

Trade Advice Note

on

Thiacloprid

in the product

**Calypso 480 SC Insecticide
(NRA Product Number 53203)**

**National Registration Authority
for Agricultural and Veterinary Chemicals
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Trade Advice Note on the Product

Calypso 480 SC Insecticide

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) has before it, an application from Bayer CropScience, to vary the registration of this product to include control of codling moth and woolly aphid on pome fruit. The application requires the establishment of MRLs for pome fruit and animal commodities.

1. Proposed additional Australian uses of thiacloprid

Crop	Pest	Rate	Comments
Pome fruit	Codling moth	Dilute: 37.5 mL/100L (18 g ai/100L) OR Equivalent concentrate spray	Apply a total of 4 sprays at 14 day intervals commencing at egg lay (110 degree days) of the first generation, as indicated by monitoring. For the remainder of the season, continue to use other control measures. Apply by dilute of concentrate spraying equipment. Apply the same total amount of product to the target crop whether applying this product by dilute or concentrate spraying methods. Do not use in equipment that requires greater than 112.5 mL product/100L (3×).
	Woolly aphid		When Calypso is used for the control of codling moth as indicated above, early season sprays for the control of woolly aphid will not be required. For the remainder of the season, monitor aphid populations and apply other control measures as required.

Withholding period: Do not harvest for 21 days after application

2. Commodities exported

The main export commodities that may be affected by the proposed new use of Calypso 480 SC are apples and pears. Additionally, export food products may be derived from livestock, which consume apple pomace in their diet.

3. Countries where these commodities are exported

The following export statistics are available for apples and pears:

Exports of apples, 1999/2000 [*The Australian Horticultural Statistics Handbook 2000-2001*]

Export market	Volume, tonnes	Value, \$'000
Malaysia	9400	8301
Singapore	6931	6746
Sri Lanka	3657	3242
United Kingdom	1589	4407
Taiwan	1929	3111
Hong Kong	1306	1409
Papua New Guinea	529	610
Fiji	340	346
Bangladesh	2096	1899
Netherlands	227	273
Other	5707	6192
Total	33711	36536

Exports of pears, 1999/2000 [*The Australian Horticultural Statistics Handbook 2000-2001*]

Export market	Volume, tonnes	Value, \$'000
Singapore	6018	6540
Hong Kong	2437	2817
Malaysia	2864	3205
Indonesia	1188	1407
New Zealand	1273	1396
Canada	709	679
Fiji	145	134
Brunei	320	730
Taiwan	26	28
United Arab Emirates	63	53
Other	966	1032
Total	16009	18021

Export statistics for Australian beef and sheep product in are shown below [*Australian Commodity Statistics 2001*].

Commodity	2000 Production (kt)	2000/01 exports (kt)	2000/01 exports value (\$m)	Main Markets
Beef and Veal	2025	959	4007	USA, Japan, S. Korea
Dairy	~11070	-	3000	Japan, Saudi Arabia, Philippines, Malaysia, US (casein), Taiwan
Mutton and Lamb	367	295	920	US, South Africa, Japan, Saudi Arabia, EU

4. Overseas Registrations

The applicant advised that Calypso is registered for use on apples and/or pears in EU, Japan, New Zealand, South Africa and Switzerland.

5. Codex Alimentarius Commission CXLs (ie Codex MRLs)

There are no CXLs established for thiacloprid.

6. MRLs applying in Australia and overseas countries

Australia

The following changes to the *MRL Standard* are proposed to accommodate the use of Calypso 480 SC on pome fruit.

Table 1

Compound	Food	MRL (mg/kg)
Thiacloprid		
Delete:	FP0009 Pome fruit	T1
Add:	FP 0009 Pome fruit	1
	ML 0106 Milks	*0.01
	MM 0095 Meat [mammalian]	*0.02
	MO 0105 Edible offal (mammalian)	*0.02

Table 3

Add:	Thiacloprid	Thiacloprid
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Table 4

Compound	Animal Feed Commodity	MRL (mg/kg)
Add:		
Thiacloprid	AB 0226 Apple pomace, dry	3

Overseas MRLs

The applicant advised that the following MRLs have been established for pome fruit:

Country	MRL, mg/kg
EU	0.5
Japan	apple 0.5, pear 2
New Zealand	nil
Switzerland	0.3

7. Potential Risk to Trade

Export of treated produce containing finite residues of thiacloprid 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.

Pome fruit

In apples and tomatoes treated with radiolabelled thiacloprid, greater than 80% of the total radioactivity was recovered on the fruit surface as unchanged parent compound. No individual metabolites accounted for more than 3% of the total radioactive residues (TRR). In cotton seed harvested from plants treated with radiolabelled thiacloprid the most significant residue

component was 6-chloronicotinic acid accounting for 45% of the TRR. Thiacloprid was the major component in leaves and gin trash accounting for 70-80% of the TRR.

