Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.3, 2.4,3.1,3.11, 3.12,-S-N-EP Application

Application Number: 2007-2316
Application: Category B. Subcategory 2.3, 2.4,3.1,3.11, 3.12,-S-N-EP
Product: Microthiol Disperss
Registration Number: TBD
Active ingredients (a.i.): Sulphur (SUL)
PMRA Document Number: 1812725

Background

Microthiol Disperss is a new end use product containing a new source of sulphur. The percent technical grade active ingredient (TGAI) and the use pattern, including host crops, pests, application rates and timing, of the proposed product are identical to those of a currently registered product.

Purpose of Application

The applicant has proposed to register a new end use product containing a new source of sulphur. The product is intended for use to control fungal diseases on apples, pears, peaches, sweet and sour cherries, and grapes, rust mites on apples, pears, and sour cherries, grape erineum mite on grapes, powdery mildew on peas and greenhouse cucumbers, and entomosporium leaf and berry spot on Saskatoon berries. Microthiol Disperss is to be applied a rate of 1.5 kg/ha to 22.5 kg/ha (equivalent to 1.2 to 18.0 kg ai/ha) which can be applied up to eight times per season.

Chemistry Assessment

Microthiol Disperss is a flowable powder containing the active ingredient sulphur at a nominal concentration of 80.0%. This product has a density of 0.89 g/mL and pH of 10.44 (1% aqueous suspension). The chemistry requirements for Microthiol Disperss have been completed.

Environmental Assessment

As the intended use pattern and label is similar to the precedent product, containing the same active ingredient, the EAD does not require any further information at this time. There are no formulants or contaminants of concern to the environment in the EP and TGAI, respectively. Label statements were amended to reflect precautionary statements and buffer zones present on the registered label of the precedent product.

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Health Assessment

The active ingredient produced at the original and new sites of manufacture of Microthiol Disperss are chemically equivalent and the guarantee of the end use product was confirmed. Therefore, the toxicology profile of Microthiol Disperss is expected to be similar to that of the currently registered product and no additional toxicological data were required.

The use pattern for Microthiol Disperss on peas, pears, apples, peaches, plums, cherries, grapes, Saskatoon berries and greenhouse cucumbers fits within the registered use pattern for the active ingredient sulphur.

Value Assessment

The registrant has indicated that Microthiol Disperss is comparable to a precedent product. Fungicide efficacy data were provided to support the claim; however, it was not necessary to review the data since the formulations are considered biologically equivalent for the following reasons:

a) The guarantee remains the same and formulation differences between Microthiol Disperss and the precedent are not significant from an efficacy or phytotoxicity perspective.

b) The proposed new product, Microthiol Disperss, fits within the existing use pattern for sulphur. All proposed crops, rates, equipment, and timing of application are identical to the precedent product.

Since Microthiol Disperss has been determined to be biologically equivalent to the precedent product, the use claims for control of the indicated diseases and mites are supported as proposed.

Conclusion

In a separate submission, the source of sulphur that constitutes the active ingredient in Microthiol Disperss was found to be chemically equivalent to its precedent product. Since the use pattern of the two products is identical, they are considered biologically equivalent. Therefore, registration of Microthiol Disperss is supported based on chemical and biological equivalency. The registration of Microthiol Disperss is dependent on the registration of the new source of sulphur.

References

1396052 Applicants Name and Office Address, DACO: 3.1.1
1396053 Formulating Plants Name and Address, DACO: 3.1.2
1396054 Trade Name, DACO: 3.1.3
1396055 Other Names, DACO: 3.1.4
1396056 Description of Starting Materials, DACO: 3.2.1
1396057 Description of Starting Materials CBI, Not applicable, MRID: Not applicable, DACO: 3.2.1 CBI

1396058 Description of the Formulation Process, DACO: 3.2.2
1396060 Description of the Formulation Process CBI, DACO: 3.2.2 CBI
1396061 Discussion of the Formation of Impurities of Toxicological Concern, DACO: 3.2.3
1396062 Specifications & Establishing Certified Limits, DACO: 3.3.1
1396063 Specifications & Establishing Certified Limits CBI, DACO: 3.3.1 CBI
1396066 Enforcement Analytical Method, DACO: 3.4.1
1396067 1992, Enforcement Analytical Method CBI, HWI 6120-167, MRID: 42459201, DACO: 3.4.1 CBI
1396068 Physical State, DACO: 3.5.2
1396069 Formulation Type, DACO: 3.5.4
1396070 Container Material and Description, DACO: 3.5.5
1396071 Density or Specific Gravity, DACO: 3.5.6
1396072 1992, Density or Specific Gravity CBI, HWI 6120-165, MRID: No applicable, DACO: 3.5.6 CBI
1396073 pH, DACO: 3.5.7
1396074 Oxidizing or Reducing Action (Chemical Incompatibility), DACO: 3.5.8
1396075 Viscosity, DACO: 3.5.9
1396076 Storage Stability Data, DACO: 3.5.10
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1396078 Flammability, DACO: 3.5.11
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1396083 Corrosion Characteristics, DACO: 3.5.14
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1454446 Chemistry Requirements for EP, DACO: 3.0
1454447 Establishing Certified Limits, DACO: 3.3.1
1454448 Establishing Certified Limits - Confidential Business Information Appendix, DACO: 3.3.1 CBI

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