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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

June 12, 2007

PC Code 128831 & 044309

DP Barcode: D335254

MEMORANDUM

SUBJECT: EFED Section 3 Registration for a Clothianidin and Beta-cyfluthrin
Combination Product for use on Sugar Beets as a Seed Treatment.

FROM: N.E. Federoff, Wildlife Biologist *NEF*
José L. Meléndez, Chemist *JLM (for)*
Environmental Risk Branch V
Environmental Fate and Effects Division (PY1 S-7507)

THROUGH: Mah T. Shamim, Ph.D., Chief *M. Shamim*
Environmental Risk Branch V
Environmental Fate and Effects Division (PY1 S-7507C) *6/15/07*

TO: Kable Davis, Risk Manager Reviewer
Venus Eagle, Risk Manager 01
Registration Division (PY1 S-7228)

EFED has completed the assessment for the use of PONCHO BETA, a seed treatment containing both Clothianidin and Beta-cyfluthrin to be used on sugar beet seed. Clothianidin is already utilized as an active ingredient in PONCHO 600 (EPA Reg. No. 264-789) and Cyfluthrin is utilized as an active ingredient in BAYTHROID 2 (EPA Reg. No. 264-745) as well as in RENOUNCE 20WP (EPA Reg. No. 264-784). Beta-cyfluthrin is an enriched isomer mixture of cyfluthrin and is utilized as an active ingredient in BAYTHROID XL (EPA Reg. No. 264-840). Risks for clothianidin will be based on a previous assessment on corn and canola seed (D278110) as well as 3 previous Section 18 Emergency Exemption requests for the use of clothianidin on sugar beet seed (D326569, D326640, D326590 and D326583). For beta-cyfluthrin, EFED will rely on a previous assessment for tobacco (D316313). Most other registered crops have multiple application rates of 0.044 lbs ai/A, which are 4X more than the current single application seed rate for sugar beets of 0.0125 lbs ai/A. The current rate is also 20X lower than the approved rate for cotton (0.25 lbs ai/A for BAYTHROID XL). Generally, seed treatments provide for less aquatic risk due to a lower potential for exposure since the seed is normally covered and there is little or no drift. Also, application rates per acre are



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usually lower than normal spray treatments. However, it should be noted that [REDACTED] is present in the PONCHO BETA formulation and may increase bioavailability of the compounds, should exposure occur. A listing of endangered species that may be at risk of exposure is attached.

Data Needs:

EFED believes that a seed leaching study would greatly increase certainty regarding a more realistic estimate of the amount of available Clothianidin and Beta-cyfluthrin residues on the seed surface.

Endangered Species Listing:

Species in Counties by State and Taxa

No species were excluded
 Minimum of 1 Acre
 All Medium Types Reported

sugarbeets for seed

AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY

California

<u>Bird</u>	<u>Bird</u>	<u>Bird</u>
Douglas	Eagle, Bald	
	<i>Haliaeetus leucocephalus</i>	
Eagle, Bald	Lane	
Polk	Arenac	
<i>Haliaeetus leucocephalus</i>		
Northern Spotted	Huron	Owl,
Imperial	St. Clair	<i>Strix</i>
<i>occidentalis caurina</i>	Tuscola	
Pelican, Brown		
Benton		
<i>Pelecanus occidentalis</i>		
	Plover, Piping	
Imperial	Clackamas	
Douglas	<i>Charadrius melodus</i>	
Rail, Yuma Clapper	Huron	
Jackson		
<i>Rallus longirostris yumanensis</i>		
	<u>Mammal</u>	
Imperial	Josephine	
Lane		
<u>Mammal</u>		
Linn	Bat, Indiana	
	<i>Myotis sodalis</i>	

