

Evaluation Report for Category B, Subcategory 3.13 Application

Application Number: 2019-5237
Application: Changes to Product Label - Precaution
Product: Acceleron NemaStrike ST
Registration Number: 32775
Active ingredient (a.i.): Tioxazafen
PMRA Document Number: 3171094

Purpose of Application

The purpose of this application was to amend the label of Acceleron NemaStrike ST by removing an advisory statement regarding carry-over and use of treated seeds in consecutive years from the Environmental Precautions and Application Instructions.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

Toxicology and occupational exposure assessments were not required for this application.

No new residue data for tioxazafen were submitted to support the removal of the environmental precautions statement regarding persistence from the end-use product label. Previously reviewed residue data from crop rotation studies conducted in/on a root or tuber vegetable (radish), a leafy vegetable (lettuce), and cereals (sorghum and wheat) were reassessed in the framework of this submission. It is concluded that the removal of the environmental persistence statement will not impact the magnitude of residues in rotational crops given that established plant-back intervals (PBIs) were based on residue data from previously reviewed crop rotation studies.

Environmental Assessment

Following the OECD Europe – North America Soil Geographic Information for Pesticide Studies (ENASGIPS) program, a reassessment of the terrestrial field dissipation study concluded that in addition to the test conducted in Manitoba, tests conducted at the Illinois and Nebraska locations are acceptable to represent Canadian ecoregions. Results showed that at the Illinois and Nebraska test sites, the percent carry-over were less than 30% after one year when applied either with treated seeds or in-furrow. Together with previously determined results for the Manitoba site, *i.e.*, less than 30% carry-over observed in the in-furrow plot and 38% carry-over observed in the treated seed plot after one year, five out of six tests showed less than 30% carry-over. Though it is uncertain why the treated seed plot had different results from the other five

plots, it has been recognized that tests with treated seeds may result in greater variability and are not recommended in the revised OECD test guideline (2016). Based on the weight-of-evidence approach, tioxazafen does not meet the criterion for carry-over.

Furthermore, as an advisory statement on the seed treatment product label, it may lead to confusion for Canadian farmers and add complexity for the management of seed ordering and planting. Consequently, it can affect the ability of seed companies to prepare corn and soybean seed efficiently for the Canadian market.

Therefore, based on considerations of the field study and practicality, the advisory statements regarding carry-over and use in consecutive years are not required, and can be removed from of the label for Acceleron NemaStrike ST.

Value Assessment

A value assessment was not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has determined that the amendment to remove the advisory statement regarding carry-over and use of treated seeds in consecutive years from the Environmental Precautions and Application Instructions is acceptable.

References

PMRA Document Number	References
3039138	2015, Terrestrial Field Dissipation of MON 102100 Applied as a Seed Treatment Under Field Conditions at Four Regional North American Locations MSL0026630, DACO: 8.3.2
3118104	2019, Application for Removal of the Persistence Advisory Label Statement on Tioxazafen Products, DACO: 8.6
3039141	2017, MON 102100 - Determination of acute toxicity to the earthworm <i>Eisenia andrei</i> in an artificial soil substrate (MSL0029086), DACO: 9.2.3
3039136	2018, MON 102100 - A laboratory test to determine the effects of fresh residues on the springtail <i>Folsomia candida</i> (Collembola, Isotomidae) in an artificial soil substrate (MSL0029868), DACO: 9.2.7
3039137	2018, MON 102100 - A laboratory test to determine the effects of fresh residues on the predatory soil mite <i>Hypoaspis aculeifer</i> (Acari, Laelapidae) in an artificial soil substrate (MSL0029877), DACO: 9.2.7

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