

Evaluation Report for Category B, Subcategory 3.1, 3.12 Application

Application Number:	2016-4129
Application:	Changes to Product Labels – Application Rate Increase and New
	Site or Host
Product:	Botector
Registration Number:	31248
Active ingredients (a.i.):	Aureobasidium pullulans DSM 14940 and DSM 14941
PMRA Document Number: 2713791	

Purpose of Application

The purpose of this application was to amend the product label for Botector for grey mold in grapes to increase the application rate on grapes and to expand the application site from the bunch zone to the whole leaf wall area of grapevine.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

No toxicology data were submitted or required in support of this submission. The amendments made to the product label do not result in changes to the toxicological profile.

Blossom Protect (Reg. No. 30552), has an identical guarantee to Botector. The maximum broadcast application rate for Blossom Protect is $1.5 \text{ kg/ha} (7.5 \times 10^{12} \text{ CFU/ha})$. The increase in application rate for Botector is less than the registered maximum application rate for Blossom Protect. The food residue exposure and the occupational and bystander exposure assessments do not require revision. The recommended protective equipment, precautions and decontamination procedures to follow in the event of product exposure and/or spills are the same as those currently found on the registered label for this product.

Environmental Assessment

No environmental toxicology data were submitted or required in support of this submission. The amendments made to the product label do not result in changes to the environmental toxicological profile.



Blossom Protect (Reg. No. 30552), has an identical guarantee to Botector. The maximum broadcast application rate for Blossom Protect is 1.5 kg Blossom Protect/ha (7.5×10^{12} CFU/ha). The increase in application rate for Botector to 1.0 kg/ha (5.0×10^{12} colony forming units [CFU]/ha) is less than the registered maximum application rate for Blossom Protect. The environmental assessment does not require revision.

Value Assessment

A scientific rationale and results from two efficacy trials conducted in Austria in 2014 were provided in support of the claim. Botector applied using the amended use pattern demonstrated a similar level of disease suppression against botrytis grey mold on grapes, compared to the Botector treatment at the currently registered use pattern. When Botector is applied to the whole leaf wall area of grapevine, it will ease the application for the grape growers and ensure better compatibility with current application methods. The use claim is supported from a value perspective.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and can support the amendments to the product label for Botector.

References

PMRA Document	References
Number	
2665063	2016, Rationale to explain the reason for this submission, DACO: 5.2, M5.0
2665065	2014, Field test to compare Botector when it is sprayed with 400 g/ha only in the
	bunch zone and with 1000 g/ha all over the canopy, DACO: 10.2.3,M10.2.2
2665066	2014, Field test to compare Botector when it is sprayed with 400 g/ha only in the
	bunch zone and with 1000 g/ha all over the canopy, DACO: 10.2.3,M10.2.2

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