Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1,2.3,2.4,2.5,3.1,3.6,3.9,3.13 Application

Application Number: 2022-6607
Application: New end use product chemistry; guarantee, formulation type, identity and proportion of formulants;
New end use product label; application rate, preharvest, level of control and precautions.
Product: Maxentis SC
Registration Number: 35471
Active ingredients (a.i.): Azoxystrobin and prothioconazole
PMRA Document Number: 3697423

Purpose of Application

The purpose of this application was to register a new fungicide, Maxentis SC, containing azoxystrobin and prothioconazole for use on cereal crops (wheat, barley, oats), legume crops (peas, lentil), soybean, lowbush blueberries, and canola.

Chemistry Assessment

Maxentis SC is formulated as a suspension containing azoxystrobin at a concentration of 200 g/L and prothioconazole at a concentration of 150 g/L. This end-use product has a density of 1.04 – 1.14 g/mL and pH of 6 – 8. The required chemistry data for Maxentis SC have been provided, reviewed and found to be acceptable.

Health Assessments

Maxentis SC is of moderate acute toxicity by the oral route. It has low acute toxicity via the dermal and inhalation routes. It is not an irritant to the eyes or skin. It is a potential skin sensitizer.

The use of Maxentis SC on various crops is not expected to result in potential occupational or bystander exposure over the registered uses of azoxystrobin and prothioconazole. No health risks of concern are expected when workers wear the required personal protective equipment and follow all label directions.

No new residue data for azoxystrobin and prothioconazole in wheat, barley, oats, canola, peas, lentils, soybeans, and lowbush blueberries were submitted to support the registration of Maxentis SC. Previously reviewed residue data from field trials conducted in/on wheat, barley, canola, dry peas, soybean, and blueberry were reassessed in the framework of this application. In addition, processing studies in treated wheat grain, canola, and soybean were also reassessed to determine the potential for concentration of residues of azoxystrobin and

prothioconazole into processed commodities. Residues are expected to be covered by the currently established maximum residue limits (MRLs).

In addition, the anticipated residues of azoxystrobin and prothioconazole in animal matrices are expected to be covered by the currently established MRLs, when feed items derived from raw agricultural commodities (RACs) are treated with Maxentis SC and fed to livestock.

Exposure to residues of azoxystrobin and prothioconazole from the registration of Maxentis SC are not likely to result in any dietary risks for the general population and all subpopulations, including infants, children, adults, and seniors.

Environmental Assessment

The registration of Maxentis SC for the control or suppression of labelled diseases on lowbush blueberries, canola, peas, lentils, soybeans, barley, wheat, and oats is within the currently registered use patterns for azoxystrobin and prothioconazole. Therefore, the risk is acceptable when Maxentis SC is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The results of 48 efficacy trials were submitted to support the claims on the Maxentis SC label. The value review supported the use rates and application timing for all claims. The registration of Maxentis SC provides cereal, legume, canola, and blueberry growers with an alternative fungicide to manage important diseases.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable for the registration of Maxentis SC.

