

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 3.1, 3.11, 3.12, 3.3 Application

Application Number: 2013-3553
Application: Product chemistry – guarantee, identify and proportion of
formulants, formulation type
Product labels – application rate increase, new pests, new site/host,
application number or frequency
Product: Botector
Registration Number: 31248
Active ingredients (a.i.): *Aureobasidium pullulans* strain DSM 14940 and strain DSM
14941 [ABC]
PMRA Document Number : 2351227

Purpose of Application

The purpose of this application is to register a new end-use product, Botector, containing the active ingredients *Aureobasidium pullulans* strain DSM 14940 and strain DSM 14941 to control *Botrytis cinerea* on grapes.

Chemistry Assessment

The domestic class end-use product, Botector, has the same guarantee as the registered end-use product BLOSSOM PROTECT™ (PCP Registration Number 30552). No further data are required for the product characterization and analysis assessment.

Health Assessments

The domestic class end-use product, Botector, has the same guarantee as the registered end-use product BLOSSOM PROTECT™. The Botector formulation is also toxicologically equivalent to the BLOSSOM PROTECT™ formulation. The proposed use pattern for Botector, with respect to occupational, bystander and food exposure, is not different from the registered use pattern for BLOSSOM PROTECT™. No further data are required to assess occupational, bystander, and food exposure.

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the Pest Management Regulatory Agency (PMRA) within a set time frame. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website www.healthcanada.gc.ca/pesticideincident. As of January 2, 2014, there were no incidents related to health or the environment reported in the PMRA Incident reporting database or the California Department of Pesticide Regulation (CalDPR) for products containing *Aureobasidium*

pullulans for use as pesticides since April 26, 2012, the date of the previous incident report assessment for these active ingredients.

Environmental Assessment

The domestic class end-use product, Botector, has the same guarantee as the registered end-use product BLOSSOM PROTECT™. The Botector formulation is also toxicologically equivalent to the BLOSSOM PROTECT™ formulation. The use pattern for Botector, with respect to non-target organism exposure, is not different from the registered use pattern for BLOSSOM PROTECT™. No further data are required to assess risks to non-target organisms.

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 Pesticides and Pest Management portion of Health Canada's website www.healthcanada.gc.ca/pesticideincident. As of January 2, 2014, there were no environmental incidents reported in the PMRA Incident reporting database nor in the United States-Environmental Protection Agency's (US-EPA) Ecological Incident Information System (EIS) for products containing *Aureobasidium pullulans* for use as pesticides since April 26, 2012, the date of the previous incident report assessment for these active ingredients.

Value Assessment

A total of 18 field trials were submitted and reviewed to support the claim. Overall, Botector provided good suppression on grey mold infection on grapes when applied according to the use pattern, especially under low and moderate disease pressure. In five out of seven trials with moderate disease pressure where commercial standards performed adequately, Botector significantly reduced grey mold incidence by average 66% (49 – 79%) compared to average 77% (68 – 79%) disease reduction obtained by the commercial standards. A level of acceptable grey mold control was achieved only in one of the six trials under high disease pressure, where Botector reduced disease incidence and severity by 64% and 76%, respectively, compared to a disease reduction of 79% (incidence) and 85% (severity) by the commercial standard applied in the same trial. The efficacy of Botector was consistently and numerically lower than the commercial standards in most field trials. A scientific rationale was provided to justify the use of value information from Europe to support the proposed use in Canada. The rationale was considered acceptable. The value of registering Botector is that it will provide Canadian growers an additional tool against this important disease on grapes, especially in the organic market.

Based on the value information provided, the use of Botector to suppress grey mold in grapes is supported according to the proposed use pattern. Label amendments are required.

Conclusion

The PMRA has completed the assessment of the available information and is able to support the registration of Botector containing the active ingredient *Aureobasidium pullulans* strain DSM 14940 and strain DSM 14941 to control *Botrytis cinerea* on grapes.

References

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