

Evaluation Report for Category B, Subcategory 2.6, 3.12 Application

Application Number: 2014-3303
Application: B.2.6 - New Combination of Active Ingredients
B.3.12 - New Site
Product: Insure Pulse
Registration Number: 32011
Active ingredients (a.i.): Pyraclostrobin, Fluxapyroxad and Metalaxyl
PMRA Document Number : **2579339**

Purpose of Application

The purpose of this application was to register the end use product, Insure Pulse. This product contains the active ingredients pyraclostrobin, fluxapyroxad and metalaxyl. This product is for use as a seed treatment on Crop Subgroup 6C (shelled pea and bean subgroup) and flax for the control of several seed-borne or soil-borne pathogens causing seed rot, seedling blight and/or root rot.

Chemistry Assessment

Insure Pulse is formulated as a suspension containing pyraclostrobin at 16.7 g/L, fluxapyroxad at 16.7 g/L and metalaxyl at 13.3 g/L. This end use product has a density of 1.05 – 1.06 g/L and a pH of 5.0 -7.0. The chemistry requirements for these products have been fulfilled.

Health Assessments

BAS 720 F ST is low acute toxicity via the oral, dermal and inhalation routes. It is non-irritating to the eyes and mildly irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

An assessment was performed for commercial and on-farm treaters and planters that may be exposed to Insure Pulse. The product should not result in health risks of concern to the active ingredients, pyraclostrobin, fluxapyroxad and metalaxyl. No unacceptable health risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Previously reviewed residue data from field trials conducted in/on CSG 6C, soybeans, and canola were reassessed in the framework of this petition. In addition, processing studies in treated soybean and canola were also reassessed to determine the potential for concentration of residues of pyraclostrobin, fluxapyroxad, and metalaxyl into processed commodities.

The resulting residues in/on these crops and transferred to animal commodities will be covered by existing MRLs. Therefore, the use of this product will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No environmental concerns were identified; the accepted use of the end use product Insure Pulse falls within the existing use patterns for the fungicides pyraclostrobin, fluxapyroxad and metalaxyl.

Value Assessment

A combination of efficacy data from 28 trials and scientific rationales were provided in support of the proposed registration. Based on the value information provided, most proposed crop-disease organism claims were supported.

Both pyraclostrobin and fluoxpyrad were shown to be efficacious against the labelled diseases caused by true fungi. Therefore the combination of these two actives ingredients, from two different mode of action groups, will aid in resistance management. In addition the inclusion of metalaxyl in the formulation, which targets diseases caused by *Pythium* spp., provides a broader spectrum of disease control. The registration of this product provides an alternative for seed and seedling disease problems, in legume crops and flax, for which few seed treatment alternatives exist.

Conclusion

PMRA has conducted a review of the information provided in support of Insure Pulse. Based on this review, Insure Pulse is acceptable for full registration.

References

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2449234	2014, BAS 720 00 F - Acute dermal toxicity study in rats, DACO: 4.6.2
2449235	2014, BAS 720 00 F: 4-hour acute inhalation toxicity study in the rat, DACO: 4.6.3
2449236	2014, BAS 720 XJ F - Acute eye irritation rabbits, DACO: 4.6.4
2449237	2014, BAS 720 XJ F - Acute dermal irritation / corrosion in rabbits, DACO: 4.6.5
2449238	2014, BAS 720 XJ F - Assessment of sensitising properties on albino guinea pig by repeated applications BUEHLER test with 3 applications, DACO: 4.6.6
2449229	2013, BAS 720 00 F - determination of physico-chemical properties according to Directive 94/37/EC (regulation (EC) No. 440/2008), DACO: 3.5.11,3.5.12
2449227	2013, Determination of Fluxapyroxad, Pyraclostrobin and Metalaxyl in FS-Formulation, DACO: 3.4.1
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2449230	2014, DACO 3.5.13 Miscibility and DACO 3.5.15 Dielectric Breakdown Voltage, DACO: 3.5.13,3.5.15
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