spray drift, and will likely move through treated fields. Further, the larvae of some lepidopterous species are aquatic and; therefore, may be exposed to both the parent formulation and the des-iodo degradate.

The Agency is concerned about the possible accumulation of flubendiamide and des-iodo in aquatic sediments and the effects that this would have on freshwater benthic organisms. However, given the benefits described below, the Agency is granting

registration for this chemical at this time. The risk mitigation required and conditions of registration for this chemical, as described below, are designed to address these concerns and to provide adequate information that will allow the Agency to determine: (1) if the required risk mitigation is adequate or, if this is still uncertain; and (2) through a monitoring program, determine the rate and extent of accumulation of the parent and degradate in the most vulnerable areas of use during the time period of the 5-year conditional registration.

Environmental Fate and Transport

Hydrolysis/Photolysis: Flubendiamide is stable to hydrolysis under laboratory conditions, but direct aqueous photolysis appears to be a main route of degradation. Flubendiamide degrades to NNI-0001-des-iodo (des-iodo), with a half-life estimated as 11.56 days. Flubendiamide degrades to des-iodo under laboratory soil photolysis with a half-life estimated as 35.3 days. Volatilization from soil and water surfaces is not expected to be an important dissipation route since flubendiamide has a relatively low vapor pressure (7.5×10^{-7} mm Hg) and Henry's Law constant (8.9×10^{-11} atm·m^3/mol).

Mobility/Transport: Flubendiamide is expected to be slightly to hardly mobile (K_{FOC} = 1,076 to 3,318 L/Kg). Des-iodo is expected to be moderately mobile (K_{FOC} = 234 to 581 L/kg). The main transformation product, des-iodo, is more mobile than the parent; however, des-iodo was only detected in a small quantity (<3.4% of the applied) at the 0 to 15 cm soil depth at 3 sites in the terrestrial field studies. Flubendiamide and des-iodo have the potential to contaminate surface water through run-off due to their persistence in soil and also have the potential for groundwater contamination in vulnerable soils with low organic carbon content, after heavy rainfall and/or in areas with high water tables (because there is less depth to travel before reaching groundwater).

Soil/Water Degradation: Flubendiamide is stable under aerobic and anaerobic soil metabolism and aerobic aquatic metabolism laboratory conditions. In aerobic and anaerobic aqueous environments, flubendiamide is expected to dissipate somewhat faster than in aerobic soil, likely as a result of metabolism. Laboratory experiments using anaerobic and aerobic aquatic systems resulted in flubendiamide half-lives (water plus soil/sediment) of 127 to 364 days and 32.8 to 533.2 days, respectively. Anaerobic aquatic metabolism is another main route of degradation for flubendiamide. Flubendiamide degrades to des-iodo under anaerobic aquatic conditions with a half-life estimated as 365 days. Flubendiamide and des-iodo's overall stability/persistence suggests that they will accumulate in soils, water column and sediments with each successive application.

Terrestrial Field Dissipation: Flubendiamide also degrades in the field condition very slowly. In terrestrial field experiments, flubendiamide half-lives in 3 soils ranging from loamy sand to silt loam were 210 to 770.2 days (leaching to a depth of 30 to 60 cm) and in a sandy loam soil under outdoor conditions, the half-life was 322 days. In an aerobic soil environment, flubendiamide is expected to dissipate slowly. In the

laboratory using 4 soils ranging from loamy sand to silt, flubendiamide was stable with <5% of the applied chemical dissipating at 371 days post-treatment.

REGULATORY DECISION

Conditional Registration: A 5-year conditional registration has been granted for flubendiamide use as an insecticidal control of various lepidopterous insect pests on corn, cotton, tobacco, tree fruit, tree nuts, vine crops and vegetable crops.

Flubendiamide may be a viable alternative to comparably registered and existing pesticides that tend to pose greater risk concerns and may also be an important tool as a rotational insecticide to limit or prevent the development of resistance to other insecticide chemistries. Flubendiamide has also been identified as an OP alternative for the control for the control of leafroller and fruitworm pests in tree fruit production, where the dominant pesticides used have been azinphos-methyl, chlorpyrifos and phosmet.

The EFED risk assessment; however, suggests that both flubendiamide and des-iodo will accumulate to concentrations in aquatic environments that will pose risk to freshwater benthic invertebrates. As a result, EPA is requiring certain measures which the Agency believes may be effective in mitigating the apparent risk, including the requirement 15-foot vegetative buffer zones which are expected to reduce run-off of both parent and degradate to the aquatic environment, reduced application rates and other labeling statements which reduce the allowable total loading in one year and environmental hazards, ground water and surface water advisories.

To confirm the utility of the 15-foot vegetative buffers, the Agency is requiring a small-scale run-off/vegetative buffer strip study. If the utility of the 15-foot buffers cannot be demonstrated to achieve reductions in off-site transport and aquatic organism risk that would alleviate the risk concern, the Agency is requiring a monitoring program, the results of which allow the Agency to determine, at the end of the 5-year conditional registration, the rate and extent of accumulation in the most vulnerable use areas. If there are risk concerns at that time that result in the Agency being unable to determine that there are no reasonable adverse effects to the environment, the registrants have agreed that the pesticide will be voluntarily cancelled.

Conditional Data: The registrant has committed to submit the following data:

1. Flubendiamide
   - (Non-guideline) **Small-Scale Runoff/Vegetative Buffer Strip Study** – The quantitative efficacy of vegetative buffers for flubendiamide use is uncertain. To determine the magnitude of the parent, flubendiamide, retained in buffer strips, the small-scale run-off/vegetative buffer strip study and monitoring program will allow the Agency to quantitatively consider the impact of such buffers on the risk picture. The protocols for the studies will be mindful of the

need to both consider the variety of proposed use sites as well as a variety of buffer conditions.

If the employment of label enforceable buffers is empirically demonstrated to alleviate the risk concern, then no further work need be conducted. However, if buffers cannot be demonstrated to achieve these meaningful risk reductions, the other areas of critical uncertainty in the modeling assumptions must be considered. In this case, there is considerable uncertainty in the application of the EXAMS pond scenario for chemicals with suspected aquatic system accumulation. Additional information on the actual potential for the pesticide to build up in receiving waters would address the uncertainty associated with current model limitations. Therefore, a monitoring study of receiving waters within watersheds where flubendiamide will be used will be required.

2. Des-iodo Degradate
   - (161-1) **Hydrolysis** – A hydrolysis study to establish the significance of chemical hydrolysis as a route of degradation for des-iodo and to identify, if possible, the hydrolytic products formed to provide initial information on whether they may exhibit structures that may potentially adversely affect non-target organisms.

   - (162-4) **Aerobic Aquatic Metabolism** – An aerobic aquatic metabolism study to determine the effects of des-iodo on aerobic conditions in water and sediments during the period of dispersal of des-iodo throughout the aquatic environment and to compare rates and formation of metabolites. The data from this study would provide the aerobic aquatic input parameter for PRZM/EXAMS; therefore, potentially reducing modeling uncertainty.

3. For the submitted GLN 860.1850 Confined Rotational Crop studies (MRIDs 46817133 and 46817134), the registrant will submit extraction and analysis dates of samples in order to confirm that samples were extracted and analyzed within the stated intervals (or within 6 months of harvest). Otherwise, additional storage stability data may be required by EPA.

