



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



## TRADE ADVICE NOTICE

on clothianidin in the product Sumitomo Samurai Systemic Insecticide

APVMA Product Number 60687

OCTOBER 2018

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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, Department of the Environment and Energy, 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 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 is a Trade Advice Notice.

It 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 vary the registration of Sumitomo Samurai Systemic Insecticide 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 8 November 2018 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. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

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)<sup>1</sup> 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:

Residues and Trade  
Scientific Assessment and Chemical Review  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
Kingston ACT 2604

**Phone:** +61 2 6210 4701  
**Fax:** +61 2 6210 4776  
**Email:** [enquiries@apvma.gov.au](mailto:enquiries@apvma.gov.au)

## Further information

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

Further information on public release summaries can be found on the APVMA website: [www.apvma.gov.au](http://www.apvma.gov.au)

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<sup>1</sup> 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 Sumitomo Chemical Australia Pty Ltd for the addition of a new use for product, Sumitomo Samurai Systemic Insecticide (containing 500 g/kg clothianidin), for use on citrus for the control of various insects.

A similar use of clothianidin on citrus is currently allowed under permit (PER81925 for oranges and PER82831 for grapefruit, lemons, limes and mandarins).

## 2 TRADE CONSIDERATIONS

### 2.1 Commodities exported

Citrus fruits, as well as meat and dairy products from animals that have been fed citrus pulp containing residues arising from the use of Sumitomo SAMURAI Systemic Insecticide may be exported.

### 2.2 Destination and value of exports

Australian exports of navel and Valencia oranges totalled 139 and 21.4 kt respectively (value \$192 and \$25.7 million) in 2016–17; of mandarins totalled 52.3 kt (value \$103 million) in 2016-17; of lemons and limes totalled 1.7 kt (value \$5 million) in 2016–17; and of grapefruit totalled 1.2 kt (value \$2.5 million) in in 2016–17<sup>2</sup>.

The major export markets for Australian oranges and mandarins in 2017 are shown below (information from CitrusAustralia<sup>3</sup>).

#### MAJOR DESTINATIONS FOR AUSTRALIAN CITRUS FRUIT EXPORTS IN 2017

| CITRUS CROP | MAJOR DESTINATIONS                                                                                                                                     |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Oranges     | China, Japan, Hong Kong, Malaysia, Singapore, United States, United Arab Emirates, India, New Zealand, Philippines, Taiwan Indonesia, Canada, Thailand |
| Mandarins   | China, Indonesia, United Arab Emirates, Hong Kong, New Zealand, Japan, United States, Singapore, Taipei, Sri Lanka, Philippines                        |

The significant export markets for Australian beef, sheep, pig meat and offals are listed in the APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B).

<sup>2</sup> Australian Commodity Statistics 2017, December 2017; [www.agriculture.gov.au/abares/publications/display?url=http://143.188.17.20/anrdl/DAFFService/display.php%3Ffid%3Dpb\\_agcstd9abcc0022017\\_luqZq.xml](http://www.agriculture.gov.au/abares/publications/display?url=http://143.188.17.20/anrdl/DAFFService/display.php%3Ffid%3Dpb_agcstd9abcc0022017_luqZq.xml)

<sup>3</sup> [www.citrusaustralia.com.au/wp-content/uploads/David-Daniels\\_Citrus-Australia.pdf](http://www.citrusaustralia.com.au/wp-content/uploads/David-Daniels_Citrus-Australia.pdf)

