

Evaluation Report for Category B, Subcategory 2.3 and 2.4 Application

Application Number: 2016-0278
Application: Changes to end-use product chemistry – Identity and proportion of formulants
Product: BAS 516 F ST
Registration Number: 30184
Active ingredients (a.i.): Boscalid and Pyraclostrobin
PMRA Document Number: 2624886

Purpose of Application

The purpose of this application was to amend the registration of BAS 516 F ST by updating the product specifications and adding an alternate formulation process.

Chemistry Assessment

BAS 516 ST is a suspension containing the active ingredients boscalid and pyraclostrobin at the nominal concentrations of 200 g/L and 100 g/L, respectively. This product has a density between 1.110 and 1.130 g/mL and a pH between 6.0 and 8.5. The chemistry requirements for BAS 516 F ST have been fulfilled.

Health Assessments

The additional manufacturing process and updated specifications do not alter the toxicological profile of the product.

The new versions of the two registered formulations and the four new formulations are not expected to alter the residues in food and feed crops from seeds treated with BAS 516 F ST. Therefore, the dietary exposure to boscalid and pyraclostrobin is not anticipated to increase, and will not pose any health risks of concern to any segment of the population, including infants, children, adults and seniors.

An occupational exposure assessment was not required for this application.

Environmental Assessment

The modification of the identity and proportion of formulants, the material preservatives and the addition of the alternate formulation process does not represent an increase in risk to non-target organisms. However, updates to the label with current environmental risk mitigation statements are required. When used according to label directions, BAS 516 F ST is not anticipated to pose an unacceptable risk to non-target organisms.

Value Assessment

The minor changes to the formulations of BAS 516 F ST are not expected to have significant impact on the performance and the crop safety of the product when used according to label directions. The value of BAS 516 F ST is therefore not affected by the formulation changes.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has determined that the updated product specifications and additional manufacturing process for BAS 516 F ST can be supported.

References

PMRA Document Number	Reference
2599126	2014, Coronet Fungicide Seed Treatment (BAS 516 09 F) [CBI]– Group A-Product Identity, Composition and Analysis, DACO: 3.2.2 and 3.4.1, CBI
2599127	2016, Comparison of F1V1 and F2V1 to F1V2 and F2V2, DACO: 3.7, CBI
2599128	2016, Labelling of Preservative on the Label Depending on the Product Produced, DACO: 3.7
2609435	2016, BASF Response to PMRA Deficiency Letter Value, DACO: 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.2.3.4, 10.3.1, 10.3.2 CBI

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