



Australian Government
Australian Pesticides and
Veterinary Medicines Authority



TRADE ADVICE NOTICE

Apiguard Gel for Beehives

APVMA Product Number 65570

JULY 2015

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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.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health, Office of Chemical Safety, Department of the Environment, and State Departments of Primary Industry.

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 changes to the *MRL Standard* where there may be trade implications.

The information and technical data considered by the APVMA to assess the safety of new chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Further details can be found on the APVMA website: <http://www.apvma.gov.au>

About this document

This is a Trade Advice Notice.

It indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application to register a new veterinary chemical product. It provides a summary of the residues 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 *Apiguard Gel for Beehives* 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 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 **Tuesday 11 August 2015** 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 Group name (if relevant)
- Postal Address
- Email Address (if available)
- The date you made the submission.

All personal and **confidential commercial information (CCI)**¹ material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the **grounds for registration** should be addressed in writing to:

Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609

Phone: (02) 6210 4701

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: <http://www.apvma.gov.au>

¹ A full definition of "confidential commercial information" is contained in the Agvet Code.

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Vita (Europe) Limited seeking shelf registration for a new product, *Apiguard Gel for Beehives*, which contains 250 g/kg of thymol.

Apiguard Gel for Beehives is for use in bee hives to treat *Varroa destructor*, a parasitic mite that is currently exotic to Australia (ie not currently present in 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 (ie Australian or State/Territory Chief Veterinary Officers or Chief Plant Protection Officers) 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 direction.²

Shelf registration involves the normal registration process (ie 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 *Apiguard Gel for Beehives* involves the consideration of a permanent Table 5 entry for thymol, the setting of withholding periods for honey and comb honey, the recommendation of appropriate Trade Advice, and approval of the product label.

² Gazette No.2, 5 February 2008 *Operational Notice – Label Claims for efficacy against pests and diseases which are exotic to Australia.*

2 RESIDUES

2.1 Proposed Australian use pattern

The proposed Australian use pattern for *Apiguard Gel for Beehives* is given below.

Table 1: Proposed use pattern for *Apiguard Gel for Beehives*

HOST	PURPOSE	DOSE RATE
Bees	For the control of <i>Varroa</i> mites in beehives	Two applications of 12.5 g thymol per hive two weeks apart. The second dose is left in the hive for 4 weeks or until supers are installed.

Dosage and Administration

Remove all honey supers before treatment.

Use in hives where comb honey is to be collected is not recommended.

To avoid potential tainting problems treatment during honey flow is not recommended.

Withholding Periods

HONEY, COMB HONEY: Zero (0) days. Taste tainting may occur if hives are treated with *Apiguard Gel for beehives* during honey flow.

Trade Advice

Export markets may be sensitive to thymol tainted honey and comb honey. To avoid potential tainting problems, treatment during honey flow is not recommended and use in hives where comb honey is to be collected is not recommended.

2.2 Thymol residues in honey and comb honey

In support of their application Vita (Europe) Limited submitted residues data, journal articles and regulatory decisions from other jurisdictions.

Overseas regulatory standards

The following regulatory standards for thymol have been established overseas:

- The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has determined that there are no safety concerns for thymol at the current levels of intake when used as a flavouring agent.
- The United States Food and Drug Administration lists thymol, thyme essential oil and thyme (spice) as foods for human consumption and as food additives. They are also considered as Generally Recognised as Safe (GRAS). Therefore, a tolerance has not been established for residues of thymol in honey, honey comb and honeycomb with honey, when thymol is used as a treatment for *Varroa* mite in bees.

- The European Union has listed thymol as not requiring an MRL when used in food animal species.

Thymol residues and human safety

Thymol residues in honey are not expected to contribute significantly to the total dietary exposure of thymol as thymol is widely used as a food additive, and thymol residues are found in many different food types, as well as being found in herbs used for cooking. Therefore, when used to treat mites in bees, thymol residues in honey or comb honey do not pose a risk to human safety.

