5-6-93

DP Barcode :D188965
PC Code No : 129099
EEB Out : MAY 6 1993

To: Dennis Edwards, Jr.
Product Manager 19
Registration Division (H7505C)

From: Anthony Maciorowski, Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 3125-URT, 3125-URA
Chemical Name : Imidacloprid
Type Product : Isecticide
Product Name : NTN 33893 2.5% G, 0.62%G
Company Name : Miles Inc.
Purpose : reconsideration of Risk Assessments

Action Code : 116 Date Due : 7/7/93
Reviewer : Dana Lateulere

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

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DP Barcode :D188961
PC Code No : 129099
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To: Dennis Edwards
Product Manager 19
Registration Division (H7505C)

From: Anthony F.Maciorowski, Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # :3125-URI
Chemical Name :Imidacloprid
Type Product :Insecticide
Product Name :NTN 33893
Company Name :Miles Inc.
Purpose :Reconsider Risk Assessments and Restricuted Use.

Action Code : 116 Date Due : 7/7/93
Reviewer : Dana Lateulere

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

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

MAY 6 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: Reconsideration of Non-food Use Risk Assessments for NTN 33893 [2.5% Granular, 0.62% Granular, NTN 33893-2 Flowable], DP#'s D188961, D188965.

To: Dennis Edwards, PM 19
Registration Division, H7505C

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division, H7507C

Douglas A. Urban 5/4/93

Miles Inc. has requested that the EEB reconsider the risk assessments for the various pending registrations for NTN 33893. Reconsideration has been made in several areas as follows:

Aquatic

The Surface Runoff model for NTN 33893 on turf has been completed by the EFGWB; the following are the results that will be used for risk assessments [as adapted by the Aquatic Field Study Team, 3/18/93]:

Acute risk:
-the range for the maximum instantaneous EEC = **0.37 - 5.53 ppb**
-the 1 in 10 year (10%) maximum instantaneous = **≥ 3.84 ppb**

Chronic risk:
-the range for the 21 day EEC = **.014 - 0.186 ppb**
-the 1 in 10 year (10%)maximum 21 day EEC = **.160 ppb**

The following are the aquatic 'Levels of Concern' (LOC) and those species that have been exceeded for each:

▸**Acute LOC = 1/10 LC50 ≤ EEC ≤ 1/2 LC50** = consideration for restricted use
- Mysid sp. (1/10 LC50 = 3.77 ppb)

▸**Chronic LOC = EEC ≥ LEL** (low effect level)
- Mysid sp. (LEL = 32.6 ppb) (1.326 ppb)

Based on the results of the runoff model, the previous concern for chronic effects to fish has been alleviated.

A computer model has not been run for the Ornamental uses. The EFGWB suggests using the results of the model for potatoes as

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an indication of the runoff concentrations expected for the various ornamental uses [R. Parker, 3/25, pers. comm.]. The following will be utilized for the risk assessments:

Acute risk:
-the range for the maximum instantaneous EEC = **2.35 - 64.5 ppb**
-the 1 in 10 year (10%) maximum instantaneous = **37.5 ppb**

Chronic risk:
-the range for the 21 day EEC = **0.136 - 1.79 ppb**
-the 1 in 10 year (10%) maximum 21 day EEC = **1.086 ppb**

The following are the aquatic 'Levels of Concern' (LOC) and those species that have been exceeded for each:

- **Acute LOC = EEC > 1/2 LC50** = high concern, regulatory action
  - Mysid sp. (1/2 LC50 = 18.9 ppb)
  - Hyalella sp. (1/2 LC50 = 27.5 ppb)
  - Midge sp. (1/2 LC50 = 34.5 ppb)

- **Acute LOC = 1/10 LC50 ≤ EEC ≤ 1/2 LC50** = consideration for restricted use
  - Mysid sp. (1/10 LC50 = 3.77 ppb)
  - Hyalella sp. (1/10 LC50 = 5.5 ppb)
  - Midge sp. (1/10 LC50 = 6.89 ppb)

- **Chronic LOC = EEC≥ LEL** (low effect level)
  - -Mysid sp. (LEL = ~~.326~~ pptr) 326 (.326 ppb)