## 2.3 Proposed Australian use-pattern

### SUMITOMO SAMURAI SYSTEMIC INSECTICIDE (500 g/kg CLOTHIANIDIN)

| CROP   | PEST                                                                   | RATE                                                                                                                                                                                                                                                                                                                                                                                      | CRITICAL COMMENTS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|--------|------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Citrus | Gall wasp<br>Leaf miner<br>Fullers rose weevil<br>California red scale | <p><b>For application through micro – irrigation.</b></p> <p><b>6–8 g per tree</b><br/><b>(3–4 g a.i./tree)</b></p> <p>Use the higher rate for larger older trees (3.5m or more tall), in high pest pressure situations or where application has been delayed. The lower rate may be used for smaller trees, higher density plantings with small trees and under lower pest pressure.</p> | <p>Apply two weeks after flowering (petal drop) has finished. For most navel orange varieties, this is in late October or November.</p> <p>DO NOT apply more than one application per season.</p> <p>Where extended or multiple flowerings occur and where the previous seasons crop is still on the tree after flowering, Samurai should only be applied after the previous crop has been picked and there is a minimum of 20 weeks until the next harvest.</p> <p>The soil must be reasonably dry to start with.</p> <p>Run the irrigation for about 30 minutes and ensure water has reached all parts of the block and wet the soil. Determine the number of trees in the block to be treated. Multiply this by the rate per tree and add this amount to the chemigation tank for injection into the irrigation system. Ensure the volume of water in the tank is sufficient to reach and wet all parts of the block.</p> <p>Apply the required amount of Samurai through the irrigation system. Continue to run the irrigation system for about 5 hours to ensure thorough wetting of the soil profile to at least 15cm depth. The soil in the irrigation zone should be free of weeds and heavy mulch. Some leaves and trash is acceptable provided sufficient water is applied to wash the Samurai down into the root zone. The speed of control achieved depends on how fast the product enters the root zone and is taken up by the tree actively growing. Quick uptake is particularly important for scale control as this becomes more difficult once they are on the fruit.</p> <p>Best results are achieved where drippers or micro-sprinklers apply water to a limited area under the tree drip line. Do not apply through larger sprinklers that wet beyond the drip line of the tree into the inter row. In these situations, a better result will be achieved by spraying a band of Samurai about 1m wide down either side of the tree trunk line under the drip line and then irrigating this in to the soil as described above, so the soil profile is wet to at least 15cm depth. To get the correct Samurai rate per hectare multiply the number of trees per hectare by the rate of 6 or 8g to be used per tree. Do not leave soil applied Samurai exposed to sunlight on the</p> |

| CROP | PEST | RATE | CRITICAL COMMENTS                                                                                                                                                                                                                                                                                      |
|------|------|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|      |      |      | <p>surface. Irrigate to incorporate within 24 hours.</p> <p>Because of the nature of these pests and the variability of soil application and uptake, complete control is difficult to achieve. Treatment with Samurai should be in conjunction with other chemical or biological control measures.</p> |

Withholding periods:

Harvest: Do not harvest for 20 weeks after application.

Grazing: Do not graze treated area or cut treated area for stock feed.

Trade advice information: Treated fruit for export to particular destinations outside Australia may require a longer interval before harvest to comply with residues standards of importing countries. Please contact your industry body, exporter or Sumitomo Chemical Australia before using Sumitomo SAMURAI Systemic Insecticide.

## 2.4 Results from residues trials presented to the APVMA

Residues of clothianidin in citrus (oranges (17), lemons (2) and mandarins (2)) following one application two weeks after flowering (petal drop) at 4 g a.i./tree using micro-irrigation at 1X the maximum proposed rate were in rank order: <0.01 (6), 0.01, 0.01, 0.02, 0.02, 0.02, 0.02, 0.03, 0.03, 0.03, 0.04, 0.05, 0.05, 0.06, 0.11 and 0.32 mg/kg at commercial maturity 132–258 days after application (Supervised Trial Median Response (STMR)=0.02 mg/kg).

Based on the available information, it is recommended that a group MRL of 0.5 mg/kg for Citrus fruits (FC 0001) for clothianidin be established for the proposed use in conjunction with a harvest WHP of 20 weeks.

Processing studies indicates that residues should not concentrate on processing in orange juice (processing factor of 0.79x). The processing factor for dry citrus pulp was 3.7x.

### Animal commodities

Citrus pulp can form 30% of the diet for beef and dairy cattle in Australia. The estimated STMR-P for dried citrus pulp for dietary is 0.074 mg/kg (3.7 x 0.02 (STMR)). For estimation of MRL on citrus pulp, dry, the estimated maximum residue on a dry weight basis is 3.7 x 0.32 (HR) = 1.18 mg/kg. Based on the available information, a permanent MRL of 2 mg/kg is recommended for Citrus pulp, dry (AB 0001) for the proposed use.

The estimated dietary burden resulting from consumption of dry citrus pulp for beef and dairy cattle following the proposed use is lower than previously considered for establishment of animal commodity MRLs for clothianidin. No changes are considered necessary to the current animal commodity MRLs and residues aspects relating to animal commodities are not considered further.

## 2.5 Codex alimentarius commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides. 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. Clothianidin has been considered by Codex. The following relevant Codex and international MRLs have been established for clothianidin (Table 1).

