Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.1, 3.5, 3.8, 3.13 Application

Application Number: 2022-0539
Application: Changes to Product Labels; Application Rate, Rotational Crops\Plantback Interval Re-Entry Interval, and Precautions
Product: A19278
Registration Number: 32681
Active ingredients (a.i.): Bromoxynil, present as octanoate ester and bicyclopyrone
PMRA Document Number: 3464395

Purpose of Application

The purpose of this application was to amend the product label of the herbicide A19278 to;

- Lower the re-entry interval from 16 days (for scouting) / 7 days (other tasks after application) to 12 hours,
- Lower the re-cropping interval for field peas from 22 months to 10 months,
- Remove a statement restricting the maximum allowable seasonal application rate for the safener cloquintocet-mexyl on wheat (spring and durum) and barley from the use of A19278 and any tank-mix partner containing cloquintocet-mexyl.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicological assessment was not required for this application.

A new human *in vitro* dermal absorption study was reviewed and found acceptable. Based on the data presented in the in vitro study, a dermal absorption value of 10% is recommended for the risk assessment of bicyclopyrone formulated as the end-use product A19278. Therefore, an updated mixer/loader/applicator exposure quantitative risk assessment and postapplication risk assessment were conducted for bicyclopyrone. For the safener, an updated mixer/loader/applicator exposure quantitative risk assessment and postapplication risk assessment were also conducted to reflect an increase in application rate due to an approved tank-mix partner containing the same safener. For bromoxynil, the mixer/loader/applicator and postapplication worker risk assessments on file are adequate.

Health risk assessments were updated for chemical handlers, postapplication workers and bystanders which allowed for the reassessment of daily handling restrictions, restricted-entry intervals, personal protective equipment and engineering controls.

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With revised precautions, no health risks of concern were identified for the use of bicyclopyrone, bromoxynil and cloquintocet-mexyl on spring wheat, durum wheat and barley, when workers follow the label directions and wear the personal protective equipment identified on the label.

No new residue data for cloquintocet-mexyl in wheat and barley were submitted to support the label amendments for A19278. Previously reviewed residue data from field trials conducted in/on wheat were reassessed in the framework of this application. In addition, previously reviewed rotational crop trials were also reassessed in the framework of this application.

The anticipated residues in wheat, barley, and associated animal commodities from the change in maximum cloquintocet-mexyl levels from 17.5 to 45 g safener/ha/season on the label will be covered by the existing maximum residue levels (MRLs) for bicyclopyrone, bromoxynil, and cloquintocet-mexyl and will not pose health risks of concern to any segment of the population, including infants, children, adults, and seniors.

Environmental Assessment

The amendments requested for the label of A19278 are supported from an environmental viewpoint. No additional risk is expected when A19278 is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The information provided for review included data from small-scale field trials. The information provided supports reducing the rotational cropping interval for field peas from 22 to 10 months. This change provides growers more flexibility to arrange field peas in their rotational cropping choices following application of A19278.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to amend the label of A19278.

References

PMRA Document Number	Reference
3318022	2016, Bicyclopyrone/Bromoxynil-octanoate EC (A19278A) - The *In Vitro* Percutaneous Absorption of Radiolabelled Bicyclopyrone in the Concentrate and Two In-Use Dilutions Through Human Skin, DACO: 5.8
3318015	2021, Field pea rotational crop from 22-months to 10-months re-cropping after application of A19278 Herbicide, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3, 10.2.4, 10.3.2, 10.5.1, 10.6.
3318016	2014, Initiate re-cropping trial (Year 1) for multi-crop plant back in year 2 (2014), DACO: 10.2.3.3.
3318017	2016, Initiate recropping (year 1) for multi-crop plant back in year 2 (2016), DACO: 10.2.3.3.
3318018	2016, Initiate recropping (year 1) for multi-crop plant back in year 2 (2016), DACO: 10.2.3.3.
3318019	2016, Initiate recropping (year 1) for multi-crop plant back in year 2 (2016), DACO: 10.2.3.3.