

Evaluation Report for Category B, Subcategory 1.1, 3.11 and 3.12 Application

Application Number: 2010-4406
Application: Changes to Product Chemistry - New source (site) same registrant.
Changes to Product Labels - New pests and new site or host.
Product: Actinovate SP
Registration Number: 28672
Active ingredients (a.i.): *Streptomyces lydicus* strain WYEC 108
PMRA Document Number English PDF: 2010378

Background

The end-use product Actinovate SP is currently registered in Canada (Registration number 28672) as a commercial fungicide on strawberry, Gerber daisy and Bell peppers in the field and greenhouse. Since the initial registration, a series of minor use label expansions for Actinovate SP have been granted for raspberries, as well as for various outdoor and/or greenhouse vegetables (cucurbits, lettuce, tomatoes) and ornamentals (unspecified varieties).

Purpose of Application

The purpose of this application was to expand the registration of Actinovate SP (Registration number 28672) for use on high and lowbush blueberries and grapes to suppress mummyberry (*Monilinia vaccinii-corymbosi*) and powdery mildew (*Erysiphe necator*), respectively, as well as to register a new site of manufacture.

Chemistry Assessment

The data submitted by the registrant to address the requirements to support the new site of manufacture were largely complete. However, representative data from five batches of end-use product produced at the new site demonstrated the presence of contaminants in the final end-use product. Therefore, the registrant will be required to screen each batch of Actinovate SP manufactured at the new site for specific contaminants to ensure that the batches meet the acceptable limits established by the Organization of Economic Cooperation and Development (OECD). The PMRA can support registration of the new site of manufacture provided that mandatory contaminant screening is incorporated into the regular Quality Assurance (QA) program.

All other information provided adequately addressed the product characterization and analysis requirements to support the new site of manufacture.

Health Assessments

The use patterns for grapes and blueberries, including rates, timing, and method of application, are consistent with the currently registered application rates for outdoor crops. The existing precautionary statements, including personal protective equipment, are adequate to mitigate the risks from exposure to *Streptomyces lydicus* strain WYEC 108 from the use of Actinovate SP and no revisions to the product label is required to accommodate the addition of the new host and new pest. Therefore, the PMRA is satisfied that the proposed extension of Actinovate SP to blueberries and grapes will not pose an unacceptable risk to human health.

Based on the evaluation of information previously submitted by the registrant in support of Actinovate SP, there is no concern for chronic risks posed by the dietary exposure of the general population and sensitive subpopulations, such as infants and children. Furthermore, existing label statements instruct users to limit spray drift, and to not allow the product to enter bodies of water during use or disposal. Municipal treatment of drinking water will also reduce the transfer of residues to drinking water. Therefore, potential exposure to *Streptomyces lydicus* strain WYEC 108 in surface and drinking water is also negligible.

Environmental Assessment

Based on the evaluation of information previously submitted by the registrant in support of Actinovate SP, the PMRA is satisfied that the extension of Actinovate SP for use on blueberries and grapes to suppress powdery mildew and mummyberry, respectively, will not pose an unacceptable risk to the environment. The appropriate precautionary statements have been included on the label and no revisions are required to accommodate the addition of the new host and new pest to the product label.

Incident Reports Related to Health and the Environment

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the PMRA website <http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/incident/index-eng.php>. Incidents from Canada and the United States were searched and reviewed for products containing the active ingredient *Streptomyces lydicus*.

As of June 3, 2011 there were no health-related incident reports submitted to the PMRA, nor to the California Department of Pesticide regulation (CalDPR), for end-use products containing *Streptomyces lydicus*.

As of June 3, 2011, no environmental incident reports were submitted to the PMRA for products containing *Streptomyces lydicus*. As *Streptomyces lydicus* is not listed in the United States Environmental Protection Agency's (U.S. EPA) Ecological Incident Information System (EIIS), the PMRA assumes that no environmental incidents have been reported to the U.S. EPA.

Value Assessment

A total of four trials on grape (three) and highbush blueberry (one) were provided by the applicant to support these crops. Four additional fungicide and nematicide tests where Actinovate SP was tested on powdery mildew of grape were found and considered as valid data in support of the corresponding claim.

Regular applications at 420, 630 and 840 g product/ha (with or without an adjuvant) provided 0-92% reduction of disease severity, for an average of 48%, under severe disease pressure. It should be noted that this mean includes data from two trials in which Actinovate SP failed to reduce powdery mildew severity. Actinovate SP alone, or mixed with the adjuvant Silwet L-77, consistently provided numerically or statistically significantly higher levels of protection than water and adjuvant controls. An increased number of Actinovate SP applications and shorter application intervals had a positive impact on powdery mildew control. The use of Actinovate SP for suppression of powder mildew on grape is supported.

