



Evaluation Report for Category B Subcategory 2.6 Application

Application Number: 2010-4861
Application: New Combination of Active Ingredients
Product: A18046A Seed Treatment
Registration Number: 30388
Active ingredients (a.i.): azoxystrobin, fludioxonil, metalaxyl-m and s-isomer, thiamethoxam, (AZY, FLD, MFN, THE)
PMRA Document Number : 2297918

Purpose of Application

The purpose of this application was to register a new seed treatment end-use product which is a pre-mix formulation based on the registered tank mix of Cruiser Maxx Beans Seed Treatment (Registration Number 28821) and Dynasty 100FS Fungicide (Registration Number 28394) for use on soybeans. The product is currently conditionally registered. The re-evaluation of the active ingredient, Metalaxyl-m and S-isomer, was published under RVD2008-03.

Chemistry Assessment

A18046A Seed Treatment, is formulated as a suspension containing four active ingredients thiamethoxam at a nominal concentration of 261 g/L, metalaxyl-M and S-isomer at 19.7 g/L, fludioxonil at 12.9 g/L and azoxystrobin at 10.4 g/L. This end-use product has a density of 1.156 g/mL and pH of 5.8. The product contains three list 2 formulants. The chemistry requirements for A18046A Seed Treatment are complete.

Health Assessments

A18046A Seed Treatment is of low acute toxicity via the oral (female $LD_{50} > 5000$ mg/kg bw), dermal ($LD_{50} > 5000$ mg/kg bw) and inhalation ($LC_{50} > 2.60$ mg/L) routes in rats. It is minimally irritating to rabbit eyes and skin. A18046A Seed Treatment is not a skin sensitizer in guinea pigs.

As all active ingredients are currently registered for use on soybean as a seed treatment at the same application rates and conditions, the registration of A18046A Seed Treatment will not result in an increase in dietary exposure to these active ingredients.

The use of A18046A Seed Treatment, a new end-use product containing azoxystrobin, fludioxonil, metalaxyl-M and thiamethoxam for the control of various fungal diseases and insect pests in soybeans, is considered acceptable when workers follow label directions and precautions, including listed personal protective equipment and application restrictions.

Environmental Assessment

The environmental risk associated with the use of the subject product on soybean is not expected to be greater than the registered uses for the active ingredients in the subject product.

Value Assessment

A data waiver rationale was provided by the applicant in support of the proposed efficacy claims. The requested fungicide use pattern for A18046A is identical to that of the registered tank-mix of Cruiser Maxx Beans Seed Treatment and Dynasty 100FS Fungicide on soybean. The formulation of A18046A is based on the registered formulation of Cruiser Maxx Beans, with the addition of azoxystrobin. The registered tank-mix of Cruiser Maxx Beans and Dynasty 100FS delivers a similar amount of active ingredients per 100 kg seed as A18046A. Considering that the formulation, active ingredient rates and fungicide use pattern of A18046A and the Cruiser Maxx Beans + Dynasty 100FS tank-mix are almost identical, it can be safely concluded that A18046A will provide similar disease control as its tank-mix counterpart. The use of A18046A is supported for control of the labelled diseases on soybean at 195 mL/100 kg seed, as proposed.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support for the product, A18046A Seed Treatment, and has found the information sufficient to support the new seed treatment end-use product.

References

PMRA Number	Reference
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1964003	2010, A18046A Seed Treatment - Identification - Formulating Plant Address, DACO: 3.1.2 CBI
1964004	2010, A18046A Seed Treatment - Starting Materials, DACO: 3.2.1 CBI
1964005	2010, A18046A Seed Treatment - Manufacturing Process, DACO: 3.2.2 CBI
1964006	2010, A18046A Seed Treatment - Certified Limits, DACO: 3.3.1 CBI
1964007	2010, Analytical Method SF-396-1 - Determination of CGA173506, CGA293343, CGA329351, ICI5504 in A18046A, DACO: 3.4.1 CBI
1964008	2010, A18046A Seed Treatment - Chemical and Physical Properties, DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9
2096170	2011, A18046A - Content of Active Ingredients and Corrosion Characteristics in Non-Fluorinated HDPE After Storage for 1 Year at 20C, DACO: 3.5.10,3.5.14
1964010	2010, Azoxystrobin/Fludioxonil/Thiamethoxam/Mefenoxam FS (A18046A) - Acute Oral Toxicity Up-and-Down Procedure in Rats, DACO: 4.6.1
1964011	2010, Azoxystrobin/Fludioxonil/Thiamethoxam/Mefenoxam FS (A18046A) - Acute Dermal Toxicity in Rats, DACO: 4.6.2
1964012	2010, Azoxystrobin/Fludioxonil/Thiamethoxam/Mefenoxam FS (A18046A) - Acute Inhalation Toxicity in Rats, DACO: 4.6.3
1964013	2010, Azoxystrobin/Fludioxonil/Thiamethoxam/Mefenoxam FS (A18046A) - Primary Eye Irritation in Rabbits, DACO: 4.6.4
1964014	2010, Azoxystrobin/Fludioxonil/Thiamethoxam/Mefenoxam FS (A18046A) - Primary Skin Irritation in Rabbits, DACO: 4.6.5
1964015	2010, Azoxystrobin/Fludioxonil/Thiamethoxam/Mefenoxam FS (A18046A) - Dermal Sensitization Test - Buehler Method, DACO: 4.6.6
1964016	2010, A18046A Seed Treatment - Residue and Efficacy - Data Waiver Request, DACO: 10.1, 10.2.3.1, 10.2.3.3, 6.1, 6.2, 6.3, 6.4, 7.1, 7.2.1, 7.2.2, 7.2.3, 7.2.4, 7.2.5, 7.3, 7.4.1, 7.4.2, 7.4.3, 7.4.4, 7.4.5, 7.4.6, 7.5.1

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