BENEFIT DETERMINATIONS: Since flubendiamide is a novel chemistry, the Agency believes that it may be a viable alternative to comparably registered and existing pesticides that tend to pose greater risk concerns. Also, it may be an important tool as a rotational insecticide to limit or prevent the development of resistance to other insecticide chemistries. BEAD's preliminary analysis of the material submitted by the registrant concludes that flubendiamide provides Lepidoptera control equivalent or superior to the insecticides currently being used for pest control in the evaluated crops. Materials submitted also suggest low toxicity to terrestrial insect predators and honey bees which should make flubendiamide an important component in IPM programs.

When assessing recent pesticide usage data for currently registered insecticide products aimed at controlling lepidopterous pests in corn, several market leaders are of concern to

the Agency. Flubendiamide's toxicity to terrestrial organisms is low, especially in comparison to the current active ingredients most commonly used against the labeled target pests.

For pesticides used to control cotton pests such as the beet armyworm and bollworm, the usage information for products used in 2007 was more broadly distributed among chemical pesticides than that indicated for corn usage, with a number of synthetic pyrethroids, namely lambda cyhalothrin, and other chemistries such as acephate and chlorpyrifos leading the usage profile.

In addition, flubendiamide has been identified as an organophosphorus pesticide alternative for the control of leafroller and fruitworm pests in tree fruit production, where the dominant pesticides used have been azinphos-methyl, chlorpyrifos and phosmet. Therefore, flubendiamide is a chemical that broadens the diversity of pest control measures available to growers for the reasons stated above.

REQUIRED LABEL STATEMENTS

The end-use product labels containing flubendiamide as an active ingredient will be amended as follows:

1. Requirement of 15-foot vegetative buffer zones and the addition updated spray drift language for aerial/ground applications for similar products with similar use patterns on both end-use labels.

2. On the proposed label for 24 WG, the registrant will reduce application rates, revise the maximum amount of product applied per acre "per year" to a "per crop season" basis and remove the number of applications per crop season for the *Brassica*, Cucurbits, Leafy Vegetables and Fruiting Vegetables crop groupings in order to reduce the per year loading allowed.

3. Addition of revised environmental hazards, ground water and surface water advisories to both end-use labels.

4. On the proposed label for 480 SC, the registrant will be required to clearly articulate what application method(s) are proposed for each listed crop.

5. The proposed rotational crop restriction for root crops (root, tuber and bulb vegetables), which specifies that "*treated areas may be replanted immediately following harvest, or as soon as practical following the last application*" will be revised to a 30-day plant-back interval on both end-use labels.

GOVERNMENT PERFORMANCE AND RESULTS ACT (GPRA)

Registering flubendiamide will meet the objectives of GPRA title 3.1.1 by assuring new pesticides that enter the market are safe for humans and the environment.

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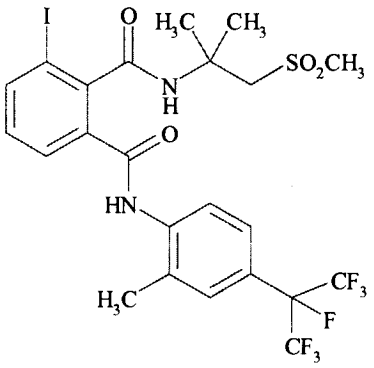
Appendix 1 -- Structure and Nomenclature

Flubendiamide Nomenclature.	
Chemical structure	
Empirical Formula	$C_{23}H_{22}F_7IN_2O_4S$
Common name	Flubendiamide (proposed ISO name)
Company experimental name	NNI-0001
IUPAC name	N^2-[1,1-Dimethyl-2-(methylsulfonyl)ethyl-3-iodo-N^1-{2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl}phthalamide
CAS name	N^2-[1,1-Dimethyl-2-(methylsulfonyl)ethyl-3-iodo-N^1-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide
CAS registry number	272451-65-7
End-use products (EPs)	NNI-0001 480 SC (EPA File Symbol 264-XXX) NNI-0001 24 WG (EPA File Symbol 264-XXX)
Chemical Class	Phthalic acid diamide insecticide
Known Impurities of Concern	None

Appendix 2 -- Physical and Chemical Properties

Physicochemical Properties of Flubendiamide.			
Parameter	Value		Reference
Molecular weight	682.39 g/mol		Product Chemistry Review of Flubendiamide Technical.
Melting point/range	217.5-220.7 °C		
pH	6.05 (20 °C)		
Density	1.659 g/mL (20 °C)		
Water solubility	29.90 µg/mL (20 °C)		
Solvent solubility	Solvent	Solubility (g/L)	
	p-xylene	0.488	
	n-heptane	0.000835	
	methanol	26.0	
	1,2-dichloroethane	8.12	
	acetone	102	
	ethyl acetate	29.4	
Vapor pressure	10^{-4} Pa (25°C)		
Dissociation constant, pK_a	Does not dissociate		
Octanol/water partition coefficient, $Log(K_{OW})$	4.2 (pH 5.9, 25°C)		
UV/visible absorption spectrum	204.4 nm (neutral methanol)		

Appendix 3 – Toxicity Profiles

Acute Toxicity Profile – Flubendiamide				
Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral – rat	46817144	LD50 = >2000 mg/kg	III
870.1200	Acute dermal- rat	46817147	LD50 = >2000 mg/kg	III
870.1300	Acute inhalation – rat	46817150	LC50 = >0.0685 mg/L	III
870.2400	Acute eye irritation –rabbit	46817203	Irritating (slight)	IV
870.2500	Acute dermal irritation – rabbit	46817206	Non-irritating	IV
870.2600	Skin sensitization – guinea pig	46817209	Negative	N/A

Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
870.3050	28-Day Oral (rat) **Not Submitted***	ppm: 0 – 20 – 50 – 200 – 2000 – 20000 mg/kg/day: M: 0 – 1.53 – 3.88 – 15.1 – 52 – 1575 F: 0 – 1.63 – 4.17 – 16.1 – 156 – 1605	NOAEL (M/F) = 15.1 / 4.17 mg/kg/day LOAEL (M/F) = 152 / 16.1 mg/kg/day based on: liver: ↑(m/f)– periportal fatty change, ↑wt [abs/rel (m/f)] ↓(f)– ALP ↑(f)– GPT
870.3050	28-Day Oral (mice) **Not Submitted***	ppm: 0 – 20 – 200 – 2000 – 20000 mg/kg/day: M: 0 – 2.73 – 26.9 – 265 – 2678 F: 0 – 2.88 – 30.0 – 299 – 3024	NOAEL (M/F) = 26.9 / 30.0 mg/kg/day LOAEL (M/F) = 265 / 299 mg/kg/day based on: liver: ↑(m/f)– hypertrophy (centrilobular hepatocytes);↑(m)–[dark-colored + fatty change (centrilobular hepatocytes)]
870.3050	28-Day oral toxicity (dog) **Not Submitted***	ppm: 0 – 40 – 400 – 4,000 – 40,000 mg/kg/day: M: 0 – 1.12 – 10.7 – 101 – 1111 F: 0 – 1.10 – 12.0 – 120 – 1180	NOAEL (M/F) = 10.7 / 1.10 mg/kg/day LOAEL (M/F) = 101 / 12.0 mg/kg/day based on: ↑(m/f)– ALP
870.3100	90-Day oral toxicity (rat)	46817210 (2003)/ Acceptable/guideline ppm: 0 – 20 – 50 – 200 – 2000 – 20000 mg/kg/day: M: 0 – 1.15 – 2.85 – 11.4 – 116 – 1192 F: 0 – 1.30 – 3.29 – 13.1 – 128 – 1320	NOAEL (F) = 13.1 mg/kg/day LOAEL (F) = 128 mg/kg/day based on: slight hepatotoxicity (↑(f) – periportal fatty change, hepatocellular hypertrophy, ↑wt [abs/rel(f)], ↑GGT

Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
870.3150	90-Day oral toxicity (mouse)	46817211 (2002)/ Acceptable/guideline ppm: 0 – 50 – 100 – 1000 – 10000 mg/kg/day: M: 0 – 6.01 – 11.9 – 123 – 1214 F: 0 – 7.13 – 14.7 – 145 – 1424	NOAEL (M/F) = 11.9 / 14.7 mg/kg/day LOAEL (M/F) = 123 / 145 mg/kg/day based on slight hepatotoxicity: (↑fatty change, hepatocellular hypertrophy, ↑ abs/rel wt [f])
870.3150	90-Day oral toxicity (dog)	46817212 and 46817242 (2003)/ Acceptable/guideline ppm: 0 – 100 – 2000 – 40000 mg/kg/day: M: 0 – 2.58 – 52.7 – 1076 F: 0 – 2.82 – 59.7 – 1135	NOAEL (M/F) = 2.58 / 2.82 mg/kg/day LOAEL (M/F) = 52.7 / 59.7 mg/kg/day based on clinical signs of toxicity (loose stool), shortened APTT, increased ALP and triglycerides, increased adrenal weights, and microscopic effects on the adrenal glands in females: adrenal: ↑(f) – cortical hypertrophy; ↑(f) – wt ↓(m/f) – APTT ↑ – [ALP(m/f), Triglycerides(f)]
870.3200	28/29-Day dermal toxicity (rat)	46817213 (2004)/ Acceptable/guideline mg/kg/day: 0 – 10 – 100 – 1000	NOAEL = 100 mg/kg/day (systemic); 1000 mg/kg/day (local skin) LOAEL = 1000 mg/kg/day based on: liver: ↑(m/f)–periportal fatty change + ↑wt [abs/rel]; thyroid: ↑(f)–follicular cell hypertrophy ↓(f) –[Hct + MCV + MCH] ↓(f) – AST
870.3700a	Prenatal developmental in (rat)	46817215 and 46817241 (2003)/ Acceptable/guideline mg/kg/day: 0 – 10 – 100 – 1000	**Maternal:** NOAEL = 10 mg/kg/day; LOAEL = 100mg/kg/day based on: liver: ↑wt[abs/rel]. **Developmental:** NOAEL >1000 mg/kg/day; LOAEL was not observed (>1000 mg/kg/day).
870.3700b	Prenatal developmental in (rabbit)	46817214 and 46817240 (2002)/ Acceptable/guideline mg/kg/day: 0 – 10 – 100 – 1000	**Maternal:** NOAEL = 100 mg/kg/day; LOAEL = 1000 mg/kg/day based on: food consumption decreaseon last day of treatment (GD27-28) and loose stool **Developmental:** NOAEL >1000 mg/kg/day; LOAEL not observed (>1000 mg/kg/day)

Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
870.3800	Two-generation Reproduction and fertility effects (rat)	46817216 (2004)/ Acceptable/guideline ppm: 0 – 20 – 50 – 2000 – 20000 mg/kg/day (premating doses): Pm: 0 – 1.30 – 3.30 – 131 – 1307 Pf: 0 – 1.59 – 3.95 – 159 – 1577 F1m: 0 – 1.64 – 4.05 – 162 – 1636 F1f : 0 – 1.84 – 4.59 – 176 – 1808	**Parental/Systemic**: NOAEL (M/F) = 3.30 / 3.95 mg/kg/day; LOAEL (M/F) = 131/159 mg/kg bw/day based on: liver: ↑P/F1m–[brown pigment deposition + wt (rel)]; ↑Pf /F1f –[enlarged/dark-colored livers + hepatocyte hypertrophy + periportal fatty change + brown pigment deposition + wt]; thyroid: ↑P/F1 –[follicular cell hypertrophy]; ↑wt (abs Pm); kidney: ↑Pf –[tubular basophilic change + urinary casts]; ↑Pf /F1f – wt; ovary: ↑Pf –interstitial cell vacuolation; uterus: ↑wt (Pf); pituitary: ↓wt (F1); spleen: ↓wt (Pf /F1f) **Reproductive**: No effect of treatment on: precoital interval; mating, fertility, or gestation indices; or gestation duration in either generation. Furthermore, the numbers of primordial ovarian follicles in the 20,000 ppm F1 dams were comparable to controls. No effects were noted on estrous cycle duration or sperm parameters. The NOAEL is 20,000 ppm (1307/1577 mg/kg/day males/females, respectively). The LOAEL for reproductive toxicity was not observed. **Offspring:** NOAEL = 3.30 mg/kg/day; LOAEL = 131 mg/kg/day based on: liver: ↑–[hepatocyte hypertrophy, diffuse fatty change, brown pigment deposition, proliferation bile ducts; wt]; thyroid: ↑follicular cell hypertrophy; spleen + thymus: ↓wt; ↑eyeball enlargement
	One-generation reproduction study in rat	46817239 (2004)/Acceptable/nonguideline ppm: 0-50-200-2000-20,000 mg/kg/day: Pm: 0-3.25-12.91-127.2-1287 Pf: 0-3.84-14.97-148.9-1490	**Parental:** LOAEL is 2000 ppm (127.2/148.9 mg/kg/day in amles/females, respectively) bsed on effects on the liver, thyroid, and kidneys. The NOAEL is 200 ppm (12.91/14.97 mg/kg/day in males/females, respectively). **Reproductive:** The LOAEL was not observed and the NOAEL is 20,000 ppm (1287/1490 mg/kg/day in males/females, respectively). **Offspring:** The LOAEL is 2000 ppm (127.2/148.9 mg/kg/day in males/females, respectively) based on effects on the eyes and liver; and on increased anogenital distance and delayed sexual maturation in the males. The NOAEL is 200 ppm (12.91/14.97 mg/kg/day in males/females, respectively).

Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
	Histopathology of the Eyes of Weanlings in a One-generation Reproduction Study in Rats	46817238/Acceptable/non-guideline ppm: 0-50-200-2000-20,000 mg/kg/day: Pm: 0-3.25-12.91-127.2-1287 Pf: 0-3.84-14.97-148.9-1490	**Offspring:** The LOAEL for offspring toxicity is 2000 ppm (127.2/148.9 mg/kg/day in males/females, respectively) bsed on confirmed microscopic effects on the eyes in both sexes. The NOAEL is 200 ppm (12.91/14.97 mg/kg/day in males/females, respectively).
	Perinatal Ocular Toxicity Study in CD-1 Mice following exposure via diet	46817236/ non-guideline approx. 1000 mg/kg/day from day 6 post conception until lactation day 21	Eye lesions of viable pups were noted neither during the lactation period nor during the follow-up period lasting from PND 22-42. **Offspring:** The LOAEL for offspring toxicity is 4500/2000 ppm (equivalent to 1052.3 mg/kg/day) based on decreased pup body weights and body weight gains. The NOAEL was not established.
870.4100a	Chronic toxicity (rat)	46817217 (2004)/ Acceptable/guideline ppm: 0 – 20 – 50 – 2000 – 20000 mg/kg/day: M: 0 – 0.8 – 2.0 – 79.3 – 822 F: 0 – 1.0 – 2.4 – 97.5 – 998	NOAEL (F) = 2.4 mg/kg/day. LOAEL (F) = 97.5 mg/kg/day based on: hepatotoxicity (periportal fatty change, hepatocyte hypertrophy, ↑wt [abs/rel] and ↑GGT
870.4100b	Chronic toxicity (dog)	46817218 Acceptable/guideline ppm: 0 – 100 – 1500 – 20000 mg/kg/day: M: 0 – 2.21 – 35.2 – 484 F: 0 – 2.51 – 37.9 – 533	NOAEL (M/F) = 2.21 / 2.51 mg/kg/day. LOAEL (M/F) = 35.2 / 37.9 mg/kg/day based on: liver: ↑wt [abs m+f, rel(m)] ↓(m) – BWG and BW ↓ –[APTT(m/f), ↑(m/f) – ALP
870.4200a	Carcinogenicity (rat)	46817219 (2004)/ Acceptable/guideline ppm: 0 – 50 – 1000 – 20000 mg/kg/day: M: 0 – 1.70 – 33.9 – 705 F: 0 – 2.15 – 43.7 – 912	NOAEL (M/F) = 1.70 / 2.15 mg/kg/day. LOAEL (M/F) = 33.9 / 43.7 mg/kg/day based on: liver: ↑(m/f)– [periportal fatty change, hypertophy] ;↑wt [abs/rel(m/f)]; kidney: ↑(m/f)– chronic nephropathy; ↑wt [rel(f)] **No evidence of carcinogenicity**
870.4200b	Carcinogenicity (mouse)	46817220 (2004)/ Acceptable/guideline ppm: 0 – 50 – 1000 – 10000 mg/kg/day: M: 0 – 4.85 – 94 – 988 F: 0 – 4.44 – 93 – 937	NOAEL (M/F) = 4.85 / 4.44 mg/kg/day. LOAEL (M/F) = 94 / 93 mg/kg/day based on: hepatotoxicity (periportal fatty changes, hypertophy); thyroid changes (↑follicular cell hypertrophy with hydropic change, ↑large sized follicles) **No evidence of carcinogenicity**

Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
870.5100	Gene mutation (in vitro bacteria)	46817221 Acceptable/guideline 0 – 3.86 – 11.6 – 34.7 – 104 – 313 µg/plate (w/o activation) 0 – 61.7 – 185 – 556 – 1,670 – 5,000 µg/plate (+ activation)	Negative
870.5100	Gene mutation (in vitro bacteria)	46817222 Unacceptable/guideline 0 – 16 – 50 – 158 – 500 – 1581 – 5000 µg /plate (+/- S9 activation) (conducted w/ NNI-0001 SC)	Negative
870.5300	Gene Mutation (*in vitro* mammalian V79)	46817224 Acceptable/guideline 0 – 7.5 – 15 – 30 – 60 - 120 – 240 µg/ml (+/ – activation)	Negative
870.5375	Mammalian Cytogenetics (*in vitro* CHL)	Acceptable/guideline 0 – 550 – 1100 – 2200 µg/ml (+ activation) 0 – (125-550) – (250-1100) – (500-2200) µg/ml; 6, 20, or 40 hrs exp. (w/o activation)	Negative
870.5395	Mammalian Cytogenetics (micronucleus mouse)	46817226 Acceptable/guideline 0 – 1000 – 2000 – 4000 mg/kg	Negative
870.5395	Mammalian Cytogenetics (micronucleus mouse)	46817225 Acceptable/guideline 0 – 500 – 1000 – 2000 mg/kg	Negative
870.6200a	Acute neurotoxicity screening battery	46817227 Acceptable/guideline mg/kg/day: 0 – 209 – 731 – 2213 (analytically determined)	NOAEL = 2213 mg/kg/day LOAEL = Not observed (>2213 mg/kg/day)
870.6300	Developmental neurotoxicity	46817228 Acceptable/non-guideline ppm: 0 – 120 – 1200 – 12000 ppm mg/kg/day (based on last 2 wks of gestation and 3 wks of lactation): 0 – 9.9 – 99.5 – 979.6	**Maternal:** NOAEL = 9.9 mg/kg/day LOAEL = 99.5 mg/kg/day based on: liver: ↑wt[abs/rel]. **Offspring:** NOAEL = 9.9 mg/kg/day LOAEL = 99.5 mg/kg/day based on ↑balanopreputial separation time: this LOAEL is also protective of adverse eye effects reported at 979.6 mg/kg/day (eye – [enlarged eyeball + exophthalamus + general ocular opacity(m)])

Subchronic, Chronic and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
870.7485	Metabolism and pharmacokinetics - rat	46817229, 46817230 and 46817231 Acceptable/guideline	Oral absorption = 23.5/34.1% in m/f, respectively (average = 29%); see Section 3.2 Appendix A.3 for more information
870.7600	Dermal penetration (monkey)	46817234 Acceptable/non-guideline	Intravenous injection of [14C]NNI-0001resulted in excretion of a large fraction of the dosed radioactivity in feces. Total recoveries through 360 hours post-dose were 80.91% in feces, 7.78% in urine, and 4.11% in cage debris/rinse samples. Dermal application of [14C]NNI-0001 resulted in a negligible absorption of 0.02% at 8 hrs post-dose. The overall mean total recovery of radioactivity from excreta and from the application site was 105.15%, the majority of which was associated with the radioactivity recovered from the application site.
870.7800	4-week Immunotoxicity (plaque-forming assay in rat)	46817243 Acceptable/guideline ppm: 0 – 40 – 400 – 4000 mg/kg/day: M: 0 – 3.34 – 33.6 – 336.3 F: 0 – 4.0 – 38.4 – 358.8	NOAEL (M/F) = 336/358.8 mg/kg/day. No evidence of primary immunotoxicity
	Effects on Thyroid Hormones and Liver Enzymes in Female Rats	46817235 Acceptable/non-guideline ppm: 0-1000-10,000 mg/kg/day: 0-83-812	Study generally support this indirect effect on the thyroid via induction of enzymes in the liver. Direct effects on the liver included increases in organ weights, cytochrome P450, UDP-GT and EROD activities, and incidences of hepatocyte hypertrophy and vacuolation.
	In vitro Metabolism in rat, mouse, dog and human microsomes	46817232 Acceptable/Non-guideline	see Appendix A.3 for more information
	Toxicokinetic study in rats and mouse	46817233 Acceptable/Non-guideline	see Appendix A.3 for more information

*The studies designated as "Not Submitted" were included in the registrant's toxicity profile table, which in turn was in the registrant's human health risk assessment (MRID 46817252, p. 42); there are reported here in order to be as thorough, complete and inclusive as possible.

Appendix 4 – Ecological Effects Data

Ecological Effects Data Requirements for Flubendiamide					
Guideline #		Data Requirement	Formulation	MRID (Accession #)	Study Classification
71-1	850.2100	Avian Oral LD_{50}	Technical 480 SC	46817003 46817004	Acceptable Acceptable
71-2	850.2200	Avian Dietary LC_{50}	Technical Technical	46817005 46817006	Acceptable Acceptable
71-4	850.2300	Avian Reproduction	Technical Technical	46817007 46817008	Supplemental Acceptable
72-1	850.1075	Freshwater Fish LC_{50}	Technical Technical Technical Technical 480 SC 480 SC	46816937 46816939 46816940 46816941 46816942 46816943	Acceptable Acceptable Acceptable Acceptable Acceptable Acceptable
72-2	850.1010	Freshwater Invertebrate LC_{50}	Technical 24 WG 480 SC 480 SC Des-iodo	46816930 46816932 46816931 46816934 46816933	Acceptable Acceptable Acceptable Supplemental Acceptable
72-3(a)	850.1075	Estuarine/Marine Fish LC_{50}	Technical	46816938	Acceptable
72-3(b)	850.1025	Estuarine/Marine Mollusk EC_{50}	Technical	46816935	Acceptable
72-3(c)	850.1035 850.1045	Estuarine/Marine Shrimp LC_{50}	Technical	46816936	Acceptable
72-4(a)	850.1400	Freshwater Fish Early Life Stage	Technical	46816947	Acceptable
72-4(b)	850.1300 850.1350 850.1300	Aquatic Invertebrate Life-cycle	Technical Technical 480 SC	46816944 46816946 46816945	Supplemental Acceptable Acceptable
	850.1790	Benthic Organisms	Technical 24 WG 480 SC Des-iodo	46817022 46817014 46817013 46817023	Supplemental Acceptable Acceptable Supplemental
		Mesocosm Study	480 SC	46817002	Supplemental
72-5	850.1500	Freshwater Fish Life-Cycle	Technical	46816948	Unacceptable
122-1(a)	850.4100	Seed Germination/ Seedling Emergence Tier 1	24 WG 480 SC	46817034 46817036(a)	Acceptable Acceptable
		Herbicidal Toxicity Terrestrial plants Tier 2	480 SC	46817035	Supplemental, Non-guideline
122-1(b)	850.4150	Vegetative Vigor Tier 1	Technical 24 WG	46817036(b) 46817037	Acceptable Supplemental
122-2	850.4400	Aquatic Plant (Non-Vascular) Tier 1&II	Technical 480 SC	46817041 46817040	Acceptable Acceptable
122-2	850.4400	Aquatic Plant (Vascular) Tier 2	Technical	46817039	Acceptable

