



Department of Pesticide Regulation



Mary-Ann Warmerdam
Director

MEMORANDUM

Arnold Schwarzenegger
Governor

TO: Ann Prichard, Branch Chief
Pesticide Registration Branch

FROM: Marylou Verder-Carlos, D.V.M., M.P.V.M.
Assistant Director
445-3984

DATE: November 24, 2010

SUBJECT: FINAL EVALUATION OF MIDAS PRODUCTS

This document discusses the final registration evaluation of Arysta LifeScience North America Corporation's (Arysta's) one technical use product and four end-use products containing the active ingredient iodomethane. The products include:

- Iodomethane Technical (U.S. EPA Registration Number 66330-44)
- Midas 98:2 (U.S. EPA Registration Number 66330-43)
- Midas 50:50 (U.S. EPA Registration Number 66330-57)
- Midas 33:67 (U.S. EPA Registration Number 66330-59)
- Midas EC Gold (U.S. EPA Registration Number 66330-60).

In 2002, the Department of Pesticide Regulation (DPR) received applications for registration from Arysta for several Midas® products. In addition to the proposed labels, Arysta submitted numerous studies, including data regarding air monitoring and worker exposure monitoring during application using the various methods allowed by the Midas labels. Midas® is a federally Restricted Use Pesticide due to acute inhalation toxicity. As a Restricted Use Pesticide, Midas can only be used by certified applicators or under their direct supervision (requires the certified applicator to be on-site). Iodomethane is not currently listed in regulation as a California restricted material. However, as part of its registration decision, DPR will propose regulations to list iodomethane as a California restricted material to require a restricted materials permit from the county agricultural commissioner prior to use.

PROBLEMS IDENTIFIED DURING INITIAL REGISTRATION EVALUATIONS

During the evaluation process for the five Midas® products, the Pesticide Registration Branch received several evaluation reports that recommended denying registration of the Midas® products. The Pesticide Registration Branch also received several evaluation reports that recommended conditional registration based on the need for additional data. The basis for these recommended denials and conditional registrations, and the responses are summarized below. Note: All other registration evaluations recommended registration of the products, and therefore, are not discussed below.



Staff Recommendations to Deny Registration:

Medical Toxicology Branch

On June 26, 2002 through September 12, 2005, Medical Toxicology Branch scientists conducted evaluations of several toxicology studies. The data reviewed was found to be adequate for a complete toxicological evaluation.

The Medical Toxicology Branch scientists recommended "...denial of registration until a risk assessment has been completed and finalized for iodomethane."

Response: DPR completed its risk assessment on iodomethane and developed mitigation measures to reduce human exposures below harmful levels. These mitigation measures include specific buffer zones for bystanders (workers and residents), lower application rates, mandatory use of highly retentive tarps, limited treatment of acreage, and other restrictions (see California-Use Only labels).

On September 7, 2005, Medical Toxicology Branch scientists conducted an evaluation of Midas product label based on the results of several acute toxicology studies. The proposed product label identified the potential acute toxicity hazards indicated by the data reviewed and the first aid statements were adequate. However, the personal protective equipment (PPE) requirements on the label were not adequate for the Category I dermal irritation hazard presented by exposure to the subject product. Registration was not recommended until the deficiencies noted were addressed.

Response: The California-Use Only labels will address this label deficiency. The labels specify:

"When performing tasks with liquid contact potential, all handlers (including applicators) must wear:

- **Loose fitting or well ventilated long-sleeved shirt and long pants,**
- **Chemical-resistant gloves,**
- **Chemical-resistant apron,**
- **Chemical-resistant footwear and socks,**
- **Full face shield or safety glasses with brow, temple and side protection. DO NOT wear goggles, and**
- **A half face air-purifying respirator with a 3M Brand No. 60928 cartridge filter, or one specifically tested against iodomethane which performs equivalent to the 60928 cartridge filter (NIOSH approval number prefix TC-23C).**

- **In addition, if sensory irritation (tearing, burning of the eyes or nose) is experienced while wearing a half-face air-purifying respirator, handlers must wear at a minimum a full-face air-purifying respirator with a 3M Brand No. 60928 cartridge filter or one specifically tested against iodomethane which performs equivalent to the 60928 cartridge filter (NIOSH approval number prefix TC-23C). See Directions for Use, Protection for Handlers, Respiratory Protection and Stop Work Triggers, number 1: “*Handlers Wearing Half-Face Air-Purifying Respirators*”, for when a full-face respirator is required.**

The label further states: “...chemical-resistant to this product are barrier laminate or viton ≥ 14 mils. For more options, follow the instructions for category H on the chemical-resistance category selection chart.” Barrier laminate and Viton have been tested against methyl iodide and are effective in blocking the passage of methyl iodide for exposures lasting more than 8 hours. Therefore, personal protective equipment requirements are no longer a concern.

