Registration Decision RD2010-21

Pseudomonas syringae strain ESC-10

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Registration Decision for *Pseudomonas syringae* – strain ESC-10

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of *Pseudomonas syringae* – strain ESC-10 Fungicide Technical and Bio-Save 10LP Biological Fungicide, containing the technical grade active ingredient *Pseudomonas syringae* – strain ESC-10 to prevent fungal rot in stored fruits (apples, cherries and pears) and potatoes.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2010-16, *Pseudomonas syringae* – strain ESC-10. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Pseudomonas syringae* – strain ESC-10 and summarizes the Agency's decision, the reasons for it. The PMRA received no comments on PRD2010-16. This decision is consistent with the proposed registration decision stated in PRD2010-16.

For more details on the information presented in this registration decision, please refer to the Proposed Registration Decision PRD2010-16, *Pseudomonas syringae* – strain ESC-10 that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act.*

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is *Pseudomonas syringae* – strain ESC-10?

Pseudomonas syringae strain ESC-10 is a non-genetically engineered bacteria isolated from apples which is used as a microbial pest control agent (MPCA). This organism enters injuries on fruit or tubers where disease-causing fungal spores are present and then it out-competes the fungal spores for nutrients. *Pseudomonas syringae* strain ESC-10 suppresses postharvest diseases on produce in storage facilities and packing houses. These diseases include blue mould and grey mould on apples, pears and cherries, mucor rot on apple and pear and dry rot on potato.

Health Considerations

Can Approved Uses *Pseudomonas syringae* – strain ESC-10 Affect Human Health?

***Pseudomonas syringae* strain ESC-10 is unlikely to affect your health when Bio-Save 10LP Biological Fungicide is used according to the label directions.**

People can be exposed to *P. syringae* strain ESC-10 when handling and applying the product and when consuming treated produce. When assessing health risks, several key factors are considered: the microorganism's biological properties (for example, production of toxic byproducts); reports of any adverse incidents; its potential to cause disease or toxicity as determined in toxicological studies and the levels to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism. When *P. syringae* strain ESC-10 was tested on laboratory animals, there were no signs that it caused any toxicity or disease.

Residues in Water and Food

Dietary risks from food and water are not of concern

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based MRLs to ensure the food Canadians eat is safe.

Strains of *P. syringae* are common in nature. The residues of *P. syringae* strain ESC-10 remaining on treated produce are expected to be higher than levels that naturally occur. When *P. syringae* strain ESC-10 was administered orally to rats, no signs that it caused toxicity or disease were observed and no metabolites of toxicological significance have been shown to be produced by this or other strains of *P. syringae*. Therefore the establishment of a MRL is not required for *P. syringae* strain ESC-10. As well, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary risks are minimal to non-existent.

Occupational Risks From Handling Bio-Save 10LP Biological Fungicide

Occupational risks are not of concern when Bio-Save 10LP Biological Fungicide is used according to label directions, which include protective measures

Workers using Bio-Save 10LP Biological Fungicide can come into direct contact with *P. syringae* strain ESC-10 on the skin, in the eyes, or by inhalation. For this reason, the label will specify that users exposed to Bio-Save 10LP Biological Fungicide must wear waterproof gloves, eye protection, long-sleeved shirts, long pants, and shoes plus socks and a dust/mist filtering NIOSH approved respirator/mask (with any N, P, R or HE filter).

For bystanders, exposure is expected to be much less than that of workers involved in loading and application activities and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Pseudomonas syringae* strain ESC-10 is Introduced Into the Environment?

Environmental risks are not of concern.

Pseudomonas syringae strain ESC-10 is a natural strain of bacteria that occurs on many kinds of plants throughout the world. Testing for pathogenicity on plants has shown that *Pseudomonas syringae* strain ESC-10 can be pathogenic to plants. However, since the use of Bio-Save 10LP Biological Fungicide is limited to enclosed spaces, exposure to non-target organisms, including plants, is negligible. Therefore the environmental risks are very low.

Value Considerations

What Is the Value of *Pseudomonas syringae* – strain ESC-10?

What Is the Value of Bio-Save 10LP Biological Fungicide?

Bio-Save 10LP Biological Fungicide is a reduced risk bio-fungicide that suppresses diseases on produce in storage.

