

**Notice of Proposed Decisions To Register Pesticide Products
Containing Methyl Iodide And Public Report**

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**Department of Pesticide Regulation
Pesticide Registration Branch**

POST THROUGH: June 14, 2010

**NOTICE OF PROPOSED DECISIONS TO REGISTER PESTICIDE PRODUCTS
CONTAINING METHYL IODIDE AND PUBLIC REPORT**

Description of the Action

The Director of the Department of Pesticide Regulation (DPR), pursuant to section 6253 (Title 3) of the California Code of Regulations, notices the Department's proposed decisions to register pesticide products containing the new active ingredient, methyl iodide or iodomethane (MeI) pursuant to Chapter 2 of Division 7 of the Food and Agricultural Code (commencing with section 12751). Included in this notice is a discussion of the regulatory reference concentration target levels for both bystander and worker exposures and mitigation measures that address those target levels. These mitigation measures must be adopted through label changes before DPR will take a final action on the registration of these products.

**Tracking Number - EPA Registration Number
Applicant / Brand Name**

ID 192894 - (66330-44)
ARYSTA LIFESCIENCE NORTH AMERICA, LLC
IODOMETHANE TECHNICAL
USE: FUMIGANT - FOR FORMULATION AND REPACKAGING INTO END-USE PRODUCTS
INTENDED FOR TERRESTRIAL NON-FOOD USES TO CONTROL SOIL-BORNE PESTS SUCH
AS NEMATODES, INSECTS, WEED AND GRASS SEEDS AND DISEASES
TYPE: SECTION 3 REGISTRATION
ACTIVE INGREDIENT(S): IODOMETHANE
CAS NUMBER(S): 74-88-4

ID 192893 - (66330-43)
ARYSTA LIFESCIENCE NORTH AMERICA, LLC
MIDAS 98:2
USE: FUMIGANT - FOR USE ON STRAWBERRIES, TOMATOES, PEPPERS AND
ORNAMENTAL FLOWERS, PLANTS AND BUSHES TO CONTROL NEMATODES, INSECTS,
WEED AND GRASS SEEDS AND DISEASES
TYPE: SECTION 3 REGISTRATION
ACTIVE INGREDIENT(S):
IODOMETHANE
CHLOROPICRIN
CAS NUMBER(S): 74-88-4, 76-06-2

ID 209995 - (66330-57)

ARYSTA LIFESCIENCE NORTH AMERICA, LLC

MIDAS 50:50

USE: FUMIGANT - FOR THE CONTROL OF SOIL-BORNE PESTS SUCH AS WEED SEEDS, NEMATODES, INSECTS, AND DISEASES ON VARIOUS CROPS SUCH AS STRAWBERRIES, PEPPERS, TOMATOES, AND TREES AND VINES

TYPE: SECTION 3 REGISTRATION

ACTIVE INGREDIENT(S):

IODOMETHANE

CHLOROPICRIN

CAS NUMBER(S): 74-88-4, 76-06-2

ID 211201 - (66330-59)

ARYSTA LIFESCIENCE NORTH AMERICA, LLC

MIDAS 33:67

USE: FUMIGANT - FOR PRE-PLANT FUMIGATIONS OF FIELDS INTENDED FOR COMMERCIAL PRODUCTION OF CROPS SUCH AS STRAWBERRIES, TOMATOES, PEPPERS, FIELD-GROWN ORNAMENTALS AND CONTROL OF SOIL-BORNE PESTS INCLUDING WEED SEEDS, NEMATODES, INSECTS, AND DISEASES

TYPE: SECTION 3 REGISTRATION

ACTIVE INGREDIENT(S):

IODOMETHANE

CHLOROPICRIN

CAS NUMBER(S): 74-88-4, 76-06-2

ID 211199 - (66330-60)

ARYSTA LIFESCIENCE NORTH AMERICA, LLC

MIDAS EC Gold

USE: FUMIGANT - FOR PRE-PLANT FUMIGATIONS OF FIELDS INTENDED FOR COMMERCIAL PRODUCTION OF CROPS SUCH AS STRAWBERRIES, TOMATOES, PEPPERS, FIELD-GROWN ORNAMENTALS AND CONTROL OF SOIL-BORNE PESTS INCLUDING WEED SEEDS, NEMATODES, INSECTS, AND DISEASES

TYPE: SECTION 3 REGISTRATION

ACTIVE INGREDIENT(S):

IODOMETHANE

CHLOROPICRIN

CAS NUMBER(S): 74-88-4, 76-06-2

Alternatives

In making the proposed decisions and determining additional mitigation measures to reduce exposures, DPR considered product labels and data submitted by the registrant and other information including the DPR risk characterization document and the external peer review, the U.S. Environmental Protection Agency's (U.S. EPA's) risk assessment document, various scientific assessments, and comments from numerous stakeholders. As a result of this evaluation and based on additional mitigation measures identified, DPR has determined that no direct or indirect significant adverse environmental impact is

anticipated from the registration of the listed products. An alternative analysis involving all anticipated crop and pest uses, under many environmental conditions and cultural practices, is beyond the scope of this process. Such analyses are more appropriate at the local level where more specific conditions of use can be identified in connection with the restricted-material permit that must be issued by the county agricultural commissioner in connection with any use of these products.

