

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2009-4229
Application: Changes to product chemistry - guarantee
Product: Lime Sulphur Insecticide Miticide Fungicide
Registration Number: 16465
Active ingredients (a.i.): Calcium polysulphide [SUS]
PMRA Document Number : 1969254

Purpose of Application

The purpose of this application is to change the source of active as well as the product guarantee for Lime Sulphur Insecticide Miticide Fungicide (Registration Number 16465).

Chemistry Assessment

Lime Sulphur Insecticide Miticide Fungicide is a liquid containing the active ingredient calcium polysulphide at a nominal concentration of 30%. This product has a specific gravity of 1.27 and pH of 11.5 – 11.8. The chemistry requirements for Lime Sulphur Insecticide Miticide Fungicide have been completed.

Health Assessments

Lime Sulphur Insecticide Miticide Fungicide is a 100% repack of the technical grade active ingredient. The new source of technical grade active ingredient is chemically equivalent to the currently registered source of technical grade active ingredient. In turn, the most recent toxicological assessment conducted for lime sulphur (per the re-evaluation decision RVD2009-13 – *Lime Sulphur*) will remain applicable and appropriate as there have been no changes to use scenario.

In Canada, sulphur residues on food crops are exempted from the *Food and Drugs Act* and Regulations, as outlined in Regulation B.15.002(2) of Division 15. Accordingly, the establishment of a Maximum Residue Limit is not necessary for lime sulphur.

The precautionary labelling statements recommended for Lime Sulphur Insecticide Miticide Fungicide are considered adequate as mitigation measures for addressing any human health risks resulting from potential occupational or bystander exposures to the product. To further protect applicators from potential post-application exposure, a 48-hour restricted entry interval is required.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

The amendment is accepted because the change in the formulation is not expected to affect efficacy.

Conclusion

The PMRA has completed an assessment of available information for Lime Sulphur Insecticide Miticide Fungicide and has found the information sufficient to support the change in source of active ingredient for Lime Sulphur Insecticide Miticide Fungicide.

References

PMRA #	Documentation
1877497	Waiver Rationale, DACO 5.2, 6.1, 6.3, 7.1, 7.2.1, 7.2.2, 7.2.3, 7.2.4, 7.2.5, 7.4.1, 7.4.2
1877498	U.S. EPA Reregistration Eligibility Decision for Inorganic Polysulfides, List D, Case No. 4054, 2005, DACO 12.5
1877492	DACO3.1.1 and 3.1.2 response, DACO: 3.1.1,3.1.2 CBI
1877493	DACO3.3.1 response, DACO: 3.3.1 CBI
1877494	DACO3.5 chem phys response, DACO: 3.5, 3.5.11 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.7, 3.5.8, 3.5.9

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