An increase in resistance of pathogens to commonly used chemical fungicides has been observed in some postharvest treatments for fruit crops. Resistance to the active ingredient, *Pseudomonas syringae* strain ESC-10, is unlikely to develop. This product has the potential to become an integral part of a postharvest IPM program.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Bio-Save 10LP Biological Fungicide to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

Because of concerns with users developing allergic reactions through repeated high exposures to *P. syringae* strain ESC-10, anyone handling, mixing/loading, or involved in clean-up/repair activities of Bio-Save 10LP Biological Fungicide must wear waterproof gloves, a long-sleeved shirt, long pants and a dust/mist filtering respirator/mask (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH-approved respirator with any N-95, R-95, P-95 or HE filter. Eye protection is also required during loading activities.

Environment

As a general precaution, statements will be added to the label to prohibit handlers from contaminating aquatic habitats including lakes, streams, ponds or other waters.

Other Information

The relevant test data on which the decision is based are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

[5] As per subsection 35(1) of the *Pest Control Products Act*

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number: 1579753
Reference: 1993, Pseudomonas syringae, strain ESC-10 Product Analysis Continued (Part B), DACO: M2.10,M2.10.1,M2.10.2,M2.10.3,M2.12,M2.14,M2.9.3 CBI

PMRA Document Number: 1579760
Reference: 1993, Pseudomonas syringae, strain ESC-10 Product Analysis (Part A), DACO: M2.10,M2.10.1,M2.14 CBI

PMRA Document Number: 1579762
Reference: 2007, BioSave M1.3 International Regulatory Status, DACO: M2.1,M2.2,M2.3,M2.4,M2.5,M2.6 CBI

PMRA Document Number: 1579763
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PMRA Document Number: 1579766
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PMRA Document Number: 1579769
Reference: 1993, Mechanism of Action (ESC-10 and ESC-11), DACO: M2.14,M2.7.1,M2.7.2 CBI

PMRA Document Number: 1579770
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PMRA Document Number: 1579771
Reference: James P. Stack; Steven N. Jeffers; Baruch Sneh; Teresa S. Wright; 1996, US Patent No. 5,554,368: Pseudomonas syringae ATCC 55389 and use thereof for inhibiting microbial decay on fruit, Published? DACO: M2.7.1,M2.8

PMRA Document Number: 1579772
Reference: Moore ERB, et al., 2004, Pseudomonas: Nonmedical. In The Prokaryotes (web version), Published? DACO: M2.7.1,M2.7.2

PMRA Document Number: 1579773
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PMRA Document Number: 1579774
Reference: Iglewski & Kabat, 1975, NAD-Dependent Inhibition of Protein Synthesis by Pseudomonas aeruginosa Toxin, Published ?DACO: M2.7.1,M2.7.2

PMRA Document Number: 1579776
Reference: 2007, N/A, DACO: M2.7.1,M2.7.2,M2.8,M2.9,M2.9.1,M2.9.2,M2.9.3 CBI

PMRA Document Number: 1579777
Reference: Palleroni, NJ, 2005, Bergey's Manual of Systematic Bacteriology: Pseudomonas, Published DACO: M2.7.1,M2.7.2,M4.7,M4.8

PMRA Document Number: 1579778
Reference: 1993, Growth Temperature of ESC-10 and ESC11, DACO: M2.7.2,M4.2

PMRA Document Number: 1579781
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PMRA Document Number: 1579782
Reference: 1993, Pseudomonas syringae, strain ESC-10 Product Analysis Continued (Part B) Confidential Attachment, DACO: M2.8,M2.9 CBI

PMRA Document Number: 1579805
Reference: 1993, HypersensitivityIncidents; Residue Analysis and Non-Target Hazard Analysis of ESC-10M2F2 (Pseudomonas syringae) strain ESC-10, DACO: M2.7.2,M4.6,M9.0,M9.1,M9.2,M9.2.1,M9.2.2,M9.3,M9.4,M9.4.1,M9.4.2,M9.5,M9.5.1,M9.5.2, M9.6,M9.7,M9.8,M9.8.1,M9.8.2,M9 References Proposed Registration Decision - PRD2010-16 Page 38

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Reference: MSDS Sheets (all ingredients), DACO: 0.9.1,M2.9,M2.9.1

