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Prodiamine Summary Document Registration Review: Initial Docket December 2010

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Case #7201

Approved By:

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12-8-2010

Date

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Please Note:

This Preliminary Work Plan and Fact Sheet summarize the Environmental Protection Agency's current position based on the following documents:

- 1. Prodiamine: Human Health Risk Scoping Document in Support of Registration Review. November 10, 2010.
- 2. Registration Review Preliminary Problem Formulation for the Ecological Risk Assessment of Prodiamine. November 17, 2010.
- 3. PRD Appendix A: Food/Feed & Non-Food/Non-Feed Uses Considered in Registration Review Work Planning Partial Listing. January 25, 2010.
- 4. *Prodiamine (110201) California Department of Pesticide Regulation Usage Data.* January 22, 2010.
- 5. Prodiamine Review of Human Incidents. August 10, 2010.

These and other supporting documents for the prodiamine registration review case may be found in the docket EPA-HQ-OPP-2010-0920 at http://www.regulations.gov.

I. PRELIMINARY WORK PLAN

Introduction

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides distributed or sold in the United States (U.S) generally must be registered by the U.S. Environmental Protection Agency (EPA or the Agency), based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at www.epa.gov/oppsrrd1/registration_review/.

The Agency is implementing the registration review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop and commit to a final work plan and schedule for the registration review of prodiamine.

Prodiamine is a dinitroaniline herbicide registered for selective, preemergent control of many grasses and broadleaf weeds. Prodiamine acts through inhibition of root growth by blocking plant cell division steps needed for chromosome separation and cell wall formation. Prodiamine was first registered in 1992 for use in non-crop areas such as rights-of-way, conifer and hardwood seedling nurseries, established perennial and wildflower plantings, established turf sites, residential and institutional lawns, commercial sod farms, golf courses, railways, and landscape ornamentals. There are also two Special Local Needs (SLN) registrations in California and Arizona for use on irrigation drainage ditches, spreading grounds, channels, canals, and levees in wastewater treatment facilities. There are over 150 prodiamine products currently registered.

Anticipated Risk Assessment and Data Needs:

The Agency anticipates the need to require data to conduct a comprehensive ecological risk assessment, including an endangered species risk assessment, and to update and revise the human health risk assessment for all uses of prodiamine. Below is a summary of the issues relevant to the registration review of prodiamine and the data the Agency anticipates requiring.

Ecological Risk:

- The Agency has not conducted an ecological risk assessment for prodiamine. An Environmental Fate review and EPA Fact Sheet were completed for prodiamine in 1991.
- EPA has not conducted a risk assessment that supports a complete endangered species determination for prodiamine. The ecological risk assessment planned during registration review will allow the Agency to determine whether prodiamine's use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service (FWS) and/or National Marine Fisheries Service (NMFS) (the Services), as appropriate.
- Prodiamine's major degradate is prodiamine benzimidazole. There is uncertainty around the amount of prodiamine benzimidazole formed after application of prodiamine, how it breaks down, and its toxicity. EPA anticipates the need to require fate and toxicity data for this degradate.
- The Agency anticipates needing the following data in order to conduct a complete ecological risk assessment.

Environmental fate data gaps

Parent Prodiamine

- GDLN 835.2240 Photodegradation in water
- GDLN 835.2410 Photodegradation in soil
- GDLN 835.4300 Aerobic aquatic metabolism
- GDLN 835.4400 Anaerobic aquatic metabolism
- GDLN 835.6100 (footnote 7) Terrestrial field dissipation soil
- GDLN 835.6200 Aquatic field dissipation

Degradate - Prodiamine Benzimidazole

- GDLN 835.2240 Photodegradation in water
- GDLN 835.1230 Adsorption/desorption (batch equilibrium)

Ecological toxicity data gaps

Parent Prodiamine

- GDLN 850.1300 Aquatic Invertebrate Life Cycle Toxicity (Freshwater), TGAI
- GDLN 850.1350 Aquatic Invertebrate Life Cycle Toxicity (estuarine/marine), TGAI
- GDLN 850.1500 Freshwater Fish Full Life Cycle Study, TGAI
- GDLN 850.1500 Estuarine/Marine Fish Life Cycle Study, TGAI
- GDLN 850.2100 Acute Avian Oral Toxicity Test using a passerine species, TGAI
- GDLN 850.4400 Aquatic Vascular Plant Tier II study using Lemna spp., TGAI

- GDLN: 850.5400 Aquatic Plant Tier II Algal toxicity study, TGAI
- No Guideline Number Available, Study Title: Whole Sediment: Chronic Invertebrates Freshwater and Marine (using *Hyaella azteca, Chironomus dilutus/C. tetans,* and *Leptocheirus plumulosus*) using TGAI (Special Study)

