

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.11, 3.12 Application

Application Number: 2022-3553
Application: New End-use Product (Product Chemistry) – Guarantee, and Identity and Proportion of Formulants; New Product Label – New Pests and New Site or Host
Product: CeraSulfur
Registration Number: 34989
Active ingredient (a.i.): Sulfur
PMRA Document Number: 3502819

Purpose of Application

The purpose of this application was to register the commercial end-use product, CeraSulfur, for use as a foliar spray for the control of powdery mildew on greenhouse tomato, greenhouse cucumber, and grape; the suppression or control of powdery mildew on pea and bean; and the suppression of septoria tritici blotch on wheat (winter and spring).

Chemistry Assessment

CeraSulfur is formulated as a suspension containing sulfur at a concentration of 700 g/L. This end-use product has a density of 1.39 g/mL and pH of 8.8. The required chemistry data for CeraSulfur have been provided, reviewed and found to be acceptable.

Health Assessments

Potential exposure to sulfur may occur by applying the end-use product or entering treated sites. Two key factors are considered when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed.

CeraSulfur is of low acute oral and dermal toxicity, it is expected to be of low acute inhalation toxicity, it is mildly irritating to the eyes, minimally irritating to the skin, and is a dermal sensitizer.

Risk from occupational exposure to individuals handling CeraSulfur is acceptable when the product is used according to label directions. Precautionary and hygiene statements on the product label aimed at mitigating worker exposure are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Bystander exposure is expected to result in acceptable risk when the product is used according to label directions.

Health risks to individuals in residential areas are considered acceptable when the product is used according to label directions.

Maximum Residue Limit

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

Although the *Food and Drugs Act* prohibits the sale of adulterated food in Canada, foods containing sulfur are exempt from this prohibition. Also, based on the low toxicity, the specification of an MRL for sulfur under the PCPA is not being requested.

Environmental Assessment

After a scientific review of the available information, it has been concluded that the environmental risks associated with the use of CeraSulfur are acceptable when used according to the label directions, which includes statements to mitigate risks to the environment.

Value Assessment

Scientific rationales and results from greenhouse and field trials conducted on greenhouse tomato, greenhouse cucumber, grape, wheat, pea and bean in Germany, France, the Netherlands, and Canada between 2018 and 2022 were reviewed to support the use claims on the CeraSulfur label. The efficacy trials demonstrated that CeraSulfur controlled powdery mildew on greenhouse tomato, greenhouse cucumber and grape, suppressed septoria tritici blotch on wheat, and suppressed or controlled (depending on application rate) powdery mildew on pea and bean.

CeraSulfur has been confirmed to have value with data and other supporting information demonstrating that CeraSulfur can be expected to protect tested crops against powdery mildew and *Septoria* disease. Registration of CeraSulfur for these uses will provide Canadian growers a new tool to combat those important fungal diseases on labelled crops.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of CeraSulfur.

