

US EPA ARCHIVE DOCUMENT



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

RCB
QUICK

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTA

DATE: DEC 15 1981

SUBJECT: EPA Reg. No. 241-243 and PP 1F2567. Request for a Tolerance for the Combined Residues of Pendimethalin and its Metabolite in/on Beans (dry, lima, snap), Bean Forage and Straw at 0.1 ppm.

FROM: John Doherty *John Doherty*
Toxicology Branch/HED (TS-769)

TOX Chem. No. 454BB

TO: Robert J. Taylor, PM #25
Registration Division (TS-767)

*694
12/11/81
ok for OEP.*

The American Cyanamid Company is requesting to amend the label for their pesticide product PROWL® Herbicide to include use on beans. A permanent tolerance is also requested for the combined residues of pendimethalin [N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine] and its metabolite [4-([1ethylpropyl]amino)-2-methyl-3,5-dinitrobenzyl alcohol] in or on beans (dry, lima, snap), bean foliage and straw at 0.1 ppm.

Conclusion:

1. The rat chronic feeding/oncogenesis and mouse oncogenesis studies on pendimethalin were rereviewed recently (see J. Doherty memo to R. J. Taylor, dated 11/27/81) and both studies were determined to be Invalid. These studies cannot be used to support permanent tolerances. Thus, Toxicology Branch has no reliable test data concerning the oncogenic potential of technical pendimethalin. In view of the fact that technical pendimethalin is known to contain small amounts of nitrosamines (known oncogenic chemicals) as impurities, and the proposed increase in the TMRC is 6.5%, Toxicology Branch considers the increase in incremental risk resulting from the proposed new uses to be significant. Therefore, Toxicology Branch does not recommend in favor of this permanent tolerance.
2. The inerts in this product are cleared for preharvest use. The labeling for this formulated product must be supported by appropriate acute studies.

