



## Evaluation Report for Category B, Subcategory 2.6 Application

**Application Number:** 2008-3575  
**Application:** B.2.6 – New EP – New Combination of TGAIs  
**Product:** Sepresto 75 WS  
**Registration Number:** 30972  
**Active ingredients (a.i.):** Clothianadin and Imidacloprid  
**PMRA Document Number :** 2412421

### Purpose of Application

The purpose of this application was to register a new seed treatment insecticide, Sepresto 75 WS Insecticide (56.25% clothianidin and 18.75% imidacloprid), for use on several vegetable field crops against a variety of insect pest species.

### Chemistry Assessment

Sepresto 75 WS is an end-use product containing the active ingredients; clothianidin and imidacloprid, at nominal concentrations of 56.25% and 18.75%, respectively. This product has a density ranging from 0.24 to 0.48 g/mL and a pH of 8 to 10 in 2% water. The chemistry requirements for Sepresto 75 WS have been fulfilled.

### Health Assessments

Sepresto 75 WS Insecticide was slightly acutely toxic via the oral route and was of low toxicity via the dermal and inhalation routes in rats. It was mildly irritating to the eyes and slightly irritating to the skin of rabbits. Sepresto 75 WS Insecticide was not considered to be a dermal sensitizer when tested using the local lymph node assay technique in mice.

A post-application worker exposure assessment was conducted for occupational exposures to imidacloprid and clothianidin residues from (field and greenhouse) planting vegetable seeds treated with Sepresto 75WS which are imported from the U.S. Worker exposures were considered acceptable when wearing the personal protective equipment of a long-sleeved shirt and long pants, chemical-resistant gloves, shoes plus socks, and when following the use directions and precautions on the product and treated seed labels. Planting treated seeds by-hand is not permitted.

## Maximum Residue Limits

### Imidacloprid

Residue data for imidacloprid in dried bulb onions and green onions (representative commodities of Crop Group 3-07) were submitted to support the registration of Sepresto 75 WS Insecticide. Data was previously submitted and reviewed for Crop Groups 1B, 4A, 5, 8 and 9.

Based on the residues observed in bulb vegetables Crop Group 3-07 commodities, maximum residue limits (MRLs) to cover residues of imidacloprid including metabolites containing 6-chloropyridinyl moiety in/on bulb vegetables crop will be established as shown in Table 1.

Table 1 Summary of Field Trial Data and Processing Data Used to Establish Maximum Residue Limits - Imidacloprid

Crop Matrix	Analyte	Application Rate (g a.i./ha)	PHI (days)	Residue Level (ppm)		Recommended MRL (ppm)
				Min.	Max.	
<b>Bulb Vegetables (Crop Group 3-07)</b>			<b>PMRA Document #1636675</b>			
Bulb onions (3-07A)	Imidacloprid including metabolites containing the 6-chloropyridinyl moiety	543 – 573	86 – 225	<0.05	0.08	0.15
Green onions (3-07B)		547 – 552	136 – 193	<0.02	1.50	2.5

Following the review of all available data, the MRLs for the crops noted in Table 1 above are recommended to cover residues of imidacloprid including metabolites containing the 6-chloropyridinyl moiety. Residues of imidacloprid including metabolites containing the 6-chloropyridinyl moiety in these crops at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

### Clothianidin

The purpose of this submission was to establish MRLs on commodities for an active ingredient currently registered in Canada. Residue data for clothianidin in carrots, radish roots, radish tops, bulb onions, green onions, head lettuce, leaf lettuce, spinach, broccoli, cabbage, mustard greens, tomatoes, bell peppers, non-bell peppers, cucumbers, cantaloupes, and summer squash were submitted to support the use expansion of this active on the Sepresto 75 WS label. Data was also submitted for wheat to establish an import MRL.

Based on the maximum residues observed in commodities treated according to label directions, MRLs to cover residues of clothianidin in/on crops, and livestock matrices will be established as shown in Table 2. Residues of clothianidin in processed commodities not listed in Table 2 are covered under established MRLs for the raw agricultural commodities.

