

THE COMMONWEALTH OF MASSACHUSETTS

EXECUTIVE OFFICE OF ENERGY AND ENVIRONMENTAL AFFAIRS



Department of Agricultural Resources

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Ashley E. Randle
COMMISSIONER

Tuesday, December 19, 2023

Zoom Meeting at:

<https://us06web.zoom.us/j/86843114982?pwd=Q3N5S0JIUXBQQXU5QVJLNW5FVIE1dz09>

Passcode: 632573

BOARD MEMBERS IN ATTENDANCE

Michael Moore, DPH, Food Protection Program (Chair)	Present
Taryn LaScola, MDAR, Designee for Commissioner Randle	Present
Meg Blanchet, DPH, Designee for Commissioner Goldstein	Present
Nicole Keleher, DCR, Designee for Commissioner Arrigo	Present
Richard Berman, Commercial Applicator	Present

The Board did meet or exceed the minimum number (3) of members present to form a quorum and conduct business.

A. REVIEW OF MINUTES for October 17, 2023:

Motion: R. Berman

Second: N. Keleher

Discussion: None

In Favor: M. Moore, R. Berman, T. LaScola, M. Blanchet, N. Keleher

Opposed: None

Abstained:

B. PRODUCT REGISTRATIONS

Motion: That the Pesticide Board Subcommittee registers the pesticide products listed on the EIPAS PR December 19, 2023, Subcommittee cover sheet.

Moved: R. Berman

Second: N. Keleher

Discussion: None

In Favor: M. Moore, T. LaScola, R. Berman, M. Blanchet, N. Keleher

Opposed: None

Abstained: None

C. SECTION 18 EMERGENCY EXEMPTION REQUEST

Wijnja gave a brief introduction of a Section 18 emergency exemption, which authorizes EPA to allow emergency exemptions for unregistered uses of pesticides to address emergency conditions. He stated that MDAR received a request for recertification of a Section 18 emergency exemption for the use of Pronamide (Kerb SC Herbicide, EPA Reg. No. 62719-578) in the 2024 use season on cranberries to control dodder. This Section 18 was first requested for the 2019 growing season and was recertified for the 2020-2023 growing seasons based on information that indicated that the emergency situation with respect to heavy dodder weed infestations continued to exist for certain growers, and that Kerb herbicide is the only effective control method in such situations. Use reports for the 2019-2023 seasons showed that a small number of growers (typically less than 10) used this product.

EPA designated this Section 18 for Kerb herbicide as eligible for recertification in 2024 using the expedited and streamlined petition process and referring to the initial 2019 petition for detailed information. The recertification process requires the need to confirm that previously submitted information is still accurate, that conditions for emergency use still exist, and that there are no changes to use directions, including application rates. The petition documents for 2024, which were in the meeting package, included information that confirms that the above listed criteria and conditions are met. EPA information indicates that the progress towards registration of the use on cranberries is adequate. The Section 18 use of Kerb is covered by a time-limited tolerance.

Dr. Hillary Sandler, UMass Cranberry Station, was in attendance and provided additional information to support this request. Sandler indicated that they were a little bit early submitting the recertification request since EPA indicated that the agency is required to allow a 15-day public comment period for this request since it will be the 6th year for this Section 18. Sandler reiterated that, although it is a small subset of growers that applied Kerb in the past few years, it remains critical for those few growers who continue to have a significant dodder problem.

Sandler described the potential impacts of dodder weed in cranberry. Dodder is an obligate parasite, that almost looks like spaghetti string, that can totally envelope and cover the plant that it's parasitizing. It's an excellent parasite, it does just enough to depress yield but does not kill the host and is able to complete its life cycle in a single year and produces tens of thousands of very long live seeds. This is why this plant can become such a problem in cranberries. Dodder remains quite a problem for cranberry growers in MA; in this past year, it was noticed that more dodder showed up and it is anticipated that the use of Kerb herbicide may go up slightly during the 2024 growing season.