Background

In October 2007, U.S. EPA granted a one-year, time-limited registration for MeI Midas® products after the completion of the risk assessment process. In the risk assessment, U.S. EPA concluded that acute exposure, compared to repeated exposures, was of primary concern. U.S. EPA also considered MeI a non-food use chemical, and thus, food tolerances were not needed. The rationale for the non-food use determination included MeI rapid metabolism, low iodide level produced and its incorporation into natural plant constituents, and difficulty associated with enforcement of a tolerance on iodide, which is also a natural element in the environment. U.S. EPA concluded that Midas® products could be registered as a restricted-use pesticide with the requirement of buffer zones, recording keeping, training and stewardship programs, restricted-entry period, and respirators for some workers (tarp monitors, shovelers, tractor drivers, and co-pilots). On September 29, 2008, U.S. EPA granted conditional registration for all Midas® products without time limitations. The conditional registration hinged on U.S. EPA's reregistration process for all fumigants. The conditional registration required the registrant to make all changes to the Midas® product labels required to assure that MeI is regulated in a manner consistent with other fumigants after completion of the reregistration process. U.S. EPA registered MeI for use as a pre-plant fumigant on a limited number of crops and field-grown ornamentals, including peppers, strawberries, tomatoes, turf, nurseries (strawberry plants, stone fruit, tree nut, and conifer trees), stone fruit, tree nut, and vine (table, raisin, and wine grapes) replants.

In 2002, concurrent with applications made at the federal level, DPR received several applications from Arysta requesting registration of MeI products. In addition to the proposed labels, Arysta submitted several studies that included air monitoring data of application methods and worker exposure. MeI products are considered restricted-use pesticides due to acute inhalation toxicity. As federally restricted-use pesticides, MeI products would be used only by certified applicators or under their direct supervision (requires the person on-site).

In January 2005, DPR began preparing a risk characterization document (RCD). The draft RCD was completed by March 2009 and sent for peer review to the Office of Environmental Health Hazard Assessment and U.S. EPA. In May 2009, DPR contracted with an external group of scientists to have its draft RCD peer reviewed. The review was completed in February 2010 and DPR published the completed RCD for MeI. The RCD focuses its risk evaluation on inhalation exposures as the primary route of exposure; dermal exposure was considered negligible, and no dietary exposure is expected. Environmental fate modeling predicted ground water contamination by the iodide metabolite in susceptible soils that may contribute to drinking water exposure. These findings are generally consistent with U.S. EPA's risk assessment.

Regulatory Target Levels

Since the risk evaluation on acute inhalation exposures poses the most concern, DPR's proposed decision to register includes regulatory guidance for bystander and worker exposures to MeI for acute exposures. This is also termed the "regulatory exposure target level" which is typically described as a concentration over a short period of time. This exposure target level was based on the no-observable effect level (NOEL) of 2 parts per million identified in the RCD for the most critical endpoint of fetal loss (effect seen after a short duration inhalation exposure to the chemical). Following standard scientific practice, the RCD relied exclusively on animal studies. Additional consideration of animal-to-human ratios of breathing rates and hours and days of exposure resulted in a calculation of the human-equivalent concentration (HEC). The exposure estimates were calculated using a very conservative (that is, health-protective) approach since it assumes that exposures occur directly downwind at the edge of the field, 8 or 24 hours a day for workers and bystanders respectively. The target level also takes into consideration interspecies and intraspecies uncertainty factors accounting for the differences between humans and animals, and consideration for sensitive individuals within the human population. These principles are used by U.S. EPA and other regulatory agencies in other nations, including the World Health Organization.

For MeI, DPR would establish a regulatory target level of 32 parts per billion (ppb) averaged over a 24-hour period for bystanders, and 96 ppb averaged over an 8-hour period for workers. In comparison with U.S. EPA's regulatory target levels of 150 ppb for bystanders and 193 ppb for workers, DPR's regulatory target levels are more health-protective.

DPR will adopt a regulation making MeI a restricted material that requires a permit issued by the county agricultural commissioner. This will add an additional level of compliance oversight and protection to assure safe use under specific local conditions for each application site. In addition, DPR will also require extensive mitigation measures to reduce exposures to levels that meet the regulatory target levels above. These measures would be established through label changes.

Mitigation Strategies

Several mitigation strategies will be required to ensure that the target levels are met. DPR plans to work with the registrant to adopt these mitigation measures through label changes specific for use in California.