U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDE PROGRAMS (WP-667) WASHINGTON, D.C. 20460 APPLICATION FOR AMENDED PESTICIDE PRODUCT REGISTRATION (Read instructions on last page before completing) B		1. REFERENCE CODE 3. REGISTRATION NO. 241-243	4. PRODUCT MANAGER Mr. Robert Taylor																																							
5. NAME AND ADDRESS OF REGISTRANT (Include Zip Code) American Cyanamid Company Agricultural Research Division P.O. Box 400 Princeton, NJ 08540 <input type="checkbox"/> CHECK HERE IF THIS IS A NEW ADDRESS		6. TYPE OF AMENDMENT																																								
		<table border="1" style="width:100%; border-collapse: collapse;"> <tr><td><input type="checkbox"/> CHANGE IN PRODUCT NAME</td></tr> <tr><td><input type="checkbox"/> MINOR CHANGE IN FORMULATION</td></tr> <tr><td><input type="checkbox"/> REQUEST FOR ADDITIONAL BRAND NAMES</td></tr> <tr><td><input type="checkbox"/> REQUEST FOR MULTIPLE INERT FORMULATION PER PR NOTICE 74-3</td></tr> <tr><td><input type="checkbox"/> DELETION OF LABEL TEXT</td></tr> <tr><td><input type="checkbox"/> ADDED USES (without data)</td></tr> <tr><td><input checked="" type="checkbox"/> ADDED USES (with data)</td></tr> <tr><td><input type="checkbox"/> GENERAL REVISION OF LABEL</td></tr> </table>		<input type="checkbox"/> CHANGE IN PRODUCT NAME	<input type="checkbox"/> MINOR CHANGE IN FORMULATION	<input type="checkbox"/> REQUEST FOR ADDITIONAL BRAND NAMES	<input type="checkbox"/> REQUEST FOR MULTIPLE INERT FORMULATION PER PR NOTICE 74-3	<input type="checkbox"/> DELETION OF LABEL TEXT	<input type="checkbox"/> ADDED USES (without data)	<input checked="" type="checkbox"/> ADDED USES (with data)	<input type="checkbox"/> GENERAL REVISION OF LABEL																															
<input type="checkbox"/> CHANGE IN PRODUCT NAME																																										
<input type="checkbox"/> MINOR CHANGE IN FORMULATION																																										
<input type="checkbox"/> REQUEST FOR ADDITIONAL BRAND NAMES																																										
<input type="checkbox"/> REQUEST FOR MULTIPLE INERT FORMULATION PER PR NOTICE 74-3																																										
<input type="checkbox"/> DELETION OF LABEL TEXT																																										
<input type="checkbox"/> ADDED USES (without data)																																										
<input checked="" type="checkbox"/> ADDED USES (with data)																																										
<input type="checkbox"/> GENERAL REVISION OF LABEL																																										
7. PRODUCT NAME PROWL® herbicide		8. EXPERIMENTAL PERMIT NO.																																								
9. SUBJECT OF AMENDMENT (See instructions) Added uses for dry, lima and snap beans																																										
12. TYPES OF DATA SUBMITTED		13. DATE APPLICATION RECEIVED (Stamped)																																								
<table border="1" style="width:100%; border-collapse: collapse;"> <tr><td>01 NONE</td><td>reference</td><td>1201</td></tr> <tr><td><input checked="" type="checkbox"/> 02 PRODUCT CHEMISTRY</td><td>reference</td><td>1202</td></tr> <tr><td><input checked="" type="checkbox"/> 03 RESIDUE CHEMISTRY</td><td></td><td>1203</td></tr> <tr><td>04 ENVIRONMENTAL CHEMISTRY</td><td></td><td>1204</td></tr> <tr><td><input checked="" type="checkbox"/> 05 EFFICACY</td><td>reference</td><td>1205</td></tr> <tr><td>06 PHYTOXICITY</td><td></td><td>1206</td></tr> <tr><td><input checked="" type="checkbox"/> 07 HUMAN SAFETY</td><td>reference</td><td>1207</td></tr> <tr><td><input checked="" type="checkbox"/> 08 DOMESTIC ANIMAL SAFETY</td><td>reference</td><td>1208</td></tr> <tr><td><input checked="" type="checkbox"/> 09 FISH AND WILDLIFE SAFETY</td><td>reference</td><td>1209</td></tr> <tr><td>10 BENEFICIAL INSECT