Ecological Effects Data Requirements for Flubendiamide					
Guideline #		Data Requirement	Formulation	MRID (Accession #)	Study Classification
123-1(a)	850.4225	Seed Germination/ Seedling Emergence Tier 2	24 WG	46817038	Acceptable
141-1	850.3020	Honey Bee Acute Contact LD_{50}	Technical 480 SC 480 SC WG 40	46817009 46817010 46817011 46817012	Acceptable Acceptable Acceptable Supplemental, Non-guideline
	850.6200	Acute Toxicity to Earthworms	Technical 480 SC Des-iodo	46817028 46817029 46817030	Supplemental Supplemental Supplemental
	850.6200	Chronic Toxicity to Earthworms	480 SC 24 WG	46817031 46817032	Supplemental Supplemental
141-2	850.3030	Honey Bee Residue on Foliage	NA	NA	NA
		Parasitoid Wasp	WG 40	46817020	Supplemental, Non-guideline
		Predatory Mite	WG 40	46817019	Supplemental, Non-guideline
		Ladybird Beetle (45 day study)	480 SC	46817015	Supplemental, Non-guideline
		Ladybird Beetle (Extended Study)	480 SC	46817016	Supplemental, Non-guideline
		Ladybird Beetle (Life Cycle Test)	480 SC	46817017	Supplemental, Non-guideline
		Parasitic Wasp (Side Effects Tests)	480 SC	46817021	Supplemental, Non-guideline
		White springtail (Reproduction Test)	480 SC	46817027	Supplemental
		Green lacewing (Extended Study)	480 SC	46817018	Supplemental

Appendix 5 – Environmental Fate Data

Environmental Fate Data Requirements for Flubendiamide				
Guideline #		Data Requirement	MRID #s	Study Classification
161-1	835.212	Hydrolysis	46816907	Acceptable
161-2	835.224	Photodegradation in Water	46816908	Acceptable
161-3	835.241	Photodegradation on Soil	46816909	Acceptable
161-4	835.237	Photodegradation in Air	NA[1]	NA
162-1	835.41	Aerobic Soil Metabolism	Parent: 46816910 Degradate:46816911	Acceptable Acceptable
162-2	835.42	Anaerobic Soil Metabolism	46816912	Supplemental
162-3	835.44	Anaerobic Aquatic Metabolism	46816914	Acceptable
162-4	835.43	Aerobic Aquatic Metabolism	46816913	Acceptable
163-1	835.1240 835.1230	Leaching-Adsorption/Desorption	Parent: 46816905 Degradate: 46816906	Supplemental Supplemental
163-2	835.141	Laboratory Volatility	NA	NA
163-3	835.81	Field Volatility	NA	NA
164-1	835.61	Terrestrial Field Dissipation	46816915 46816916 46816917	Acceptable Acceptable Acceptable
165-4	850.173	Accumulation in Fish	46816949 46817001	Acceptable Acceptable
		Quantum Yield in Water	46816919	Supplemental

[1] Not Available.

Appendix 6 – Bibliography

71-2 Avian Dietary Toxicity

MRID	Citation Reference
46817005	Bowers, L. (2005) Technical NNI 0001: A Subacute Dietary LC50 with Mallards. Project Number: AS720801, 201263. Unpublished study prepared by Bayer Corp. 41 p.

71-4 Avian Reproduction

MRID	Citation Reference
46817007	Sabbert, T. (2004) Effect of Technical NNI 0001 on Mallard Reproduction. Project Number: EBAM0221. Unpublished study prepared by Bayer Corp. 114 p.
46817008	Bowers, L. (2005) Effect of Technical NNI 0001 on Northern Bobwhite Reproduction. Project Number: AS741701, 201138. Unpublished study prepared by Bayer Corp. 143 p.

72-1 Acute Toxicity to Freshwater Fish

MRID	Citation Reference
46816937	Kern, M.; DeHann, R. (2004) Acute Toxicity of NNI 0001 Technical to the Fathead Minnow (Pimephales promelas) Under Static Conditions. Project Number: EBAM0390/AS811201, 200713. Unpublished study prepared by Bayer Corp. 42 p.
46816939	Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 (Tech.) to Fish (Lepomis macrochirus). Project Number: E/280/2291/4, DOM/22043. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 49 p.
46816940	Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 (Tech.) to Fish (Oncorhynchus mykiss). Project Number: DOM/22044, E/280/2292/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 75 p.
46816942	Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 480 SC to Fish (Lepomis macrochirus). Project Number: E/280/2352/2, DOM/22081, 00789. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 42 p.
46816943	Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 480 SC to Fish (Oncorhynchus mykiss). Project Number: E/280/2354/4, DOM/22082, 00789. Unpublished study prepared by Bayer Ag, Institute of Product

Info. & Residue Anal. 42 p.

72-2 Acute Toxicity to Freshwater Invertebrates

MRID	Citation Reference
46816930	Dorgerloh, M. (2006) Acute Toxicity of NNI-0001 (tech.) in Water Fleas (Daphnia magna). Project Number: DOM/22041, E/320/2283/0, MR/391/02. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 39 p.
46816931	Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 SC 480 to Water Fleas (Daphnia magna). Project Number: E/320/2284/1, DOM/22042. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 43 p.
46816932	Dorgerloh, M. (2005) Acute Toxicity of NNI-0001 WG 24 to the Waterflea Daphnia magna in a Static Laboratory Test System. Project Number: P/684/027017, MR/188/02, EBAMX018. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 58 p.
46816933	Dorgerloh, M. (2004) Acute Toxicity of NNI-0001-des-iodo to the Waterflea Daphnia magna. Project Number: DOM/23055, MR/029/04, E/320/2503/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 43 p.
46816934	Dorgerloh, M. (2005) Acute Toxicity of NNI-0001 SC 480 in the Waterflea Dahnia magna Under Different Feeding Conditions in a Static Laboratory Test System. Project Number: E/320/2849/8, EBAMX028, MR/188/02. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 59 p.