When Calypso 480 SC is used late in the season it is likely that detectable residues will occur on pome fruit. The maximum residue observed on pome fruit harvested 21 days after treatment was 0.38 mg/kg. The majority of Australia's export markets do not have appropriate MRLs or import tolerances in place.

The recommended application timing for Calypso 480 SC is to apply 4 applications at 14 day intervals commencing at egg lay (110 degree days). This treatment regime would result in an estimated pre-harvest interval of 50-65 days, which is significantly longer than the label withholding period. Residues in apples and pears harvested 55-64 days after treatment were 0.03, 0.03, 0.04 and 0.09 mg/kg. Washing of apples in water was shown to reduce residues by a factor of approximately 0.8x. Residues arising from early season use of the product will be significantly lower compared to late season use but may still be detectable at the method LOQ of 0.02 mg/kg.

The applicant has proposed that the following advisory statement appear on the product label: "Export of treated produce: Apple and pear growers should note that suitable MRLs or import tolerances may not be established in all markets for fruit harvested from Calypso treated trees. If you are using this product on apples and pears for export, please check with Bayer for the latest information on MRLs and import tolerances before using Calypso"

Provided that the proposed label statement is adopted and there is adequate consultation with the grower industry, it is likely that the risk to trade can be managed.

Animal commodities

In a goat dosed with [pyridinyl-¹⁴C-methyl]-thiacloprid for 3 days and sacrificed 6 hours after the last dose, 54% of the administered radioactivity was excreted with 48% in the urine, 5% in faeces and 1% in milk. At sacrifice about 6% of the dose was estimated to be associated with edible tissue. The predominant residue in all tissues and milk was unchanged parent compound accounting for 28% (kidney) to 92% (muscle) of the TRR. In kidney 2 other components each accounted for greater than 10% of the TRR. Significant metabolites in kidney were a glucuronide conjugate of the parent compound (up to 10%) and a thiazolidine-ring opened compound (up to 12%).

In laying hens dosed orally with [pyridinyl-¹⁴C-methyl]-thiacloprid for 3 days and sacrificed 6 hours after the last dose, 75% of the administered radioactivity was recovered in excreta. Less than 0.06% of the administered radioactivity was found in the eggs with about 0.7% of the dose associated with edible tissues and organs. The major residue in eggs and tissues was parent compound, accounting for between 61% and 92% of TRR.

In a dairy cattle transfer study animals were dosed with thiacloprid at dose levels equivalent to 2, 6 and 21 ppm in the diet for 28 days. The highest residues of thiacloprid observed in individual animals were as follows:

Dose, ppm	Thiacloprid, mg/kg				
	Milk	Muscle	Fat	Kidney	Liver
2	0.03	0.02	0.02	0.04	0.11
6	0.06	0.08	0.04	0.12	0.32
21	0.17	0.18	0.18	0.32	1.12

There was no preferential accumulation of thiacloprid in fat compared to muscle. The log P_{ow} for thiacloprid is 1.26 (NRA Public Release Summary, November 2001) indicating that the compound would not be expected to accumulate in fat.

The estimated dietary exposure of livestock to thiacloprid from consumption of apple pomace is 0.42 ppm in the diet (dry weight basis). Based on the available cattle transfer data residues of thiacloprid in milk, muscle, fat and kidney should be less than the LOQ of the analytical method. The maximum expected residue in liver would be around the LOQ for that tissue (0.02 mg/kg). Based on available metabolism data detectable residues are not expected to occur in poultry.

There is no indication that MRLs or import tolerances have been established in major export markets.

The potential for undue prejudice to trade is likely to be low as (i) residues in tissues most likely to be monitored (ie. muscle and fat) should be less than the LOQ and (ii) the maximum expected residue in liver is around the LOQ and is based on the assumption that livestock consume 20% of their diet (dry weight basis) as apple pomace derived from apples treated late season and harvested at the minimum withholding period.

8. Conclusions

The above discussion has highlighted that quantifiable residues of thiacloprid may occur in pome fruit treated with Calypso 480 SC, particularly when the product is applied late in the growing season. The applicant has proposed a label statement advising growers to seek further information prior to using the product on crops destined for export.

The risk to Australia's export trade in animal commodities is considered to be low. Residues in milk, muscle, fat and kidney of animals consuming apple pomace should be less than LOQ. The maximum residue in liver is expected to be around the LOQ.

Comments are sought on the potential for Calypso 480 SC to unduly prejudice Australian export trade when it is used to control codling moth and woolly aphid on pome fruit.