SAFETY</td><td></td><td>1210</td></tr> <tr><td>11 ACCIDENT EXPOSURE EXPERIENCE</td><td></td><td>1211</td></tr> <tr><td><input checked="" type="checkbox"/> 12 OTHER (Specify) metabolism</td><td></td><td>1212</td></tr> <tr><td>13 OTHER (Specify)</td><td></td><td>1213</td></tr> </table>		01 NONE	reference	1201	<input checked="" type="checkbox"/> 02 PRODUCT CHEMISTRY	reference	1202	<input checked="" type="checkbox"/> 03 RESIDUE CHEMISTRY		1203	04 ENVIRONMENTAL CHEMISTRY		1204	<input checked="" type="checkbox"/> 05 EFFICACY	reference	1205	06 PHYTOXICITY		1206	<input checked="" type="checkbox"/> 07 HUMAN SAFETY	reference	1207	<input checked="" type="checkbox"/> 08 DOMESTIC ANIMAL SAFETY	reference	1208	<input checked="" type="checkbox"/> 09 FISH AND WILDLIFE SAFETY	reference	1209	10 BENEFICIAL INSECT SAFETY		1210	11 ACCIDENT EXPOSURE EXPERIENCE		1211	<input checked="" type="checkbox"/> 12 OTHER (Specify) metabolism		1212	13 OTHER (Specify)		1213	<div style="font-size: 2em; font-weight: bold; letter-spacing: 0.5em;">RECEIVED</div> SEP 4 1981 REGISTRATION DIVISION (TS-767)	
01 NONE	reference	1201																																								
<input checked="" type="checkbox"/> 02 PRODUCT CHEMISTRY	reference	1202																																								
<input checked="" type="checkbox"/> 03 RESIDUE CHEMISTRY		1203																																								
04 ENVIRONMENTAL CHEMISTRY		1204																																								
<input checked="" type="checkbox"/> 05 EFFICACY	reference	1205																																								
06 PHYTOXICITY		1206																																								
<input checked="" type="checkbox"/> 07 HUMAN SAFETY	reference	1207																																								
<input checked="" type="checkbox"/> 08 DOMESTIC ANIMAL SAFETY	reference	1208																																								
<input checked="" type="checkbox"/> 09 FISH AND WILDLIFE SAFETY	reference	1209																																								
10 BENEFICIAL INSECT SAFETY		1210																																								
11 ACCIDENT EXPOSURE EXPERIENCE		1211																																								
<input checked="" type="checkbox"/> 12 OTHER (Specify) metabolism		1212																																								
13 OTHER (Specify)		1213																																								
13. METHOD OF SUPPORT (See instructions) <input type="checkbox"/> Required Supporting Data Attached. (2A) <input type="checkbox"/> Required Supporting Data is Submitted by Reference. (2B) <input type="checkbox"/> Proceed on the Basis of Submitted Test Results. (2C)																																										
14. CONTACT POINT Complete items directly below for identification of individual to be contacted, if necessary, to process this application.																																										
OFFER TO PAY STATEMENT I hereby offer to pay reasonable compensation to the extent provided under Section 3 (c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and in accordance with the Regulations and Guidelines published thereunder for use of any test data which has been submitted to the U.S. Environmental Protection Agency in connection with an application for the registration of a pesticide for the first time on or after October 21, 1972 and which may be used in support of the registration application for the subject pesticide.																																										
16. SIGNATURE <i>Lynne A. Melville</i>																																										
17. TITLE Registrations Coordinator																																										
18. DATE SIGNED September 2, 1981																																										
18. DATE APPLICATION RECEIVED (Stamped)		19. TELEPHONE NO. (Include Area Code) 609-799-0400, Ext. 2363																																								
19. TYPE NAME		20. DATE SIGNED																																								