Environmental Monitoring Branch: (Review Area- Off-site Air Concentration Mitigation)

During April 21-29, 2010, the Environmental Monitoring Branch (Air Program) scientists evaluated three flux studies for fumigations that used virtually impermeable film (VIF) to suppress emissions. Environmental Monitoring scientists found that the three methyl iodide studies using VIF likely underestimate the air concentrations and flux, and use poor methodology, as indicated by the quality control results. In addition, the studies did not include measurements during tarp cutting or removal.

Response: Despite the problems with the studies, it is possible to use them to estimate the maximum possible flux for VIF applications. As described in the April 29, 2010 memo from Randy Segawa and Terrell Barry to John Sanders, changing from standard tarps to VIF likely reduces methyl iodide flux 30–40 percent. The buffer zone distances on the California-Use Only labels reflect a 40 percent reduction in flux due to VIF. As described in a separate memorandum from Terrell Barry to John Sanders, dated April 29, 2010, data on dissipation of methyl iodide in soil indicates that a period of 14 days before cutting and removing tarps likely results in acceptable air concentrations.

In addition, Environmental Monitoring scientists later discovered errors in some of the flux values used for the buffer zone calculations described in the memorandum from Randy Segawa and Terrell Barry to John Sanders on April 29, 2010, First, an application adjustment for the Oxnard bed/tarp method study was too large because the application rate for the study was assumed to be 139 pounds per acre rather than the 171 pounds per acre actually applied. Thus, the adjustment for scaling to other application rates was too

large, resulting in buffer zones larger than necessary to achieve the desired mitigation goal. Second, for the Guadalupe bed/tarp study, Environmental Monitoring staff removed an adjustment made by Arysta in the first two sampling periods to account for less than the full field being treated. Arysta divided the actual measured flux by the proportion of the total area treated for sampling periods 1 and 2. Thus, the reported flux for periods 1 and 2 were 30 percent and 60 percent of the actual flux, respectively. Environmental Monitoring staff did not agree that an adjustment to the measured flux should be made, so the final flux profile used the actual measured flux for periods 1 and 2. These flux values were higher than the values reported in the study report.

Once the final flux profile for each field study was derived, Environmental Monitoring scientists checked the buffer zone distances developed by Arysta for the California-Use Only labels based on the following specifications: 1) all flux profiles from the Arysta field studies were standardized to the maximum allowed label application rate, 2) for each method an average flux profile was derived by aligning the start of application at 8:00 a.m. and averaging the flux in each hour, 3) the PERFUM model was run using the average flux profiles for each application method and 5 years of Ventura weather data, 4) the 95th percentile maximum direction buffer zone was chosen for each field size and application rate of interest. Application rates less than the maximum label rates were derived by proportional reduction of the maximum application rate flux profile. *(NOTE: The California-Use Only labels specify a maximum application rate of 100 pounds per acre, less than the 125 pounds per acre in DPR's proposed registration decision)* Based on these specifications, the calculated buffer zones vary from 0 to 1,400 feet, depending on application rate, acreage, and method of application. The California-Use Only labels establish a minimum buffer zone of 100 feet for scenarios where the calculated buffer zone is less than 100 feet. For the reasons stated above, these revised buffer zones are smaller than those in DPR's proposed registration decision in most cases.

On February 6, 2003, March 3, 2003, and April 8, 2005 the Environmental Monitoring Branch scientists evaluated the labels and data from two monitoring studies (volatility of iodomethane; and environmental monitoring and direct/indirect flux) for Midas products and recommended against registration of the products (memorandum attached). **(Note- this recommendation was based on the review of old labels, prior to EPA registration)** Environmental Monitoring scientists identified the following label issues as its basis for recommending that "Data/Information Do Not Support Registration" of Midas products:

1. The proposed label does not have any buffer zones included on the label. Buffer zones will need to be developed and included on the label.
2. The Pre-plant Soil Fumigation Table contains application rates in conflict with other statements on the labels. The conversion of bed application rates to the equivalent broadcast rates should be illustrated since buffer zones for off-site exposure will be expressed on the

broadcast acre basis. The label statements related to broadcast versus bed fumigation need to be clarified.

3. Tarpaulin/Shallow/Broadcast and Bed application rates of 235 lbs of iodomethane is substantially more than the 165 lbs iodomethane/treated acreage in the Table.
4. The limitation of application block to 40 acres or less is not supported by field studies. This limitation will need to be developed as the buffer zone development process proceeds.
5. California does not currently have any tarpaulins (VIF) approved.
6. The term "outer buffer zone" is undefined.

Response: DPR developed mitigation measures to include specific buffer zones as discussed in the previous response. The wording of California-Use Only Labels related to broadcast versus bed fumigation were revised to ensure consistency and bed fumigations now contain adjusted maximum rates. Labels were also amended to decrease the maximum amount of acres treated (20 acres versus 40 acres on the federal product labels). Additionally, DPR required highly-retentive tarps for applications of all the Midas products intended for use in California. DPR developed mitigation measures that were incorporated in the California-Use Only labels to establish one buffer zone for workers and bystanders thereby eliminating the need to define an outer buffer zone.

