Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1,2.3,2.4,3.1,3.6 Application

Application Number: 2024-1207
Application: New end-use product chemistry - guarantee, identity and proportion of formulants; and new end-use product label – application rate and timing
Applicant: Veto-Pharma SAS
Product: Apivar 2.0
Registration Number: 35663
Active ingredient (a.i.): Amitraz
PMRA Document Number: 3756047

Purpose of Application

The purpose of this application was to register a commercial acaricide, Apivar 2.0, containing amitraz, to control varroa mites in honey bee hives. Apivar 2.0 is a sustained release solid strip that is applied in the brood box.

Chemistry Assessment

Apivar 2.0 is formulated as a solid strip containing amitraz at a concentration of 3.00 %. This end-use product has a density of 1.1 g/mL. The required chemistry data for Apivar 2.0 have been provided, reviewed and found to be acceptable.

Health Assessments

Apivar 2.0 is considered to be slightly acutely toxic via the dermal route of exposure, and of low acute toxicity via the inhalation route of exposure. It is considered minimally irritating to the eyes and skin, and a potential dermal sensitizer. Apivar 2.0 is not expected to pose an acute oral hazard.

Use of Apivar 2.0 on beehives is not expected to result in potential occupational or bystander exposure over the registered use of amitraz. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

Residue data from supervised residue trials were submitted to support the use of Apivar 2.0 in beehives. Amitraz was applied to beehives at 1-2X the labelled rate, and honey samples were collected according to label directions. No processing study was required as honey and honey-derived products are typically consumed as raw commodities.

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Based on this assessment, residues of amitraz are not expected to be greater than those from currently registered uses and will be covered by the established maximum residue limit (MRL) of 0.1 ppm. Exposure to residues of amitraz in honey and honey-derived products is not likely to result in any dietary risks for the general population and all subpopulations, including infants, children, adults and seniors.

Environmental Assessment

The use of Apivar 2.0 is within the currently registered use pattern for amitraz. Therefore, the risk is acceptable when Apivar 2.0 is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

Value information submitted in support of Apivar 2.0 consisted of scientific rationales and three bridging trials conducted in France, which tested a precedent product compared to Apivar 2.0, and assessed both product performance and hive safety. The submitted trials demonstrated no significant differences between the two formulations either in product performance or in adverse effects on honey bee colonies. Apivar 2.0 is for application in colonies for a minimum of 42 days and a maximum of 70 days, compared to a maximum of 56 days for a precedent product. The submitted trials tested application periods of up to 71 days. The submitted value information is sufficient to support use of Apivar 2.0 for control of varroa mite in honey bee hives, with an application rate of 2 strips per brood box and an application period of at least 42 days and no more than 70 days. As varroa mites develop in capped brood cells where they cannot be controlled by amitraz, the longer maximum treatment period may provide additional control of varroa mites as they leave brood cells, and may provide beekeepers with more flexibility in hive management and in timing the removal of treatments.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of Apivar 2.0.

References

PMRA Document Number	Reference
3569890	2022, Prod chem part B - Apivar 2.0 - V3.docx, DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9
3569891	2023, Apivar Plus: Physical and chemical characteristics for guidelines 830.6314 and 830.6317, DACO: 3.5.10,3.5.8
3578009	2024, Volume 1 - Revised chem group A - Apivar 2.0 strips_87243-X- V5, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1 CBI
3633318	2024, OCSPP guideline 830.1650, DACO: 3.2.1 CBI
3633322	2024, Physical & chemical properties, DACO: 3.5,3.5.1,3.5.11,3.5.12,3.5.13,3.5.15,3.5.16,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9
3633323	2024, Response to part 3 notice of deficiencies, DACO: 3.5.10,3.5.14
3732448	2022, Method validation report -L11565-2.1_DEV6964_V1_assay of amitraz_, DACO: 3.4.1 CBI
3569892	2024, Response to acute toxicity data requirements for end-use product: Apivar 2.0, DACO: 4.1,4.6.1,4.6.2,4.6.3,4.6.4,4.6.5,4.6.6 CBI
1937899	2010, Value, DACO: 10.2.1, 10.2.2
1937900	2010, Non-safety adverse effects, DACO: 10.3.1, 10.3.2
3578003	2024, Value assessment_v15032024, DACO: 10.1
3578004	2024, Rationale Supporting proposed application of Apivar 2.0 to honeybee hives for control of varroa mite, DACO: 10.2.3.1
3578005	2022, Efficacy against *Varroa destructor* and associated honeybee tolerance of Apivar New and Apivar Gold in comparison with Apivar. Application in Dadant hives - Summer/Autumn 2021, DACO: 10.2.3.3
3578006	2023, Efficacy against *Varroa destructor* and associated honeybee tolerance of Apivar Gold in comparison with Apitraz. Application in Dadant hives - Summer/Autumn 2021, DACO: 10.2.3.3
3578007	2022, Efficacy against *Varroa destructor* and associated honeybee tolerance of Apivar New and Apivar Gold in comparison with Apivar. Application in Langstroth hives - Summer/Autumn 2021, DACO: 10.2.3.3

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