72-3 Acute Toxicity to Estuarine/Marine Organisms

MRID	Citation Reference
46816935	Dionne, E. (2004) NNI-0001-Acute Toxicity to Eastern Oysters (Crassostrea virginia) Under Flow-Through Conditions. Project Number: AS881501, 13798/613, EBAM0380. Unpublished study prepared by Springborn Smithers Laboratories. 53 p.
46816936	Dionne, E. (2004) NNI-0001 - Acute Toxicity to Mysids (Americamysis bahia) Under Static Conditions. Project Number: 13798/6131, AS883101, EBAMO376. Unpublished study prepared by Springborn Smithers Laboratories. 49 p.
46816938	Banman, C.; Kern, M.; Lam, C. (2004) Acute Toxicity of NNI 0001 Technical to the Sheepshead Minnow (Cyprinodon variegatus) Under Static Conditions. Project Number: 200992, EBAM0370. Unpublished

study prepared by Bayer Corp. 31 p.

72-4 Fish Early Life Stage/Aquatic Invertebrate Life Cycle Study

MRID	Citation Reference
46816944	Dorgerloh, M. (2003) Influence of NNI-0001 (Tech.) on Development and Reproductive Output of the Waterflea Daphnia magna in a Static Renewal Laboratory Test System. Project Number: E/321/2267/3, DOM/22035, 00760. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 88 p.
46816945	Dorgerloh, M. (2003) Influence of NNI-0001 SC 480 on Development and Reproductive Output of the Waterflea Daphnia magna in a Static Renewal Laboratory Test System. Project Number: E/321/2372/0, DOM/23001, 00760. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 81 p.
46816946	Putt, A. (2005) NNI-0001 - Life-Cycle Toxicity Test with Mysids (Americamysis bahia). Project Number: 13798/6156, EBAMO377. Unpublished study prepared by Springborn Smithers Laboratories. 89 p.
46816947	Kern, M; Lam, C. (2004) Early Life Stage Toxicity of NNI 0001 Technical to the Fathead Minnow (Pimephales promelas) Under Flow-Through Conditions. Project Number: EBAMX005, 200995, AS841201. Unpublished study prepared by Bayer Corp. 86 p.

72-5 Life cycle fish

MRID	Citation Reference
46816948	Cafarella, M. (2005) NNI-0001 - The Full Life-Cycle Toxicity Test with Fathead Minnow (Pimphales promelas). Project Number: 13798/6155, EBAM0393. Unpublished study prepared by Springborn Smithers Laboratories. 141 p.

72-6 Aquatic org. accumulation

MRID	Citation Reference
46816949	Dorgerloh, M.; Weber, E. (2005) (Carbon 14)-NNI-0001-Bioconcentration and Biotransformation in Fish (Lepomis macrochirus). Project Number: DOM/23026, E/244/2330/8. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 156 p.

122-1 Seed Germination/Seedline Emergence and Vegetable Vigor

MRID	Citation Reference

46817036 Christ, M.; Lam, C. (2005) Tier I Seedling Emergence and Vegetative Vigor: Nontarget Phytotoxicity Study Using NNI-0001 480SC. Project Number: 201376, EBAMX007, EBAM0367. Unpublished study prepared by Bayer Corp. 62 p.

123-1 Seed germination/seedling emergence and vegitative vigor

MRID **Citation Reference**

46817038 Christ, M.; Lam, C. (2006) Tier II Seedling Emergence: Nontarget Phytotoxicity Study using NNI-0001 WG24. Project Number: EBAMX049. Unpublished study prepared by Bayer Corp. 32 p.

123-2 Aquatic plant growth

MRID **Citation Reference**

46817039 Kern, M.; Banman, C.; Lam, C. (2004) Toxicity of NNI 0001 Techncial to Duckweed (Lemna gibba G3) Under Static-Renewal Conditions. Project Number: EBAMX010, AS883701, 200604. Unpublished study prepared by Bayer Corp. 41 p.

132-1 Dissipation of Dislodgeable Foliar & Soil Residues

MRID **Citation Reference**

46817245 Fischer, D. (2006) NNI-0001 480 SC - Dislodgeable Foliar Residue on Sweet Corn and Grape Plant Foliage: Final Report. Project Number: RAAMY004, AM001/05DA, AM002/05D. Unpublished study prepared by Bayer Corp. 494 p.

161-1 Hydrolysis

MRID **Citation Reference**

46816907 Yamashita, A. (2001) Hydrolysis Study of NNI-0001: Final Report. Project Number: LSRC/A01/078A, GC/03, 01/0034. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 56 p.

161-2 Photodegradation-water

MRID **Citation Reference**

46816908 Motoba, K. (2005) Study on Aqueous Photolysis of NNI-0001: Final Report (Amended II). Project Number: GC/03, LSRC/A01/128A, 01/0036. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 88 p.

161-3 Photodegradation-soil

MRID	Citation Reference
46816909	Shepler, K. (2004) Photodegradation of [(Carbon 14)]NNI-0001 in/on Soil by Artificial Light. Project Number: 1050W/1, 1050W. Unpublished study prepared by PTRL West, Inc. 141 p.

162-1 Aerobic soil metabolism

MRID	Citation Reference
46816910	Babczinski, P.; Eberhardt, R. (2004) NNI-0001: Aerobic Soil Degradation/Metabolism in Four Different Soils. Project Number: MEF/04/280, M1251206/7, M/125/1206/7. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 123 p.
46816911	Fliege, R. (2004) [Phthalic Acid Ring-UL-(Carbon 14)]-and [Aniline Ring-UL-(Carbon 14)]-NNI-0001-des-iodo: Aerobic Soil Metabolism in Four Soils. Project Number: M1251289/8, MEF/04/388, M/125/1289/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 114 p.

162-2 Anaerobic soil metabolism

MRID	Citation Reference
46816912	Hellpointner, E. (2004) Anaerobic Degradation/Metabolism of NNI-0001 in Soil. Project Number: M1261225/9, MEF/04/067, M/126/1225/9. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 56 p.

162-3 Anaerobic aquatic metab.

MRID	Citation Reference
46816914	Mathew, A. (2005) [Phthalic Acid Ring-UL-(Carbon 14)]NNI-0001: Anaerobic Aquatic Metabolism. Project Number: AS042401, MEAM6026. Unpublished study prepared by Bayer Corp. 72 p.

163-1 Leach/adsorp/desorption

MRID	Citation Reference
46816905	Babczinski, P.; Heinemann, O. (2004) Adsorption/Desorption of NNI-0001 on Soils. Project Number: M1311243/5, MR/201/03, M/131/1243/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 75 p.

46816906 Volkel, W. (2005) Adsoprtion/Desorption of [(Carbon 14)]-NNI-001-DES-IODO on Soils. Project Number: 855843. Unpublished study prepared by RCC Umweltchemie Ag. 108 p.

164-1 Terrestrial field dissipation

MRID	Citation Reference
46816916	Lee, R. (2006) Terrestrial Field Dissipation of NNI-0001 in Mississippi Soil, 2003. Project Number: 03EFAMY002, AS022102, AM/001/S04/01. Unpublished study prepared by Bayer Corp., A & L Great Lakes Laboratories and Bayer CropScience Mississippi Field Station. 186 p.
46816917	Lee, R. (2006) Terrestrial Field Dissipation of NNI-0001 in Washington Soil, 2003. Project Number: 03EFAMY003, AS022103, AM/001/S04/01. Unpublished study prepared by Bayer Corp., A & L Great Lakes Laboratories and Agvise Inc. 192 p.

165-4 Bioaccumulation in fish

MRID	Citation Reference
46816949	Dorgerloh, M.; Weber, E. (2005) (Carbon 14)-NNI-0001-Bioconcentration and Biotransformation in Fish (Lepomis macrochirus). Project Number: DOM/23026, E/244/2330/8. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 156 p.