In one highbush blueberry trial, four applications of Actinovate SP at 210 or 840 g product/ha reduced the number of leaf lesions and mummy berries on the ground by 0-39%, for an average of 23%. Considering that 1) such levels of protection do not correspond to a suppression claim, 2) the rate of 840 g product/ha did not improve disease reduction over the lower tested rate of 210 g product/ha, 3) no statistically significant difference was noted among treatments at most assessment dates, and 4) no data were provided other than the one trial on highbush blueberry, it cannot be safely concluded that Actinovate SP will adequately suppress mummyberry on highbush and lowbush blueberry. Given that the reduced risk product, Actinovate SP, did show some disease reduction on highbush blueberry and may improve yields, a claim of partial suppression of mummyberry on highbush and lowbush blueberry may be conditionally supported. The product may be applied on a 7-14 day schedule at 425-840 g product/ha. Additional data are required to support a full registration of the suppression claim.

Conclusion

The PMRA has completed an assessment of available information for Actinovate SP and has found the information sufficient to support a full registration of the claim of suppression of powdery mildew (*Erysiphe necator*) on grape, and support a conditional registration of the claim of partial suppression of mummyberry (*Monilinia vaccinii-corymbosi*) on high and lowbush blueberries. In addition, the addition of a new manufacturing site has full registration provided that mandatory contaminant screening is incorporated into the QA program.

References

Applicant submitted:

PMRA

Document

Number	Reference
--------	-----------

1956659	2010, Description of Pest Problem Blueberry Mummyberry, DACO: 10.2.2
---------	--

- 1956660 2010, Description of Pest Problem Powdery Mildew Grape, DACO: 10.2.2
 1956661 2010, Actinovate SP Blueberry Mummyberry Trial, DACO: 10.2.3.3
 1956663 2006, Grape Powdery Mildew Fungicide Trial 2, DACO: 10.2.3.3
 1956664 2007, Control of Powdery Mildew in Grapes 2007 Field Trials, DACO: 10.2.3.3
 1956665 2008, Chemical and Biological Control of Grape Powdery Mildew: 2008 Field Trials, DACO: 10.2.3.3
 1956666 2007, Raw Data for Grape Powdery Mildew 2007 Trial, DACO: 10.2.3.3
 1956668 2008, Raw Data for Grape Powdery Mildew 2008 Trial, DACO: 10.2.3.3
 1956669 2010, Actinovate SP Blueberry Mummyberry Trial Summaries, DACO: 10.1, 10.2.3.1, 10.3.1, 10.3.2
 1956670 2010, Actinovate SP Grape Powdery Mildew Trial Summaries, DACO: 10.1,10.2.3.1,10.3.1,10.3.2
 1956671 2010, The Benefits of Expanding the Use of Actinovate in Canada, DACO: 10.5
 1956657 2010, DACO 5.2 Use Scenario or Description for Blueberry, DACO: 5.2
 1956658 2010, DACO 5.2 Use Scenario or Description for Grape, DACO: 5.2

Additional information considered:

- 1998099 American Phytopathological Society - Plant Disease Management Reports, 2009, Evaluation of Actinovate and AMV-4024 (caprylic acid) for powdery mildew management in grape, PDMR Volumn 4, Report No. 4:SMF010. <http://www.plantmanagementnetwork.org/pub/trial/pdmr/volume4/abstracts/smf10.asp>, DACO: 10.2.3.3
 1998100 American Phytopathological Society - Plant Disease Management Reports, 2009, Mixtures and rotations of microbial antagonists for powdery mildew management in grape, PDMR Volumn 4, Report No. 4:SMF031. <http://www.plantmanagementnetwork.org/pub/trial/pdmr/volume4/abstracts/smf31.asp>, DACO: 10.2.3.3
 1998104 American Phytopathological Society - Plant Disease Management Reports, 2009, Evaluation of fungicide programs for control of grapevine powdery mildew, PDMR Volumn 4, Report No. 4:SMF054. <http://www.plantmanagementnetwork.org/pub/trial/pdmr/volume4/abstracts/smf54.asp>, DACO: 10.2.3.3
 1998105 American Phytopathological Society - Plant Disease Management Reports, 2009, Evaluation of fungicide programs for control of powdery mildew on Rosette grapes, PDMR Volumn 4, Report No. 4:SMF055. <http://www.plantmanagementnetwork.org/pub/trial/pdmr/volume4/abstracts/smf55.asp>, DACO: 10.2.3.3

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2011

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.