



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



Trade Advice Notice

on amitraz in the product APIVAR 500 mg Bee Hive Strips For Honey Bees for use
in bee hives

APVMA product number 88615

December 2020

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ISSN 2200-3894 (electronic)

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Comments and enquiries regarding copyright:

Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001 Australia

Telephone: +61 2 6770 2300

Email: communications@apvma.gov.au.

This publication is available from the [APVMA website](#).

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Preface

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

The APVMA has a policy of encouraging openness and transparency in its activities and of seeking stakeholder involvement in decision making. Part of that process is the publication of Trade Advice Notices for all proposed extensions of use for existing products where there may be trade implications.

The information and technical data required by the APVMA to assess the safety of new chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in regulatory guidance published on the APVMA website.

About this document

This Trade Advice Notice indicates that the APVMA is considering an application to vary the use of an existing registered agricultural or veterinary chemical.

It provides a summary of the APVMA's residue and trade assessment.

Comment is sought from industry groups and stakeholders on the information contained within this document.

Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application to provide a 'shelf' registration for APIVAR 500 mg Bee Hive Strips For Honey Bees should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds relate to the trade implications of the extended use of the product. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on **Thursday 14 January 2021** and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether to grant the application and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or organisation name (if relevant)
- email or postal address (if available)

- the date you made the submission.

Please note: submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the [public consultation coversheet](#)).

Please lodge your submission using the [public consultation coversheet](#), which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Unless you request for your submission to remain confidential, the APVMA may release your submission to the applicant for comment.

Written submissions should be addressed to:

Executive Director, Risk Assessment Capability
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au

Further information

Further information can be obtained via the contact details provided above.

Further information on Trade Advice Notices can be found on the APVMA website: apvma.gov.au.

Introduction

The APVMA has before it an application from Veto-Pharma SAS seeking a shelf registration for a new product to register the use of APIVAR 500 mg Bee Hive Strips For Honey Bees, containing 500 mg amitraz/strip.

APIVAR 500 mg Bee Hive Strips For Honey Bees is for use in bee hives to control *Varroa destructor* mites which are currently exotic to Australia. While the APVMA does not approve label claims for efficacy against pests and diseases which are exotic to Australia, the APVMA will consider allowing such claims by registering 'shelf' products or approving labels, which can be supplied and used only under official direction (for example the Chief Plant Protection Officers of the Commonwealth) in the event of an incursion of the pest or disease. The product must then only be used in accordance with the approved label directions or as specified under official direction¹.

Shelf registration involves the normal registration process (the APVMA must be satisfied of all section 14 criteria of the Agvet Code, which includes consideration of efficacy, trade, and safety to humans, target and non-target animals, and the environment), however restrictions are placed on the supply of the registered product. Should the disease/pest become endemic the applicant may request that the restrictions be removed.

The application for shelf registration of APIVAR 500 mg Bee Hive Strips For Honey Bees involves the consideration of a permanent MRL entry for amitraz, the setting of a withholding periods for honey, the recommendation of appropriate Trade Advice, and approval of the product label.

¹ Australian Pesticides and Veterinary Medicines Authority, [Operational Notice – Label Claims for efficacy against pests and diseases which are exotic to Australia](#), Gazette No.2, APVMA website, 5 February 2008, accessed November 2020.

Trade considerations

Commodities exported

Bees are considered to be a species producing a major export food commodity² and as such the implication on the international trade of honey associated with the proposed use pattern is considered.

Destination and value of exports

The estimated gross value of production of the Australian honey bee industry was \$101 million in 2014–15³. Approximately 14% of the total Australian national honey production (approximately 4.6 kilotonnes of honey), is exported per year.

The applicant has indicated that the largest current export markets are likely to be the United States of America (USA), Canada, Asian regions (Indonesia, Malaysia and Singapore) and the Middle East (Saudi Arabia).

Proposed Australian use pattern

APIVAR 500 mg Bee Hive Strips For Honey Bees is proposed to be administered to honey bee hives by applying 2 strips (presented as impregnated plastic strips, each containing 500 mg of amitraz) per brood chamber in spring before the first honey flow, for a duration of 6 to 10 weeks, with a repeat of the treatment carried out in autumn if required.

The proposed label instructions are presented in Table 1.

² Australian Pesticides and Veterinary Medicines Authority, [Veterinary drug residues in food commodities and overseas trade](#), APVMA website, 1 July 2014, accessed November 2020.

³ ABARES research report, [Australian honey bee industry: 2014–15 survey results](#), Australian government website, December 2016, accessed November 2020.