171-11 Tobacco Uses: Total Residues and Pyrolysis Products

MRID	Citation Reference
46817244	Ponte, M.; Schick, M. (2006) Tobacco Pyrolysis of [14-Carbon]NNI-0001. Project Number: 1426W/1, 1426W, RAAMX049. Unpublished study prepared by PTRL West, Inc. 94 p.

830.1550 Product Identity and composition

MRID	Citation Reference
46816901	Fontaine, L. (2006) Product Chemistry of NNI-0001 Technical. Project Number: BR/2485, VB1/2005/0013501, ANR/07406. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. 474 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. &

Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

46816904 Frank, J. (2006) Product Chemistry of NNI-0001 24 WG. Project Number: ANR/06406, ANR/06606, ANR/06706. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 155 p.

830.1600 Description of materials used to produce the product

MRID	Citation Reference
46816901	Fontaine, L. (2006) Product Chemistry of NNI-0001 Technical. Project Number: BR/2485, VB1/2005/0013501, ANR/07406. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. 474 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.
46816904	Frank, J. (2006) Product Chemistry of NNI-0001 24 WG. Project Number: ANR/06406, ANR/06606, ANR/06706. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 155 p.

830.1620 Description of production process

MRID	Citation Reference
46816901	Fontaine, L. (2006) Product Chemistry of NNI-0001 Technical. Project Number: BR/2485, VB1/2005/0013501, ANR/07406. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. 474 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.1650 Description of formulation process

MRID	Citation Reference
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

46816904 Frank, J. (2006) Product Chemistry of NNI-0001 24 WG. Project Number: ANR/06406, ANR/06606, ANR/06706. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 155 p.

830.1670 Discussion of formation of impurities

MRID	Citation Reference
46816901	Fontaine, L. (2006) Product Chemistry of NNI-0001 Technical. Project Number: BR/2485, VB1/2005/0013501, ANR/07406. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. 474 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.
46816904	Frank, J. (2006) Product Chemistry of NNI-0001 24 WG. Project Number: ANR/06406, ANR/06606, ANR/06706. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 155 p.

830.1700 Preliminary analysis

MRID	Citation Reference
46816901	Fontaine, L. (2006) Product Chemistry of NNI-0001 Technical. Project Number: BR/2485, VB1/2005/0013501, ANR/07406. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. 474 p.

830.1750 Certified limits

MRID	Citation Reference
46816901	Fontaine, L. (2006) Product Chemistry of NNI-0001 Technical. Project Number: BR/2485, VB1/2005/0013501, ANR/07406. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. 474 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.
46816904	Frank, J. (2006) Product Chemistry of NNI-0001 24 WG. Project Number: ANR/06406, ANR/06606, ANR/06706. Unpublished study

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830.1800 Enforcement analytical method

MRID	Citation Reference
46816901	Fontaine, L. (2006) Product Chemistry of NNI-0001 Technical. Project Number: BR/2485, VB1/2005/0013501, ANR/07406. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. 474 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.
46816904	Frank, J. (2006) Product Chemistry of NNI-0001 24 WG. Project Number: ANR/06406, ANR/06606, ANR/06706. Unpublished study prepared by Bayer Corp and Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 155 p.

830.6302 Color

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.6303 Physical state

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.6304 Odor

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.6313 Stability to sunlight, normal and elevated temperatures, metals, and metal ions

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

830.6314 Oxidizing or reducing action

MRID	Citation Reference
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.6315 Flammability

MRID	Citation Reference
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.6316 Explodability

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A.

Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

830.6317 Storage stability of product

MRID	Citation Reference
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.6320 Corrosion characteristics

MRID	Citation Reference
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.7000 pH of water solutions or suspensions

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.7050 UV/Visible absorption

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

830.7100 Viscosity

MRID	Citation Reference

46816903 Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.7200 Melting point/melting range

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

830.7300 Density/relative density

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.
46816903	Frank, J. (2006) Product Chemistry of NNI-001 480 SC. Project Number: ANR/05806, 14/1050/5280, 2001/0054102/02E. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Bayer Ag Institut fuer Ruckstands-Analytik. 93 p.

830.7370 Dissociation constant in water

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

830.7560 Partition coefficient (n-octanol/water), generator column method

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

830.7840 Water solubility: Column elution method, shake flask method

MRID	Citation Reference

46816902 Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

830.7950 Vapor pressure

MRID	Citation Reference
46816902	Folsom, B. (2005) Product Chemistry of NNI-0001 Technical: (Final Report). Project Number: 608/58, GE/03/01/0008, LSRC/A01/012A. Unpublished study prepared by Bayer Corp, Bayer Ag, Institute of Product Info. & Residue Anal. and Covance Laboratories, Ltd. 287 p.

835.1240 Soil column leaching

MRID	Citation Reference
46816906	Volkel, W. (2005) Adsoprtion/Desorption of [(Carbon 14)]-NNI-001-DES-IODO on Soils. Project Number: 855843. Unpublished study prepared by RCC Umweltchemie Ag. 108 p.

835.2120 Hydrolysis of parent and degradates as a function of pH at 25 C

MRID	Citation Reference
46816907	Yamashita, A. (2001) Hydrolysis Study of NNI-0001: Final Report. Project Number: LSRC/A01/078A, GC/03, 01/0034. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 56 p.

835.2240 Direct photolysis rate of parent and degradates in water

MRID	Citation Reference
46816908	Motoba, K. (2005) Study on Aqueous Photolysis of NNI-0001: Final Report (Amended II). Project Number: GC/03, LSRC/A01/128A, 01/0036. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 88 p.

835.2410 Photodegradation of parent and degradates in soil

MRID	Citation Reference
46816909	Shepler, K. (2004) Photodegradation of [(Carbon 14)]NNI-0001 in/on Soil by Artificial Light. Project Number: 1050W/1, 1050W. Unpublished study prepared by PTRL West, Inc. 141 p.

835.4100 Aerobic soil metabolism

MRID	Citation Reference
46816910	Babczinski, P.; Eberhardt, R. (2004) NNI-0001: Aerobic Soil Degradation/Metabolism in Four Different Soils. Project Number: MEF/04/280, M1251206/7, M/125/1206/7. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 123 p.
46816911	Fliege, R. (2004) [Phthalic Acid Ring-UL-(Carbon 14)]-and [Aniline Ring-UL-(Carbon 14)]-NNI-0001-des-iodo: Aerobic Soil Metabolism in Four Soils. Project Number: M1251289/8, MEF/04/388, M/125/1289/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 114 p.

835.4200 Anaerobic soil metabolism

MRID	Citation Reference
46816912	Hellpointner, E. (2004) Anaerobic Degradation/Metabolism of NNI-0001 in Soil. Project Number: M1261225/9, MEF/04/067, M/126/1225/9. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 56 p.

835.4300 Aerobic aquatic metabolism

MRID	Citation Reference
46816913	Sneikus, J. (2004) Aerobic Degradation and Metabolism of NNI-0001 in the Water/Sediment System. Project Number: M1511248/2, MEF/414/03, M/151/1248/2. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 91 p.

835.4400 Anaerobic aquatic metabolism

MRID	Citation Reference
46816914	Mathew, A. (2005) [Phthalic Acid Ring-UL-(Carbon 14)]NNI-0001: Anaerobic Aquatic Metabolism. Project Number: AS042401, MEAM6026. Unpublished study prepared by Bayer Corp. 72 p.

835.6100 Terrestrial field dissipation

MRID	Citation Reference
46816915	Lee, R. (2006) Terrestrial Field Dissipation of NNI-0001 in California Soil, 2003. Project Number: 03EFAMY001, AS022101. Unpublished study prepared by Bayer Corp., A & L Great Lakes Laboratories and

Bayer CropScience. 187 p.