PMRA Document Number: 1798983
Reference: 2009, PMRA Notification, DACO: M2.0

2.0 Human and Animal Health

PMRA Document Number: 1579787
Reference: 1993, Acute Oral Toxicity/Pathogenicity Study of ESC 10 (Pseudomonas syringae) In Rats, DACO: M4.2.2

PMRA Document Number: 1579791
Reference: 1993, Acute Oral Toxicity Study in Rats, DACO: M4.2.2

PMRA Document Number: 1579792
Reference: 1993, Acute Pulmonary Toxicity/Pathogenicity Study of pSeudomonas syringae (Strain ESC 10) in Rats, DACO: M4.2.3

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Reference: 1993, Acute Intravenous Toxicity/Pathogenicity Study of Pseudomonas syringae (Strain ESC 10) In Rats, DACO: M4.3.2

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PMRA Document Number: 1579803
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PMRA Document Number: 1579804
Reference: 1993, Pseudomonas syringae, strain ESC-10 (ESC-10M2) Hypersensitivity Incidents, Residue Analysis and Non-target Organism Hazard, DACO: M4.6

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PMRA Document Number: 1579808
Reference: 1993, Primary Eye Irritation Study of ESC10M2F2 in New Zealand White Rabbits, DACO: M4.9

PMRA Document Number: 1579809
Reference: 1994, Determination of the Concentration of ESC-10 Residue remaining on Pears after Treatment, DACO: M7.0

PMRA Document Number: 1579810
Reference: 1993, Determination of the Concentration of ESC-10 Residue remaining on Apples after Treatment followed by Storage, DACO: M7.0

3.0 Environment

PMRA Document Number: 1579780
Reference: 2008, Supplemental information, DACO: M12,M12.5,M12.7,M5.0,M7.0,M8.0,M9.0

PMRA Document Number: 1579805
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PMRA Document Number: 1579811
Reference: 1993, Residue Analysis and Non-Target hazard Analysis of ESC10-M2F2 (Pseudomonas syringae) strain ESC-10, DACO: M7.0,M8.0,M8.1,M9.0,M9.1,M9.2,M9.2.1,M9.2.2,M9.3,M9.4,M9.4.1,M9.4.2,M9.5,M9.5.1,M9.5.2,M9.6,M9.7,M9.8,M9.8.1,M9.8.2,M9.9

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PMRA Document Number: 1579813
Reference: 1994, Non-target Terrestrial Plant Test for ESC-10M2 and ESC-11M2 on Citrus, DACO:M10.3.1,M9.8.1

4.0 Value

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Reference: 1994, Control of Potato Fusarium Dry Rot, Silver Scurf and Soft rot with Bio-Save 110 and 1000, DACO: M10.2,M10.2.2

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Reference: Control of Potato Fusarium Dry Rot, Silver Scurf and Soft rot with Bio-Save 110 and 1000, DACO: M10.2,M10.2.2

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PMRA Document Number: 1617869
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PMRA Document Number: 1617870
Reference: Biosave 100 with TBZ in a drench to control blue mold in Fuji apples, DACO: M10.2,M10.2.2,M7.0

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Reference: Jabobson, B, 2002, Control of Potato Fusarium Dry Rot, Silver Scurf and Soft rot with Bio-Save 110 and 1000, Published? DACO: M10.2,M10.2.2

PMRA Document Number: 1617872
Reference: 1993, Laboratory Efficacy Studies of ESC-10 (Apples), DACO: M10.2,M10.2.1

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Reference: 2008, Efficacy Summary Table, DACO: M10.3,M10.3.1,M10.3.2,M10.3.2.1,M10.3.2.2,M10.4,M10.4.1,M10.4.2,M10.4.3,M10.4.4

PMRA Document Number: 1645576
Reference: 2008, Management of silver scurf and Fusarium dry rot of potatoes in storage using Bio-Save 10LP and Bio-Save 11LP (Pseudomonas syringae), DACO: M10.2,M10.2.1,M10.2.2

B. Additional Information Considered

i) Published Information

1.0 Chemistry

PMRA Document Number: 1776540
Reference: 1997, Series on Harmonization of Regulatory Oversight in Biotechnology No. 6 CONSENSUS DOCUMENT ON INFORMATION USED IN THE ASSESSMENT OF ENVIRONMENTAL APPLICATIONS INVOLVING PSEUDOMONAS OCDE/GD(97)22, DACO: M2.0,M4.0,M9.0

2.0 Human and Animal Health

3.0 Environment

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