241-243

LABEL TECHNICAL DATA

(See INSTRUCTIONS on back of last part)

PROWL® herbicide

4. APPLICATION SITES (Check all that apply)		5. PEST TYPE (Check all that apply)		7. USER TYPE (Check all that apply)	
<input type="checkbox"/> 01 CROPS (Fruit)		<input type="checkbox"/> 01 ALGAE		<input checked="" type="checkbox"/> 01 UNSPECIFIED GENERAL USE	
<input type="checkbox"/> 02 CROPS (Vegetable)		<input type="checkbox"/> 02 AMPHIBIAN/REPTILE		<input type="checkbox"/> 02 UNSPECIFIED RESTRICTED USE	
<input checked="" type="checkbox"/> 03 CROPS (Field)		<input type="checkbox"/> 03 BACTERIA		<input type="checkbox"/> 03 HOMEOWNER USE	
<input type="checkbox"/> 04 CROPS (Grain)		<input type="checkbox"/> 04 BIRDS		<input type="checkbox"/> 04 JANITORIAL USE	
<input type="checkbox"/> 05 CROPS (Nut)		<input type="checkbox"/> 05 FISH		<input type="checkbox"/> 05 PEST CONTROL OPERATOR USE	
<input type="checkbox"/> 06 CROPS (Other)		<input type="checkbox"/> 06 FOULING ORGANISMS		<input type="checkbox"/> 06 COMMERCIAL APPLICATOR USE	
<input type="checkbox"/> 07 SOIL TREATMENT (No crop specified)		<input type="checkbox"/> 07 FUNGI		<input checked="" type="checkbox"/> 07 FARMER USE	
<input type="checkbox"/> 08 FOREST		<input type="checkbox"/> 08 INSECTS AND MITES		<input type="checkbox"/> 08 MEDICAL USE	
<input type="checkbox"/> 09 ORNAMENTALS		<input type="checkbox"/> 09 MAMMALS		<input type="checkbox"/> 09 VETERINARY USE	
<input type="checkbox"/> 10 TURF		<input type="checkbox"/> 10 NEMATODES		<input type="checkbox"/> 10 GOVERNMENT AGENCY USE	
<input type="checkbox"/> 11 STORED PRODUCTS TREATMENT	<input checked="" type="checkbox"/>	<input type="checkbox"/> 11 PLANTS		<input type="checkbox"/> 11 MANUFACTURING USE	
<input type="checkbox"/> 12 ANIMALS (Livestock)		<input type="checkbox"/> 12 RODENTS		8. FORMULATION (Check one only)	
<input type="checkbox"/> 13 ANIMALS (Poultry)		<input type="checkbox"/> 13 SLIME		<input type="checkbox"/> 01 TECHNICAL CHEMICAL	
<input type="checkbox"/> 14 ANIMALS (Pet)		<input type="checkbox"/> 14 SLUGS AND SNAILS		<input type="checkbox"/> 02 FORMULATION INTERMEDIATE	
<input type="checkbox"/> 15 ANIMALS (Laboratory)		<input type="checkbox"/> 15 VIRUS		<input type="checkbox"/> 03 DUST	
<input type="checkbox"/> 16 ANIMALS (Other)		<input type="checkbox"/> 16 OTHER (Specify)		<input type="checkbox"/> 04 GRANULAR	
<input type="checkbox"/> 17 OUTDOOR (No crop Agricultural)		6. MODE OF ACTION (Check all that apply)		<input type="checkbox"/> 05 PELLETED/TABLETTED	
<input type="checkbox"/> 18 OUTDOOR (Resident/Commercial)				<input type="checkbox"/> 06 WETTABLE POWDER	
<input type="checkbox"/> 19 OUTDOOR (Non agricultural)		<input type="checkbox"/> 01 ATTRACTANT		<input type="checkbox"/> 07 WETTABLE POWDER/DUST	
<input type="checkbox"/> 20 BUILDINGS (Agricultural)		<input type="checkbox"/> 02 BIOLOGICAL CONTROL		<input type="checkbox"/> 08 CRYSTALLINE	
<input type="checkbox"/> 21 BUILDINGS (Commercial)		<input type="checkbox"/> 03 CHEMOSTERILANT		<input type="checkbox"/> 09 MICROENCAPSULATED	
<input type="checkbox"/> 22 BUILDINGS (Food Processing)		<input type="checkbox"/> 04 DEFOLIANT		<input type="checkbox"/> 10 IMPREGNATED MATERIALS	
<input type="checkbox"/> 23 BUILDINGS (Medical)		<input type="checkbox"/> 05 DESICCANT		<input checked="" type="checkbox"/> 11 SELF-GENERATING SMOKE	
<input type="checkbox"/> 24 BUILDINGS (Residential)		<input type="checkbox"/> 06 FEEDING DEPRESSANT		<input type="checkbox"/> 12 EMULSIFIABLE CONCENTRATE	
<input type="checkbox"/> 25 EQUIPMENT (Commercial)		<input checked="" type="checkbox"/> 07 GROWTH INHIBITOR		<input type="checkbox"/> 13 INVERT EMULSION	
<input type="checkbox"/> 26 EQUIPMENT (Food)		<input type="checkbox"/> 08 GROWTH REGULATOR		<input type="checkbox"/> 14 FLOWABLE CONCENTRATE	
<input type="checkbox"/> 27 EQUIPMENT (Agricultural)		<input type="checkbox"/> 09 POISON (Single dose)		<input type="checkbox"/> 15 SOLUBLE CONCENTRATE	
<input type="checkbox"/> 28 EQUIPMENT (Medical)	<input checked="" type="checkbox"/>	<input type="checkbox"/> 10 POISON (Multiple Dose)		<input type="checkbox"/> 16 SOLUTION (Ready to Use)	
<input type="checkbox"/> 29 EQUIPMENT (Transportation)		<input type="checkbox"/> 11 PRESERVATIVE		<input type="checkbox"/> 17 OILS (No added pesticide)	
<input type="checkbox"/> 30 LAUNDRY AND DRY CLEANING		<input type="checkbox"/> 12 REPELLENT		<input type="checkbox"/> 18 PRESSURIZED (Gas)	
<input type="checkbox"/> 31 INDUSTRIAL PRESERVATIVES		<input type="checkbox"/> 13 OTHER (Specify)		<input type="checkbox"/> 19 PRESSURIZED (Liquid)	
<input type="checkbox"/> 32 PESTICIDE (Manufacturing only)				<input type="checkbox"/> 20 PRESSURIZED (Dust)	
<input type="checkbox"/> 33 OTHER (Specify)				<input type="checkbox"/> 21 OTHER (Specify)	

REMARKS