Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2016-2912
Application: Conversion to full registration without consultation
Product: Fortenza
Registration Number: 30899
Active ingredients (a.i.): Cyantraniliprole
PMRA Document Number: 2675869

Purpose of Application

The purpose of this application was to address the conditions of registration (occupational exposure and environment) for Fortenza and convert from conditional to full registration.

Chemistry and Value Assessments

Chemistry and value assessments were not required for this application.

Health Assessments

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

A human health risk assessment was performed for workers that are exposed to potato seed pieces treated with cyantraniliprole during planting activities. The exposure data from the observational study demonstrated that risks are not of concern when workers follow the label directions and wear the personal protective equipment identified on the label. The data deficiency which necessitated the conditional registration was only relevant to planters. Exposure and risks to workers treating potato seed pieces with cyantraniliprole were addressed in the Registration Decision RD2013-25, *Cyantraniliprole* and the Proposed Registration Decision PRD2013-09, *Cyantraniliprole*. Since the original registration, the toxicological endpoints and use pattern have not changed, and as such, risks to treaters were not revisited under the current application.

Incident Report

As of October 13, 2016, no human or domestic animal incidents involving the active ingredient cyantraniliprole were reported to the PMRA.

Environmental Assessment

Previously, corn pollen residue data were identified as necessary in order to confirm negligible risk to pollinators from oral exposure to cyantraniliprole. A corn pollen residue study was provided and assessed with the current application. The study found that levels of cyantraniliprole and its transformation products were below limits of quantitation and the limits of detection in corn pollen.

Canada

A new acute bee larvae toxicity study was reviewed. The study, considered acceptable, derived 72-hour NOEL and LD_{50} values of 0.0145 and 0.037 µg a.i./larva, respectively. The lowest adult bee oral toxicity endpoint, used for this assessment, was an acute study with an LD_{50} value of 0.39 µg a.i./bee.

Therefore, using the above studies, a new Tier I risk assessment for acute exposures indicated that the level of concern is not exceeded for adult and larval honey bee exposure to cyantraniliprole from use as a seed treatment on corn. Environmental risks are mitigated through environmental precautionary statements on the label.

Incident Report

As of October 13, 2016, no environment incidents involving cyantraniliprole were reported to the PMRA.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and is able to support the conversion of Fortenza from conditional to full registration.

References

PMRA Document Number | References

A. List of Studies/Information Submitted by Registrant

2557310 2015, Observational Study to Determine Dermal and Inhalation Post-Application Exposure of Workers to Difenoconazole during Handling and Planting of Treated Potato Seed Pieces, DACO: 5.6

2647167 2016, Cyantraniliprole SC (A17960A) – Residue Levels in or on Corn (Pollen) from Trials Conducted in Canada During 2014, Syngenta Canada Inc., Laboratory Report Number TK0222937, 155 pp., DACO: 9.2.9.

B. Additional Information Considered

i) Unpublished Information

2589314 2014, Cyantraniliprole (DPX-HGW86) 100 g/L OD: Honey Bee (*Apis mellifera* L.) larval toxicity test (single feeding exposure), Eurofins Agroscience Services EcoChem GmbH, Study Code S14-00331, 46 pp., DACO: 9.2.4.3.

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