- a. Minimum buffer zones will be established: 100 feet for drip and deep injection Auger-probe application methods; and 200 feet for shank injection (bed and broadcast) application methods, regardless of field application size or application rate. U.S. EPA requires a minimum buffer zone of 25 feet. The following tables present the proposed buffer zones according to field size, application rate, and application method:

Buffer Zones for 1-Acre Field Treated with Iodomethane

Pounds MeI per Acre	Drip Application Method with VIF Tarp (feet)	Shank-Bedded Application Method with VIF Tarp (feet)	Shank-Broadcast Application Method with VIF Tarp (feet)
50	100	200	200
75	100	200	200
100	100	261	200
125	152	357	211

Buffer Zones for 5-Acre Field Treated with Iodomethane

Pounds MeI per Acre	Drip Application Method with VIF Tarp (feet)	Shank-Bedded Application Method with VIF Tarp (feet)	Shank-Broadcast Application Method with VIF Tarp (feet)
50	100	369	200
75	184	630	310
100	295	884	470
125	434	1133	656

Buffer Zones for 10-Acre Field Treated with Iodomethane

Pounds MeI per Acre	Drip Application Method with VIF Tarp (feet)	Shank-Bedded Application Method with VIF Tarp (feet)	Shank-Broadcast Application Method with VIF Tarp (feet)
50	184	636	255
75	356	1034	503
100	528	1419	750
125	719	1788	1031

Buffer Zones for 20-Acre Field Treated with Iodomethane

Pounds MeI per Acre	Drip Application Method with VIF Tarp (feet)	Shank-Bedded Application Method with VIF Tarp (feet)	Shank-Broadcast Application Method with VIF Tarp (feet)
50	289	1065	455
75	555	1614	830
100	819	2134	1201
125	1112	2617	1597

Buffer Zones for 30-Acre Field Treated with Iodomethane

Pounds MeI per Acre	Drip Application Method with VIF Tarp (feet)	Shank-Bedded Application Method with VIF Tarp (feet)	Shank-Broadcast Application Method with VIF Tarp (feet)
50	406	Not Allowed	Not Allowed
75	740	Not Allowed	Not Allowed
100	1069	Not Allowed	Not Allowed
125	1420	Not Allowed	Not Allowed

- b. Require no occupied hospitals, nursing homes, prisons, schools, licensed day-care facilities, and licensed assisted-living facilities (licensed by state or local government) within one-half mile of the fumigated area during the buffer-zone period. U.S. EPA requires buffer zones of one-quarter mile from these sites.
- c. Require a restriction to prohibit buffer zones from overlapping during the buffer-zone duration. U.S. EPA also prohibits buffer zones from overlapping.
- d. Require the certified applicator to use an appropriate means to maintain the buffer zone from the start of application until 48 hours following the end of the application. An appropriate means to maintain the buffer zone could include posting warning signs around the perimeter of the buffer zones, using trained workers to patrol the buffer zones, or other equivalent measures. U.S. EPA also requires certified applicators to maintain buffer zones using these approaches.
- e. Require the following restrictions to prevent the leaching of MeI into ground water: 100-foot buffer zones for unprotected wellheads, or as an alternative, construct berms adjacent to the wellheads to prevent surface water run-off from contaminating wellheads; and limit the irrigation efficiency to 133% of crop need after fumigation in leaching ground water protection areas. This is in addition to U.S. EPA's requirement that tarp cutting or removal for broadcast applications must take place before noon and when rainfall is not expected within 12 hours.
- f. Limit acreage treated to a maximum of 30 acres per site for drip applications, and 20 acres for shank applications. U.S. EPA established a 40-acre maximum regardless of application method.
- g. Prohibit standard tarps for all application methods. All application methods will require virtually impermeable film (VIF) tarps, regardless of application rates and field size. A list of acceptable VIF tarps will be defined. U.S. EPA allows both standard and VIF tarps.
- h. Prohibit applications at night (after sunset and before sunrise). U.S. EPA does not have restrictions on time of application.
- i. Establish maximum rates of methyl iodide: 75 pounds MeI per acre (broadcast equivalent) for the drip and shank (bedded) application methods; 100 pounds MeI per acre (broadcast equivalent) for the shank (broadcast) application method for strawberries, peppers, tomatoes, field-grown ornamentals, and turf; 125 pounds MeI per acre (broadcast equivalent) for the shank (broadcast) application method for stone fruits, tree nuts, vines, and nurseries (strawberries, stone fruits, tree nuts, and conifer trees). U.S. EPA has a maximum rate of 175 pounds MeI per acre.
- j. Require a minimum of 14 days before workers can reenter the field for other activities such as tarp-cutting, tarp removal, or planting. U.S. EPA requires a minimum of five days before reentry.
- k. For the deep injection Auger-probe application method, require applications to be limited to 25 sites per acre. U.S. EPA currently allows 50 sites per acre for this application method.
- l. Require fumigation equipment to be operated in a manner that eliminates pesticide drip by using check valves close to the injection points, or clearing the fumigant from the injection device before it is lifted or removed from the soil. U.S. EPA has no restrictions.

Interested persons may comment on these proposed decisions up to and including the date shown in the top line of this notice. Send comments to the Pesticide Registration Branch, Department of Pesticide Regulation, P.O. Box 4015, Sacramento, California 95812-4015; or by e-mail to <mei_comments@cdpr.ca.gov>. Contacts regarding this notice should be made to the Pesticide Registration Branch at 916-445-4400.

30 April 2010
Date


Mary-Ann Warner
Director