Worker Health and Safety Branch

On January 14, 2005 and September 19, 2006, Worker Health and Safety Branch scientists evaluated the labels and worker exposure data for Midas products (98:2 and 50:50) and prepared recommendations to the Pesticide Registration Branch.

Worker Health and Safety scientists found the Midas labels to be unacceptable because the 4 parts per million (ppm) threshold level for chloropicrin (before requiring supplied air or self contained breathing apparatus) is inadequate. The labels needed to require a 2 ppm level, consistent with the NIOSH Immediately Dangerous to Life or Health Concentration (1994).

Response: The California-Use Only labels have been revised to address this label deficiency. The following statements are on the label:

"If at any time (1) a handler experiences any sensory irritation when wearing a full-face air-purifying respirator; or (2) an air sample is greater than or equal to 1.0 ppm, then all handler activities must cease and handlers must be removed from the application block and buffer zone.

If operations cease, the emergency plan detailed in the FMP must be implemented. Handlers can remove full-face air-purifying respirators or resume work activities if the following conditions exist provided that a half-face air-purifying respirator is worn:

- **Two consecutive breathing zone samples for chloropicrin taken at the handling site at least 15 minutes apart must be less than 0.10 ppm,**
- **Handlers do not experience sensory irritation, and**
- **Air-purifying respirator cartridges have been changed.**
- **During the collection of air samples a full-face air-purifying respirator must be worn by the handler taking the air samples. Samples must be taken where the sensory irritation is first experienced.”**

Staff Recommendations for Conditional Registration :

Pesticide Registration Branch

On August 10 and 13, 2009, the Pesticide Registration Branch's (Pest and Disease Protection Station) scientists evaluated the labels and efficacy data for Midas products and prepared recommendations. Registration scientists identified the following efficacy issue, and recommended additional data as part of a conditional registration:

The data submitted demonstrated that the products were effective against soil-borne diseases and nematodes. The registrant did not submit data to support claimed efficacy of the Midas products against soil-borne insect pests (e.g., wireworms, cutworms, grubs, rootworms, garden symphylans, ants, and termites). A conditional registration was requested for two years to allow Arysta sufficient time to develop efficacy data for these soil-borne insect pests.

Response: Arysta deleted the term soil-borne insect pests from all the labels submitted for registration in California. The currently approved California-Use Only labels reflect this change.

On November 14, 2007, the Pesticide Registration Branch's (Product Chemistry Station) scientists evaluated the labels and product chemistry data for Midas products and prepared recommendations. Registration scientists identified the following chemistry issue, and recommended additional data as part of a conditional registration:

These data were evaluated and all studies were determined to adequately comply with 40 CFR 158.150-190 product chemistry data requirements except storage stability and corrosion characteristics. A conditional registration was recommended to allow Arysta one-year to develop and submit storage and stability and corrosion characteristics data for the Midas products.

Response: After the evaluation was written, Arysta submitted storage and stability and corrosion characteristics data for the Midas products. In February 2010, Registration

Branch scientists completed the evaluation of submitted storage stability and corrosion characteristics data and found the data to be acceptable. No further action is warranted.

Environmental Monitoring Branch

On January 11, 2010, the Environmental Monitoring Branch (Ground Water Program) scientists evaluated the labels and terrestrial field dissipation data for Midas products and prepared recommendations to the Pesticide Registration Branch. Environmental Monitoring scientists identified the following ground water contaminant issue as their basis for recommending additional data as part of a conditional registration:

The potential for iodomethane contamination of well water is low because of high volatility and relatively fast hydrolysis when compared to long travel times of surface water to drinking water wells. However, there is a large amount of uncertainty with respect to iodide's environmental fate, which was reflected in the disparity of soil mass between actual measurements and the potential amount determined from a mass balance approach calculated from iodomethane recovery in air and soil. Based on this uncertainty, the Environmental Monitoring Branch recommended conditional registration to allow Arysta addition time to provide information on the environmental fate of iodomethane:

1. Conduct soil sampling after field applications of iodomethane at course-textured soil sites in California that are vulnerable to leaching of residues to ground water. The objective is to provide the concentration distribution in the soil profile of iodide and its other chemical forms.
2. Apply existing methods or develop additional chemical analytical techniques that are capable of measuring iodide and its other chemical forms in soil. For example, the predominant oxidized form in soil could be iodide. Snyder et al. (2005) report on a method to measure trace concentration of iodide in water using LC-MS/MS.
3. Explain why the lapse in time from the start of each study until the measurement of iodide using the specific ion electrode was nearly identical for both studies. Although the studies were conducted six months apart, both were subject to the same analytical problems with respect to iodide measurement in soil. Were the samples from both studies analyzed at the same time?

Response: The California-Use Only labels impose health-conservative mitigation measures that do not require submission of additional data. Those measures include 100-foot buffer zones for unprotected well heads (or the alternative to construct berms next to wellheads to prevent runoff from contaminating wellheads) and limits irrigation to 133% of crop needs for six month following fumigation in ground water protection areas. These requirements are consistent with DPR's regulations to protect areas vulnerable to ground water contamination, as specified in Title 3, California Code of Regulations, section 6487.5.