

## Evaluation Report for Category B, Subcategory 3.12 Application

**Application Number:** 2019-4553  
**Application:** Changes to Product Labels: New Site  
**Product:** Avodigen  
**Registration Number:** 33311  
**Active ingredients (a.i.):** *Bacillus subtilis* Strain FMCH002  
*Bacillus licheniformis* Strain FMCH001  
**PMRA Document Number:** 3091153

### Purpose of Application

Avodigen is registered for use in Canada as a biological fungicide and nematocide seed treatment for the partial suppression certain fungal diseases and nematodes in corn (field, sweet, pop and corn grown for seed), soybean and sunflower. The purpose of this application was to amend the label of Avodigen to add canola, mustard and rapeseed as sites for seed treatment.

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Health Assessments

No new toxicological data were submitted to support the use expansion to add canola, mustard and rapeseed as sites for seed treatment. Based on a recent review of Avodigen and associated technical grades of the active ingredients, *Bacillus licheniformis* strain FMCH001 and *Bacillus subtilis* strain FMCH002 are not infectious or pathogenic to mammals based on the results of pulmonary and intravenous studies. Avodigen is minimally irritating to the skin and eyes. The EP is also considered to be of low toxicity via the oral, pulmonary and dermal routes based on results of TGAI testing. However, Avodigen is considered to be a potential sensitizer since the formulation contains microorganisms. For additional information on the risk assessment, see Proposed Regulatory Decision, PRD2018-18, *Bacillus licheniformis* strain FMCH001, *Bacillus subtilis* strain FMCH002 and F4018-4. No additional toxicological information or data are required to support the addition of canola, mustard and rapeseed as sites for seed treatment.

When handled according to the label instructions, the potential for dermal, eye and inhalation exposure for applicators, mixer/loaders, and handlers exists, with primary exposure routes being dermal. Risk mitigation measures, such as personal protective equipment, including waterproof gloves, long-sleeved shirts, long pants, a NIOSH-approved particulate filtering facepiece respirator, and shoes with socks are required to minimize exposure and protect applicators, mixer/loaders, and handlers that are likely to be exposed.

Precautionary statements found on the current end-use product label are adequate to protect individuals from any risk due to the additional occupational exposure resulting from the use expansion to add canola, mustard and rapeseed as sites for seed treatment. Overall, occupational risks to workers are acceptable when the precautionary statements on the labels are followed which include PPE.

The use as seed treatments are not anticipated to significantly increase residential and bystander exposures beyond naturally occurring levels for these microorganisms. Furthermore, the toxicology profiles for Avodigen, and the two associated technical grades of the active ingredients, FMCH001 Technical and FMCH002 Technical, are low. Consequently, the health risks to individuals in residential areas and bystanders are acceptable.

The use expansion to add canola, mustard and rapeseed as sites for seed treatment is not expected to result in direct dietary exposure. Avodigen will not be applied to the edible portions of crops and the seed treatment applications of *B. licheniformis* strain FMCH001 and *B. subtilis* strain FMCH002 are not expected to yield any growth on the edible portions of the crops. Furthermore, exposure in drinking water resulting from operational use of Avodigen as a seed treatment will be low. The label for Avodigen instructs users not to contaminate irrigation or drinking water supplies or aquatic habitats through equipment cleaning or waste disposal. Also, municipal treatment of drinking water is expected to reduce the transfer of residues to drinking water. Health risks from residues in food and drinking are acceptable due to the limited exposure following application of Avodigen and its low toxicity profile.

### **Environmental Assessment**

No new environmental fate or toxicology data were submitted to support the use expansion to add canola, mustard and rapeseed as sites for seed treatment. Based on a recent review of Avodigen and associated technical grades of the active ingredients, the use of Avodigen on variety of seeds as a seed treatment is not expected to significantly increase the levels of *B. licheniformis* strain FMCH001 and *B. subtilis* strain FMCH002 in soil. Similarly, exposure to aquatic environments is also expected to be low and limited to leaching and runoff after the seeds are sowed in fields. Furthermore, no significant effects to birds, wild mammals, fish, terrestrial and aquatic arthropods, terrestrial and aquatic non-arthropod invertebrates and plants were anticipated from its use as a seed treatment. For additional information on the risk assessment, see Proposed Regulatory Decision, PRD2018-18, *Bacillus licheniformis* strain FMCH001, *Bacillus subtilis* strain FMCH002 and F4018-4.

The use expansion as seed treatments is not expected to significantly increase the levels of these microorganisms in terrestrial and aquatic environments. Consequently, no harm will be caused to terrestrial and aquatic non-target organisms. No additional environmental fate or toxicology information or data are required to support the addition of canola, mustard and rapeseed as sites for seed treatment.

## **Value Assessment**

The results of six greenhouse and three field efficacy trials conducted in SK and AB were submitted to support the addition of a claim against seed rot and seedling blight caused by *Rhizoctonia solani* on canola, mustard (oil and condiment) and rapeseed to the Avodigen label. Application of Avodigen to canola seeds was found to partially suppress seed rot and seedling blight symptoms. Field trials demonstrated that application of Avodigen to canola seed resulted in significant yield increases.

Seed rot and seedling blight are destructive diseases of canola, mustard and rapeseed that are commonly managed by the application of pre-plant seed treatments. Avodigen will provide growers with an additional mode-of-action that may serve to delay the development of resistance to other seed treatment fungicides. As a solo biofungicide seed treatment, Avodigen provides growers with an alternative to synthetic fungicides for this use.

## **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to amend the label of Avodigen to add seed treatment of canola, mustard and rapeseed.

## References

### PMRA

#### Document

Number	Reference
3028163	2019, Value Summary for Avodigen (F4018-4) PCP 33311, Containing <i>Bacillus licheniformis</i> FMCH001 and <i>Bacillus subtilis</i> FMCH002 on canola, mustard and rapeseed crops, DACO: M10.1
3028164	2019, 10.4.2 Performance Benefits, DACO: M10.4.2
3028165	2019, SECTION 10.3.1 Crop Tolerance (Seed Safety), DACO: M10.3.1
3028166	2019, Table CT4: Safety of F4018-4 with a synthetic base on germinating plants on blotter (Canola), DACO: M10.3.1
3028174	2019, SECTION 10.2 Efficacy Results, DACO: M10.2
3028175	2018, Control of <i>Rhizoctonia</i> of canola with biological seed treatments, DACO: M10.2.2
3028176	2018, Control of <i>Rhizoctonia</i> of canola with biological seed treatments, DACO: M10.2.2
3028177	2018, Control of <i>Rhizoctonia</i> of canola with biological seed treatments, DACO: M10.2.2
3028178	2019, Control of <i>Rhizoctonia</i> of canola with biological seed treatments, DACO: M10.2.1
3028179	2019, Control of <i>Rhizoctonia</i> of canola with biological seed treatments, DACO: M10.2.1
3028180	2019, Control of <i>Rhizoctonia</i> of canola with biological seed treatments, DACO: M10.2.1
3028181	2019, Control of <i>Rhizoctonia</i> of canola with biological seed treatments, DACO: M10.2.1
3028182	2019, Control of <i>Rhizoctonia</i> of canola with biological seed treatments, DACO: M10.2.1
3028183	2018, Control of <i>Rhizoctonia</i> of canola with biological seed treatments, DACO: M10.2

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