Sheep, Peninsular Bighorn
Marion
Ovis canadensis
Polk

Imperial
Washington

Reptile
Yamhill

Tortoise, Desert
Brown
Gopherus agassizii
occidentalis

Imperial
Lane

Colorado

Western Snowy

Bird

Douglas
Crane, Whooping
Lane
Grus americana

Mammal

Weld
Columbian White-tailed
Eagle, Bald
Odocoileus virginianus leucurus
Haliaeetus leucocephalus

Douglas
Weld

Mammal

Mouse, Preble's Meadow Jumping
Zapus hudsonius preblei
Bald

Weld
leucocephalus

Michigan

marmoratus

Linn
Huron

Sanilac
Polk
St. Clair

Tuscola

Oregon

Bird

Eagle, Bald

Haliaeetus leucocephalus
Charadrius alexandrinus nivosus

Benton

Clackamas

Douglas

Jackson

Josephine

Lane

Linn

Marion

Polk

Washington

Murrelet, Marbled

Brachyramphus marmoratus

Box Elder

Pelican,

Pelecanus

Plover,

Deer,

Utah

Bird

Eagle,

Haliaeetus

13 Species Affected:

Inverse Name: Status:	Taxa:	Co. occurrence:
Bat, Indiana Endangered	Mammal	4
Crane, Whooping Endangered	Bird	1
Deer, Columbian White-tailed Endangered	Mammal	1
Pelican, Brown Endangered	Bird	2
Plover, Piping Endangered	Bird	1
Rail, Yuma Clapper Endangered	Bird	1
Sheep, Peninsular Bighorn Endangered	Mammal	1
Eagle, Bald Threatened	Bird	17
Mouse, Preble's Meadow Jumping Threatened	Mammal	1
Murrelet, Marbled Threatened	Bird	3
Owl, Northern Spotted Threatened	Bird	11
Plover, Western Snowy Threatened	Bird	2
Tortoise, Desert Threatened	Reptile	1

No species were selected for exclusion.

Dispersed species included in report.

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Date: 23 February 2006
Chemical Code: 044309
DP Barcodes: 326569, 326640,
326590, 326583

MEMORANDUM

SUBJECT: Section 18 Request for Use of Clothianidin on Sugar Beet Seed to Control the Beat Leafhopper (Vector of Beet Curly Top Virus).

FROM: Jennifer Leyhe, M.S., Biologist
Ronald Parker, Ph. D., Senior Environmental Engineer
Environmental Risk Branch 5
Environmental Fate and Effects Division 7507C

Jennifer Leyhe 23 Feb 06
Ronald Parker 2/23/06

THROUGH: Jean Holmes, Acting Branch Chief
Environmental Risk Branch 5
Environmental Fate and Effects Division 7507C

Jean Holmes 2/23/06

TO: Stacie Groce, Risk Manager Reviewer
Dan Rosenblatt, Risk Manager
Emergency Exemption Section 1
Registration Division

The Environmental Fate and Effects Division (EFED) have completed its review of a Section 18 Emergency Exemption request (DP Barcode 326590) for the treatment of clothianidin to sugar beet seed in treatment facilities in Colorado, North Dakota, Oregon, and Wyoming from 15 January 2006 to 31 July 2006. These seeds would then be planted to control leaf hoppers (vector of beet curly top virus) in Colorado, Idaho, Montana, Oregon, Washington, and Wyoming. The State Departments of Agriculture in Colorado, North Dakota, Oregon, and Wyoming are requesting the commercial application of 60g a.i. per ~100,000 seeds (~1 kg by weight of raw seeds). A maximum of 1 treatment may be made to sugar beet seed prior to shipping. They suggest this would amount to 30 g a.i. clothianidin/Acre (1.6 oz a.i./Acre or 0.07 lb/Acre).

