NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION

Division of Materials Management, Bureau of Pest Management
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September 30, 2016

Ms. Jodi Hemphill
Arysta LifeScience North America, LLC
15401 Weston Parkway, Suite 150
Cary, NC 27513

Dear Ms. Hemphill:

Re: Registration of Vacciplant Containing the New Active Ingredient Laminarin (Active Ingredient Code 123200)

The New York State Department of Environmental Conservation (Department) has evaluated your application materials received in support of registration of the above-mentioned product. Vacciplant (EPA Reg. No. 83941-2-66330) contains 3.51% of the active ingredient laminarin.

The Vacciplant label indicates applications can be made as a foliar spray (including aerial application), plant dip, or soil drench to prevent fungal diseases on various agricultural crops, ornamentals and turf. The maximum application rate is 60 fluid ounces of Vacciplant (0.15 pounds of laminarin) per acre per application. A maximum seasonal or yearly application rate is not specified within the product label.

The application package was deemed complete for purposes of technical review on May 11, 2016. Pursuant to the review time frame specified in Environmental Conservation Law §33-0704.2, a registration decision date of October 7, 2016 was established.

Technical reviews of the proposed uses included on the Vacciplant product label have been performed by the Department and the New York State Department of Health. These reviews encompassed the expected impacts of labeled use of the subject product with respect to human health and ecological effects. Neither the human health review nor the ecological effects review resulted in objections to registration. **As a result, Vacciplant has been registered in New York State.** The technical reviews are presented in the Appendix of this letter.

Enclosed for your record are copies of the Certificate of Pesticide Registration and stamped “Accepted for Registration” label.

Please note that a proposal by Arysta LifeScience North America, LLC or any other registrant to register a product that contains laminarin, and whose labeled uses are likely to increase the potential for significant impact to humans, nontarget organisms, or the environment, would constitute a major change in labeling. Such an application must be accompanied by a new application fee and meet the requirements listed in Appendix 1.B. of “New York State Pesticide Product Registration Procedures” (November 2014). Such information, as well as forms, can be accessed at our website as listed in our letterhead.

Please contact Shaun Peterson, of our Pesticide Product Registration Section, at 518-402-8768, if you have any questions regarding this letter.

Sincerely,

/s/

Scott Menrath, P.E.
Director
Bureau of Pest Management

Enclosures

Appendix

HUMAN HEALTH ASSESSMENT:

The following assessment was produced by staff within the Bureau of Toxic Substance Assessment at the New York State Department of Health (NYSDOH):

Toxicity

Laminarin is a naturally occurring polysaccharide carbohydrate (oligosaccharide) present in all edible plants, which stimulates the natural defense reactions – as a systemic acquired resistance (SAR) inducer – to help build immunity to disease organisms in plants such as mold and bacteria. The U.S. Environmental Protection Agency (U.S. EPA) required limited data for federal registration of laminarin. Neither laminarin nor the formulated product was very toxic in acute oral, dermal or inhalation exposure studies in laboratory animals. The active ingredient and the formulated product were also not very irritating to skin or eyes (tested on rabbits) or skin sensitizers (tested on guinea pigs). Laminarin did not cause any toxicity in 90-day feeding studies in rats and dogs at doses up to 1,000 milligrams per kilogram body weight per day (mg/kg/day), the highest dose tested. Laminarin was negative in several genotoxicity studies and no maternal or developmental effects were reported in oral developmental toxicity studies in rats and rabbits at doses up to 1,000 mg/kg/day. No other toxicity studies were required for federal registration and the U.S. EPA did not derive a reference dose (RfD) for laminarin and granted an exemption from the requirement of a tolerance (Federal Register 75(36):8,252 – 6, February 24, 2010). The U.S. EPA concluded that “any residues that are present in or on food at the time of consumption as a result of pesticide use are likely to be indistinguishable from naturally occurring laminarin due to its natural occurrence and ubiquitous presence in foods and dietary supplements.” A search of the toxicological literature by NYSDOH staff found no additional data on the toxicity of laminarin.

Drinking Water/Groundwater Standards

There are no chemical specific federal or New York State drinking water/groundwater standards for laminarin. Based on its chemical structure, this chemical falls under the 50 microgram per liter (µg/L) New York State drinking water standard for “unspecified organic contaminants” (10 NYCRR Part 5, Public Water Systems).

