

## Evaluation Report for Category B, Subcategory 3.12 Application

**Application Number:** 2020-4055  
**Application:** Changes to Product Labels-New Site or Host  
**Product:** PureSpray FX  
**Registration Number:** 33347  
**Active ingredient (a.i.):** Mineral oil  
**PMRA Document Number :** 3257947

### Purpose of Application

The purpose of this application was to expand the label of the commercial end-use product PureSpray FX to add use on field grown cannabis and industrial hemp grown for cannabinoid extraction (field grown and produced in enclosed growing structures) to control powdery mildew and mites, and deter feeding of aphids.

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Health Assessments

Mineral oil is of low acute toxicity by the oral, dermal and inhalation routes, considered to be a mild eye and skin irritant, and non-sensitizing.

Occupational risk to individuals handling and applying PureSpray FX is acceptable when the product is used according to label directions. Precautionary, personal protective equipment and directions for use statements on the product label aimed at mitigating user exposure are adequate to protect individuals from any potential risk due to occupational exposure.

Bystander exposure will not result in health risks of concern when the product is used according to label directions. Consequently, the risk to bystanders and individuals in residential areas is acceptable.

There are no food, drinking water or consumer exposure concerns when the product is used according to label directions.

### Maximum Residue Limit (MRL)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that 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 specified as an MRL

under the Pest Control Products Act (PCPA) for the purposes of adulteration provision of the Food and Drugs Act (FDA). Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

The specification of an MRL is not required for mineral oil.

### **Environmental Assessment**

No additional risk to the environment is expected from the use of PureSpray FX on field grown cannabis and industrial hemp grown for cannabinoid extraction (field grown and produced in enclosed growing structures).

### **Value Assessment**

The applicant submitted a scientific rationale to support claims of suppressing powdery mildew and mites, and deterring feeding by aphids on field grown cannabis, and industrial hemp grown for cannabinoid extraction (field grown and produced in enclosed growing structures). Considering the fact that mineral oil has an established history of use against soft-bodied arthropod pests and powdery mildew on many crops and plants, including the same use on cannabis produced in enclosed growing structures on the current PureSpray FX label, it is expected that PureSpray FX will provide suppression of the targeted disease and mites, and deterrence of aphid feeding on both industrial hemp grown for cannabinoid extraction and cannabis. All claims are supported from a value perspective.

### **Conclusion**

The Pest Management Regulatory Agency has completed a review of the available information and has found it sufficient to add use on field grown cannabis and industrial hemp grown for cannabinoid extraction (field grown and produced in enclosed growing structures) to control powdery mildew and mites, and deter feeding of aphids, to the label of PureSpray FX.

### **References**

#### **PMRA**

#### **Document**

<b>Number</b>	<b>Reference</b>
3161611	2020, 5.2 Use Description Scenario (Application and Post Application), DACO: 5.2
3192040	2021, Cover Letter to Address Clarification, DACO 0.8
3150908	2020, DACO Part 10 Efficacy Rationale, DACO: 10.6

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