

US EPA ARCHIVE DOCUMENT

IRB/TSS PRECAUTIONARY LABEL REVIEW

IN 9-16-87 OUT 10-28-87

ACTION CODE: 760

REVIEWER: Dona Williams

PRODUCT MGR. NO. 16

U.S. REGULATORY AFFAIRS

Record Number(s)  
202128

MAY 5 1988

FILE OR REG NO. \_\_\_\_\_

PETITION OR EUP NO. 241-EUP-RR0

PRODUCT NAME AC 301, 467 Insecticide/Nematicide

COMPANY NAME & American Cyanamid Co., Ag Res Div.

ADDRESS P.O. BOX 400

SUBMISSION PURPOSE Experimental Use Permit. Review of acute toxicity data.

CHEMICAL & FORMULATION Powder [ 20% Terbufos ai., 80% inert ingredients].

PRODUCT USES Application to field corn, sugar beets and grain sorghum.

COMMENTS AND RECOMMENDATIONS:

1. Submitted acute studies are acceptable. Based upon review the product was assigned the following categories.

	<u>CORE CLASS</u>	<u>TOX CAT</u>	<u>MRID#</u>
Acute Oral LD50	MINIMUM	I	403223-04
Acute Dermal LD50	MINIMUM	I	403223-05
Eye Irritation	GUIDELINE	IV	403223-06
Skin Irritation	GUIDELINE	IV	403223-07
Dermal Sensitization	GUIDELINE	Non-Sensitizer	403223-08

2. Precautionary language is acceptable.

FILE OR REG NO. 241-EUP-RR0

TEST ARTICLE: AC 92, 100 20P

TEST FACILITY & Toxicology Dept., American Cyanamid Co., Ag. Res. Div.

ADDRESS P.O. Box 400

Princeton, NJ 08540

STUDY SUMMARIES:

• ACUTE ORAL LD<sub>50</sub> EPA ACC/MRID NO. 403223-04  
STUDY NO. A87-60; STUDY INITIATED 4-29-87  
Conforms with Health Assessment Guidelines (81-1) Y/N Yes  
Deviations from guidelines None  
Level(s) Tested Groups of 5M & 5F SD rats: 30, 40, 60 mg/kg undiluted. Oral gavage.  
14-day observation period.  
Significant Toxic Signs Salivation, tremors, and chromodacryorrhea.  
Significant Necropsy Findings Unremarkable.  
LD<sub>50</sub>= (Males) 38 mg/kg ( confidence limits not calculated)  
(Females) 32 mg/kg ( confidence limits not calculated)  
(Combined) 34 mg/kg (13-34) 95% C.L.  
Core Classification MINIMUM (If Supplementary list deficiencies)  
Product Toxicity Category for this route of exposure I  
( See addendum for sex specific mortalities)

• ACUTE DERMAL LD<sub>50</sub> EPA ACC/MRID NO. 403223-05  
STUDY NO. A87-59; STUDY INITIATED 4-15-87  
Conforms with Health Assessment Guidelines (81-2) Y/N Yes  
Deviations from guidelines None  
Level(s) Tested Groups of 5M & 5F NZ White rabbits: 80, 160, 320, 640 mg/kg undiluted  
Clipped intact skin. 24-hr occluded dermal exposure.  
Significant Toxic Signs Tremors, diarrhea, salivation, decreased respiration and  
prostration.  
Significant Necropsy Findings Congestion of liver, kidneys and lungs, pale liver and  
edema of application site.  
LD<sub>50</sub>= (Males) 180 mg/kg (93-348) 95% CL  
(Females) 269 mg/kg (164-443) 95% CL  
(Combined) Not provided  
Core Classification MINIMUM (If Supplementary list deficiencies)  
Product Toxicity Category for this route of exposure I  
( See addendum for sex specific mortalities)

3. PRIMARY EYE IRRITATION  
EPA ACC/MRID NO. 403223-06  
STUDY NO. 87-30; STUDY INITIATED 4-06-87  
Conforms with Health Assessment Guidelines (81-4) Y/N Yes  
Deviations from guidelines None.  
Level(s) Tested 6 NZ White rabbits: 100 mg undiluted. Instilled into left eye. Treated eyes were rinsed for one second. All treated eyes recieved rinse with tap water following 24-hr exposure period. 72-hrs observation period. Fluorescein staining.  
Ocular Findings [list number of animals eliciting response and period of duration]  
corneal opacity: None exhibited  
iritis: None exhibited  
conjunctivae: grade (1) redness (6/6) clearing in all by 72-hrs.  
Core Classification GUIDELINE (If Supplementary list deficiencies)  
Product Toxicity Category for this route of exposure IV.

