Evaluation Report ERC2013-04, Amitraz

Pest Management Regulatory Agency
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To obtain an electronic copy of the document, Evaluation Report ERC2013-04, *Amitraz*, please contact our publications office.

Should you require further information please contact the Pest Management Information Service.

Summary

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Registration Decision for Amitraz

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of Amitraz Technical and Apivar Strips, containing the technical grade active ingredient amitraz, to control the parasitic mite (*Varroa destructor*) on honey bees.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Although the risks and value have been found acceptable when all risk reduction measures are followed, the applicant must submit additional scientific information as a condition of registration.

This summary describes the key points of the evaluation, while the Science Evaluation of Evaluation Report ERC2013-04, *Amitraz* provides detailed technical information on the human health, environmental and value assessments of Amitraz Technical and Apivar Strips.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please refer to the following:

What Is Amitraz?

Amitraz is a formamidine contact acaricide and insecticide which is used to kill ectoparasites. It appears to act on the nervous system, leading to overexcitation and consequently paralysis and death in arthropods.

Apivar Strips consist of a plastic polymer strip embedded with amitraz. The strips are placed in the hive with one strip used for every five frames of bees in each brood chamber. The strip is hung between the frames, with the frames separated slightly so that both sides of the strip come into contact with the bees. The bees rub against the strips as they move through the brood chamber, and then pass the chemical on to other bees as they rub up against each other in the hive. The strips should be removed after six weeks.

Health Considerations

Can Approved Uses of Amitraz Affect Human Health?

Amitraz is unlikely to affect your health when used according to label directions.

Potential exposure to amitraz may occur through the diet (food only) or when handling and applying the product. When assessing health risks, two key factors are considered:

- the levels where no health effects occur and
- the levels to which people may be exposed.

The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, the acute oral toxicity of the technical grade active ingredient amitraz varies widely among species. Amitraz was of low toxicity in mice and of high toxicity in several other test species via the oral route. Amitraz was slightly toxic via the dermal route, of low toxicity via the inhalation route, minimally irritating to the eyes and skin, and was determined to be a potential skin sensitizer.

No acute toxicology data were available for the end-use product, Apivar Strips, and therefore the acute toxicity data for the active ingredient were used to characterize the hazards of the end-use product. Although data indicated that amitraz may be highly acutely toxic via the oral route, this route was not expected to be of concern with the proposed use since the active ingredient is embedded in plastic strips. Overall, Apivar Strips were considered to be slightly acutely toxic via the dermal route, of low acute toxicity via the inhalation route, minimally irritating to the eyes and skin, and capable of causing allergic skin reactions. Consequently the signal words "CAUTION POISON" and "POTENTIAL SKIN SENSITIZER" are required on the product label.

The available toxicology studies indicate the main effects caused by amitraz were related to suppression of the central nervous system, and included sedation, as well as decreases in body temperature, blood pressure, and heart rate. Generally, these effects tended to have a rapid onset, were short-lived, and did not appear to accumulate over time. Amitraz did not damage genetic material and was not considered to pose a cancer risk.

When amitraz was given to pregnant rats, effects on the urinary system of the developing fetus were observed at doses that also caused toxic effects in the mother, indicating that the young do not appear to be more sensitive to amitraz than the adult animal. However, it was not possible to fully describe the effects on young and developing animals, as the full complement of studies required to fully assess these effects was not available. Consequently, an additional protective factor was used in the risk assessment to further reduce the allowable level of human exposure to amitraz. Furthermore, consideration was given to the anticipated low exposure potential resulting from the physical form of the product as well as the dietary and occupational exposure aspects outlined below.

To address this, an extended one-generation reproductive toxicity study, including a neurotoxicity component, is currently being conducted for submission to the Agency.