Table 2 Summary of Field Trial Data and Processing Data Used to Establish Maximum Residue Limits - Clothianidin

Crop Matrix	Analyte	Application Rate (g a.i./1000 seeds)	PHI (days)	Residue Level (ppm)		Recommended MRL (ppm)
				Min.	Max.	
<b>Root Vegetables (Crop Subgroup 1B) and leaves (Crop Group 2)</b>				<b>PMRA Document #1636673</b>		
Carrot	Clothianidin	0.12	90 – 196	<0.01	0.011	0.8
Radish roots	Clothianidin	0.50	34 – 60	<0.01	0.625	
Radish tops	Clothianidin	0.50	34 – 60	<0.01	0.343	0.35
<b>Bulb Vegetables (Crop Group 3-07)</b>				<b>PMRA Document #1636675</b>		
Dry bulb onions	Clothianidin	0.20	106 – 269	<0.01	0.017	0.45
Green onions		0.12	90 – 153	0.013	0.142	
<b>Leafy Greens (Subgroup 4A)</b>				<b>PMRA Document #1636676</b>		
Head lettuce	Clothianidin	0.80	53 – 143	<0.01	0.091	0.70
Leaf lettuce		0.65	45 – 67	0.033	0.349	
Spinach		0.16	47 – 96	<0.01	0.078	
<b>Brassica Leafy Vegetables (Crop Group 5)</b>				<b>PMRA Document #1636677</b>		
Broccoli	Clothianidin	1.2	74 – 195	<0.01	0.409	0.40
Cabbage		1.2	74 – 177	<0.01	<0.01	
Mustard greens		0.1	28 – 62	<0.01	0.011	
<b>Fruiting Vegetables (Crop Group 8-09)</b>				<b>PMRA Document #1636678</b>		
Tomato	Clothianidin	0.10	112 – 174	<0.01	<0.01	0.02
Bell pepper		0.50	90 – 196	<0.01	<0.01	
Non-bell pepper (fresh)		0.50	119 – 149	<0.01	<0.01	
Non-bell pepper (dried)			130 – 149	<0.01	0.013	
<b>Cucurbit Vegetables (Crop Group 9)</b>				<b>PMRA Document #1636679</b>		
Cucumber	Clothianidin	1.0	46 – 53	<0.01	<0.01	0.01
Cantaloupe		1.0	75 – 98	<0.01	<0.01	
Summer squash		1.0	41 – 49	<0.01	<0.01	

Crop Matrix	Analyte	Application Rate (g a.i./1000 seeds)	PHI (days)	Residue Level (ppm)		Recommended MRL (ppm)
				Min.	Max.	
<b>Wheat (as import from the U.S.)</b>				<b>PMRA Document #1636680</b>		
Wheat grain	Clothianidin	125 g a.i./100 kg seeds	86 – 307	<0.01	<0.01	0.01

An MRL of 0.02 ppm is proposed to cover residues of clothianidin in fat, meat and meat byproducts of cattle, goats, hogs, horses, and sheep.

Following the review of all available data, the MRLs for the crops noted in Table 2 are recommended to cover residues of clothianidin. Residues of clothianidin in these crops, including livestock matrices, at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

### Environmental Assessment

Sepresto 75 WS Insecticide is a new end use product with a new combination of active ingredients; clothianidin and imidacloprid. Currently, clothianidin is conditionally registered for use as a seed treatment on a number of different crops. Imidacloprid is registered for use as a seed treatment on a number of crops.

The fate and behaviour of imidacloprid in the environment has been presented previously in Regulatory Note REG2001-11, *Imidacloprid*, Regulatory Note R97-01, *Admire*, and in the Evaluation Report ERC2011-03, *Confidor 200 SL containing Imidacloprid*.

The fate and behaviour of clothianidin in the environment has been presented previously in Regulatory Note REG2004-06, *Clothianidin - Poncho 600 Seed Treatment Insecticide*.

Imidacloprid and clothianidin are persistent, systemic insecticides which may result in exposure to pollinators via residues in pollen, nectar and guttation water in crops. Precautionary label statements to minimise the effects on bees were required for Sepresto 75 WS Insecticide. As the crops and application rates for Sepresto 75 WS Insecticide were similar to the registered individual application rates for imidacloprid and clothianidin, the use of Sepresto 75 WS Insecticide as a seed treatment for various seeds was considered comparable to existing uses.

Imidacloprid is currently undergoing re- evaluation, announced under Health Canada's Pest Management Regulatory Agency's (PMRA) re-evaluation initiation schedule for 2010-2013 (please refer to REV2011-03, *Pest Management Regulatory Agency Re-evaluation Initiation Schedule*). Clothianidin has outstanding environmental data requirements for conversion to full registration. During these upcoming evaluations, the PMRA will re-assess the risks to pollinators.

