

3

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**



OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 6 October 2010

SUBJECT: Clothianidin – Human Health Risk Assessment for the Proposed Use as a Trunk Spray to Ornamental Trees.

PC Code: 044309	DP Barcode: D374643
MRID No.: None	Registration No.: 59639-152
Petition No.: N/A	Regulatory Action: Section 3
Assessment Type: Single Chemical	Registration Case No.: N/A
TXR No.: None	CAS No.: 210880-92-5
Decision No.: 428318	40 CFR 180.586

FROM: Michael A. Doherty, Ph.D., Senior Chemist *Michael A. Doherty*
Shih-Chi Wang, Ph.D., Biologist *Shih-Chi Wang*
Risk Assessment Branch II
Health Effects Division (7509P)

THROUGH: Richard A. Loranger, Ph.D., Senior Scientist *R. Loranger*
Risk Assessment Branch II
Health Effects Division (7509P)

TO: Dani Daniel/Venus Eagle, RM 01
Insecticide-Rodenticide Branch
Registration Division (7505P)

The petitioner, Valent Corporation, has requested use of the insecticide clothianidin {(E)-N-[(2-Chloro-5-thiazolyl)methyl]-N'-methyl-N''-nitroguanidine} as a basal bark trunk application to ornamental trees. The requested use is for Arena 50 WDG Insecticide (EPA Reg. No. 59639-152), containing 50% active ingredient (a.i.).

The most recent aggregate risk assessment for clothianidin showed no risks of concern for any population subgroup (M. Doherty *et al.*, D355373, 13 August 2009). As this use is restricted to ornamental trees and the use is unlikely to result in residues of clothianidin in drinking water which are greater than those already assessed, there are no concerns regarding dietary exposure. HED has assumed that the requested use includes potential treatments by homeowners and has assessed residential exposure for mixer/loader/applicators (S. Wang, D375369, 30 September 2010). The MOE associated with this use is 2,600 (Table 1).

*Health RHC
10/29/10
WJ*

Occupational risks associated with the proposed use have been evaluated (S. Wang, D375369, 30 September 2010) and no risks of concern were identified. Although a margin of exposure (MOE) for handlers was calculated to be less than 100 (the level of concern), the occupational assessment notes that the MOE is based on very conservative assumptions and that the MOE is considered not to exceed HED's level of concern. Due to the nature of this use, a quantitative post-application assessment was not conducted. The handler MOE is summarized below.

Table 1. Summary of Handler Margins of Exposure Associated with Basal Bark Application of Clothianidin (from S. Wang, D375369). All estimates are for mixer/loader/applicator activities with application by low-pressure hand wand.					
Exposure Scenario	Mitigation Level	Application Rate (lb ai/Gal)	Amount Treated (Gal/day)	Combined Daily Dose (mg/kg/day)	MOE ^a
Residential	Long Pants, Long-Sleeved Shirt	0.15	5	0.003798	2,600
Occupational	Baseline + Gloves	0.15	40	0.1186	83

^a MOE = NOAEL (9.8 mg/kg/d) / combined daily dose. UF = 100.

Residential Exposure

For adults the residential application and post-application exposure estimates from the use of clothianidin on turf have been combined with the residential exposure estimate from the requested basal bark application to provide a highly conservative estimate of combined residential exposure (Table 2). Even with this conservative assumption, the combined residential MOE is are greater than 1000 and therefore adult residential exposures are not of concern. Total post-application exposure for toddlers from the turf use were calculated previously and also are not of concern (MOE = 1300).

Table 2. Summary of Residential Post-Application Exposure and Risk Estimates.		
Activity	Exposure (Dose) mg a.i./kg bw/day	MOE
Adult dermal application to turf	0.000026	370,000
Adult dermal post-application turf contact	0.00108	9,100
Adult golfer post-application turf contact	0.000075	130,000
Adult basal bark application (from Table 1)	0.003798	2,600
Adult combined	0.004979	1,900
Toddler oral hand to mouth from contacting treated turf	0.0059	1,700
Toddler incidental oral ingestion of treated soil	0.00002	490,000
Toddler dermal post-application turf contact	0.00155	6,300
Toddler combined	0.00747	1,300

Aggregate Risk

Acute and chronic aggregate risk estimates are equivalent to the acute and chronic dietary risk estimates which, as noted above, are not of concern.

Short- and intermediate-term aggregate risk estimates for clothianidin have been re-calculated to include potential residential exposure to adults from the proposed use on tree trunks. The revised estimates are provided in Table 3 along with the unchanged exposures for infants and young

children (M. Doherty, D355373, 13 August 2009). As with the previous assessment, the short- and intermediate-term aggregate risk MOEs are all greater than 100 and indicate that aggregate risks are below HED's level of concern.

Population Subgroup	Total Residential Exposure, mg/kg/day	Chronic Dietary Exposure, mg/kg/day	Aggregate Exposure ¹ , mg/kg/day	MOE ²
U.S. Population (total)	0.004979	0.004582	0.009561	1,000
All infants (< 1 year)	0.00747	0.012680	0.020150	480
Children 1-2 yrs	0.00747	0.018429	0.025899	380
Children 3-5 yrs	0.00747	0.012188	0.019658	500
Children 6-12 yrs	0.004979	0.005801	0.010780	910
Youth 13-19 yrs	0.004979	0.003194	0.008173	1,200
Adults 20-49 yrs	0.004979	0.003229	0.008208	1,200
Adults 50+ yrs	0.004979	0.003438	0.008417	1,200
Females 13-49 yrs	0.004979	0.003325	0.008304	1,200

The population subgroup with the highest estimated exposure/risk is **bolded**.

¹ Aggregate Exposure = Residential Exposure + Chronic Dietary Exposure

² Aggregate MOE = NOAEL (9.8 mg/kg/day) ÷ Aggregate Exposure (mg/kg/day)

Conclusion

There are no human health concerns that would preclude granting the requested use.



13544

R186730

Chemical Name: Clothianidin

PC Code: 044309

HED File Code: 14000 Risk Reviews

Memo Date: 10/6/2010

File ID: 00000000

Accession #: 000-00-0136

HED Records Reference Center
11/2/2010