Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5, 3.1 Application

Application Number: 2016-3293
Application: New End-Use product - changes to product chemistry, identity and proportion of formulants, formulation type and application rate
Product: Confound SBW
Registration Number: 32730
Active ingredients (a.i.): (E,Z)-11-tetradecenal
PMRA Document Number: 2760962

Purpose of Application

The purpose of this application was to register a micro-encapsulated pheromone product, Confound SBW, containing (E,Z)-11-tetradecenal (guarantee: 11% w/w), for use to disrupt mating of populations of the eastern spruce budworm (*Choristoneura fumiferana*) in coniferous forests and mixed woodlands. The active (E,Z)-11-tetradecenal is a straight chain lepidopteran pheromone (SCLP).

Chemistry Assessment

Confound SBW is formulated as a microcapsule suspension containing (E,Z)-11-tetradecenal at a nominal concentration of 11.0%. This end-use product has a density of 0.92 g/mL and pH of 6.54. The required chemistry data for Confound SBW have been provided, reviewed and found to be acceptable.

Health Assessments

Toxicity studies on SCLPs have generally indicated low mammalian toxicity, following oral, dermal and pulmonary exposure. In general, SCLPs are biodegraded to non-toxic compounds by enzyme systems that are present in most living organisms. Available information suggests that Confound SBW is expected to have low acute oral, dermal and inhalation toxicity and minimally irritating to the eye and skin.

There is no occupational concern anticipated from the commercial end–use product's forestry use because of its low toxicity profile and adequate exposure mitigation measures present on the label. The label, instructs users to wear personal protective equipment (PPE) during mixing loading and cleanup or repair, and to avoid breathing any dust generated prior to and during application. Bystander exposure is not of concern.

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Environmental Assessment

The use of Confound SBW for mating disruption on populations of the eastern spruce budworm is acceptable from an environmental perspective. The pheromone in this formulation is similar to that released by the female spruce budworm; it has a non-toxic mode of action and is considered to be of low toxicity to non-target organisms. The microencapsulation delivery method is not expected to be of environmental concern due to the capsule size, location and timing of application.

Value Assessment

A field trial conducted in New Brunswick in 2015 demonstrated the ability of Confound SBW to disrupt the response of male spruce budworm moths to their sex pheromone. Confound SBW may have particular value in an early intervention strategy, applied when populations are still low but begin to increase, to prevent the spruce budworm from reaching outbreak levels.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of Confound SBW.

References

PMRA Document Number	Reference
2655289	2016, Lipocapsule PMU LT81710 process, DACO: 3.2.2 CBI
2655291	2016, 95:5Z (E,Z)-11-tetradecenal Confound SBW specifications and analytical methodology, DACO: 3.5,3.5.1,3.5.10,3.5.2,3.5.3,3.5.4,3.5.6,3.5.7
2655292	2016, Physical and chemical properties testing of SBW Sprayable 2015-01, DACO: 3.5,3.5.1,3.5.2,3.5.3,3.5.6,3.5.7 CBI
2655293	2016, Update on product stability testing, DACO: 3.5,3.5.10 CBI
2701969	2016, Description of starting materials, DACO: 3.2.1 CBI
2701970	2016, Lipocapsule PMU LT81710 process, DACO: 3.2.1 CBI
2701975	2016, Determination of (E,Z)-11-tetradecenal in PMU microcapsules, DACO: 3.4.1 CBI
2701976	2016, Storage stability testing of SBW Sprayable 2015-01, DACO: 3.5.10 CBI
2729718	2017, Development and validation of an analytical method for the determination of the active ingredient in prototype products for the management of spruce budworm, DACO: 3.4.1
2751410	2016, Description of starting material, DACO: 3.2.1
2751411	2016,: Product specification clarification, DACO: 3.2.1
2751414	2016,: Product specification clarification, DACO: 3.4.2
2655294	2016, Summary, DACO: 5.1
2655295	2015, Use description/scenario (application and post application), DACO: 5.2
2655296	2016, Use description/scenario (application and post application), DACO: 5.2
2751412	2017, Impurities of toxicological concern, DACO: 3.4.2
2655301	Potential economic losses from the next spruce budworm outbreak, DACO: 10.2.2
2655303	Understanding of spruce budworm population dynamics: development of early intervention strategies, DACO: 10.2.2
2655305	2008, Experimental pheromone applications using Disrupt Micro-Flakes SBW® for the control of the spruce budworm populations: Quebec mating disruption trials 2008, DACO: 10.2.2, 10.2.3.3
2655306	Report on efficacy testing of the sprayable microencapsulated formulation containing 95E:5Z (E/Z)-11-tetradecenal for the management of spruce budworm populations, DACO: 10.2.3.3
2655307	2008, A tool for evaluating mating disruption in SBW, DACO: 10.2.3.3

Additional Information Considered

Published Information

2004 Luttik, R. and G.R. de Snoo. Characterization of grit in arable birds to improve pesticide risk assessment. Ecotoxicology and Environmental Safety 57: 319-329.

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