Commonwealth of Australia

Gazette

Special Gazette, Tuesday, 19 January 2016

Published by The Australian Pesticides and Veterinary Medicines Authority

AGRICULTURAL AND VETERINARY CHEMICALS

Australian Government

Australian Pesticides and Veterinary Medicines Authority

The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

ISSN 1837 - 7629

Director Public Affairs and Communications
The Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

Email: communications@apvma.gov.au
Website: www.apvma.gov.au.

GENERAL INFORMATION

The *APVMA (Australian Pesticides and Veterinary Medicines Authority) Gazette* is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 8J(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

DISTRIBUTION AND SUBSCRIPTION

The *APVMA Gazette* is published in electronic format only and is available from the APVMA website, www.apvma.gov.au/publications/gazette/.

If you would like to receive email notification when a new edition is published, please subscribe on the APVMA website.

APVMA CONTACTS

For enquiries regarding the publishing and distribution of the *APVMA Gazette*: Telephone: +61 2 6210 4988

For enquiries on the *APVMA Gazette* content, please refer to the individual APVMA contacts listed under each notice.

CONTENTS

NEW CHEMICAL PRODUCT BOLLGARD III

as produced by the *Cry1Ac* and *Cry2Ab* genes and their controlling sequences
***Bacillus thuringiensis* strain AB88 exotoxin**
as produced by the *Vip3A(A)* gene and its controlling sequence

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing a new active constituent. The product is **BOLLGARD III**.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	**BOLLGARD III**
Applicant company:	Monsanto Australia Ltd
Name of active constituent:	*Bacillus thurigiensis* susp. *Kurstaki* delta endotoxins as produced by the Cry1Ac and Cry2Ab genes and their controlling sequences and *Bacillus thuringiensis* strain AB88 exotoxin as produced by the Vip 3A (A) gene and its controlling sequences.
Signal heading:	Unscheduled
Summary of proposed use:	Plant incorporated insecticidal cotton event for protection *against Helicoverpa Armigera* (Cotton Bollworm) and *Helicoverpa punctigera* (Native Budworm)
Pack sizes:	NA
Withholding period:	NA

SUMMARY OF THE APVMA'S EVALUATION OF BOLLGARD III IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 14(1)(C) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE *AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994*

1. The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, and proposes to determine that:

(i) The APVMA is satisfied that the proposed use of **BOLLGARD III** would not be an undue hazard to the safety of people exposed to it during its handling and use.

Plant breeders, seed distributors, farm workers and those associated with cotton gin processing will be the main occupations exposed to the product. Direct exposure is unlikely to occur except if damaged cotton plant material is extensively handled or ingested. In such a scenario the amount of exposure to the intact active constituents is expected to be negligible.

As the toxicity of the active constituents is very low and the active constituents are readily degraded and as the exposure of employees in occupations working directly with cotton plants and their raw products to the active constituents is expected to be minimal, no risk management measures are required. Therefore, no First Aid Instructions or Safety Directions are warranted.

(ii) The APVMA is satisfied that the proposed use of **BOLLGARD III** will not be an undue hazard to the safety of people using anything containing its residues.

The product will exist as seeds through to cotton plants of all growth stages and is limited to certain products (cotton plant trash and cotton seeds) of those plants. The introduced genes and expressed proteins are not present in cotton products such as cottonseed oil, fibres and lints. Finite residues are not expected to be in any food commodities as a result of the use of this product.

(iii) The APVMA is satisfied that the proposed use of **BOLLGARD III** containing the active constituents *Bacillus thurigiensis* susp. *Kurstaki* delta endotoxins as produced by the Cry1Ac and Cry2Ab genes and their controlling sequences and *Bacillus thuringiensis* strain AB88 exotoxin as produced by the Vip 3A (A) gene and its controlling sequences, is not likely to be harmful to human beings if used in accordance to the product label directions.

(iv) The APVMA is satisfied that the proposed use of the new product **BOLLGARD III** containing the active constituents *Bacillus thurigiensis* susp. *Kurstaki* delta endotoxins as produced by the Cry1Ac and Cry2Ab genes and their controlling sequences and *Bacillus thuringiensis* strain AB88 exotoxin as produced by the Vip 3A (A) gene and its controlling sequences, is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label directions.

2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, proposes to determine that:

(i) In relation to its assessment of efficacy under section 14(3)(f), the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed uses.

3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:

(ii) The APVMA is satisfied that the proposed use of **BOLLGARD III** would not adversely affect trade between Australia and places outside Australia as finite residues are not expected to be present in any exported food commodities.

FURTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website's 'Public Consultation' page, www.apvma.gov.au/consultation/public or by contacting the evaluator listed below.

MAKING A SUBMISSION

In accordance with section13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether **BOLLGARD III** should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

Submissions must be received by the APVMA within **28 days** of the date of this notice 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 the product should be registered and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or group name (if relevant)
- email or postal address
- the date you made the submission.

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

Written submissions should be addressed in writing to:

Case Management and Evaluation Unit (CMAU)
Registration Management and Evaluation
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4700
Fax: +61 2 6210 4776
Email: enquiries@apvma.gov.au