Based on available effects data and treatment concentration, estimated risk quotient (RQ) values exceed the endangered species level of concern for acute risk ($RQ \geq 0.1$) to birds and acute and chronic risk to birds and mammals. Eleven species of birds and mammals are listed



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

OFFICE OF PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

2/20/03

Subject: EFED Risk Assessment for the Seed Treatment of Clothianidin 600FS on Corn and Canola (PC Code 044309; DP Barcode: D278110)

To: Meredith F. Law, Chief Insecticide Branch
Terri Stowe, NAFTA Joint Review Coordinator
Registration Division (7505C)

From: Miachel Rexrode, Ph.D., Senior Aquatic Biologist *Miachel Rexrode 2/20/03*
Michael Barrett, Ph.D., Senior Chemist *Michael Barrett 2/20/03*
Jerry Ellis, Biologist *M. Rexrode for J. Ellis 2/20/03*
Gabe Patrick, Biologist *M. Rexrode for G. Patrick 2/20/03*
Allen Vaughan, Biologist *Allen W. Vaughan*
James Felkel, Biologist, Secondary Environmental Effects Reviewer *J. Felkel 2/20/03*
Jose Melendez, Chemist, Secondary Environmental Fate Reviewer *Jose Melendez for J. Melendez 2/20/03*
Environmental Risk Branch V
Environmental Fate and Effects Division (7507C)

Through: Mah Shamim, Ph.D., Chief *Mah Shamim 2/21/03*
Environmental Risk Branch V
Environmental Fate and Effects Division (7507C)

Attached is the Environmental Fate and Effects Division's (EFED) environmental risk assessment of the Section 3 registration of the insecticide, clothianidin for seed treatment on corn and canola to control a host of insect pests (e.g., aphids, flea beetles, wireworms, chinch bugs, black cutworm, etc.). This registration is being conducted as a joint review between the regulatory agencies of Canada (PMRA), the United States (EPA), and Australia (NRA).

Based on laboratory and field studies submitted to the Agency, EFED has concluded that the proposed seed treatment use of clothianidin on corn and canola should result in minimal acute

toxic risk to birds. However, our assessment also shows that exposure to treated seeds through ingestion may result in chronic toxic risk to non-endangered and endangered small birds (e.g., songbirds) and acute/chronic toxicity risk to non-endangered and endangered mammals. The ingestion of treated seeds is a concern because several species of birds and mammals frequent corn and canola fields seeking forage and grit. This feeding strategy, raises a concern at the chronic level because only a few seeds may be necessary to cause reproductive and/or developmental effects (e.g., 1 - 2 corn seeds for small and medium size mammals). EFED is also concerned with the possibility of chronic toxic exposure to honey bees. Considering the toxicity profile and reported incidents of other neonicotinoids (e.g., imidacloprid), the proposed seed treatment with clothianidin has the potential for toxic risk to honey bees, as well as other pollinator insects. As a result of this concern, EFED is asking for additional chronic testing on bee hive activity (e.g., effects to queen, larvae, etc.). The results of our Tier I screening level exposure assessment also suggest that exposure to aquatic systems may occur through runoff after treated seed have been planted. Although this runoff should not result in toxic risk to fish (freshwater or estuarine/ marine), there is the possibility of acute toxic risk to aquatic invertebrates. However, with regard to plants, clothianidin does not appear to present a risk to terrestrial or aquatic vascular and nonvascular plants.

The fate and disposition of clothianidin in the environment suggest a compound that is a systemic insecticide that is persistent and mobile, stable to hydrolysis, and has potential to leach to ground water, as well as runoff to surface waters. The high persistence of clothianidin (aerobic soil metabolism and terrestrial field dissipation half-lives ranging from half a year to several years) would cause accumulation of the chemical in soils with repeated uses.

Outstanding Data Requirements

OPPTS 850.1735: Whole Sediment Acute Toxicity Invertebrates, Freshwater. This is a 28 day test that measures survival, growth and emergence of *Chironomus riparius* that have been exposed to pesticide spiked sediment. EFED is requesting this acute sediment toxicity test because clothianidin is toxic to aquatic invertebrates, persistent in the environment, and binds to sediment over time.