4. PRIMARY DERMAL IRRITATION  
EPA ACC/MRID NO. 403223-07  
STUDY NO. A87-34; STUDY INITIATED 4-07-87  
Conforms with Health Assessment Guidelines (81-5) Y/N Yes  
Deviations from guidelines None  
Level(s) Tested 6M NZ White rabbits: 0.5 gms undiluted. Clipped intact skin. 4-hour dermal occluded exposure. 72-hr observation period.  
Dermal Findings [list number of animals eliciting response and period of duration]  
erythema Slight (6/6) at 4-hrs. Clear by 24-hours.  
edema None elicited.  
PDIS 0.00  
Core Classification GUIDELINE (If Supplementary list deficiencies)  
Product Toxicity Category for this route of exposure IV.

5. DERMAL SENSITIZATION 1  
EPA ACC/MRID NO. 403223-08  
STUDY NO. DRC 4904; STUDY INITIATED 4-13-87  
Test Method Used Modified Buehler  
Deviations from accepted test method None.  
Concentration Tested 10M Harlan Sprague Dawley guinea pigs: 100% undiluted. Nine 6-hr occluded induction applications. Challenge (100% concen) 2 wks post-final induction at a virgin site. 24 and 48-hr readings.  
Postive Control 0.1% DNCB in 50% ethanol.  
Induction Findings/ Mean Score No dermal irritation.  
Challenge Findings/ Mean Score No dermal irritation.  
Product Classification Non-Sensitizer  
Core Classification GUIDELINE

ADDENDUM

ORAL LD50:

CONCENTRATION (mg/kg)	PERCENT MORTALITY	
	Males	Females
30	60	10
40	20	100
60	80	100

ACUTE DERMAL LD50:

CONCENTRATION (mg/kg)	PERCENT MORTALITY	
	Males	Females
80	10	-
160	40	10
200	80	60
400	-	100

1- Dermal Sensitization study conducted by:

Dawson Research Corporation  
P.O. Box 30666  
Orlando, FL 32862

AC 261,467  
REG. NO./FILE SYMBOL: 241-  
APPLICANT'S NAME AND ADDRESS: American Cyanamid Company  
Princeton, New Jersey

DATA MATRIX FOOTNOTES

- (1) Data not submitted, because end-use product is not produced by an integrated formulation system. (See CFR 158.120, 62-1, Note 4.)
- (2) Not required for this End-use product (see CFR 158.120 Note 9).
- (3) Data not submitted, because end-use product does not contain an oxidizing or reducing agent. (See CFR 158.120, 63-14, Note 10.)
- (4) Data not submitted, because end-use product does not contain combustible liquids. (See CFR 158.120, 63-15, Note 11.)
- (5) Product does not contain explosive ingredients (Sec. CFR 158.120, 63-16, Note 12).
- (6) Data not submitted, because end-use product is not a liquid. (See CFR 158.120, 13-18, Note 13.)
- (7) Data not submitted, because end-use product is not an emulsifiable liquid and will not be diluted in petroleum solvents. (See CFR 158.120, 63-19, Note 14.)
- (8) Data not submitted, because end-use product will not be used around electrical equipment. (See CFR 158.120, 63-21, Note 15.)
- (9) Data not submitted, because end-use product is formulated as a water dispersible granule with a particle size (>700 and <2000) which is greater than 15 micron and not considered to be inhalable.  
(See CFR 158.135, Guidelines for 81-3 as contained in the "Pesticide Assessment Guidelines, Subdivision F, Hazard Evaluation: Human and Domestic Animals (Nov. 82).")

acute  
inhalation  
study

Reg. # \_\_\_\_\_

CHEMISTRY CHECKLIST CONT'D

9. Data Matrix Requirements

- a) Statement of Composition - a complete description of the manufacturing/formulation process. Describe equipment used, mixing time, temperature etc.
- b) Discussion of Formation of [Unintentional] Ingredients - a brief description of impurities formed during the manufacturing/formulation process, in packaging, or during storage. If you do not expect any impurities during these stages, please so state.
- c) Certification of Limits - upper and lower limits of each active and individually added inert component. The lower limit for the actives, including solvents declared as active, must not fall below label claim.
- d) Analytical Methods - provide the methods used to analyze for the active ingredients.
- e) Color - in common terms.
- f) Physical State - e.g. solid, liquid, pressurized liquid, etc.
- g) Odor - in common terms.
- h) Density - e.g. lbs/gallon for liquids or lbs/cu. ft. for solids.
- i) pH - provide pH of product or pH of a specified water dilution.
- j) Oxidizing or Reducing - note these characteristics if any.
- k) Flammability - flash point/flame extension.
- l) Explosibility - note these characteristics if any.
- m) Storage Stability - the formulated product must be analyzed for its active ingredient at time zero and during a year of storage. The storage should be in warehouse conditions and in similar marketable containers you will be using in the trade.  
Note: For the Storage Stability study you cannot reference the concentrate you are using to formulate your product.
- n) Viscosity - can be expressed in centipoise or centistokes.
- o) Miscibility - note these characteristics if product is an emulsifiable liquid and mixed with oil.
- p) Corrosion Characteristics - this information can be noted during the storage stability study.
- q) Dielectric Breakdown Voltage - for products used near electrical equipment.

1 mo - ab  
R.T.

3 months storage stability data are available

We need 1 yr R.T. data

10/31/87  
B. J. W.

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