

Evaluation Report for Category B, Subcategory 3.4, 3.12, 3.13 Application

Application Number: 2013-1029
Application: Product Labels – New site or host, precautions, application method
Product: Trilex Component B
Registration Number: 30645
Active ingredients (a.i.): metalaxyl (MTA)
PMRA Document Number : 2304912

Purpose of Application

The purpose of this application was to amend the Trilex Component B label as follows: 1) clarify the Directions for Use section to allow for on-farm treatment of the registered crops; 2) to remove the limitation to low tannin varieties of lentil and allow for treatment of lentil seed for domestic planting in Canada; 3) modify the current PPE under the Precautions section.

Chemistry Assessment

A chemistry evaluation was not required for this application.

Health Assessments

A toxicological evaluation was not required for this application.

No new residue data were submitted for metalaxyl to support the changes to the Trilex Component B label. Metalaxyl is currently registered for use domestically on lentils at comparable rates. Residues of metalaxyl in/on lentil seed resulting from these revisions to the registered label will be covered under the MRL of 0.05 ppm established for metalaxyl in/on dry lentils (EMRL2008-02 - *Transitioning the Legal Establishment of Maximum Residue Limits (MRLs) for Pesticides From the Food and Drugs Act to the Pest Control Products Act: Establishment of MRLs*). Exposure to residues on metalaxyl in/on treated lentil seed will therefore not increase for any population subgroup and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

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

Environmental Assessment

The label amendments do not affect use patterns and application rates and therefore, do not change environmental exposure for metalaxyl. The existing label statements are adequate to mitigate environmental concerns.

Value Assessment

In support of making similar label revisions to the Allegiance FL (PMRA Reg. No. 26674) and Trilex Component B labels, a total of four field trials and three laboratory studies were submitted to support the use expansion. The field trials demonstrated that Allegiance FL consistently increased stand count compared with the control. Allegiance FL also increased yield in two trials. In laboratory studies, seed treated with Trilex AL resulted in a significantly higher percentage emergence than the non-treated inoculated control at 6 – 10 days after seeding. The percent germination was 49 – 92% (average 63%) for Trilex AL and 12 – 41% (average 28%) for the control across all three studies.

The registrant also submitted other evidence to support the use expansion. Among ten metalaxyl-containing products that are currently registered for control of *Pythium* seedling and root diseases on lentil in Canada, six products are registered on all lentils without the restrictions associated with low tannin and export or seed production use. Published literature indicates that *Pythium* is an important seed-rotting, damping-off and root rot pathogen in lentil as described by the registrant. Lentil stand establishment can be improved by proper *Pythium* control measures even in regular lentils containing tannins in the seed coat. The low- or zero-tannin lentil seeds have a thinner seed coat than regular lentil seeds, which may make the seed more susceptible to *Pythium* and other pathogens. However, regular lentil seeds may not have full protection against *Pythium* infection without proper fungicide treatment. A seed treatment is warranted for *Pythium* control in all types of lentils.

Therefore, the label expansion was deemed supported from a value perspective.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Trilex Component B, and has found the information sufficient to remove the “for export only” and “low tannin lentil” limitations for seed treatment use in lentil and to allow both commercial and on-farm seed treating applications.

References

PMRA Document Number	Reference
2273614	2012, Allegiance FL - Data and rationale to support amended lentil statements. DACO: 10.1, 10.2.3.1, 10.2.3.3(D), 10.3.1, 10.3.2(B)

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