Degradate – Prodiamine Benzimidazole

- GDLN 850.1010 Acute Toxicity Freshwater Invertebrates (Daphnia)
- GDLN 850.1075 Acute Freshwater Fish Toxicity Test (using rainbow trout)
- GDLN 850.1075 Acute Saltwater Fish Toxicity Test (using sheepshead minnow)
- GDLN 850.1300 Aquatic Invertebrate Life Cycle Toxicity (Freshwater)
- GDLNs 850.1025/850.1035/850.1055, Study Title: Acute Toxicity Estuarine/Marine Invertebrates
- GDLN 850.1400 Freshwater Fish Early Life Stage Study (using a species for which acute data is available)
- GDLN 850.1400 Estuarine/Marine Fish Early Life Stage Study (using a species for which acute data is available)
- GDLN 850.1350 Aquatic Invertebrate Life Cycle Toxicity (Esturarine/Marine)
- GDLN 850.4400 (122-2) Aquatic Vascular Plant Tier II study using *Lemna spp*.
- GDLN 850.5400 (122-2) Aquatic Plant Tier II Algal toxicity study

Studies on Typical End-use Product

- GDLN 850.1010 Acute Toxicity Freshwater Invertebrates (Daphnia), TEP
- GDLN 850.1025/850.1055 Estuarine Invertebrate Acute Toxicity (Mysid and Eastern Oyster are the preferred species), TEP

Please refer to the *Registration Review – Preliminary Problem Formulation for the Ecological Risk Assessment of Prodiamine*, dated November 16, 2010, for a more detailed discussion of the anticipated ecological risk assessment and data needs.

Human Health Risk:

- An analysis of toxicity studies and an assessment of occupational and residential exposure were conducted for prodiamine in December 1991 in support of the registration of prodiamine.
- The toxicity data base for prodiamine is substantially complete. However, data evaluation records (DERs) for the available toxicity studies need to be reevaluated and updated based on current policies and procedures. In addition, a comprehensive evaluation of the available toxicity data is needed for the purpose of selecting points of departure (PODs) based on current endpoint selection criteria for all potential routes of exposure for registered uses of prodiamine.
- There were no food uses of prodiamine in 1992 when prodiamine was first registered. Therefore a dietary assessment was not required. However, Special Local Need (SLN) registrations issued in 2005 and 2008 provide for use of prodiamine on irrigation ditches. The label language on the SLNs is unclear as to whether the use is a food or a non-food use. Unless the registrations and the label language are modified so that this use is

clearly a non-food use, EPA will require data to establish tolerances and will complete a dietary exposure assessment. If the registrations and the label language of the SLNs are modified so that it is clear that the use is a non-food use, EPA would then not expect to need to require these data or conduct a dietary assessment.

- A quantitative drinking water assessment has not been conducted for prodiamine. A quantitative drinking water assessment will be conducted for prodiamine during Registration Review.
- A residential exposure assessment was conducted for prodiamine in December 1991. Agency policies, standard operating procedures, and exposure assessment methodologies have changed since the residential exposure assessment was conducted in 1991. In addition, a number of registrations for use of prodiamine on turf have been approved in recent years. A quantitative assessment of residential exposure and risk is anticipated.
- An aggregate risk assessment has not been conducted for prodiamine. An aggregate assessment may be required during registration review depending on the results of EPA's reevaluation of dietary, drinking water, and/or residential exposures.
- An occupational assessment was completed for prodiamine in December 1991. An updated occupational risk assessment may be conducted for prodiamine during registration review due to changes in exposure protocols and updated PODs identified as part of an updated hazard identification assessment.
- Prodiamine's major degradate as identified in fate studies is prodiamine benzimidazole. Prodiamine benzimidazole was observed in rat metabolism studies. Since the results of the rat metabolism studies reflect the toxicity of both the parent and degradate, additional data are not anticipated to be required on prodiamine benzimidazole for mammalian toxicity.
- The database is complete with the exception of the following studies, which the Agency anticipates requiring in order to conduct a complete human health assessment:
 - o 870.3250 Subchronic inhalation study
 - o 870.7800 Immunotoxicity (rats)
- If the registrations and the language on the labels of the prodiamine SLNs are not changed so that it is clear that the irrigation ditch use is a non-food use, then the Agency anticipates the need to require data to establish tolerances for this use. The following studies would be expected to be required under that circumstance:
 - o 860.1300 Nature of the Residue--Plants, Livestock
 - o 860.1380 Storage Stability Data
 - o 860.1400 Water, Fish, Irrigated Crops
 - o 860.1480 Meat/Milk/Poultry/Eggs
 - o 860.1500 Crop Field Trials
 - o 860.1520 Processed Food/Feed (August 1996)
 - o 860.1850 Confined Accumulation in Rotational Crops
 - o 860.1900 Field Accumulation in Rotational Crops
- Please refer to *Prodiamine: Human Health Risk Scoping Document in Support of Registration Review,* dated November 10, 2010, located in the prodiamine docket, for a detailed discussion of the anticipated human health risk assessment needs.

