

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

33

MAY - 8 1991

Mr. John J. Arthur
 American Cyanamid Company
 Agricultural Research Division
 P.O. Box 400
 Princeton, NJ 08540

Dear Mr. Arthur :

Subject: Second Health Effects Division Peer Review on
 Carcinogenic Classification of Amdro (Hydramethylnon)
 AMDRO[®] Technical Insecticide
 EPA File Symbol 241-ETN → registered 5/8/91 241-270
 Your Submission Dated October 7, 1988

The Peer Review Committee, which met September 19, 1990 to discuss and evaluate the data in evidence on Amdro in order to determine the chemical's carcinogenic potential, has concluded that Amdro should be classified as a Group C, Possible Human Carcinogen, and recommends that for the purpose of risk characterization the Reference Dose (RfD) approach should be used for the quantification of human risk.

Please refer to the enclosed copy of the subject peer review for a complete explanation of the Agency's findings concerning the evaluation of carcinogenicity evidence for Amdro, based on the studies submitted for this purpose.

Should you have any questions or comments with respect to this review, please contact me at (703) 557-2400.

Sincerely,

George T. LaRocca
 Product Manager (15)
 Insecticide-Rodenticide Branch
 Registration Division (H7505C)

Enclosures

CONCURRENCES

SYMBOL							
SURNAME	TML						
DATE	5/8/91						

US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (75-767) WASHINGTON, DC 20460 NOTICE OF PESTICIDE: <input type="checkbox"/> REGISTRATION <input checked="" type="checkbox"/> REREGISTRATION <i>(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</i>	EPA REGISTRATION NO. 241-270	DATE OF ISSUANCE MAY 8 1991
	TERM OF ISSUANCE Until Reregistration	
	NAME OF PESTICIDE PRODUCT AMDRO® Technical Insecticide	

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

American Cyanamid Company
 Agricultural Research Division
 P.O. Box 400
 Princeton, NJ 08540

345 538-498
18/

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right of exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data or other material required for registration/reregistration of your product under FIFRA sec. 3(c)(5) or FIFRA sec. 4 when the Agency requires all registrants of similar products to submit such data.
2. The acute toxicity data submitted in support of this registration is acceptable. However you must provide the required Quality Assurance Statements for each study submitted as outlined in 40 CFR 160.35, indicating that:
 - a. No deviation from approved protocol or standard operating procedures were made without proper authorization and documentation.
 - b. The final study report accurately described the methods and standard operating procedures and that the reported results accurately reflected the raw data of the study.

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL	DATE
---------------------------------	------

Based on their acute toxicities the product was assigned the following categories:

<u>STUDY</u>	<u>STUDY CLASSIFICATION</u>	<u>TOXICITY CATEGORY</u>	<u>MRID NUMBER</u>
Acute Oral	Guideline	III	416125-03
Acute Dermal	Guideline	III	416125-04
Acute Eye Irritation	Guideline	III	416125-05
Skin Irritation	Guideline	III	416125-06

3. Make the labeling changes listed below before you release the product for shipment:

- a. Add the phrase, "EPA Registration No. 241-270."
- b. Under the Statement of Practical Treatment, revise the **IF ON SKIN** statement as follows:

Remove contaminated clothing and wash affected areas with plenty of soap and water. Get medical attention if irritation persists.

- c. Under Precautionary Statements, the subheading should read: **HAZARDS TO HUMANS AND DOMESTIC ANIMALS.**
- d. Under Environmental Hazards, add the statement, "This product is toxic to fish." as the first statement of the paragraph.

- e. Under Directions for Use, revise the sentence beginning "For Formulation Only into....etc" to:

This technical product may be used for the manufacture of insecticide baits for commercial/domestic indoor use for fire ant baits outdoor use including terrestrial non-food crop, pasture and range grass sites.

4. Submit five copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

65

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager 15
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

**AMDRO®
insecticide
Technical**

FOR FORMULATION INTO INSECTICIDE PRODUCTS ONLY

ACTIVE INGREDIENT:

Hydramethylnon: Tetrahydro-5,5-dimethyl-2(1H)-pyrimidinone
(3-[4-(trifluoro-methyl)phenyl]-1-(2-[4-(trifluoromethyl)
phenyl]ethenyl)-2-propenylidene)hydrazone 95%

INERT INGREDIENTS..... 5%

TOTAL.....100%

EPA Reg. No. 241-

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN

CAUTION!

PRECAUCION!

PRECAUCION AL USUARIO: Si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

In case of an emergency endangering life or property involving this product, call collect, day or night, Area Code 201-835-3100.

See Next Page For Additional Precautionary Statements

Net Weight:

Product Code No.

In EPA Lab.

8/90

MAY 8 1991

®Registered Trademark of American Cyanamid Company

Under the Federal Insecticide, Fungicide, and Rodenticide Act, amended for the pesticide, registered under EPA Reg. No.

241-270

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION!

Harmful if swallowed, absorbed through skin, or inhaled. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

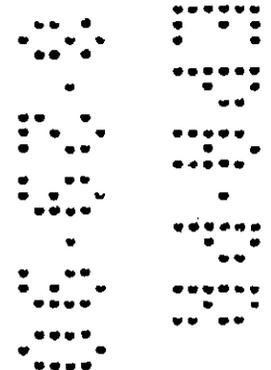
Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Consult American Cyanamid Company before using this product for formulating purposes.

Each formulator is responsible for obtaining FFA registration for his end use product(s). For formulation only into end-use products for use on indoor food and non-food, residential outdoor, terrestrial non-food crop, pasture, and range grass sites.



STORAGE AND DISPOSAL

Prohibitions: Do not contaminate water, food, or feed by storage and disposal. Store in a secure place. Open dumping is prohibited. Store in a cool, dry place and keep container tightly closed.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If drum cannot be reused, dispose of in the same manner.

DISCLAIMER

American Cyanamid Company warrants only that the material contained herein conforms to the chemical description on the label and is reasonably fit for the use therein described when used in accordance with the directions for use.

Any damages arising from a breach of this warranty shall be limited to direct damages, and shall not include consequential commercial damage such as loss of profits or values, etc.

American Cyanamid Company makes no other express or implied warranty, including any other express or implied warranty of FITNESS or of MERCHANTABILITY.

User assumes the risk of any use contrary to label instructions or, under abnormal conditions, or under conditions not reasonably foreseeable by American Cyanamid Company.

American Cyanamid Company
Agricultural Division
VPC Ventures
Wayne, NJ 07470 ©1990

