

Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2016-4629

Application: Conversion to full registration without consultation

Product: Apivar Strips

Registration Number: 29092

Active ingredients (a.i.): Amitraz

PMRA Document Number: 2706262

Background

Apivar Strips (guarantee 3.3% amitraz) were first registered for use in Canada in 2008 to control Varroa mites in bee hives. The registration status of the end-use product is dependent on the registration status of Amitraz Technical (Insecticide) (Registration Number 23485). The conditions of registration for Amitraz Technical (Insecticide) are related to information identified as part of the re-evaluation of amitraz (2004-0084).

Purpose of Application

The purpose of this application was to convert the registration of the end-use product, Apivar Strips, from conditional to full. A related application (2016-4599) to convert the registration of the technical grade active ingredient, Amitraz Technical (Insecticide), from conditional to full registration is being reviewed concurrently.

Chemistry, Value and Environmental Assessments

Chemistry, value and environmental assessments were not required for this application.

Health Assessments

No acute toxicity data were available for the end-use product, Apivar Strips, containing amitraz; therefore, the acute toxicity data for the active ingredient were used for hazard characterization. Although data indicated that amitraz may be highly acutely toxic via the oral route, the Apivar Strips product is not considered to pose a hazard via the oral route due to its physical form, as the active ingredient is embedded in plastic strips. Overall, the Apivar Strips product was characterized as slightly acutely toxic via the dermal route, of low acute toxicity via the inhalation route, minimally irritating to the eyes and skin, and a potential dermal sensitizer.

The occupational exposure and risks were assessed to support the conversion of Apivar Strips from conditional to full registration. No risks of concern are expected provided that workers follow the label directions and wear the personal protective equipment identified on the label.

Previously reviewed residue data from field trials conducted in/on honey were reassessed in the framework of this application. Considering the toxicological endpoints were revised as a result of the new toxicology data provided within application 2016-4599, a new dietary risk assessment was conducted. Following the review of the available data and the results of the new risk assessment, residues in honey at the established maximum residue limit (MRL) will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

As of August 9, 2016, one minor human incident and twelve domestic animal incidents were received by the PMRA. None of these incidents involved Apivar Strips. All incidents occurred following the use of pet collars containing amitraz. The human incident reported a transient skin reaction following application of a collar to a dog. The label for Apivar Strips warns that skin sensitization can occur, and chemical resistant gloves are required during use. Therefore, similar effects would not be expected to occur. Twelve domestic animal incidents were received, but they are not considered relevant to the current use pattern.

These incident reports were considered in this evaluation and did not affect the risk assessment.

Conclusion

The assessment has concluded that the health and risks of Apivar Strips are acceptable. The PMRA has also completed a review of all available information for Amitraz Technical (Insecticide) under application 2016-4599 and found it sufficient to grant full registration. Apivar Strips, which was given a conditional registration under section 15 of the Pests Control Products Regulations as a result of conditions placed on Amitraz Technical (Insecticide), is also granted full registration.

References

None

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8 Sa Majesté la Reine du chef du Canada, représentée par le ministre des Travaux publics et Services gouvernementaux Canada 2017

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