US EPA ARCHIVE DOCUMENT

098301
SHAUGHNESSY NO.

REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 9/9/85 OUT 12/09/85

FILE OR REG. NO. 264-331

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 8/14/85

DATE RECEIVED BY HED 9/5/85

RD REQUESTED COMPLETION DATE 11/4/85

EEB ESTIMATED COMPLETION DATE 11/4/85

RD ACTION CODE/TYPE OF REVIEW 651

TYPE PRODUCT(S): I, D, H, F, N, R, S Insecticide

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. J. Ellenberger (12)

PRODUCT NAME(S) Temik

COMPANY NAME Union Carbide Agricultural Products Company, Inc.

SUBMISSION PURPOSE Registrant's response to Registration Standard to support not conducting the avian field study.

SHAUGHNESSY NO.	CHEMICAL & FORMULATION	% A.I.

Environmental Safety Review
Fish and Wildlife

100.0 Submission Purpose

A compilation of 36 studies or letters of the effects of aldicarb on wildlife to determine whether these data fulfill the Registration Standard field data requirements.

104.0 Discussion

We have already seen most of the data presented by Union Carbide in Accession Numbers 259125, 259126, and 259127. The short-term studies (acute/subacute/palatability/age sensitivity) are familiar to us and confirm the high acute toxicity of aldicarb. Laboratory studies have shown that a single granule of Temik-10G can be lethal, particularly to small birds.

Balcomb et al. 1984
Beavers and Fink 1979
Beliles et al. 1966
Hilbig 1979
Hill et al. 1975
Hill and Camardese 1984
Hudson et al. 1984
Hudson et al. 1972
Medd and Roberts 1972
Medd et al. 1972
Ross et al. 1977
Ross et al. 1978
Ross et al. 1979
Schafer et al. 1983

Six of the field studies submitted were reviewed under the Registration Standard for Aldicarb:

Ashton and Jackson 1983
Back 1968
Clarkson et al. 1969
Clarkson and Row 1970
Haines 1970
Lund 1970

These studies were classified supplemental, that is, they contributed scientifically sound information, but they do not satisfy Registration Standard data requirements in this area. Various reasons result in these studies being incomplete:

1. Insufficient details given on procedures.

2. Monitoring activities were limited in terms of size of treatment area and duration.

3. Pen studies are too limited to be of much value for defining hazards and fulfilling guideline requirements.

4. Application rates or methods, in some cases, were not representative.

5. Test organisms were not representative of nontarget species most likely to be at risk in the U.S. (i.e., smaller birds and mammals).

Five other field studies submitted had not been reviewed before. Likewise, they contribute scientifically sound information, however, they do not satisfy the requirements because they are also weak in one or more of the areas listed above.

Relton 1970
Ross et al. 1977
Tait 1972
U.K. Ministry and Agriculture 1974
U.K. Ministry of Agriculture 1975

Two additional studies, Benjamini (1981), as well as certain studies previously reviewed, concern liquid formulations of aldicarb. Liquid formulation are not as great a concern as granular formulations of aldicarb. As crop seedlings begin to emerge there apparently are comparatively low levels of aldicarb, either from liquid spray or translocation to seedlings from applied granules is relateively small. Sprout-pulling birds are then subject to sublethal amounts of aldicarb that 'schools' the birds against further feeding, is short-lived and recovery is complete.

Acute oral exposure is perhaps the principal route of pesticide uptake for outdoor applications of granular formulations, principally through the accidental ingestion of granules left on the soil surface either from incomplete incorporation or spillage.

The agricultural use of aldicarb on millions of acres of cultivated cropland will result in significant exposure to nontarget birds. Mortalities can be expected from accidental ingestion of pesticide granules. The likelihood of an avian species ingesting a lethal dose of

aldicarb will increase if granules are not immediately or properly incorporated. Incorporation only serves, however, to reduce the potential for nontarget wildlife exposure, not eliminate it. Erbach and Tollefson (1983), using the best conventional procedure, spring-tined incorporation in front of press wheels, incorporated 95 percent of pesticide granules applied. Under these conditions 5 percent of the granules remained on the soil surface and would be available to wildlife. Fink (1980) also examined the degree with which corn planters could incorporate granular pesticides. Counts conducted immediately after incorporation revealed that both row areas and end row turn areas contained large numbers of exposed granules (70 and 344 granules per sq ft, respectively). Balcomb et al. (1982) also reported seeing exposed granules while conducting field searches for nontarget mortality. Field studies with aldicarb and other granular pesticides have documented that nontarget birds and mammals can ingest lethal doses of granular pesticides during the course of their normal feeding activites (Balcomb et al., 1982; Bunyan et al., 1981). Birds that would most likely be affected are small birds that would be harmed after ingesting one or two granules.

Incidents and field studies indicate that aldicarb applications can pose a hazard to bird species that typically probe the soil surface. Balcomb et al. (1982) noted that the majority of pesticide related mortality occurred in robins, a species known to repeatedly probe surfaces for earthworms. Avian mortalities are expected to occur primarily in small birds (less than 200 grams) and to be heaviest during the first week following product application. Mortality is expected to occur within a short time following application via acute toxicity. Predation of temporarily paralyzed or moribund individuals is expected to occur rapidly.

In conclusion, the available data indicate that aldicarb applications may result in avian mortality. Birds may eat the granules if there is an opportunity to do so. Although bird kills have not been large or consistent, despite the use of aldicarb on millions of acres of croplands every year, the detection of kills may be related to the monitoring effort and the proximity and accessibility of the site to human activity. Reported incidents can be a very small sample of a regularly occuring phenomenon.