Residues in Water and Food

Dietary intake estimates (food only) revealed that the general population is expected to be exposed to less than 4.3% of the acceptable daily intake. A dietary intake estimate (food only) for the highest exposed population (children 1-2 years old) used less than 25.42% of the acute reference dose, which is not a health concern. Based on these estimates, the chronic and acute dietary risks from amitraz are not of concern for all population sub-groups.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Supervised residue trials conducted in France according to the Canadian GAP were found acceptable to support the registration of Apivar Strips in Canada. The MRL for this active ingredient can be found in the Science Evaluation of Evaluation Report ERC2013-04,*Amitraz*.

Risks in Residential and Other Non-Occupational Environments

Due to the nature of the application and the treatment location, bystander and residential exposures are not of concern.

Occupational Risks From Handling Apivar Strips

Occupational risks are not of concern when Apivar Strips are used according to the label directions, which include protective measures.

Apivar Strips are sustained-release, hardened plastic strips containing amitraz. For workers handling the strips, exposure via the inhalation route is expected to be minimal, and relative to the dermal exposure incurred, it is expected to be negligible.

The use of amitraz in honey bee colonies potentially represents a risk of concern for chemical handlers of amitraz; however, the mitigation measures recommended on the label, such as the use of chemical resistance gloves (for example, nitrile), should address this risk.

No restricted entry interval is required on the end-use product label for Apivar Strips.

Environmental Considerations

What Happens When Amitraz Is Introduced Into the Environment?

Amitraz is used in the formulation for Apivar Strips for the control of varroa mites on honey bees. Since the end-use product will be used in beehives, the risk to non-target organisms is considered to be negligible, when used according to the label directions. Because of the use pattern, amitraz is unlikely to be introduced to the environment.

Value Considerations

What Is the Value of Apivar Strips?

Apivar Strips have value as they control varroa mites (*Varroa destructor*) in honey bee hives.

Varroa mites are the most important parasitic pest of honey bees, and have a severe economic impact on the Canadian beekeeping industry. Significant varroa mite infestations in a honey bee colony will cause the loss of the infested colonies. Varroa mites are the main cause of honey bee colony loss in Canada.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being placed on the label of Apivar Strips to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Since there is a potential for users to come into direct contact with amitraz on the skin, anyone applying Apivar Strips must wear chemical resistant gloves (for example, nitrile). In addition, the label statements "Do not handle more than 100 pairs of strips per person per day." is required on the label.

Environment

Standard precautionary measures are required to mitigate potential risks to non-target organisms. These include adding precautionary statements to the label regarding environmental hazards and the directions for use.

What Additional Scientific Information Is Being Requested?

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of Evaluation Report ERC2013-04, *Amitraz* or in the Section 12 Notice associated with these conditional registrations. The applicant must submit the following information within the time frames indicated (by September 1, 2013).

Human Health

The following data gaps, which have been identified as part of the ongoing PMRA re-evaluation, will have to be addressed as a condition of registration of the technical active ingredient used in the Apivar Strips:

- DACO 4.5.3 - Prenatal developmental toxicity study in rabbits
- DACO 4.5.1 - Rat reproductive toxicity study
- DACO 4.5.14 - Developmental neurotoxicity study
- DACO 4.5.12 - Acute neurotoxicity[Footnote1]
- DACO 4.5.13 - 90-day neurotoxicity[Footnote2]

Other Information

As these conditional registrations relate to a decision on which the public must be consulted[Footnote3], the PMRA will publish a consultation document when there is a proposed decision on applications to convert the conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

The test data cited in Evaluation Report ERC2013-04, *Amitraz* (i.e. the test data relevant in supporting the registration decision) will be made available for public inspection when the decision is made to convert the conditional registrations to full registrations or to renew the conditional registrations (following public consultation). If more information is required, please

contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Footnotes

Footnote 1

These studies were recently submitted to the Agency, and will be evaluated as part of the re-evaluation activities.

Return to footnote1referrer

Footnote 2

These studies were recently submitted to the Agency, and will be evaluated as part of the re-evaluation activities.

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Footnote 3

As per subsection 28(1) of the *Pest Control Products Act.*