

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2019-5155
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy - Equivalency/ Data Compensation Assessment
Product: SPIRO SC MITICIDE
Registration Number: 34247
Active ingredient (a.i.): Spirodiclofen
PMRA Document Number: 3234423

Purpose of Application

The purpose of this application was to register a new insecticide, SPIRO SC MITICIDE, for control of listed mites in pome fruit, stone fruit, tree nuts (crop group 14), grapes, hops, and highbush and lowbush blueberries, based on a precedent.

Chemistry Assessment

SPIRO SC MITICIDE is formulated as a suspension containing spirodiclofen at a concentration of 253 g/L. This end-use product has a density between 1.0758 and 1.0776 g/mL and pH of 7.1 (1 % solution). The required chemistry data for SPIRO SC MITICIDE have been provided, reviewed and found to be acceptable.

Health Assessments

SPIRO SC MITICIDE was considered toxicologically equivalent to the precedent product; therefore, no toxicology data are required. SPIRO SC MITICIDE is considered to be of low acute toxicity via the oral, dermal and inhalation routes. It is considered to be non-irritating to the eyes and skin, and is a potential dermal sensitizer.

The use of SPIRO SC MITICIDE on the listed crops, is not expected to result in potential occupational or bystander exposure over the registered use of spirodiclofen. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No new residue data for spirodiclofen were submitted to support the registration of SPIRO SC MITICIDE. While the use rates are higher than the registered use rates on the precedent label, all other aspects of the use pattern are identical. The data on file are adequate to support the use pattern.

As such, residues of spiroticlofen in/on treated crops and animal commodities will be covered under the maximum residue limits (MRLs) established for spiroticlofen. The dietary exposure assessment on file for spiroticlofen is also adequate to cover the use of SPIRO SC MITICIDE. No health risks of concern are expected to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The registration of SPIRO SC MITICIDE to control mites on the listed crops throughout Canada, does not pose any additional risk to the environment when used according to the label.

Value Assessment

The claims on the SPIRO SC MITICIDE label were supported based on extrapolation from a precedent product. SPIRO SC MITICIDE is expected to provide efficacy equivalent to the precedent product for control of various mite species on hops and on the listed fruit and nut crops.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found it sufficient to support the registration of SPIRO SC MITICIDE.

References

PMRA Document Number	References
3036521	2015, Spirodiclofen 24 % SC: Validation of the Analytical Method for the Determination of the Active Ingredient Content, DACO: 3.4.1
3036524	2015, Spirodiclofen 24 % SC: Determination of the Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.7
3036525	2018, Spirodiclofen 24% SC: Two Years Storage Stability and Corrosion Characteristics, DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.7 CBI
3036526	2018, Spirodiclofen 24 % SC: Determination of the Oxidizing Properties and Explosive Properties, DACO: 3.5.12,3.5.8
3036527	2019, Additional Product Chemistry for SPIRO 240 SC Miticide, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.13,3.5.15,3.5.4,3.5.5
3036529	2015, Spirodiclofen 24 % SC: Determination of the Physico-Chemical Properties, DACO: 3.5.1,3.5.11,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9
3223617	2021, Description of formulation process to Spirodiclofen 253 g/L SC (Spiro SC Miticide), DACO: 3.2.1,3.2.2,3.3.1 CBI

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