

Evaluation Report for Category A, Subcategory 1.1 Application

Application Number: 2010-2962
Application: A.1.1-New Active Ingredient-Domestic Registration
Product: Isomate-PTB Dual
Registration Number: 30042
Active ingredients (a.i.): (E,Z)-3,13-octadecadienyl Acetate (PTC)
 (Z,Z)-3,13-octadecadienyl Acetate (PTZ)
PMRA Document Number : 2034725

Purpose of Application

The purpose of this application was to register the new end use product Isomate-PTB Dual (Registration Number 30042) containing straight-chain lepidopteran pheromones.

Chemistry Assessment

Property	Result
Colour	Colourless or light yellow
Odour	Mild waxy and sweet odour
Physical state	Liquid
Formulation type	Slow-release generator (SR)
Guarantee	(E,Z)-3,13-Octadecadien-1-yl Acetate...44.20% (Z,Z)-3,13-Octadecadien-1-yl Acetate...43.74%
Container material and description	High density polyethylene tube in vacuum sealed pouch, 500 dispensers per packet, foil pouch.
Specific gravity	0.889 at 20°C
pH of 1% dispersion in water	3.57
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	Storage stability study was conducted for 12 months at two temperatures 5°C and room temperature in the vacuum sealed foil packages which is intended for commercial use. The results show that when stored for 12 months at room temperature and 5°C, losses of 22.4% and 1.2% can occur respectively. For storage beyond a month, Isomate-PTB Dual should be stored at 5°C or below as indicated on the label.
Corrosion characteristics	The product is not expected to be corrosive to the packaging material.
Explosibility	The product is not explosive.

The method provided for the analysis of the active ingredients and the impurities in PTB Dual Pheromone Technical have been validated and assessed to be acceptable for the determinations.

The method provided for the analysis of the active ingredients in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

Health Assessments

The active ingredients in Isomate-PTB Dual [(E,Z)-3,13-octadecadien-1-yl acetate 80.4 % (Z,Z)-3,13-octadecadien-1-yl acetate] have been evaluated in the Proposed Regulatory Decision Document *PRDD2004-03: Isomate-P Pheromone* for use in Orchards for Mating Disruption of the Peach Tree Borer. It was determined that Peachtree Borer Pheromone Technical (Registration Number 27140) was of low acute toxicity by the oral, dermal, and inhalation routes in rats, while it was mildly irritating to the skin and minimally irritating to the eyes of rabbits. It was not considered a dermal sensitizer, and was not mutagenic. The evaluation concluded that the available information on these active ingredients was adequate to address the toxicological requirements for registration of a pheromone technical grade active ingredient and a pheromone end-use product. Therefore, no further toxicological information was required for Isomate-PTB Dual.

An assessment of occupational and bystander exposure to (E,Z)-3,13-octadecadien-1-yl acetate and (Z,Z)-3,13-octadecadien-1-yl acetate in Isomate-P Pheromone in the Proposed Regulatory Decision Document for Isomate-P Pheromone (*PRD2004-03: Isomate-P Pheromone* for use in Orchards for Mating Disruption of the Peach Tree Borer) concluded that based on the toxicological profile of the active ingredients, Isomate-P Pheromone (Registration Number 27141) is not likely to present a risk to workers when used according to label directions. Accordingly, a quantitative estimate of exposure was not required for Isomate-P Pheromone, and will not be required for Isomate-PTB Dual.

Based on the low toxicity of (E,Z)-3,13-octadecadien-1-yl acetate and (Z,Z)-3,13-octadecadien-1-yl acetate, the conclusions of the review of the precedent product, and the application rate of Isomate-PTB Dual, there are no food residue concerns regarding the use of Isomate-PTB Dual.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

Efficacy data were submitted from two field trials, one conducted on peaches and nectarines in New Jersey as an experimental trial and one conducted on peaches in Virginia on an operational basis (no untreated control). Both trials were continued over three consecutive growing seasons (Submission Number 2007-2009). The experimental trial clearly showed that Isomate-PTB Dual disrupts the attraction of lesser peachtree borer to pheromone-baited traps, and both trials showed large declines in the numbers of pupal exuviae and sites of potential larval activity of both peachtree borer and lesser peachtree borer.

Furthermore, the submitted efficacy data and available information support the use of Isomate-PTB Dual for mating disruption of both peachtree borer and lesser peachtree borer in stone fruits and almonds (*Prunus* spp.) by application of 375-675 dispensers/ha prior to adult moth emergence in the spring.

Development of resistance to mating disruption has not been clearly established and the development of resistance to pheromone-based pest management strategies in general is considered unlikely.

Due to the non-toxic and species-specific mode of action of the active ingredients, Isomate-PTB Dual should have no direct adverse effects on non-target organisms and may reduce the need for application of conventional insecticides.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information sufficient to register the new end-use product.

References

- 1926207 2010, Part 3, Product Chemistry for Registration of an end-use product, DACO: 3.0 CBI
- 1926208 2010, CBI Reference to Parent Document, Part 3, Product Chemistry for Registration of an end-use product, DACO: 3.0 CBI
- 2023184 2011, Part 3, Product Chemistry for Registration of an end-use product, DACO: 3.3.1 CBI
- 2023185 2011, CBI Reference to Parent Document, Part 3, Product Chemistry for Registration of an end-use product, DACO: 3.3.1 CBI
- 1926191 2010. Part 10, Value for Registration of an EP: Isomate-PTB Dual. DACO 10.1-10.5

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