Table 1: Proposed Australian use pattern – APIVAR 500 mg Bee Hive Strips For Honey Bees, containing 500 mg amitraz/15 g strips

Situation	Claims	Dosage and administration
Honey bee hives	<p>For the control of mites (<i>Varroa destructor</i>) on honey bees.</p> <p>This product must only be supplied in the event the Chief Plant Protection Officer of the Commonwealth declares an outbreak of varroa mite (<i>Varroa destructor</i>) in accordance with the emergency Plant Pest Response Deed.</p> <p>This product must only be used by persons authorised by the Chief Plant Protection Officer of the Commonwealth in accordance with the Emergency Plant Pest Response Deed in the event of a declared outbreak of varroa mite (<i>Varroa destructor</i>).</p>	<p>Dosage rate:</p> <p>Use 2 APIVAR strips per brood chamber or 1 APIVAR strip per nuclei. Hang each strip within 2 frames from the edge of the cluster, for example between frames 3 and 4 and between frames 7 and 8. APIVAR strips are suspended in the brood chamber in such a way that the bees can walk on both sides of the strips. Dose must not exceed the stated dose rate in a fully populated hive.</p> <p>If possible, strips should be checked halfway through the treatment interval. If it is noted that the bee cluster has moved away from the strips, reposition the strips into the bee cluster.</p> <p>Timing:</p> <p>APIVAR is an effective treatment in both the spring and the autumn. Start the treatment in early spring before the first honey flow. If APIVAR is used in the autumn, strips are not to be placed until after all supers containing honey for human consumption have been removed. DO NOT USE APIVAR while honey supers are present. Recycling of brood frames and honey frames is not advised.</p> <p>Duration:</p> <p>The strips must remain in the hive for the full 6 to 10 week treatment period. Treatment strips must be removed after a maximum of 10 weeks of use. DO NOT re-use the strips.</p>

Restrains:

DO NOT USE during honey flow.

DO NOT extract honey from the brood chamber.

DO NOT harvest honey when the treatment is in place.

DO NOT USE APIVAR while honey supers are present.

COMB HONEY/PROPOLIS/ROYAL JELLY: DO NOT make comb honey, propolis, royal jelly from treated bees or hives available for human consumption.

Brood combs should be replaced with a new foundation at least every three years. Do not recycle brood frames as honey frames.

Withholding periods:

Honey: 'Zero (0) days after the removal of the strips. DO NOT harvest honey when the treatment is in place.'

Trade advice:

Apiarists should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for honey and other bee products treated with APIVAR 500 mg Bee Hive Strips For Honey Bees. If you are collecting honey for export, please check with Findex (Aust) Pty Limited +61 29619 1955 for the latest information on MRLs and import tolerances before using APIVAR 500 mg Bee Hive Strips For Honey Bees.

Results from residues trials presented to the APVMA

The proposed use pattern for the product is to apply 2 strips (presented as impregnated plastic strips, each containing 500 mg of amitraz) per brood chamber in spring before the first honey flow, for a duration of 6 to 10 weeks, with a repeat of the treatment carried out in autumn if required. A number of restraints are proposed to prevent the use of the product during honey flow and when supers are present and to prevent the collection of honey from the brood chamber or when the treatment is in place.

The applicant has submitted 3 GLP compliant European residues studies for consideration. The residue definition (marker residue) used in the residues depletion studies includes all metabolites containing the 2, 4-dimethylaniline moiety (which is compliant with the European residues definition for amitraz). The EU definition includes all metabolites containing the 2,4-dimethylaniline moiety and therefore may include additional metabolites to the Australian definition (sum of amitraz and N-(2,4-dimethylphenyl)-N'-methylformamidine, expressed as N-(2,4-dimethylphenyl)-N'-methylformamidine). The residue concentrations reported in the submitted study reports may therefore represent a worst case scenario in relation to the Australian residues definition for amitraz. However, based on available metabolism and pharmacokinetic information, the additional potential metabolites are considered to occur at minor levels and therefore the results as reported in the submitted studies are considered acceptable for the purposes of the current evaluation.

The 3 residue depletion studies differed in treatment regime with some studies including treatments not relevant to the proposed use pattern (such as the presence of honey supers during treatment or a higher number of strips per hive than is proposed). The treatment regimes of each study, which are most relevant to the proposed Australian use pattern, are summarised below.