References

PMRA

Document

Number	Reference
3388974	2022, Description of formulation process, DACO: 3.2.2 CBI
3388985	2022, Explodability, DACO: 3.5.12 CBI
3388986	2022, Miscibility, DACO: 3.5.13 CBI
3388988	2022, Dielectric breakdown voltage, DACO: 3.5.15 CBI
3388995	2016, Physical-chemical properties of CeraSulfur - DSPF011 - Stability and shelf-life determination - Part 1: Physical-chemical properties upon receipt, after accelerated storage and after cold storage, DACO: 3.5,3.5.1,3.5.10, 3.5.11,3.5.12,3.5.2,3.5.4,3.5.6,3.5.7,3.5.8,3.5.9 CBI
3388996	2018, Physical-chemical properties of CeraSulfur - DSPF011 - Stability and shelf-life determination Part 2: Shelf-life, DACO: 3.5,3.5.10 CBI
3388997	2022, CF900 : Determination of the physico-chemical properties, DACO: 3.5,3.5.1,3.5.10,3.5.14,3.5.2,3.5.3 CBI
3375171	2022, 5.2 Use Description and Scenario, DACO: 5.2
3416668	2015, DSPF011 - Evaluation of acute oral toxicity in rats - Acute toxic class method, DACO: 4.6.1
3416669	2015, DSPF011 - Evaluation of acute dermal toxicity in rats, DACO: 4.6.2
3416670	2015, DSPF011 - Assessment of the skin sensitization potential in the mouse using the local lymph node assay, DACO: 4.6.6
3416671	2015, DSPF011 - Assessment of acute eye irritation, DACO: 4.6.4
3416672	2015, DSPF011 - Assessment of acute dermal irritation, DACO: 4.6.5
3375172	2022, 10.1 Value Summary, DACO: 10.1
3375174	2022, 10.2.1 Mode of Action and Description of the product, DACO: 10.2.1
3375175	2022, 10.2.2 Description of the Pest Problem in Canada, DACO: 10.2.2
3375188	2022, 10.2.3.3 Efficacy Small Scale Field Trials, DACO: 10.2.3.3(D)
3375192	2019, 10.2.3.3 Appendix 1 Determination of efficacy of Biosulfur applied up to 6 times against powdery mildew in cucumber (greenhouse) in 2019, DACO: 10.2.3.3(D)
3375194	2019, 10.2.3.3 Appendix 2 Determination of efficacy of Biosulfur applied up to 6 times against powdery mildew in tomato (greenhouse) in 2019, DACO: 10.2.3.3(D)
3375196	2022, 10.2.3.3 Appendix 3 Determination of efficacy of Biosulfur applied up to 6 times against powdery mildew in tomato (greenhouse) in 2019, DACO: 10.2.3.3(D)
3375198	2019, 10.2.3.3 Appendix 4 Determination of efficacy of KC1901 (Biosulfur) applied up to 8 times against powdery mildew in grapevine in 2019, DACO: 10.2.3.3(D)
3375200	2019, 10.2.3.3 Appendix 5 Determination of efficacy of KC1901 (Biosulfur) applied up to 8 times against powdery mildew in grapevine in 2019, DACO: 10.2.3.3(D)
3375202	2020, 10.2.3.3 Appendix 6 Determination of efficacy of KC1901 (Cerasulfur) applied up to 8 times against powdery mildew in grapevine in 2020, DACO: 10.2.3.3(D)

3375204	2020, 10.2.3.3 Appendix 7 Determination of efficacy of KC1901 (Cerasulfur) applied up to 8 times against powdery mildew in grapevine in 2020, DACO: 10.2.3.3(D)
3375207	2020, 10.2.3.3 Appendix 8 Determination of efficacy of KC1901 (Cerasulfur) applied up to 8 times against powdery mildew in grapevine in 2020, DACO: 10.2.3.3(D)
3375208	2020, 10.2.3.3 Appendix 9 Determination of Efficacy / Crop Safety of DSPF011 against leaf spot of wheat (<i>Septoria tritici</i>) in Winter wheat, 2018, DACO: 10.2.3.3(D)
3375209	2018, 10.2.3.3 Appendix 10 Determination of Efficacy / Crop Safety of DSPF011 against leaf spot of wheat (<i>Septoria tritici</i>) in Winter wheat, 2018, DACO: 10.2.3.3(D)
3375210	2019, 10.2.3.3 Appendix 11 Efficacy and Selectivity of DSPF011 used in program against <i>Septoria tritici</i> on winter wheat, DACO: 10.2.3.3(D)
3375211	2018, 10.2.3.3 Appendix 12 Efficacy and Selectivity of DSPF011 used in program against <i>Septoria tritici</i> on winter wheat, DACO: 10.2.3.3(D)
3375212	2019, 10.2.3.3 Appendix 13 Efficacy and selectivity of DSPF011 against leaf spot of wheat (<i>Zymoseptoria tritici</i>) in Winter wheat, 2019, DACO: 10.2.3.3(D)
3375213	2021, 10.2.3.3 Appendix 14 Efficacy of Cerasulfur against Powdery Mildew on Legumes – Beans, DACO: 10.2.3.3(D)
3375214	2021, 10.2.3.3 Appendix 15 Efficacy of Cerasulfur against Powdery Mildew on Legumes – Pea, DACO: 10.2.3.3(D)
3375215	2022, 10.2.4 Use History, DACO: 10.2.4
3375216	2022, 10.2.4 Appendix 1 Agricultural Use History Template, DACO: 10.2.4
3375218	2022, 10.2.4 Appendix 3 Efficacy Considerations Table, DACO: 10.2.4
3375220	2022, 10.3.2 Non-Safety Adverse Effects, DACO: 10.3.2(B)
3375221	2020, 10.3.2 Appendix 1 Cerasulfur phytotoxicity test on Field Peas, DACO: 10.3.2(B)
3375224	2022, 10.4 Social and Economic Impact, DACO: 10.4
3375225	2022, 10.5.1 Survey of Alternatives, DACO: 10.5.1
3375230	2022, 10.5.2 Compatibility with Current Management Practices, DACO: 10.5.2
3375232	2022, 10.5.3 Resistance Management, DACO: 10.5.3

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