References

PMRA Document Number	Reference
3419996	2022, Product identity and composition, Description of materials used to produce the product, Description of production process, Discussion of formation of impurities, Certified Limits, Submittal of Samples and Enforcement Analytical Method for Maxentis SC, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1, 3.7 CBI
3419997	2021, Physical and Chemical Properties and determination of accelerated storage stability (40°C for 8 weeks) of one batch of Prothioconazole 150 Azoxystrobin 200 SC (product code ADM.03509.F.1.A), DACO: 3.4.1, 3.5.1, 3.5.10, 3.5.11, 3.5.14, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9
3548660	2024, 2022-6607 Maxentis SC DACO 3, DACO: 3.5.12, 3.5.13, 3.5.15, 3.5.4, 3.5.5
3597935	2018, Physical and Chemical Properties for Maxentis SC, DACO: 3.5, 3.5.11, 3.5.2, 3.5.6, 3.5.7, 3.5.8, 3.5.9
3597936	2024, Storage Stability Deficiency Response, DACO: 3.7
3597937	2023, Physical and Chemical Properties of one batch of Prothioconazole 150 Azoxystrobin 200 SC (product code ADM.03509.F.1.A) after a storage period - Shelf Life at ambient temperature for 2 years, DACO: 3.5.10
3419998	2019, Acute oral toxicity (up and down procedure) in the rat with MCW-2073, DACO: 4.6.1
3419999	2019, Acute dermal toxicity (fixed dose procedure) in the rats with MCW-2073, DACO: 4.6.2
3420000	2020, Acute inhalation toxicity of MCW-2073 in Sprague Dawley rats: OECD NO. 436, DACO: 4.6.3
3420001	2019, Acute eye irritation/corrosion in the rabbit with MCW-2073, DACO: 4.6.4
3420002	2019, Acute dermal irritation/corrosion in the rabbit with MCW-2073, DACO: 4.6.5
3420003	2019, Test for sensitization(Local lymph node assay- LLNA) with MCW-2073, DACO: 4.6.6
3420004	2022, Use Description/Scenario (Application and Post Application) for Maxentis sc, DACO: 5.2
3328289	2019, Prothioconazole Formulations in Wheat for Foliar Disease Control, DACO: 10.2.3.3(D)
3328291	2020, Prothioconazole Mixes in Lentils for Foliar Disease Control, DACO: 10.2.3.3(D)
3328294	2021, Maxentis EC in Canola for Sclerotinia Control, DACO: 10.2.3.3(D)
3328296	2021, Maxentis EC For Disease Control in Wild Blueberries, DACO: 10.2.3.3(D)
3328297	2018, Prothioconazole Formulations in Wheat for Foliar Disease Control, DACO: 10.2.3.3(D)
3328299	2021, Maxentis EC for Disease Control in Pulses, DACO: 10.2.3.3(D)
3328302	2020, Prothioconazole Mixes in Canola for Sclerotinia Control, DACO: 10.2.3.3(D)
3328304	2018, Prothioconazole Formulations in Barley for Foliar Disease Control, DACO: 10.2.3.3(D)
3328305	2019, Prothioconazole Formulations in Barley for Foliar Disease Control, DACO: 10.2.3.3(D)

3328306	2019, Prothioconazole Formulations in Wheat for Foliar Disease Control, DACO: 10.2.3.3(D)
3328311	2019, Prothioconazole Mixes in Peas for Foliar Disease Control, DACO: 10.2.3.3(D)
3328312	2020, Prothioconazole Mixes in Peas for Foliar Disease Control, DACO: 10.2.3.3(D)
3328313	2021, Maxentis EC for Disease Control in Soybeans, DACO: 10.2.3.3(D)
3328314	2021, Maxentis EC for Disease Control in Oats - Morris, DACO: 10.2.3.3(D)
3328316	2018, Prothioconazole Mixes for Disease Control in Peas, DACO: 10.2.3.3(D)
3328317	2020, Prothioconazole Formulations in Wheat for Foliar Disease Control, DACO: 10.2.3.3(D)
3328318	2019, Prothioconazole Formulations in Wheat for Foliar Disease Control, DACO: 10.2.3.3(D)
3328319	2021, Maxentis EC for Disease Control in Soybeans, DACO: 10.2.3.3(D)
3328321	2018, Prothioconazole Mixes for Disease Control in Lentils., DACO: 10.2.3.3(D)
3328322	2021, Prothioconazole Mixes in Peas for Foliar Disease Control, DACO: 10.2.3.3(D)
3328324	2018, Prothioconazole Formulations in Winter Wheat for Foliar Disease Control, DACO: 10.2.3.3(D)
3328325	2019, Prothioconazole Formulations in Barley for Foliar Disease Control, DACO: 10.2.3.3(D)
3328328	2019, Prothioconazole Mixes in Peas for Foliar Disease Control, DACO: 10.2.3.3(D)
3328331	2020, Prothioconazole Formulations in Wheat for Foliar Disease Control, DACO: 10.2.3.3(D)
3328332	2019, Prothioconazole Formulations in Wheat for Foliar Disease Control, DACO: 10.2.3.3(D)
3328333	2020, Prothioconazole Formulations in Wheat for Foliar Disease Control, DACO: 10.2.3.3(D)
3328334	2019, Prothioconazole Mixes in Canola for Sclerotinia Control, DACO: 10.2.3.3(D)
3328335	2019, Prothioconazole Mixes in Lentils for Foliar Disease Control, DACO: 10.2.3.3(D)
3328336	2019, Prothioconazole Formulations in Barley for Foliar Disease Control, DACO: 10.2.3.3(D)
3419994	2022, Summary of Value for Maxentis SC containing 350 gai/L, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3, 10.3.1, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4