Field Test for Pollinators (141-5): The possibility of toxic exposure to nontarget pollinators through the translocation of clothianidin residues that result from seed treatment (corn and canola) has prompted EFED to require field testing (141-5) that can evaluate the possible chronic exposure to honey bee larvae and queen. In order to fully evaluate the possibility of this toxic effect, a complete worker bee life cycle study (about 63 days) must be conducted, as well as an evaluation of exposure and effects to the queen.

Aerobic Aquatic Metabolism (162-4): 1) Although two studies were submitted for this requirement, the experimental design was not in compliance with guidelines (soil and water were pre-incubated before applying the test substance) and (2) aerobic conditions were not fully

maintained during the course of the study as indicated by the low redox potential that developed in the sediment in another study, no sediment was used. A new study is required.

Seed Leaching Study: EFED believes that a seed leaching study would greatly increase certainty regarding a more realistic estimate of the amount of available clothianidin residues on the seed surface. This in turn would allow a refinement of exposure estimates and environmental concentration values (EECs).

Endangered Species

The Agency's level of concern for endangered and threatened birds, mammals and nontarget insects is exceeded for the proposed use of clothianidin on corn and canola. This concern to mammals and birds is based on chronic endpoints such as reproductive and developmental effects. The concern for nontarget insects is based on the uncertainty regarding potential chronic effects to honey bees and the toxicity profile and reported incidents to honey bees from seed treatment of other neonicotinoids (e.g., imidacloprid). The registrant must provide information on the proximity of Federally listed birds, mammals and nontarget insects to the proposed use sites. This requirement may be satisfied in one of three ways: 1) having membership in the FIFRA Endangered Species Task Force (Pesticide Registration [PR] Notice 2000-2); 2) citing FIFRA Endangered Species Task Force data; or 3) independently producing these data, provided the information is of sufficient quality to meet FIFRA requirements. The information will be used by the OPP Endangered Species Protection Program to develop recommendations to avoid adverse effects to listed species.

Uncertainty

Environmental Fate and Exposure

There is additional uncertainty with regard to aquatic photolysis of clothianidin where the half-life was calculated at < 1 day (core study) while a slow rate of dissipation was observed in field studies. The range of values given for surface water-source drinking water represents uncertainty with regard to the importance of photodegradation in the long-term fate of clothianidin in natural waters.

Clothianidin has the properties of a chemical which could lead to widespread ground-water contamination, but no ground-water monitoring studies have been conducted to date. Should the registrant request field uses involving direct application of clothianidin to the land surface, Prospective Ground-Water Monitoring Studies may be needed to evaluate fully the potential impact of such uses.

Ecological Effects

There is concern for the persistence of clothianidin in aquatic sediments, and uncertainty about effects on benthic organisms. Therefore, EFED requests submission of a sediment toxicity test on the midge, *Chironomus riparius*, as a condition of registration.

Other neonicotinoid compounds like imidacloprid (e.g., sunflower seed treatment) have resulted in incidents to honey bees. The National Union of French Beekeepers had concerns regarding imidacloprid (GAUCHO) seed treatment to sunflowers after beekeepers noted that honey bees were showing modifications of behavior that were reflected in foraging and orientation that eventually resulted in a drastic change in hive conditions and bee survival. Further research by the Le Centre Technique Interprofessionnel des Oleagineux (CETIOM) confirmed imidacloprid toxic residue levels in the sunflower nectar. This action has prompted France to ban the use of imidacloprid for sunflower seed treatment. Since clothianidin has a similar toxicity profile as imidacloprid and is a member of the same family of compounds, there is uncertainty regarding the toxic risk to developing honey bee larvae, as well as the welfare of the queen from long term exposure to clothianidin residues that can be stored in the hive in honey and/or pollen.