Summary/NYS DOH Recommendation

The biochemical pesticide laminarin is a naturally occurring polysaccharide carbohydrate with a history of human consumption without known toxicological effect. The available information indicates that neither laminarin nor the formulated product Vacciplant were very acutely toxic or irritating to eyes and skin. In addition, laminarin is a natural component of any diet containing plant material and the available data on its toxicity indicates that the potential for significant risks to public health via dietary

exposure is minimal. Occupational risks are also expected to be minimal as neither dermal nor inhalation endpoints were identified in the toxicity database. Furthermore, laminarin acts through a non-toxic mode of action as it stimulates plant defenses rather than acting on the disease organism itself. **Given the above, NYSDOH does not object to registration of Vacciplant in New York State.**

ECOLOGICAL EFFECTS ASSESSMENT:

The following assessment was produced by staff within the Department's Division of Fish, Wildlife & Marine Resources' Bureau of Habitat (BOH):

Vacciplant is labeled for use as a systemically acquired resistance (SAR) inducer on virtually all agricultural food crops grown in New York State, plus ornamentals and turf. It stimulates the treated plants immune response, making them more resistant to a variety of pathogens.

I. CHEMICAL BACKGROUND

Laminarin is a naturally occurring glucan, a polysaccharide of glucose used as a carbohydrate energy reserve. It is present in most plants. The active ingredient in Vacciplant is extracted from the brown algae *Laminaria digitata* which grows commonly along the nearshore of the Atlantic Ocean.

As a biopesticide with a nontoxic mode of action the data requirements for the purified laminarin extract are much reduced. It has a water solubility of 88.6 g/L, an octanol/water partition coefficient, K_{OW}, of 0.025. Its vapor pressure is 1.95×10^{-7} mmHg.

Use Profile

Vacciplant is labeled for use on every major NY crop. BOH staff did not perform a crop-by-crop analysis of uses but all groups appear to be represented. The end-use product is 3.51% laminarin.

Applications of 14-60 fluid ounces per acre, fl oz/A, equaling 0.035 - 0.15 pounds active ingredient (ai/A) are made using water as the carrier. As a preventative product, applications are begun early in crop development and continued through the growing season. Repeat applications are made at 7-14 day intervals. No seasonal maximum rate is stated.

II. TOXICITY

A limited set of toxicity studies was submitted for laminarin. It proved to be practically nontoxic to all study species for which data were submitted. There was no mortality, clinical signs, or sub-lethal effects in any of the submitted studies except in two beneficial terrestrial arthropod tests.

An exposure trial with the parasitic wasp *Aphidius rhopalosiphi* showed a 26% reduction in fecundity at exposures equal to 5.7 times the maximum labeled single application field rate and a 46% fecundity reduction at 18.6 times the field rate. A similar but much less significant effect was seen in the predatory mite *Typhlodromus pyri*. They showed a 9% decrease in number of eggs per female at the 18.6 times exposure level.

III. EXPOSURE

Submitted environmental fate data is limited to a single ready biodegradability study. In this study, 76% of the initial laminarin was biodegraded by study termination at 28 days. The U.S. EPA Biopesticide Registration Action Document (BRAD) states that 65-71% of laminarin was degraded by day 14. Elsewhere in the BRAD the authors state "Aquatic exposure is unlikely due to the rapid biodegradation and hydrolysis of laminarin." No hydrolysis data was submitted in the BOH laminarin data package, the study DER is identified as being "unavailable." The BRAD lists the study source but does not report the hydrolysis half-life other than being "rapid."

Worst-case BOH screening level modeling was conducted for aquatic and terrestrial nontarget organisms. Field exposures are expected to be several orders of magnitude below toxic levels.

Modeling results and risk assessment

Highly exaggerated screening level exposure modeling shows no toxicity to nontarget organisms. For example, if the maximum seasonal application rate (assuming weekly applications for 20 weeks at the highest labeled rate) is applied to the 1 acre model pond with a 6 inch depth, the resulting laminarin concentration is 0.256 mg/L. No toxicity was observed in any aquatic test organism at concentrations up to 100.0 mg/L.

No adverse nontarget resource impacts are anticipated from the Vacciplant product. As a result, Bureau of Habitat staff has no objection to registration of Vacciplant in New York State.