



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2019-2239
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy (PPIP)
Product: SHAPE SC Fungicide
Registration Number: 34661
Active ingredient (a.i.): Pyrimethanil
PMRA Document Number: 3136736

Purpose of Application

The purpose of this application was to register SHAPE SC Fungicide, an end-use product containing pyrimethanil for the control or suppression of various leaf and fruit diseases in pomefruits, grapes, strawberries, potatoes, field tomatoes, bulb vegetables, ginseng, highbush and lowbush blueberries, raspberries and gooseberries based on a precedent.

Chemistry Assessment

SHAPE SC Fungicide is formulated as a suspension containing pyrimethanil at a concentration of 400 g/L. This end-use product has a density of 1.06 - 1.10 g/mL and pH of 7.6. The required chemistry data for SHAPE SC Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

SHAPE SC Fungicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. SHAPE SC Fungicide is considered to be of low acute toxicity via the oral and dermal routes, of slight acute toxicity via the inhalation route of exposure, minimally irritating to the eyes and slightly irritating to the skin, and is not considered to be a dermal sensitizer.

SHAPE SC Fungicide for use as a foliar treatment on pome fruits, grapes, strawberries, potatoes, field tomatoes, bulb vegetables, ginseng, highbush and lowbush blueberries, raspberries and gooseberries to control various leaf and fruit diseases fits within the registered use pattern of the precedent product. As such, exposure to pyrimethanil is not expected to exceed that of the registered uses. No health risks of concern are expected, provided that workers wear the appropriate personal protective equipment and follow all label directions for use.

No new residue data for pyrimethanil were submitted to support SHAPE SC Fungicide. The use pattern on the SHAPE SC Fungicide label (including the target crops, application rates, timing and number of applications, application methods, spray volumes, pre-harvest

intervals, recropping intervals, and proposed tank-mix partners) are the same or within the currently registered use pattern for pyrimethanil. Therefore, residues in/on treated crops are not expected to increase and will be covered under the maximum residue limits (MRLs) established for pyrimethanil. Consequently, the dietary exposure to residues of pyrimethanil is not expected to increase with the registration of SHAPE SC Fungicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The uses are within the currently registered use pattern of the active ingredient pyrimethanil and therefore, no additional risk is expected from the use of SHAPE SC Fungicide. The label includes the required environmental precautions and hazards statements, including the buffer zones information, which adequately mitigate risks to the environment.

Value Assessment

The applicant provided comparative bridging efficacy trials on grape, strawberry and field tomato to support the label claims for SHAPE SC Fungicide. Results from the trials showed that SHAPE SC Fungicide and the cited precedent product are biologically equivalent. Therefore, the use claims of SHAPE SC Fungicide are supported from the value perspective.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of SHAPE SC Fungicide.

References

PMRA Document

Number	Reference
2995739	2019, Product Identity, DACO: 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.5.13, 3.5.15, 3.5.5 CBI
2995740	2019, Description of Process Formulation, DACO: 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI
2995741	2017, Pyrimethanil [CBI Removed] SC: Validation of the Analytical Method for the Determination of the Active Ingredient Content, DACO: 3.4,3.4.1 CBI
2995742	2017, Pyrimethanil [CBI Removed] SC : Determination of the Physico-chemical Properties, DACO: 3.5,3.5.1,3.5.11,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9
2995743	2017, Pyrimethanil [CBI Removed] SC: Determination of the Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14.
2995744	2017, Pyrimethanil [CBI Removed] SC: Two Years Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14.
2995745	2018, Pyrimethanil [CBI Removed] SC : Determination of the Oxidizing Properties and Explosive Properties, DACO: 3.5.12,3.5.8
3117867	2020, Container material, DACO: 3.5.5
3119415	2016, Formulation process, DACO: 3.2.2 CBI.
3131769	2020, Pyrimethanil [CBI Removed] SC: Two Years Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14.
2995747	2017, Final Trial report, DACO: 10.2.3,10.2.3.3,10.2.3.3(C)
2995748	2017, Final Trial report, DACO: 10.2.3,10.2.3.3,10.2.3.3(C)
2995749	2016, Final Trial report, DACO: 10.2.3,10.2.3.3,10.2.3.3(C)
2995750	2016, Final Trial report, DACO: 10.2.3,10.2.3.3,10.2.3.3(C)
2995751	2016, Report of Evaluation and Presentation of Results, DACO: 10.2.3,10.2.3.3,10.2.3.3(C)
2995752	2017, Efficacy and Crop Selectivity Of Pyrimethanil 40% SC in European Grape (Vitvi) for the Control of Botryotinia Cinerea (Botrci) Open Field - Italy, 2016, DACO: 10.2.3,10.2.3.3,10.2.3.3(C)
2995753	2017, Efficacy and Crop Selectivity Of Pyrimethanil 40% SC In European Grape (Vitvi) for the Control of Botryotinia Cinerea (Botrci) Open Field - Italy, 2016, DACO: 10.2.3,10.2.3.3,10.2.3.3(C)
3021877	2019, Value Summary, DACO: 10.2.3.1

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