There is uncertainty surrounding clothianidin's possible role as an endocrine disrupter as noted from mammalian developmental and avian reproductive effects. This issue is compounded by the fact that clothianidin is an analog of nicotine and that studies in the published literature suggest that nicotine, when administered, causes developmental toxicity, including functional deficits, in animals and/or humans that are exposed in utero. Mammalian data shows that exposure to clothianidin can result in developmental effects (rabbit) that include premature deliveries, decreased gravid uterine weights, and increase incidence of missing lung lobe in fetus. The mammalian data also suggests that chronic toxicity in mammals can be manifested as systemic effects that can include decreased body weight gains and delayed sexual maturation (males only); decreased absolute thymus weight in F1 pups (both sexes), and increased stillbirths (F1 and F2 litters). Reproductive effects were also noted for adult rats that included decreased sperm motility and increased number of sperm with detached heads. Although these effects did not reduce rat fecundity they do raise an uncertainty as to possible reproductive effects to other species that may have a more limited (less frequent) reproductive capability.

Label Recommendations

Manufacturing Use Product

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

End Use Product

This chemical has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.

This compound is toxic to birds and mammals. Treated clothianidin seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect clothianidin seeds spilled during loading.

This product is toxic to aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters.

This compound is toxic to honey bees. The persistence of residues and the expression of clothianidin in nectar and pollen suggests the possibility of chronic toxic risk to honey bee larvae and the eventual stability of the hive.

Executive Summary

The registrant, Bayer Corporation, is submitting a proposal for clothianidin to be used as a seed treatment on corn and canola and to be considered as a Reduced Risk chemical at EPA. This registration is also being proposed for joint review between the regulatory agencies of Canada (PMRA), the United States (EPA), and Australia (NRA).

This compound is a member of the neonicotinoids (chloronicotinyl insecticides) that were developed as a chlorinated analog of nicotine. These compounds target the same receptor site (AChR) and activate post-synaptic acetylcholine receptors. Clothianidin, like other neonicotinoids, is an agonist of acetylcholine, the neurotransmitter that stimulates the nAChR. The fate and disposition of clothianidin in the environment shows a compound that is persistent, stable to hydrolysis, and mobile with the potential to leach to ground water and runoff to surface water. This proposed seed treatment use reduces the possibility of acute toxic risk to birds and mammals. However, EFED believes that this use pattern has the potential for chronic toxic risk to birds (≤ 0.178 kg) and mammals (0.15 - 0.035 kg) through seed ingestion during foraging in treated fields, as well as acute toxic risk to aquatic invertebrates from runoff. The possible chronic effects to birds (eggshell thinning) and mammals (reproductive, developmental) from ingestion of treated seeds suggest chronic toxic risk, Endocrine Disruption concerns, and Endangered Species triggers. These chronic effects in mammals can include decreased body weight gains and delayed sexual maturation (males only); decreased absolute thymus weight in F1 pups (both sexes), and increased stillbirths (F1 and F2 litters). Reproductive effects were also noted for adult rats that included decreased sperm mobility and increased number of sperm with detached heads. These effects could especially result in toxic risk to those species that have a limited reproductive capacity (e.g., few litters or broods, or those animals that reproduce only once per year). Although effects on sperm mobility may not effect the number of offspring in some cases, there can be an impact on the ratio of gender composition (e.g., more males produced as opposed to females) which will directly result in population reductions. Developmental effects were also noted in rabbits at 75 mg/kg/day (LOAEL = 75 mg/kg/day), and included premature deliveries, decreased gravid uterine weights, and increased litter incidence of missing lung lobe in the fetus. Although EFED does not develop a risk assessment on non target insects, information from standard tests and field studies, as well as incidents noted from the seed treatment application of other neonicotinoids (imidacloprid), suggest an uncertainty regarding the potential for chronic toxic risk of this compound to honey bees and other beneficial insects. The persistence of residues and the expression of clothianidin in nectar and pollen suggests the possibility of chronic toxic risk to honey bee larvae that may eventually affect the stability of the hive. With regard to phytotoxicity, clothianidin does not appear to present a risk to terrestrial or aquatic vascular and nonvascular plants.