

NOTICE*Lactobacillus reuteri***[in the product: REUTERI PIG POWDER]**

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Agriliance Pty Ltd for registration of a new product containing the new active constituent *Lactobacillus reuteri*. The product is REUTERI PIG POWDER. The product is for use in pigs.

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of the active constituent and the registration of the product should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to matters outlined below that the APVMA is required to take into account in deciding whether to grant the application. Comments must be received by the APVMA within 28 days of the date of this notice.

Particulars of Application

Proposed product name:	REUTERI PIG POWDER
Applicant company:	Agriliance Pty Ltd
Name of active constituent:	<i>Lactobacillus reuteri</i>
Taxonomy	Strain conforms to characteristics specified in Bergey's Manual of Systematic Bacteriology for the species.
Strain	1063S
Culture Collection and Registration of Deposit	<i>L. reuteri</i> DSM 20016 American Type Culture Collection Patent deposit designation PTA-3609
Signal heading:	Unscheduled
Statement of claims:	For the establishment of gastrointestinal microflora in newborn piglets and maintenance of performance of healthy animals during normal animal husbandry practices from birth to 3 weeks after weaning.
Pack sizes:	250g
Withholding period:	nil

Summary of the APVMA's evaluation of *Lactobacillus reuteri* in REUTERI PIG POWDER in accordance with Section 14(3)(e) and (f) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the Agricultural and Veterinary Chemicals Code Act 1994

The APVMA has evaluated the application and in its assessment in relation to human and environmental safety under section 14(3)(e) of the Agvet Code, proposes to determine that:

- (i) The APVMA is satisfied that the proposed use of *Lactobacillus reuteri* in REUTERI PIG POWDER would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Office of Chemical Safety (OCS) in the Commonwealth Department of Health and Aging assessed the human toxicological aspects of this application. The product is a direct fed microbial for use in pigs. The product will be formulated in Sweden; repackaging will not be required in Australia.

OCS advised the APVMA that use of the product would not be an undue hazard to the safety of people exposed to it during its handling and use. The APVMA accepts the findings and recommendations of OCS on this criterion.

- (ii) The APVMA is satisfied that the proposed use of *Lactobacillus reuteri* in REUTERI PIG POWDER will not be an undue hazard to the safety of people using anything containing its residues.

Lactobacillus reuteri is a normal inhabitant of the gastrointestinal tract of pigs and as such does not produce residues in food-producing animals.

- (iii) The APVMA is satisfied that the proposed use of the *Lactobacillus reuteri* in REUTERI PIG POWDER is not likely to be harmful to human beings if used according to the product label directions.

The APVMA has evaluated the active constituent *Lactobacillus reuteri*. *Lactobacillus reuteri* is listed by the US Food and Drug Administration (FDA) and the Association of American Feed Control Officials (AAFCO) as suitable for use as a direct fed microbial and is Generally Recognised as Safe (GRAS) when used for this purpose. The active constituent is unscheduled. The appropriate Signal Heading is on the label.

First Aid and Safety Directions for *Lactobacillus reuteri* have been recommended by OCS to conform with those for other *Lactobacillus spp* and have been included on the label.

The APVMA accepts the findings and recommendations of OCS on this criterion.

- (iv) The APVMA is satisfied that the proposed use of *Lactobacillus reuteri* in REUTERI PIG POWDER in pigs is not likely to have an unintended effect that is harmful to animals, plants or the environment. The active constituent *Lactobacillus reuteri* is a normal inhabitant of the environment and is covered by the Phase 1 Environmental Impact Assessment criteria of VICH Guideline 6 which the APVMA has adopted.

- (v) The APVMA is satisfied that the proposed use of *Lactobacillus reuteri* in REUTERI PIG POWDER would not adversely affect trade between Australia and places outside Australia because the product does not generate residues.

In relation to its assessment of efficacy under section 14(3)(f), the APVMA proposes to determine that:

- (i) The APVMA is satisfied the data from trials supporting the efficacy of REUTERI PIG POWDER adequately demonstrate that under local conditions this product is effective for the proposed uses.

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

Judith Platt
Veterinary Medicines Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Phone: (02) 6210 4735

Fax: (02) 6210 4741

Email: judith.platt@apvma.gov.au

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