Other Anticipated Data Needs:

• GLN 830.7050 UV/Visible Light Absorption – this study is a new data requirement under 40 CFR part 158 (Product Chemistry Data Requirements) for registration of a pesticide (food and non-food uses). The Agency anticipates requiring this study to obtain basic information about the compound's identity/composition and the wavelengths at which the compound may be susceptible to photochemical degradation.

Endocrine Disruptor Screening Program (EDSP):

As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a quantitative relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients (ais) and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

Prodiamine is not among the group of 58 pesticide ais on the initial list to be screened under the EDSP. Under FFDCA sec. 408(p) the Agency must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP orders/data call-ins for all registration review cases, including those for which EPA has already opened a registration review docket for a pesticide ai.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/.

Timeline:

EPA has created the following estimated timeline for the completion of the prodiamine registration review.

Registration Review for Prodiamine – Projected Registration Review Timeline		
Activities	Estimated Date	
Opening the Docket		
Open Docket and Public Comment Period	2010 – December	
Close Public Comment	2011 – February	
Case Development		
Final Work Plan	2011 – May	
Issue DCI	2012 – Jan. – March	
Data Submission	2014 – Jan. – March	
Open Public Comment Period for Draft Risk Assessments	2015 – July – Sept.	
Close Public Comment Period	2015 – Oct. – Dec.	
Registration Review Decision		
Open Public Comment Period for Proposed Registration Review	2016 – Jan. – March	
Decision		
Close Public Comment Period	2016 – April – June	
Registration Review Decision and Begin Post-Decision Follow-up	2016	
Total (years)	6	

Guidance for Commenters:

The public is invited to comment on EPA's preliminary work plan and rationale. The Agency will carefully consider all comments as well as any additional information or data provided in a timely manner prior to issuing a final work plan for the prodiamine case.

Trade Irritants

• Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. There are currently no U.S. tolerances for prodiamine. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Levels (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

Water Quality

• Prodiamine is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at http://iaspub.epa.gov/tmdl waters10/attains nation cy.cause detail 303d?p cause grou p_id=885. In addition, no Total Maximum Daily Loads (TMDL) have been developed for prodiamine, based on information provided at http://iaspub.epa.gov/tmdl waters10/attains nation.tmdl pollutant detail?p pollutant group id=885&p pollutant group name=PESTICIDES. More information on impaired

water bodies and TMDLs can be found at <u>http://www.epa.gov/owow/tmdl/</u>. The Agency invites submission of water quality data for this pesticide. To the extent possible, data should conform to the quality standards in Appendix A of the *OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process* (see: <u>http://www.epa.gov/oppsrtd1/registration_review/water_quality_sop.htm</u>) in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

Environmental Justice

• EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to prodiamine, compared to the general population. Please comment if you are aware of any sub-populations that may have atypical or unusually high exposure compared to the general population.

Additional Information

Stakeholders are also specifically asked to provide information and data that will assist the Agency in refining risk assessments, including any species-specific ecological effects determinations. The Agency is interested in receiving the following information:

- 1. Confirmation on the following label information.
 - a. sites of application
 - b. formulations
 - c. application methods and equipment
 - d. maximum application rates
 - e. frequency of application, application intervals, and maximum number of applications per season and per year
 - f. geographic limitations on use
- 2. Use or potential use distribution (*e.g.* geographical distribution of relevant uses).
- 3. Use history.
- 4. Median and 90th percentile reported use rates (lb/A, lb 1K sq.ft) from usage data national, state and county.
- 5. Application timing (date of first application and application intervals) by use national, state, and county.
- 6. Usage/use information for non-agricultural uses.
- 7. Directly acquired county-level usage data (not derived from state level data).
 - a. maximum reported use rate (lb/cc) from usage data county
 - b. median and 90^{th} percentile number of applications county
 - c. total pounds per year county
 - d. the year the pesticide was last used in the county/sub-county area
 - e. the years in which the pesticide was applied in the county/sub-county area

- 8. Typical application interval (days).
- 9. State or local use restrictions.
- 10. Ecological incidents specific to prodiamine (non-target plant damage and avian, fish, reptilian, amphibian, mammalian mortalities, and bee or beneficial insect mortalities) not already reported to the Agency.

