Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1 2.3 3.1 3.4 Application

Application Number: 2024-0563
Application: New End Use Product Chemistry- Guarantee, Identity of Formulantsn, Application Rate Change and Application Method.
Applicant: Veto-Pharma SAS
Product: Amiflex
Registration Number: #####
Active ingredient (a.i.): Amitraz
PMRA Document Number: 3780214

Purpose of Application

The purpose of this application was to register Amiflex, containing amitraz, for control of varroa mite in honey bee hives.

Chemistry Assessment

Amiflex is formulated as a paste containing amitraz at a concentration of 1.98 %. This end-use product has a density of 0.9 – 0.95 g/mL and a pH of 9.7 (1% solution). The required chemistry data for Amiflex have been provided, reviewed and found to be acceptable.

Health Assessments

Amiflex is of low acute toxicity via the oral and dermal routes of exposure. Amiflex is considered to be of low acute toxicity via the inhalation route of exposure, and not likely to result in an eye irritation hazard. Amiflex is minimally irritating to the skin and not a dermal sensitizer.

The use of Amiflex on beehives is not expected to result in potential occupational or bystander exposure. 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 Amiflex in beehives. Amitraz was applied to beehives at 1-2X the 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.

Residue 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.

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Environmental Assessment

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

Value Assessment

Value information submitted in support of Amiflex consisted of three efficacy trials, two hive safety trials, and scientific rationales. All trials were conducted in France using Dadant or Langstroth hives. The submitted value information was sufficient to support a claim of suppression of phoretic varroa mites in honey bee hives when applied at a rate of two 3 mL doses of product per brood box (6 mL product total per brood box) with a 7-day treatment period. When varroa infestations are high, 2 consecutive applications with a 7-day interval between applications may be applied. Honey supers must not be present on hives during application and no more than 3 applications may be made per year. Amiflex is intended as a mid-season quick treatment to reduce varroa mite numbers, and not as a stand-alone end-of-season treatment to control varroa mite. Amiflex has value as it provides an additional product that can be used as a short mid-season treatment to reduce varroa mite populations to ensure they do not increase to critical levels before end-of-season control treatments are applied.

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 Amiflex.

References

PMRA Document Number	Reference
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3556531	2021, 51681802_Amiflex Method Validation Study Final Report, DACO: 3.4.1 CBI
3556532	2021, 28549 Phys-Chem GLP Final Study Report, DACO: 3.5.1,3.5.2,3.5.3,3.5.4,3.5.9
3556533	2022, VET21034- Amiflex stability study report , DACO: 3.5.10,3.5.14
3556534	2022, VET21027- Study Amiflex physico-chemical properties report, DACO: 3.5.6,3.5.7
3556535	2023, Part 3 Waiver Requests, DACO: 3.5.11,3.5.12,3.5.13,3.5.15,3.5.8
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3720911	2025, 3628370 Corrosion statement, DACO: 3.5.14 CBI
3556537	2021, 27310 GLP (AOT May 12, 2021), DACO: 4.6.1
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3556546	2023, 87243-4_MRID52301801_Dermal Irritation_20230311, DACO: 4.6.5
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3623728	2022, Amitraz, DMPF, DMF and DMA residue levels in honey after one or two in-hive application of FLASH PATE and in-hive application of FLASH PATE associated with 2 strips of Apivar GOLD in Dadant shaped hives and associated effects on honeybee colonies - spring and summer 2021., DACO: 7.4.1
3623729	2022, Amitraz, DMPF, DMF and DMA residue levels in honey after one or two in-hive application of FLASH PATE and in-hive application of one application of FLASH PATE associated with 2 strips of Apivar GOLD per brood box in Langstroth shaped hives and associated effects on honeybee colonies - spring and summer 2021, DACO: 7.4.1
3556550	2021, 51681808_Amiflex residue report - honey and honeycomb.pdf, DACO: 7.2.2
3556524	2024, 10.1 Value assessment template_v240118.doc, DACO: 10.1
3556525	2023, CA Tolerance efficacy use scenario rationale_V230919, DACO: 10.2.3.1, 10.3.2
3556526	2022, 507-2021_Final_report, DACO: 10.2.3.3
3556527	2022, 514-2021_Final_report, DACO: 10.2.3.3
3556528	2022, 552-2021_Final_report, DACO: 10.2.3.3
3628369	2024, Amiflex responses to deficiency letter_final_20240823, DACO: 10.2.3, 10.3, 3.4.1, 3.5.10, 3.5.14, 4.6.1, 4.6.2, 4.6.4, 4.6.5, 4.6.6 CBI
3628373	2022, VTP21RE183_503-2021_final-report, DACO: 10.3
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3628375	2024, D21020 and D21051 formulation, DACO: 10.3 CBI

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