Terrestrial

Mallard

Miles Inc. resubmitted eggshell thickness data for reanalysis of the Avian Reproduction Study performed on the Mallard Duck (MRID No. 424805-02). (This is the second submission for this guideline requirement, the first, MRID NO. 420553-13, was classified as invalid due to a high percentage of cracked eggs). Analysis of the data shows that the eggshell thicknesses are rather high, thus questioning whether the birds used were "phenotypically indistinguishable from wild birds" as recommended in the protocols. The mean eggshell thickness of the control birds was 0.45 mm, the range of control bird eggshell thickness was 0.38 - 0.54 mm. Compared with historical data, these numbers are relatively high:

	Mean	Range
Mallard Repro. Test 1992 [1]	**.45**	**.38 - .54 mm**
Mallard Repro. Test 1991 [2]	.37	.32 - .41 mm
Wildlife International (1983-87)	.39	.37 - .43 mm
Huntington Labs (1980)	.32	.31 - .33 mm
Miles Inc. "normal range" (1991) [3]		.31 - .33 mm

[1] *MRID NO. 424805-02, NTN second Avian Repro. submission.*
[2] *MRID No. 420553-13, NTN first Avian Repro. submission.*
[3] *Miles Inc. (formerly Mobay Corp., Attachment 4 of memo to J. Akerman from T. Stafford regarding Avian Reproduction Study of Baytan/Summit, 5/13/91).*

The eggshells in the latest Reproduction submission were found to be thicker than historically "normal" eggs. Therefore, the original concern, 'if eggshell thickness is being affected by exposure to NTN 33893', has yet to be addressed. The data cannot be used to determine a NOEC or LEL. Senior Avian Biologists within EEB concur that the data are questionable. If the registrant can explain why the eggshell thicknesses are not in the "normal range", even by their own standards, EEB will reconsider this matter. Otherwise, the eggshell thickness portion of the study will need to be repeated.

A simulated turf study (MRID No. 422563-07) with NTN 33893 240 FS at a rate of 0.5 lb a.i./A was performed by the registrant to determine the magnitude of residues in treated turf verdure. Residues ranged from 40 to 45 ppm immediately after treatment and dissipated to 0.15 to 0.31 ppm 62 days after treatment. The turf grass residues obtained from the registrant will be utilized to determine the exposure to herbivorous birds. However, the risk to these birds cannot be determined until the question of a NOEC for eggshell thickness is resolved.

Songbird

Granular exposure to songbirds is still of concern. The acute oral LD50 for House sparrows was determined to be 41 mg/kg; as stated in CFR 40, 152.170 (c)(2)(i), a granular pesticide intended for outdoor use with an avian oral LD50 of 50 mg/kg or less will be "considered for restricted use classification". EEB concludes that there is a potential for exposure to songbirds by the proposed ornamental uses such as trees, shrubs, evergreens, flowers, foliage plants and bulb crops, nurseries, plantscapes and garden center areas [only Christmas tree and wood production plantations are limited to "in furrow applications only"]. By labeling a pesticide as Restricted Use the Agency is acknowledging there is a level of risk to wildlife. While restricted use does not reduce the potential risk from application according to the label, it would limit use to those especially trained in the correct application procedures. This would limit hazardous exposure that would occur from problems such as over-application, treatment of non-target areas, application when conditions favor transport from the treated area or failure to follow risk reduction measures. As mentioned in other reviews, mandatory incorporation of the granules after application may minimize the avian risk. At this time, EEB has not received the Terrestrial Field Study on Merit 0.62% Granular which Miles Inc. states may refute the presumption of risk to songbirds.

EEB has stated that the risks to waterfowl and upland gamebirds from dietary exposure are minimal. However, there is a concern, based upon the evidence from the songbird acute oral toxicity data, that this class of birds can also be at risk from eating food items contaminated with residues of imidacloprid. As there is no song bird dietary data, EEB used its standard approach and calculated a songbird LC50 value from the house sparrow LD50 value.

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According to our SEP for Ecological Risk Assessment (EPA-540/9-85-001) the LD50 is converted to the LC50 according to the relationship from Lehman (1959). EEB acknowledges that the LC50 value calculated from the LD50 value for songbird (house sparrow) is theoretical. The SEP discusses the weaknesses of this approach and cites work done on this issue by McCann, et al., 1981. However, from the discussion in the SEP it can be inferred that 65% of the time similar hazard decisions were reached when the converted LC50 value and the actual LC50 value were compared. EEB's data base indicates that this relationship is valid for a number of chemicals and is standard branch policy. A mistake was made in the disulfoton review in which the EEB biologist used a correction factor to calculate a songbird LC50 value.