Hazards to wildlife cannot be estimated with certainty from laboratory tests, therefore, field studies when available should be the primary focus of risk assessment. The effects of pesticides on bird communities can be variable and complex. It is seldom possible to identify any one field monitoring study as defining the hazard and fulfilling the guideline requirement for such testing.

The available field studies and use history for aldicarb (and other granular pesticides with comparable toxicity) provide sufficient information to indicate that granular pesticide treatments may result in some mortality if not local population reductions in certain bird species. Whether these effects are excessive, long-lasting, or likely to diminish wildlife resources cannot be said with any degree of certainty. It is a fundamental function of the Agency to discern environmental hazards based on reasonable potentialities, and such, we believe, have been demonstrated. Regulatory decisions should be based on the best available information. Although the data here may not be scientifically definitive, one way or the other, we believe that the evidence is persuasive in its cohesiveness to require further testing.

Field studies that would further quantify nontarget avian impact, performed according to the state-of-the-art, are still needed. Such studies should be conducted, after protocol review with EEB (particularly with the EEB field studies committee), over at least a three year period with granular aldicarb treatments to sorghum and citrus.

Richard R. Stevens 12/6/85
Section 1
Ecological Effects Branch
Hazard Evaluation Division

Ray Matheny, Head Raymond W. Matheny 12/6/85
Section 1
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Michael Slimak, Chief 12/6/85
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(HED PROVIDE) CASWELL NO.:

REGISTRATION DIVISION DATA REVIEW RECORD
—TO BE USED FOR REVIEW OF STUDIES PPA ONLY—

Confidential Business Information—
Does Not Contain National Security Info. (E.O. 12065)

(HED PROVIDE) PACK No.: 11596 9/5/85

(RD PROVIDE) SHAUGNESSY NO. 098301

CHEMICAL NAME: Aldicarb

Identifying Number	Action Code	Reference Number	Record Number	Study Guideline or Narrative Description	Review Submission Criteria Policy Note #31	Accession Number	(RSERB Provide) MRID Number	(HED/BUD/TSS Complete) Review Results: Acceptable (A)/ Unacceptable(U)
264-331	651	2	157605	71-5	3	259125		
						259126		
						259127		

PRODUCT MANAGER (PM) or REVIEW MANAGER (RM) AND NUMBER: Ellenberger / Edwards (12)

PM/RM TEAM MEMBER AND NUMBER: Edwards (12)

DATE RECEIVED (EPA): 8-15-85

RD BRANCH CHIEF INITIALS: JAH 9/4

CHECK APPLICABLE BOX:

- ☐ Adverse 6(a)(2) Data (405,406)
- ☐ Suspect Data (415,416)
- ☐ IBT Data (485,486)
- ☐ Groundwater Data (495,496)
- ☐ Data Waiver Request (Reregistration) (650,651)
- ☐ Formulation and Labeling Data (Reregistration) (655,656)
- ☒ Generic Data (Reregistration) (660,661)
- ☐ Special Review Data (870,871)

AH

RELATED ACTIONS:

TO BE COMPLETED BY RSERB

DATE SENT TO HED/BUD/TSS: 9-5-85

INSTRUCTIONS: Data in support of Carbides request to not conduct the avian field study on the basis that sufficient data is available to assess aldicarb hazard potential to birds.

PRIORITY NUMBER: 50

PROJECTED RETURN DATE: 11-4-85

DATE RETURNED TO RD (HED PROVIDE):

REVIEWS SENT TO:

HED: ☐ SIS ☐ TB ☐ RCB ☐ EAB ☐ EEB RD: ☐ TSS BUD: ☐ EAB ☐ SSB

TO:		TYPE OF REVIEW	NUMBER OF ACTIONS: Reregistration	Special Review	Other
HED		Toxicology			
	✓	Ecological Effects	✓		
		Residue Chemistry			
		Exposure Assessment			
RD/TSS		Product Chemistry			
		Efficacy			
		Precautionary Labeling			
BUD		Science Support			
		Economic Analysis			

FOR DATA SUBMITTED UNDER A REGISTRATION STANDARD
Review Submission Criteria
Policy Note #31

1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria

2 = data of particular concern

3 = data necessary to determine tiered testing requirements

UNION CARBIDE AGRICULTURAL PRODUCTS COMPANY, Inc.
P. O. BOX 12014, T. W. ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, N. C. 27709
(919) 549-2000

EPA Correspondence 378-85

August 14, 1985

259125
126
127
67

Jay S. Ellenberger, Product Manager
U.S. ENVIRONMENTAL PROTECTION AGENCY
Registration Division (TS-767)
Insecticide/Rodenticide Branch
Crystal Mall Building 2 - Room 202
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: Aldicarb Registration Standard
Field Testing for Mammals and Birds

Dear Mr. Ellenberger:

This letter and enclosures are to follow-up on my May 16, 1985, letter on this subject. We have compiled 36 studies of the effect of TEMIK® brand Granular Aldicarb Pesticide on wildlife and contracted Dr. Donald A. Spencer to prepare a review of those data. Dr. Spencer is a recognized expert ornithologist, formerly with the U.S. Department of Interior.

Two complete copies of those data and Dr. Spencer's review are bound in three volumes and submitted for EPA's review. We request that these data be reviewed as quickly as possible to determine whether the data fulfill the registration standard data requirements in this area.

12605

Sincerely yours,

J. S. Lovell

J. S. Lovell, Registration Manager
Insecticides/Intermediates
Registration & Regulatory Affairs

JSL/jh

Enclosures