The registrant Corteva is supportive of this use of Kerb under a Section 18. EPA is currently reviewing the documentation that Corteva has provided to them. The registration of use on cranberry is currently anticipated during the third quarter of 2024. Therefore, a recertification of the Section 18 is being requested to allow use during the 2024 season.

Berman asked how significant of a problem dodder is in other growing areas like New Jersey and Wisconsin. Sandler stated that the situation in Massachusetts is probably worse than in New Jersey and Wisconsin. In the past, UMass Cranberry Station partnered with Extension specialists in those states in looking at some alternative herbicides, indicating that growers in those states also deal with dodder weeds.

VOTED

Move: That due to the lack of currently registered pesticide products for the control of the emergency pest problem, the Pesticide Board Subcommittee approves of a FIFRA Section 18 Emergency exemption petition for the use of Kerb SC, EPA Reg. No. 62719-578, containing the active ingredient ***pronamide*** for the control of weed pest dodder in cranberries.

This motion also takes into account the following data provided by the Department, the University of Massachusetts Cooperative Extension, and product registrant:

- Recertification Request from the University of Massachusetts Cooperative Extension;

- Registrant's letter of support;
- Proposed supplemental labeling; and
- Any other data or conditions as included.

Moved: R. Berman

Second: T. LaScola

Discussion: None

In Favor: M. Moore, T. LaScola, R. Berman, M. Blanchet, N. Keleher

Opposed: None

Abstained: None

D. NEW ACTIVE INGREDIENT

Discussion of registration of Madex® XLV (EPA Reg. No. 69553-12-70051), containing the new active ingredient *Cydia pomonella* Granulovirus Isolate GV0017. The product is a pre-harvest biological insecticide labeled for control of codling moth and oriental fruit moth on pome fruit trees, stone fruit trees, and nut trees.

Miller provided information on the product and new active ingredient under consideration for registration in the state of Massachusetts.

Madex XLV, EPA No. 69553-12-70051, is a selective insecticide containing *Cydia pomonella* Granulovirus Isolate GV0017 (GV-17). The product contains a minimum of 30 trillion viral inclusion bodies per liter of product, which by weight is approximately 0.06% of the Madex XLV formulation.

GV-17 is a baculovirus from a family of insecticidal viruses that only appears to target specific species within the tortrix, or leafroller, moth family. These viruses are naturally-occurring and this strain was isolated from *Cydia pomonella* larvae. The target moths damage fruits by internal feeding during the larval stage. The virus only becomes active after susceptible larvae ingest the inclusion bodies. The protein overcoats disintegrate in the larval gut and the released virions then infect digestive cells. A few days after ingestion, the larvae stop eating, weaken, and die.

Massachusetts currently has four approved products with a *Cydia pomonella* GV strain registered as an active ingredient. The first CPGV strain isolated was used for several decades before codling moth field resistance was observed in 2004 in European orchards. GV-17 was identified in the search for alternatives and appears to have a slightly broader range of hosts that also includes oriental fruit moths.

Handling Precautions

The signal word on the Madex XLV label is 'Caution'. Handlers are required to wear personal protective equipment to cover skin, including waterproof gloves, protective eyewear, and specified NIOSH-approved particulate or air-purifying respirators. Users are warned that repeated exposures to high concentrations of microbial protein materials can cause allergic sensitization. The Restricted Entry Interval (REI) for agricultural workers is 4 hours.

Uses

Allowed uses are strictly terrestrial. Direct applications to water bodies, areas where surface water is present, and intertidal areas below the mean high-water mark are all prohibited.

Madex XLV is a pre-harvest biological insecticide labeled for controlling codling and oriental fruit moths on pome fruit trees, stone fruit trees, and nut trees. The most relevant Massachusetts orchard crop likely would be primarily apples, followed by peaches and pears.

The product is mixed with water and sprayed on fruit and foliage shortly before larvae hatch. Label application rates range from 0.5 to 3 oz. per acre and the label suggests more frequent applications at lower doses may maximize effectiveness. A minimum of two but no more than six applications are allowed per larval generation. The product can be applied up to and including the day of harvest.

