Health Canada Santé Canada

Evaluation Report for Category A, Subcategory 1.1 Application

Application Number: 2010-2961
Application: New Active Ingredient – Domestic Registration
Product: PTB Dual Pheromone Technical
Registration Number: 30041
Active ingredients (a.i.): (Z,Z)-3,13-Octadecadien-1-yl acetate [PTZ], (E,Z)-3,13-Octadecadien-1-yl acetate [PTC]
PMRA Document Number : 2337626

Purpose of Application

The purpose of this application was to register a new technical grade active ingredient (TGAI) PTB Dual Pheromone Technical for use in the end use product (EP) Isomate-PTB Dual (Registration Number 30042).

Chemistry Assessment

Property	Description
Active substance	(E,Z)-3,13-octadecadien-1-yl acetate and (Z,Z)-3,13-octadecadien-1-yl acetate
Function	pheromone
1. International Union of Pure and Applied Chemistry (IUPAC)	(Z,Z)-3,13-Octadecadien-1-yl acetate (E,Z)-3,13-Octadecadien-1-yl acetate
2. Chemical Abstracts Service (CAS)	3,13-Octadecadien-1-ol, 1-acetate, (3Z, 13Z)- 3,13-Octadecadien-1-ol, 1-acetate, (3E, 13Z)-
CAS number	53120-27-7 53120-26-6
Molecular formula	$C_{20}H_{36}O_2$
Molecular weight	308.5

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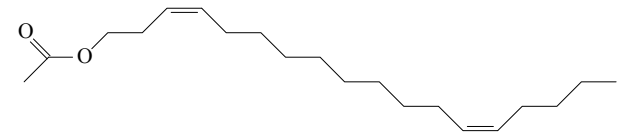
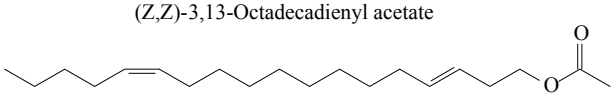
Structural formula	 (Z,Z)-3,13-Octadecadienyl acetate  (E,Z)-3,13-Octadecadienyl acetate
Purity of the active ingredient	(E,Z)-3,13-Octadecadien-1-yl Acetate…46.23% (Z,Z)-3,13-Octadecadien-1-yl Acetate…45.75%

Property	**Result**
Colour and physical state	Colourless or light yellow liquid
Odour	Mild waxy and sweet odour
Melting range	N/A
Boiling point or range	178 - 180°C at 2 mm Hg
Specific gravity	0.889
Vapour pressure at 20°C	1.795×10^{-5} mm Hg
Henry's law constant at 20°C	*to be filled in by EAD*
Ultraviolet (UV)-visible spectrum	No absorbance above $\lambda > 400$ nm
Solubility in water at 20°C	Not soluble in water
Solubility in organic solvents at 20°C (g/100 mL)	Soluble in all common organic solvents.
n-Octanol-water partition coefficient (K_{ow})	Log $K_{ow} = 4.83$
Dissociation constant (pK_a)	AIs do not contain dissociable moiety.
Stability (temperature, metal)	Stable against sunlight and hydrolysis when exposed to water.

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 (*PRDD2004-03: 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

The active ingredients are SCLPs. Exposure to the environment will be very limited because the technical grade active ingredient will be applied by dispenser units that are to be manually attached to fruit trees for control of the pest.

Value Assessment

No value assessment was required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information sufficient to register the technical grade active ingredient.

References

1793569	2000, PTZ-SHJ-1 Peach Tree Borer Pheromone Technical (A Biochemical Mating Disruptant for the Peach Tree Borer). Establishing Certified Limits, Revised Methodology/ Validation, Revised Batch Data, DACO: 2.12.1,2.13.1,2.13.3 CBI
1793619	1999, PTZ-SHJ-1 Peach Tree Borer Pheromone Technical (A Biochemical Mating Disruptant for the Peach Tree Borer), DACO: 2.1,2.10,2.14.1,2.14.10,2.14.11,2.14.12,2.14. 13,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.9,2.2,2.3 CBI

1793627	1999, PTZ-SHJ-1 Peach Tree Borer Pheromone Technical (A Biochemical Mating Disruptant for the Peach Tree Borer), DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.12.1,2.13.1,2.13.2,2.13.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI
1793653	2001, PTZ-SHJ-1 Peach Tree Borer Pheromone Technical (A Biochemical Mating Disruptant for the Peach Tree Borer) Methodology/ Validation, Confirmation of Identity, DACO: 2.13.1,2.13.2 CBI
1793660	2001, PTZ-SHJ-1 Peach Tree Borer Pheromone Technical (A Biochemical Mating Disruptant for the Peach Tree Borer) Water Solubility, Vapor Pressure, Octanol/Water partition Coefficient, DACO: 2.14.11,2.14.7,2.14.9 CBI
1925919	2010, Part 2, Product Chemistry for Registration of a TGAI, DACO: 2.0 CBI
1925931	2010, CBI Reference to Parent Document, Part 2, Product Chemistry for Registration of a TGAI, DACO: 2.11.4,2.13.1 CBI
2023170	2011, Part 2, Product Chemistry for Registration of a TGAI, DACO: 2.13.1 CBI
2023171	2011, CBI Reference to Parent Document, Part 2, Product Chemistry for Registration of a TGAI, DACO: 2.13.1 CBI

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