Environmental hazard statements were required on the label for Sepresto 75 WS Insecticide, including statements regarding risks to bees.

In Canada, three incident reports have been submitted to the PMRA suggesting possible honey bee mortality from exposure to clothianidin. The PMRA conclusion for these incidents can be found under Incident Reports 2010-4374, 2010-3100 and 2010-3391 which are posted on the PMRA electronic Public Registry. The PMRA will consider these three incidents and any other reported incidents on honey bees in conjunction with new data requested when clothianidin is reconsidered for full registration.

### Value Assessment

Reports from 30 field trials conducted in Europe (Netherlands, Germany, France, Spain and Italy) and the U.S. (Ohio, California and Florida) between 2005 and 2007 were submitted in support of the use claims for Sepresto 75 WS. These studies tested 20 pest/crop combinations. In addition, 10 laboratory studies and 23 field trials were submitted which tested seed safety and crop tolerance.

Efficacy trials tested either Sepresto 75 WS, a combination of clothianidin and imidacloprid in the same ratio as that found in Sepresto 75 WS, or both. The rates tested in these efficacy trials ranged from 0.047 up to 1.33 g a.i. per 100 kg seed. Trials also included treatments of imidacloprid or clothianidin only and an untreated control (UTC). All trials were conducted in small plots in a randomised complete block design with 4 replicates per treatment. In some trials, all seeds including the UTC were treated with a fungicide seed treatment, which was generally applied prior to the insecticide treatment.

Crop tolerance data on a variety of parameters including germination, abnormal seedlings, plant emergence and injury were submitted for many of the proposed crops. No significant adverse effects were seen in the crop tolerance data.

The value information supported the use of Sepresto 57 WS on carrots, onions (bulb), leek, onion (bunching), lettuce (head and leaf), cabbage, broccoli, squash (winter and summer), melon, cucumber, tomato, and pepper. Supported pests are carrot rust fly, thrips, leafminer, aphids, flea beetle, onion maggot, and seed corn maggot. The supported use claims and rates for Sepresto 75 WS are summarised in Table 3.

Table 3 Supported Control Claims for Sepresto 75 WS

Crop	Supported Claim
Carrot	Control of carrot rust fly at 0.062 to 0.12 g Sepresto per 1000 seeds
Onion (bulb), leek	Control of thrips, onion maggot and seed corn maggot at 0.21 g Sepresto per 1000 seeds
Onion (bunching)	Control of thrips, onion maggot and seed corn maggot at 0.16 g Sepresto per 1000 seeds
Lettuce (head and leaf)	Leafminer (suppression) and aphids (control) at 1.06 g Sepresto per 1000 seeds
Cabbage and broccoli	Control of aphids and flea beetle at 1.6 g Sepresto per 1000 seeds
Tomato	Thrips and aphids (control) and leafminer (suppression) at 0.067 g Sepresto per 1000 seeds

Pepper	Control of thrips, aphids and leafminer at 0.44 g Sepresto per 1000 seeds
Squash (winter and summer), melon, and cucumber	Control of aphids and thrips at 1.33 g Sepresto per 1000 seeds

## Conclusion

The PMRA has completed an assessment of available information and has found the information sufficient to support the registration of a new seed treatment insecticide, Sepresto 75 WS Insecticide (56.25% clothianidin and 18.75% imidacloprid), for use on several vegetable field crops against a variety of insect pest species.

## References

PMRA Document Number	References
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1175493	Dust Testing of Gaucho 75WP Treated Westar Canola Seed. (2985; RD2240) (Gaucho 75ST; Date of Submission: July 23, 1997). Uniroyal Chemical Ltd.
1571553	Determination of Operator Exposure to Imidacloprid During Loading/Sowing of Gaucho Treated Maize Seeds Under Realistic Field Conditions in Germany and Italy
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1636673	2008, Poncho-Beta 453.3 FS - Magnitude of the residue in/on carrots and radishes, DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.2
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1636676	2008, Clothianidin+imidacloprid WS (56.25 percent+18.75 percent w/w) - Magnitude of the residue in/on leafy greens (Crop Subgroup 4A), DACO: 7.7,IIIA 8.3.4
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