Human Health Risk

The Environmental Protection Agency's (EPA) human health risk assessment states GV-17 has no demonstrated mammalian infectivity and low acute toxicity, as indicated from acute oral, inhalation, and injection studies on rats at doses of up to a billion occlusion bodies. EPA calculated that the maximum application rate would result in about ten million occlusion bodies per ml diluted solution, or 10 to 100 times less than study concentrations. Tier 2 testing was not required because no toxicity, pathogenicity, or infectivity was observed at the maximum hazard doses of these studies.

EPA reported toxicity category classifications for the Madex XLV end product, with acute oral, dermal, and inhalation toxicity all Category IV, or practically non-toxic. Primary dermal irritation is also Category IV. Based on studies of similar baculovirus strains, Madex XLV is categorized as Category III for acute eye irritation.

EPA review of the scientific literature found no reports of baculovirus replicating in cell types other than specific insects.

Because no adverse effects were identified in the toxicological tests, EPA did not conduct a quantitative exposure assessment. Instead, exposure risks to humans were considered qualitatively. Dietary and drinking water exposures are expected to be negligible due to the low application rates and residues not being expected to exceed background levels already present in the environment and on commonly consumed foods. There is potential for occupational and non-occupational exposures through drift from applications. However, no toxicological endpoints were identified at maximum doses in guideline studies.

EPA has determined that available evidence indicates no unreasonable adverse effects to humans are expected from the use of this active ingredient as a pesticide when the product label instructions are followed. There is also reasonable certainty no expected harm will come to the US population, including infants and children, from aggregate exposure to residues resulting from the proposed uses.

Environmental Risk

Baculoviruses generally only infect specific insects and cannot replicate in other organisms due to the specifics of host physiology and virus characteristics. Birds and wild animals may be exposed through contact during application or by touching treated surfaces. Oral exposure could occur through consumption of food items contacted during application. However, there is no evidence of birds or mammals being infected by baculoviruses, so they are not a host or reservoir of GV-17.

Registrant studies showed no treatment-related mortality in supplemental studies on freshwater fish and invertebrates using similar strain V22. Marine fish and invertebrate tests were not required due to scientific rationales that demonstrated significant concentrations would not be expected to reach marine or estuary environments from proposed label uses.

A 30-day oral toxicity and pathogenicity laboratory study with honey bees determined that the LD50 to be > 800 million inclusion bodies of GV17 per milliliter, which was adopted as the No Observed Effects Concentration (NOEC). Cumulative bee mortality, which was not dose-dependent, ranged from 16 to 22% with no treatment-related behavioral effects observed.

EPA has determined that no adverse effects are expected in non-target insects outside the leafroller moth family as a result of proposed GV-17 applications. The agency calculated that spray drift and runoff will reduce the concentration of GV-17 by ~88 %, which would also reduce exposure risks for non-target insects.

Non-target plants are not expected to be at risk from this product because baculoviruses are not able to infect plants and are not taxonomically related to known plant pathogens. Therefore, no plant testing was required.

Granulovirus is not persistent in the environment.

Endangered Species Act

There are no federally listed species within the target leafroller moth family group and no threatened or endangered species exclusively feed on GV-17-targeted moths.

Groundwater Protection

Madex XLV, EPA Reg. No. 69553-12-70051, does not meet the criteria for being classified as a potential groundwater contaminant in Massachusetts.

Move: that the Pesticide Board Subcommittee approve the product registration for Madex® XLV (EPA Reg. No. 69553-12-70051) containing the new active ingredient *Cydia pomonella* Granulovirus Isolate GV-0017, which has never before been registered in Massachusetts.

Moved: R. Berman

Second: T. LaScola

Discussion: None

In Favor: M. Moore, T. LaScola, R. Berman, M. Blanchet, N. Keleher

Opposed: None

Abstained: None

E. NEW BUSINESS

No new business was brought forward.

ADJOURN

Motion: To adjourn the December 19, 2023, Subcommittee Meeting.

Moved: R. Berman

Second: T. LaScola

In Favor: M. Moore, T. LaScola, R. Berman, M. Blanchet, N. Keleher

Opposed: None