46816916 Lee, R. (2006) Terrestrial Field Dissipation of NNI-0001 in Mississippi Soil, 2003. Project Number: 03EFAMY002, AS022102, AM/001/S04/01. Unpublished study prepared by Bayer Corp., A & L Great Lakes Laboratories and Bayer CropScience Mississippi Field Station. 186 p.

46816917 Lee, R. (2006) Terrestrial Field Dissipation of NNI-0001 in Washington Soil, 2003. Project Number: 03EFAMY003, AS022103, AM/001/S04/01. Unpublished study prepared by Bayer Corp., A & L Great Lakes Laboratories and Agvise Inc. 192 p.

835.6200 Aquatic field dissipation

MRID	Citation Reference

46817033 Sommer, H. (2002) Method for the Determination of NNI-0001 in Test Water from Aquatic Toxicity Test by HPLC-UV. Project Number: MR/391/02, 00789. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 12 p.

850.1010 Aquatic invertebrate acute toxicity, test, freshwater daphnids

MRID	Citation Reference

46816930 Dorgerloh, M. (2006) Acute Toxicity of NNI-0001 (tech.) in Water Fleas (Daphnia magna). Project Number: DOM/22041, E/320/2283/0, MR/391/02. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 39 p.

46816931 Dorgerloh, M. (2003) Acute Toxicity of NNI-0001 SC 480 to Water Fleas (Daphnia magna). Project Number: E/320/2284/1, DOM/22042. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 43 p.

46816932 Dorgerloh, M. (2005) Acute Toxicity of NNI-0001 WG 24 to the Waterflea Daphnia magna in a Static Laboratory Test System. Project Number: P/684/027017, MR/188/02, EBAMX018. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 58 p.

46816933 Dorgerloh, M. (2004) Acute Toxicity of NNI-0001-des-iodo to the Waterflea Daphnia magna. Project Number: DOM/23055, MR/029/04, E/320/2503/5. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 43 p.

46816934 Dorgerloh, M. (2005) Acute Toxicity of NNI-0001 SC 480 in the Waterflea Dahnia magna Under Different Feeding Conditions in a Static Laboratory Test System. Project Number: E/320/2849/8, EBAMX028,

MR/188/02. Unpublished study prepared by Bayer Ag, Institute of Product Info. & Residue Anal. 59 p.

850.1025 Oyster acute toxicity test (shell deposition)

MRID	Citation Reference
46816935	Dionne, E. (2004) NNI-0001-Acute Toxicity to Eastern Oysters (Crassostrea virginia) Under Flow-Through Conditions. Project Number: AS881501, 13798/613, EBAM0380. Unpublished study prepared by Springborn Smithers Laboratories. 53 p.

850.1035 Mysid acute toxicity test

MRID	Citation Reference
46816936	Dionne, E. (2004) NNI-0001 - Acute Toxicity to Mysids (Americamysis bahia) Under Static Conditions. Project Number: 13798/6131, AS883101, EBAMO376. Unpublished study prepared by Springborn Smithers Laboratories. 49 p.

850.1075 Fish acute toxicity test, freshwater and marine

MRID	Citation Reference
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850.1300 Daphnid chronic toxicity test

MRID	Citation Reference
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850.1400 Fish early-life stage toxicity test

MRID	Citation Reference
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850.1500 Fish life cycle toxicity

MRID	Citation Reference
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850.1730 Fish BCF

MRID	Citation Reference
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850.1850 Aquatic food chain transfer

MRID	Citation Reference
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850.1950 Field testing for aquatic organisms

MRID	Citation Reference
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850.2100 Avian acute oral toxicity test

MRID	Citation Reference
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850.2200 Avian dietary toxicity test

MRID	Citation Reference
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850.2500 Field testing for terrestrial wildlife

MRID	Citation Reference
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850.3020 Honey bee acute contact toxicity

MRID	Citation Reference
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850.3040 Field testing for pollinators

MRID	Citation Reference
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MRID	Citation Reference
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MRID	Citation Reference
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MRID	Citation Reference
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MRID	Citation Reference
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860.1000 Background

MRID	Citation Reference
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860.1300 Nature of the residue - plants, livestock

MRID	Citation Reference
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860.1340 Residue analytical method

MRID	Citation Reference

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860.1360 Multiresidue method

MRID	Citation Reference
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MRID	Citation Reference
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860.1480 Meat/milk/poultry/eggs

MRID	Citation Reference
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MRID	Citation Reference
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860.1520 Processed food/feed

MRID	Citation Reference
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860.1850 Confined accumulation in rotational crops

MRID	Citation Reference

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860.1900 Field accumulation in rotational crops

MRID	Citation Reference

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870.1000 Acute toxicity testing--background

MRID	Citation Reference
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870.1100 Acute oral toxicity

MRID	Citation Reference
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870.1200 Acute dermal toxicity

MRID	Citation Reference
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870.1300 Acute inhalation toxicity

MRID	Citation Reference
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870.2400 Acute eye irritation

MRID	Citation Reference
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Project Number: AT01758, T/9074396, TXAMX028. Unpublished study prepared by Bayer Ag Inst. of Toxicology. 20 p.

870.2500 Acute dermal irritation

MRID	Citation Reference
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870.2600 Skin sensitization

MRID	Citation Reference
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870.3100 90-Day oral toxicity in rodents

MRID	Citation Reference
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46817211	Takeuchi, Y. (2002) NNI-0001: Repeated Dose 90-Day Oral Toxicity Study in Mice: Final Report. Project Number: IET/01/0049. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 258 p.

870.3150 90-day oral toxicity in nonrodents

MRID	Citation Reference
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870.3200 21/28-day dermal toxicity

MRID	Citation Reference
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870.3700 Prenatal developmental toxicity study

MRID	Citation Reference
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870.3800 Reproduction and fertility effects

MRID	Citation Reference
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870.4100 Chronic toxicity

MRID	Citation Reference

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870.4200 Carcinogenicity

MRID	Citation Reference
46817219	Enomoto, A. (2004) NNI-0001: Carcinogenicity Study in Rats: Final Report. Project Number: IET/02/0035, T/8059. Unpublished study prepared by Institute of Environmental Toxicology. 691 p.
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870.5100 Bacterial reverse mutation test

MRID	Citation Reference
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870.5375 In vitro mammalian chromosome aberration test

MRID	Citation Reference
46817223	Miyahana, K. (2004) In Vitro Chromosome Aberration Test of NNI-0001 in Cultured Chinese Hamster Cells: Final Report. Project Number: GA/08, 02/0116. Unpublished study prepared by Nihon Nohyaku Co., Ltd. 32 p.
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36 p.

870.5395 Mammalian erythrocyte micronucleus test

MRID	Citation Reference
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870.6200 Neurotoxicity screening battery

MRID	Citation Reference
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870.6300 Developmental neurotoxicity study

MRID	Citation Reference
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870.7485 Metabolism and pharmacokinetics

MRID	Citation Reference
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870.7600 Dermal penetration

MRID	Citation Reference
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MRID	Citation Reference
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875.1300 Inhalation exposure--outdoor

MRID	Citation Reference
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875.2100 Foliar dislodgeable residue dissipation

MRID	Citation Reference
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875.2400 Dermal exposure

MRID	Citation Reference
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875.2500 Inhalation exposure

MRID	Citation Reference
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850.7100 Data reporting for environmental chemistry methods

MRID	Citation Reference
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850.1790 Chironomid Sediment Toxicity Test

MRID	Citation Reference
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850.6200 Earthworm subchronic toxicity test

MRID	Citation Reference
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MRID	Citation Reference

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