Table 1: Comparison of clothianidin MRLs (mg/kg) for citrus

| COMMODITY     | TOLERANCE FOR RESIDUES ARISING FROM THE USE OF CLOTHIANIDIN (mg/kg) |      |        |        |      |         |                 |           |           |       |
|---------------|---------------------------------------------------------------------|------|--------|--------|------|---------|-----------------|-----------|-----------|-------|
|               | AUSTRALIA                                                           | EU4  | JAPAN5 | CODEX6 | USA7 | TAIWAN8 | KOREA9          | HONG KONG | INDONESIA | CHINA |
| Citrus fruits | 0.5<br>proposed<br>(T0.2<br>Current)                                | 0.06 | 2      | 0.07   | 0.07 | 1       | 1<br>(Mandarin) | 0.07      | 0.07      | -     |

## 2.6 Current and proposed Australian MRLs for clothianidin

Table 2: Current MRL Standard

| COMPOUND     | FOOD                     | MRL (mg/kg) |
|--------------|--------------------------|-------------|
| Clothianidin |                          |             |
| FC 0001      | Citrus fruits            | T0.2        |
| MO 0105      | Edible offal (Mammalian) | *0.02       |
| PE 0112      | Eggs                     | *0.02       |
| MM 0095      | Meat (mammalian)         | *0.02       |
| ML 0106      | Milks                    | *0.01       |

<sup>4</sup> EU: <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.CurrentMRL&language=EN&pestResidueId=775>

<sup>5</sup> Japan: [http://db.ffcr.or.jp/front/pesticide\\_detail?id=20000](http://db.ffcr.or.jp/front/pesticide_detail?id=20000)

<sup>6</sup> Codex: [http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p\\_id=238EU](http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p_id=238EU):

<sup>7</sup> USA: [https://www.ecfr.gov/cgi-bin/textidx?SID=aeb519aadec6efb69aba3edff1eafce&mc=true&node=se40.26.180\\_1586&rgn=div8](https://www.ecfr.gov/cgi-bin/textidx?SID=aeb519aadec6efb69aba3edff1eafce&mc=true&node=se40.26.180_1586&rgn=div8)

<sup>8</sup> Taiwan: <https://consumer.fda.gov.tw/Law/Detail.aspx?nodeID=518&lang=1&lawid=127>

<sup>9</sup> Korea: <http://www.foodsafetykorea.go.kr/residue/prd/mrls/list.do?currentPageNo=1&searchCode=P00332&searchFoodCode=&menuKey=1&subMenuKey=161&subChildMenuKey=&searchConsonantFlag=&searchConsonantFlag2=&searchValue2=&searchFlag=prd&searchClassLCode=&searchClassMCode=&searchClassSCode=&searchValue=>

Table 3: Proposed MRL Standard—Table1

| COMPOUND     | FOOD          | MRL (mg/kg) |
|--------------|---------------|-------------|
| Clothianidin |               |             |
| DELETE:      |               |             |
| FC 0001      | Citrus fruits | T0.2        |
| ADD:         |               |             |
| FC 0001      | Citrus fruits | 0.5         |

Table 4: Proposed MRL Standard—Table4

| COMPOUND     | ANIMAL FEED COMMODITY | MRL (mg/kg) |
|--------------|-----------------------|-------------|
| Clothianidin |                       |             |
| DELETE:      |                       |             |
| AB 0001      | Citrus pulp, dry      | T1          |
| ADD:         |                       |             |
| AB 0001      | Citrus pulp, dry      | 2           |

## 2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of clothianidin may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

A clothianidin MRL of 0.5 mg/kg for citrus fruit is proposed. This MRL is lower than the Japanese (2 mg/kg), Taiwanese (1 mg/kg) and Korean (1 mg/kg, for mandarins) MRLs. The proposed MRL is higher than that established in the Codex (0.07 mg/kg), EU (0.06 mg/kg), and the USA (0.07 mg/kg for citrus fruits). It is noted China does not have an MRL for clothianidin on citrus.

The STMR of 0.02 mg/kg was estimated from a citrus data set addressing the proposed GAP. This is lower than the established citrus MRLs in the major key export markets.

The following statement is proposed by the applicant to mitigate risk for produce destined for exports:

Treated fruit for export to particular destinations outside Australia may require a longer interval before harvest to comply with residues standards of importing countries. Please contact your industry body, exporter or Sumitomo Chemical Australia before using Sumitomo Samurai Systemic Insecticide.

## 3 CONCLUSIONS

Comments are sought on the potential for Sumitomo Samurai Systemic Insecticide to unduly prejudice Australian export trade in citrus fruits following the proposed use.