Study API005 was conducted in Vendargues, France during 1998. Hives were treated with 2 APIVAR strips for 42 days and supers were added 30 days after the start of treatment. Residues in honey collected from supers increased following removal of treatment on day 42 from 67 to 117 µg/kg on the day of treatment removal to 58 to 165 µg/kg (1 day after treatment removal) and 71 to 431 µg/kg (2 days after removal of treatment). It is noted that honey supers were added (day 30) while the treatment strips were still in place for another 12 days. This is not considered to be reflective of the restraints of the proposed use pattern where treatment should not occur during honey flow or when supers are present and honey should not be harvested during treatment and therefore the results of this study will not directly be considered for MRL setting purposes.

Study API002 was conducted in Vendargues, France during 1993. The relevant treatment regime (applied to 10 colonies) involved the application of 2 strips which remained in treated hives for 42 days (which is shorter than the maximum 10 week treatment period proposed in the current application). On Day 42 a honey super was added to hives selected for sampling to allow for the collection of honey. Amitraz residues in honey were <LOD (5 µg/kg) on the final day of treatment.

Study ATL-15-1348 was conducted in Testapi, France during 2015. The relevant treatment groups (8 colonies per treatment group) involved the application of 3 amitraz strips per hive (1.5× the proposed maximum treatment) for 6 weeks and 10 weeks, respectively. On the final day of treatment, supers that were present during treatment were removed and replaced with new supers to allow for honey collection. Residues of amitraz in honey samples collected on the final day of treatment were 65 to 72 µg/kg for the 6 week treatment duration and were 91 to 95 µg/kg for the 10 week treatment duration.

Based on the available information, an amitraz MRL of 0.2 mg/kg (200 µg/kg) for honey is considered appropriate for the proposed use pattern noting the proposed label restraints relating to honey collection during treatment and from the brood chamber.

Overseas registration and approved label instructions

The applicant indicated that amitraz products are registered for use on bees in New Zealand, Canada, the United Kingdom (UK), European Union (EU), USA, Japan and Algeria.

Codex Alimentarius Commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides and veterinary medicines. Codex CXLs are primarily intended to facilitate international trade, and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Some countries may accept Codex CXLs when importing foods. An amitraz MRL for honey has not been established by Codex.

The relevant international MRLs in Table 2 have been established for amitraz.

Table 2: International amitraz MRLs relevant to honey

Compound	Commodity	MRL (mg/kg)
Canada ⁴	Honey	0.1
Codex ⁵	-	Not established
EU ⁶	Honey	0.2

⁴ Government of Canada, [MRL Database](#), Government of Canada website, accessed November 2020.

⁵ Codex Alimentarius International Food Standards, [Pesticide Index](#), Codex website, accessed November 2020.

⁶ European Union Law, [Pharmacologically active substances and their classification regarding maximum residue limits \(MRL\)](#), European Law website, accessed November 2020.

Compound	Commodity	MRL (mg/kg)
Japan ⁷	Honey (including royal jelly)	0.2
New Zealand ⁸	Honey	0.2
	Other bee products	1
USA ⁹	Honey	0.2
	Honeycomb	9

Current and proposed Australian MRLs for amitraz

Table 3: Current MRL Standard

Compound	Food	MRL (mg/kg)
Amitraz		
SO 0691	Cotton seed	*0.1
OC 0691	Cotton seed oil, crude	1
MO 0105	Edible offal (mammalian)	0.5
MM 0095	Meat (mammalian)	0.1
ML 0106	Milks	0.1

Table 4: Proposed MRL

Compound	Food	MRL (mg/kg)
Amitraz		
Add:		
	Honey	0.2

⁷ The Japan Food Chemical Research Foundation, [Maximum Residue Limits \(MRLs\) List of Agricultural Chemicals in Foods](#), The Japan Food Chemical Research Foundation website, accessed November 2020.

⁸ New Zealand Government, [Food notice: Maximum Residue Levels for Agricultural Compounds](#), New Zealand Government website, 7 October 2020, accessed November 2020.

⁹ USA: Part 180 – [Tolerances and exemptions for pesticide chemical residues in food](#), United States Electronic code of Federal Regulations, 24 November 2020, accessed November 2020.

Potential risk to trade

This product must only be supplied in the event the Chief Plant Protection Officer of the Commonwealth declares an outbreak of varroa mite (*Varroa destructor*). Should that occur, the risk to the international trade of honey to the EU, Japan, New Zealand and the USA should not be adversely influenced as these markets have an established amitraz MRL at 0.2 mg/kg, equal to that proposed in Australia. CODEX has however not established an amitraz honey MRL and therefore the proposed use may present a potential risk to the trade of honey to markets that may adopt Codex MRLs in the absence of national MRLs such as Indonesia, Singapore, Malaysia and Saudi Arabia.

Conclusion

Comments are sought on the potential risk to trade in honey and other bee products from the proposed use and the ability of the industry to manage any potential risk.