<u>Next Steps:</u> After the 60-day public comment period closes, the Agency will review and respond to any comments received in a timely manner and then issue a Final Work Plan for prodiamine.

II. FACT SHEET

Background Information:

- Prodiamine Registration Review Case Number: 7201
- Prodiamine PC Code: 110201; CAS#: 29091-21-2
- Technical Registrants: Syngenta Crop Protection, Inc., Nufarm Limited, Control Solutions, Inc., Sipcam Agro USA, Inc., Proactive LLC, and Celsius Property BV Amsterdam (NL).
- Prodiamine was first registered in 1992, therefore it was not subject to the reregistration requirements of FIFRA.
- Currently there are no tolerances for prodiamine.
- Pesticide Re-evaluation Division (PRD) Chemical Review Manager (CRM) Katie Weyrauch (weyrauch.katie@epa.gov)
- Registration Division (RD) Contact: Dianne Morgan (morgan.dianne@epa.gov)
- There are approximately 150 registered prodiamine products. All FIFRA Section 3 registrations are non-food/feed use registrations.
- There are Special Local Need (SLN) registrations for prodiamine in California and Arizona for use on ditchbanks. Based on the current label directions, it is unclear whether these SLN registrations should be considered food-use registrations.

Use & Usage Information:

- Prodiamine is a preemergent dinitroaniline herbicide registered for use to control many grasses and broadleaf weeds. Prodiamine is registered for use in non-crop areas such as rights-of-way, conifer and hardwood seedling nurseries, established perennial and wildflower plantings, established turf sites, residential and institutional lawns, commercial sod farms, golf courses, railways, and landscape ornamentals. There are Special Local Need (SLN) registrations in California and Arizona for use on irrigation drainage ditches, spreading grounds, channels, canals, and levees in wastewater treatment facilities.
- National usage data are unavailable for prodiamine. According to data from the California Department of Pesticide Regulation, approximately 54,000 lbs a.i. were applied in 2008 in California, with the majority of usage on landscape maintenance, ornamental turf, and rights-of-way.

Recent Actions

• There are no pending actions for prodiamine. SLN registrations in California and Arizona for use on ditchbanks were registered in 2005 and 2008.

Ecological Risk Assessment Status:

Please refer to the *Registration Review Preliminary Problem Formulation for the Ecological Risk Assessment of Prodiamine*, dated November 17, 2010, and located in the prodiamine docket at regulations.gov (EPA-HQ-OPP-2010-0920).

• An ecological risk assessment has not been conducted for prodiamine. An Environmental Fate review and EPA Fact Sheet were completed for prodiamine in 1991.

Fate Discussion

- Given the known and potential persistence and mobility of prodiamine, terrestrial and aquatic organisms are likely to be exposed when prodiamine is used in accordance with the label.
- Prodiamine's solubility in water is very low 13 ppb.
- There is uncertainty regarding the formation and fate of prodiamine's major degradate, prodiamine benzimidazole.

Ecological Effects

- For terrestrial species, prodiamine is practically non-toxic to birds, mammals, and invertebrates on an acute basis. Chronic effects were seen in rats at levels of 2000 ppm and at 1000 ppm for birds. Given its mode of action and use as an herbicide, prodiamine poses risk to terrestrial non-target plants.
- For aquatic species, prodiamine is practically non-toxic to aquatic invertebrates and fish on an acute basis. Chronic effects were seen in aquatic invertebrates at 2.6 ppb. No chronic fish data have been submitted for prodiamine. No data have been submitted on prodiamine's effect on aquatic plants, but given its use as an herbicide, risk to aquatic plants should be expected.

Human Health Risk Assessment Status:

Please refer to *Prodiamine: Human Health Risk Scoping Document in Support of Registration Review,* dated November 10, 2010, and located in the prodiamine docket at regulations.gov (EPA-HQ-OPP-2010-0920), for a discussion of the key findings of the most recent human health risk assessment for prodiamine. A summary follows:

Hazard Characterization:

- Prodiamine exhibits low acute toxicity via inhalation, dermal (Toxicity Category III), and oral (Category IV) routes of exposure.
- The most recent cancer evaluation of prodiamine conducted in 1991 classified prodiamine as a "possible human carcinogen." This classification was used for agents with limited evidence of carcinogenicity in animals and in the absence of human data. While carcinogenic potential was identified for prodiamine, the potential was not quantified.

