

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

Application Number: 2013-0578
Application: New End Use Product: New guarantee and formulants (identity and proportions)
Product: Xiren
Registration Number: 32150
Active ingredients (a.i.): Metaldehyde
PMRA Document Number : 2585866

Purpose of Application

The purpose of this application was to register a new domestic class product containing the technical active ingredient metaldehyde. Xiren is a molluscicide for the control of snails and slugs on ornamental plants, vegetables and berries.

Chemistry Assessment

Xiren is formulated as solid (pellet) product containing metaldehyde at a nominal concentration of 3.0%. This end-use product has a density of 0.84 g/ml and pH of 5.9-7.9. The chemistry requirements for Xiren have been fulfilled.

Health Assessments

Xiren is considered to be of low acute toxicity via the oral, dermal and inhalation routes of exposure. It is minimally irritating to the eye and non-irritating to the skin of rabbits. Xiren is considered to be a potential skin sensitizer.

Homeowners who handle and apply Xiren to outdoor and greenhouse soil surfaces surrounding labeled crops, are not expected to be exposed more than currently registered products. Post-application exposures are expected to be negligible, and children are restricted from treated areas when pellets are present. The risks to homeowners, including children, in residential areas are acceptable when following the precautions and directions on the label.

Previously reviewed residue data from field trials conducted in/on blackberries, cabbage, lettuce, strawberries, and tomatoes were reassessed in the framework of this petition. Residues in these crop commodities will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

Data on the product specifications and environmental data on the acute toxicity to honeybees were required to support the registration of Xiren. As the application rates are

lower than registered application rates, no additional environmental risk is expected from the use of this product. Environmental concerns are mitigated on the existing label.

Value Assessment

Based on three trials and information provided by the applicant the use of Xiren molluscicide pellets at 70 g/100 m² on vegetables, berries, artichokes (annual, perennial) and ornamentals plants (greenhouse and outdoors) was supported with a claim of “attracts and kills slugs and snails”. Re-application intervals of 21 days for ornamentals, 18 days for artichokes and 14 days for all other crops were supported. A claim that the products remain effective after watering was also supported.

Conclusion

Following review of the application, the PMRA granted full registration of Xiren for the control of snails and slugs on ornamental plants, vegetables and berries.

References

PMRA

Document

Number	Reference
2268226	2012, US-LON-A Product Identity, Manufacturing Process, Impurity Discussion and Certified Limits, DACO: 3.2.1,3.2.2,3.2.3,3.4.1,3.4.2 CBI
2268227	2012, CBI: US-LON-A Product Identity, Manufacturing Process, Impurity Discussion and Certified Limits, DACO: 3.2.1,3.2.2,3.2.3,3.4.1,3.4.2 CBI
2268228	2012, CSF Wider Limits Justification, DACO: 3.3.1 CBI
2268229	2011, LON10001M Phsio-chemical Properties, DACO: 3.5.1,3.5.2,3.5.3,3.5.4,3.5.6,3.5.7 CBI
2268231	2013, General Information and waivers, DACO: 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.8, 3.5.9 CBI
2268232	2012, LON10001M Two Year Storage Stability (Interim report, 12 month data), DACO: 3.5.10,4.6.3 CBI
2269548	2013, Product Identification, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
2269556	2013, Container Description, DACO: 3.5.5 CBI
2307786	2012, US-LON-H Product Identity, Manufacturing Process, Impurity Discussion and Certified Limits, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1 CBI
2307788	2012, CBI: US-LON-H Product Identity, Manufacturing Process, Impurity Discussion and Certified Limits, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1 CBI
2268232	2012, LON10001M Two Year Storage Stability (Interim report, 12 month data), DACO: 3.5.10 CBI
2268234	2010, Acute Oral Toxicity Study of Test Item LON20001M in Rats, DACO: 4.6.1
2268235	2010, Acute Dermal Toxicity (Limit Test) with LON20001M in the Rat, DACO: 4.6.2
2268236	2010, Acute Eye Irritation Study with LON20001M, DACO: 4.6.4

- 2268237 2010, Acute Skin Irritation Study with LON20001M, DACO: 4.6.5
- 2268238 2010, Skin Sensitisation Test (Guinea Pig Maximisation Test) with LON20001M, DACO: 4.6.6
- 2268239 2013, Waiver Request, DACO: 4.6.3
- 2279044 2013 Use Description/Scenario DACO 5.2
- 2268241 2012, M2011_01: Molluscicide caged arena study Efficacy Trials Agro 7 Kg/ha DACO 10.2.3.3
- 2268243 2012, M2011_07: Molluscicide caged arena study Efficacy Arion lusitanicus s.l DACO 10.2.3.3
- 2363643 2013, Efficacy evaluation of LON10001M against snails on tomato in 2013 Caged Arena Trial (Spain) DACO 10.2.3.3
- 2363638 2013, Product Specifications. DACO 8.6
- 2424507 1999. LZ1060.00: An Acute Oral Toxicity Study with the Honey Bee. DACO 9.2.4.2.

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