The registrant's calculation using a correction factor is a moot point since their songbird dietary LC50 value is still in the 'highly toxic' category.

The dietary risk to songbirds meets our Restricted Use criteria as the estimated residues on small insects exceeds 1/5 the calculated LC50 value (Kenega, 1973).

Endangered Species

Label modifications limiting the use of NTN 33893 to in furrow applications to "wood production plantations" with trees 5 years old or less will minimize the concern for the Federally Endangered Red Cockaded Woodpecker.

Endangered species concerns will be triggered for all uses based on the acute and chronic toxicity to aquatic invertebrates. A decline in invertebrate populations may cause indirect effects to federally endangered birds and fish species that depend on aquatic invertebrates as a food source.

Risk Reconsideration for each Formulation

NTN 33893 0.62% and 2.5% Granulars

The only Ornamental use site of concern is that for the "Flowers and Ground cover"; all other uses state to incorporate or irrigate ('water-in'). For Flowers and Ground cover, the label states that the granules may be applied after plants are established, thus eliminating the possibility of incorporation. Therefore, the estimated aquatic concentrations for this use exceed the acute levels of concern for songbirds and aquatic invertebrates, and the chronic level of concern for aquatic invertebrates. 'Watering-in' may minimize the exposure to songbirds and reduce the risk of runoff that may expose aquatic invertebrates to unacceptable levels of NTN 33893. However, the chronic toxicity to Mysids is in the nanograms per liter range; irrigation (watering-in) of the granules will not reduce the expected environmental concentrations from runoff to below the level of chronic concern.

NTN 33839-2 Flowable Systemic Insecticide

The use sites of concern are "Turf" and "Flowers and Ground Cover". The expected runoffs exceed the level of concern for acute and chronic risk to aquatic invertebrates; the expected residues on small insects exceed the dietary level of concern for songbirds. 'Watering-in' may minimize the exposure due to runoff to aquatic habitats for both use sites and minimize residues on insects. However, as the chronic toxicity to Mysids is in the nanograms per liter range, irrigation (watering-in) will not reduce the expected environmental concentrations from runoff to below the level of chronic concern.

The risk to herbiverous birds cannot be determined until the question of a NOEC for eggshell thickness is resolved.

NTN 33893 is very highly toxic to bees from acute exposure and exposure to residues. Based on the foliar application to Ornamentals, a precautionary statement must be displayed indicating the acute and residual toxicity of NTN 33893 to bees.

Conclusion

The Mysid is used as a representative test organism to generalize the expected effects to estuarine invertebrates. As taken from the OPPT "Technical Support Document for Using Mysidopsis bahia in Acute and Life Cycle Toxicity Tests: "...the Mysid occupies an important position in near shore food webs. They constitute a major source of food for many fish species, including catfish, flounder, anchovy, silverside, sunfish and seatrout (Darnell 1958, Schuster 1959, Odum and Herald 1972, Powel and Schwartz 1979). In addition to their role in food chains of fish, mysids are important in the conversion of organic detritus to living tissue in estuarine environments (Hopkins, 1965)." Indirect effects to waterfowl may also be expected if the Mysid population, or similar organisms, is depleted. Based on the numerous fish species that are dependent on Mysids as a food source, the impact would be both economical as well as ecological if the aquatic invertebrate population of estuarine habitats is affected.

In closing, EEB has concerns for aquatic invertebrates (acutely and chronically), songbirds (acutely for the granulars and subacutley for dietary exposure) and perhaps waterfowl (reproductively). Mitigation by means of incorporation and/or irrigation may minimize the acute risks to aquatics and the chronic avian risks. If the registrant is interested in proposing risk mitigation measures, EEB will request a runoff model from the EFGWB utilizing the mitigation techniques to determine the expected environmental concentrations. However, it is not expected that irrigation of the chemical will reduce the aquatic concentrations from runoff to less than the chronic level of concern for Mysids.

Questions regarding this matter, please contact Dana Lateulere of my staff, 308-2856.

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