Dietary (Food Only):

- Prodiamine's initial registration in 1992 only consisted of non-food uses. Therefore a dietary assessment was not conducted.
- Special Local Need (SLN) registrations issued in 2005 and 2008 provide for use of prodiamine on irrigation ditches. The label language on the SLNs is unclear as to whether the use is a food use or a non-food use.

Drinking Water:

• A quantitative drinking water assessment has not been conducted for prodiamine.

Residential:

- A qualitative residential exposure assessment was conducted for prodiamine in December 1991.
- The assessment concluded that since prodiamine's carcinogenic risk was not quantified, and prodiamine uses and do not involve repeated or chronic exposure, exposure and risk to residents/bystanders is assumed to be negligible. Therefore, a quantitative risk assessment was not conducted at that time.

Aggregate:

• An aggregate risk assessment integrates the assessments conducted for dietary/drinking water and residential exposure. Since dietary, drinking water, and residential exposure assessments were not quantitatively assessed in previous risk assessments conducted for prodiamine, an aggregate assessment was not required.

Occupational:

- An occupational exposure assessment addressing both cancer and non-cancer risks was conducted for prodiamine in December 1991.
- Scenarios assessed were mixing, loading, and applying a 65% wettable granular formulation to turf and landscape areas with groundboom or handwand equipment. PODs for both dermal and inhalation exposure were selected from a chronic feeding study in rats. Dermal and inhalation absorption were assumed to be 100%. No risks of concern were identified.

Cumulative assessment:

• The Food Quality Protection Act (FQPA) requires the Agency to consider the cumulative risks of chemicals sharing a common mechanism of toxicity. There is insufficient evidence to suggest prodiamine shares a common mechanism of toxicity with other chemical substances.

Human Studies:

• Past prodiamine risk assessments rely in part on data from studies in which adult human subjects were intentionally exposed to a pesticide to determine their dermal and inhalation exposure. Many such studies, involving exposure to many different pesticides, comprise generic pesticide exposure databases such as the Pesticide Handlers Exposure Database (PHED) and the Agricultural Reentry Task Force (ARTF) Database. EPA has reviewed all the studies supporting these multi-pesticide generic exposure databases, and has found no clear and convincing evidence that the conduct of any of them was either fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time the research was conducted. All applicable requirements of EPA's

Rule for the Protection of Human Subjects of Research (40 CFR Part 26) have been satisfied, and there is no regulatory barrier to continued reliance on these studies.

Incidents:

Ecological:

- A preliminary review of the Ecological Incident Information System (EIIS, version 2.1), which is maintained by the Agency's Office of Pesticide Programs, indicates reported ecological incidents associated with the use of prodiamine.
- One incident was reported for aquatic animals and seven were reported for terrestrial plants. All incidents were reported between 1998 and 2000. Four of the incidents were associated with registered uses of prodiamine, three were associated with applications not determined definitively to have been registered uses. None of the incidents were clearly associated with misuse of prodiamine.

Human:

- The OPP Incident Database System (IDS) was searched for human incidents involving prodiamine in the United States from 2000 to May 25, 2010. IDS includes reports of twenty-seven incidents from various sources, including mandatory FIFRA Section 6 (a) (2) reports from registrants, other federal and state health and environmental agencies, and individual consumers. All effects were determined to be minor, unknown, or there were no effects.
- In general, incidents involving prodiamine were of low or moderate severity; the most frequently reported symptoms were related to the dermal, respiratory, and neurological systems.
- The National Institute for Occupational Safety and Health (CDC/NIOSH) Sentinel Event Notification System for Occupational Risk-Pesticides (SENSOR) data from 1998 to 2007 identified two cases that involved the active ingredient prodiamine. Of these cases, one was reviewed because prodiamine was used as a single chemical and had a certainty classification of definite, probable, or possible. A 50-year old male was exposed to prodiamine when it soaked through his personal protective equipment. He experienced dermal symptoms.
- Based on the low frequency of incident cases, there does not appear to be a concern at this time that would warrant further investigation. The Agency will continue to monitor the incident information and, if a concern is triggered, additional analysis will be included in the risk assessment.

Data Call-In Status:

• No chemical-specific data call-ins (DCIs) have been issued for prodiamine since it was first registered in 1992, and was not subject to reregistration.

Tolerances and International Harmonization:

• No tolerances have been established for prodiamine.

Labels:

Labels can be obtained from the Pesticide Product Label System (PPLS) website: <u>http://oaspub.epa.gov/pestlabl/ppls.home</u>.