Health Canada Santé Canada

Evaluation Report for Category B, Subcategories 2.1, 2.3, 2.4, 2.5 Application

Application Number: 2017-8198
Application: New EP Product Chemistry-Guarantee
New EP Product Chemistry-Identity of Formulants
New EP Product Chemistry-Proportion of Formulants
New EP Product Chemistry-Formulation Type
Product: Dyno-Mite SC Miticide/Insecticide
Registration Number: 33434
Active ingredient (a.i.): Pyridaben
PMRA Document Number: 2972526

Purpose of Application

The purpose of this application was to register an insecticide end-use product containing pyridaben for control of listed mites and whiteflies in greenhouses on ornamental plants, flower and foliage crops and listed mites on greenhouse peppers, cucumbers and tomatoes and outdoor ornamental plants for nursery stock.

Chemistry Assessment

Dyno-Mite SC Miticide/Insecticide is formulated as a suspension containing pyridaben at a concentration of 450 g/L. This end-use product has a density of 1.06 g/mL and pH of 6.74. The required chemistry data for Dyno-Mite SC Miticide/Insecticide have been provided, reviewed and found to be acceptable.

Health Assessments

Dyno-Mite SC Miticide/Insecticide is of moderate acute toxicity to rats via the oral route and of low acute toxicity to rats via the dermal and inhalation routes of exposure. It is mildly irritating to the eyes and skin of rabbits and is a dermal sensitizer in mice according to the local lymph node assay method.

An updated quantitative mixer/loader/applicator risk assessment was conducted for Dyno-Mite SC Miticide/Insecticide. For postapplication workers, the risk assessment on file for pyridaben was adequate to address the potential exposure for workers entering sites treated with Dyno-Mite SC Miticide/Insecticide. No health risks of concern are expected provided that workers wear the appropriate personal protective equipment and follow all other label directions.

No new residue data were submitted in support of the registration Dyno-Mite SC Miticide/Insecticide. The use pattern was determined to be within that of previously registered products. Therefore, the previously reviewed data were reassessed and it was

confirmed that the use of Dyno-Mite SC Miticide/Insecticide is not expected to result in an increase in the magnitude of pyridaben residues in/on the treated crops. Therefore, the registration of Dyno-Mite SC Miticide/Insecticide will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The uses of Dyno-Mite SC Miticide/Insecticide are within the previously registered use patterns of the active ingredient pyridaben, and therefore, no additional environmental risk is expected from the use of Dyno-Mite SC Miticide/Insecticide. The label includes all the required environmental precautionary statements, hazards and directions for use statements, including buffer zone specifications which adequately mitigates risks to the environment.

Value Assessment

Three bridging trials demonstrated that Dyno-Mite SC Miticide/Insecticide has efficacy similar to that of a previously registered precedent product; therefore, Dyno-Mite SC Miticide/Insecticide was supported from a value perspective.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to register Dyno-Mite SC Miticide/Insecticide.

References

PMRA Document Number	Reference
2836598	2016, Nexter SC: Physical and Chemical Properties Waiver Requests, DACO: 3.5.11,3.5.12,3.5.13,3.5.15 CBI
2836599	2016, Nexter SC: Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, Viscosity, and Density/Relative Density, DACO: 3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI
2836600	2016, Product Identity and Composition, Description of the Materials Used, Description of the Formulation Process, Discussion of the Formation of Impurities, and Certified Limits for Nexter SC, DACO: 3.2,3.2.1,3.2.2, 3.2.3,3.3.1 CBI
2836601	2016, Nexter SC: Enforcement Analytical Method for the Determination of Pyridaben by High Performance Liquid Chromatography, DACO: 3.4.1 CBI
2836602	2016, Nexter SC: Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14 CBI
2836606	2016, Nexter SC: Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO: 4.2.1
2836608	2016, Nexter SC: Acute Dermal Toxicity in Rats, DACO: 4.2.2
2836607	2016, Nexter R SC: Acute Inhalation Toxicity in Rats, DACO: 4.2.3
2836604	2016, Nexter SC: Primary Eye Irritation in Rabbits, DACO: 4.2.4
2836603	2016, Nexter SC: Primary Skin Irritation in Rabbits, DACO: 4.2.5
2836605	2016, Nexter R SC: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.2.6
2836609	2017, Pyridaben SC Value Package - Value Dossier, DACO: 10.1, 10.2.3, 10.2.3.1, 10.2.3.3
2836610	2017, Pyridaben SC Value Package - Excel Data Summary, DACO: 10.1, 10.2.3, 10.2.3.1, 10.2.3.3
2836611	2017, Pyridaben SC Value Package - Trial GOW17I01, DACO: 10.1, 10.2.3, 10.2.3.1, 10.2.3.3
2836612	2017, Pyridaben SC Value Package - Trial NXT-17-05-T01-PM3, DACO: 10.1, 10.2.3, 10.2.3.1, 10.2.3.3
2836613	2017, Pyridaben SC Value Package - Trial NXT-17-05-T01-PM1, DACO: 10.1, 10.2.3, 10.2.3.1, 10.2.3.3

ISSN: 1911-8082