

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.6, 3.6 and 3.12 Application

Application Number: 2015-3387
Application: New End-Use Product Chemistry – Guarantee, Identity of Formulants, Proportion of Formulants and New Combination of TGAIs
New End-Use Product Label – Pre-Harvest and New Site
Product: Cotegra Fungicide
Registration Number: 32530
Active ingredients (a.i.): Boscalid, Prothioconazole
PMRA Document Number: 2690701

Purpose of Application

The purpose of this application was to register an end-use product, Cotegra Fungicide, containing a new combination of active ingredients, boscalid and prothioconazole, to be used as a foliar application on various crops.

Chemistry Assessment

Cotegra Fungicide is formulated as a suspension containing contain boscalid at a nominal concentration of 250 g/L and prothioconazole at a nominal concentration of 150 g/L. This end-use product has a density of 1.148 kg/L and a pH of 5.65. The chemistry requirements for this product have been fulfilled.

Health Assessments

In rats, Cotegra Fungicide is of low acute toxicity by the oral, dermal, and inhalation routes of exposure. It is minimally irritating to the rabbit eye and slightly irritating to the rabbit skin. The formulation is a not a skin sensitizer in mice.

The end-use product, Cotegra Fungicide, for use on the dried shelled pea and bean subgroup (including dried beans, dried peas, chickpeas, and lentils), soybeans, and oilseed crops (including canola, rapeseed, Oriental mustard) fits within the use pattern for prothioconazole. The potential exposure to prothioconazole for mixers, loaders, applicators and postapplication re-entry workers is not expected to exceed the current exposure to the active ingredient from the registered products. For the second active ingredient, boscalid, the use pattern does not fit within the use pattern as the inclusion of application to soybeans is not currently registered. Quantitative mixer/loader/applicator and postapplication re-entry worker risk assessments were conducted for this submission and no risk to human health is expected from handling Cotegra Herbicide

provided workers follow label directions and wear personal protective equipment as stated on the label.

No residue data for boscalid and prothioconazole in Crop Subgroup 6C, soybeans and oilseeds (canola, rapeseed and oriental mustard) were submitted to support the new combination of actives on the Cotegra Fungicide label. Residue data on file were reassessed in the context of this submission and the dietary burden calculations as well as the dietary exposure assessments were updated for boscalid. The dietary exposure to residues of boscalid and prothioconazole do not represent health risks of concern and residues will be covered under the MRLs currently established for these actives.

Environmental Assessment

Both actives are currently registered for use on same crops with higher or same rates. With the buffer zones, the use of Cotegra Fungicide for the control of fungal diseases in dried shelled pea and bean subgroup (dried beans, dried peas, chickpeas, and lentils), soybeans and oilseed crops (canola, rapeseed and oriental mustard) is not expected to pose additional environmental concerns.

Value Assessment

A combination of efficacy data and scientific rationales were provided in support of the registration of Cotegra Fungicide. Based on the value information provided the following claims were supported: suppression of white mold (*Sclerotinia sclerotia*) on beans (eight trials), peas (rationale), chickpeas (rationale), lentils (three trials) and soybean (2 trials). Efficacy data from 13 trials were also provided in support of the claim of suppression of Sclerotinia stem rot (*Sclerotinia sclerotia*) on oilseed crops including canola, rapeseed, Oriental mustard (*Brassica juncea*).

Boscalid is currently registered for control of the claims listed above, but at a rate significantly higher (56-116%) than that in Cotegra. Boscalid at the reduced rate, in combination with prothiconazole, will provide growers with another tool to manage certain diseases caused by *Sclerotinia sclerotia*.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information sufficient to support registration of Cotegra Fungicide.

References

PMRA Document Number	Reference
2554276	2015, Product Identification for Cotegra, DACO: 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI
2554277	2015, Group A Product Identity, Compositions and Analysis, DACO: 3.2, 3.2.1, 3.2.2, 3.3.1 CBI
2554278	2014, Validation of Analytical Method AFR0102/01: Determination of Prothioconazole and/or Boscalid Content in BAS 793 00 F Formulations, Mill Bases, Intermediates and TGAs [CBI Removed], DACO: 3.3.1, 3.4.1 CBI
2554279	2015, BAS 793 00 F: Determination of Physical Properties and Oxidation Reduction, DACO: 3.5, 3.5.1, 3.5.2, 3.5.3, 3.5.4, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
2554280	2015, Chemical and Physical Properties for Cotegra a new foliar fungicide product containing Boscalid and Prothioconazole, DACO: 3.5.11, 3.5.12, 3.5.13, 3.5.15 CBI
2554281	2015, BAS 793 00 F: Storage Stability and Corrosion Characteristics in Commercial Type Containers, DACO: 3.5.10, 3.5.14, 3.5.5 CBI
2554283	2015, BAS 793 00 F - Acute oral toxicity study in rats, DACO: 4.6.1
2554284	2015, BAS 793 00 F - Acute dermal toxicity study in rats, DACO: 4.6.2
2554285	2015, Acute (4-hour) inhalation toxicity study with BAS 793 00 F in rats, DACO: 4.6.3
2554286	2015, BAS 793 00 F - Acute eye irritation in rabbits, DACO: 4.6.4
2554287	2015, BAS 793 00 F - Acute dermal irritation / corrosion in rabbits, DACO: 4.6.5
2554288	2015, BAS 793 00 F - Skin Sensitisation: Local Lymph Node Assay, DACO: 4.6.6
2554289	2015, Use Site Description: Cotegra a new foliar fungicide product containing Boscalid and Prothioconazole for use on Pulses, Soybeans and Oilseeds, DACO: 5.2
2554271	2015, Value - Summary, DACO: 10.1, 10.3.1, 10.3.2
2554274	2013, Trial abstracts, DACO: 10.2.3.3(D)
2554275	2014, Trial abstracts, DACO: 10.2.3.3(D)

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