Residues and taste tainting of honey and comb honey

Thymol has strong flavour properties and may alter the natural flavour of honey. International food legislation³, states that honey *shall not have any objectionable flavour, aroma, or taint absorbed from foreign matter during its processing and storage*. The taste threshold for thymol in honey is 1.1-1.3 mg/kg⁴.

The submitted residues data shows that when hives were treated with 12.5 g thymol/hive, highest thymol residues in brood nest honey and comb honey on the last day of treatment, before removal of *Apiguard Gel for Beehives*, were 2.1 mg/kg and 680 mg/kg, respectively. As thymol residues in brood nest honey and comb honey immediately after treatment are above the taste threshold, there is a risk of “thymol” tasting honey and comb honey being harvested after treatment of hives with *Apiguard Gel for Beehives*. However, brood honey and comb honey is not generally harvested for human consumption and it is recommended not to treat hives with *Apiguard Gel for Beehives* during honey flow.

Furthermore, when bee hives were treated with *Apiguard Gel for Beehives* in the absence of supers, and the supers were placed in the hives after the treatment was removed, highest thymol residues in super honey collected 35 days after placement of the supers were 0.26 mg/kg. Therefore, it is unlikely that the honey harvested from supers placed in bee hives after *Apiguard Gel for Beehives* is removed will have thymol residues above the taste threshold.

While residues of thymol in honey and comb honey do not pose a risk to human safety, to reduce the risk of “thymol” tainted honey or comb honey, it is recommended not to treat hives with *Apiguard Gel for Beehives* during honey flow. The following wording is recommended for inclusion under the DOSAGE AND ADMINISTRATION heading:

Remove all honey supers before treatment.

Use in hives where comb honey is to be collected is not recommended.

To avoid potential tainting problems treatment during honey flow is not recommended.

³ Codex Standard for honey (World-wide standard) Codex Stan 12-1981 Rev 1 (1987)

⁴ S Bogdanov *et al*, *Influence of organic acids and components of essential oils on honey taste* Swiss Bee Research Centre

MRL recommendations

Thymol, when used to treat mites in bees, fulfils the requirements that residues of thymol 'are otherwise of no toxicological significance' and that they are 'identical to or indistinguishable from natural food components'. Therefore, the use of thymol in bees is eligible for a Table 5 entry in the *MRL Standard*.

The following entry is recommended:

SUBSTANCE	USE
Thymol	<ul style="list-style-type: none">• Treatment and control of <i>Varroa</i> mites on bees

Withholding period - Honey and honey comb

As the use of thymol in bees is eligible for a Table 5 entry in MRL Standard, the following withholding period statement is recommended:

HONEY, COMB HONEY: Zero (0) days. Taste tainting may occur if hives are treated with *Apiguard Gel for beehives* during honey flow.

3 RESIDUES-RELATED ASPECTS OF TRADE

3.1 Potential risk to trade

Honey from hives that have been treated with *Apiguard Gel for beehives* may pose a risk to Australian trade. While thymol residues do not pose a risk to human safety, the *Codex Standard for honey* states that honey *shall not have any objectionable flavour, aroma, or taint absorbed from foreign matter during its processing and storage*. So, to ensure residues of thymol in honey and comb honey remain below the taste threshold of 1.3 mg/kg, it is recommended not to treat hives with *Apiguard Gel for beehives* during honey flow or to use *Apiguard Gel for beehives* in hives where comb honey is to be collected.

3.2 Trade advice statement

The following trade advice statement has been recommended to address the trade concerns:

Export markets may be sensitive to thymol tainted honey and comb honey. To avoid potential tainting problems, treatment during honey flow is not recommended and use in hives where comb honey is to be collected is not recommended.

4 CONCLUSIONS

The APVMA has considered whether use of *Apiguard Gel for Beehives*, in accordance with the recommended label instructions, could unduly prejudice trade and commerce between Australia and places outside Australia, as per Section 14(3)(e)(iv) of the Agvet Codes. The risk to Australia's export trade in honey is considered to be low if *Apiguard Gel for Beehives* is not used during honey flow or used in hives where comb honey is collected.

The APVMA is seeking comment from relevant industry groups and stakeholders in relation to the perceived level of risk to Australia's export trade in honey.