3-2-81

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

000544

MEMORANDUM

DATE: MAR 2 1981

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: PP 0F2401 Request for Establishment of a Tolerance of 0.05 ppm of Pendimethalin on Rice Grain. Caswell #454 BB

FROM: John Doherty
Toxicology Branch/HED (TS-769) ADK 3/2/81

TO: Robert Taylor
Registration Division (TS-769)

Background:

The American Cyanamid Company has requested the establishment of a tolerance of 0.05 ppm in/on rice grain for the herbicide pendimethalin.

Conclusion:

This tolerance on rice grain can be toxicologically supported. However, when the registration application for the use of Prowl on rice is submitted at a later date the registration, if issued, would be on a conditional basis.

Reviewer, please note that RCB recommended against issuance of the tolerances.

8-Point "Free Standing" Summary

1. Data considered in "setting" the tolerance (selected studies).

	Study	Results
i.	Acute Oral LD50, rats	1.25 gm/kg, males 1.05 gm/kg, females
iii.	Acute Dermal LD50, rabbits	>5.0 gm/kg
ii.	Skin and Eye Irritation, rabbits	Not irritating
iv.	21-day Dermal, rabbits	NOEL = 1 gm/kg/day
v.	90-day feeding study, rats	NOEL = 500 ppm
vi.	90-day feeding study, dogs	NOEL = 62.5 mg/kg/day (or 2500 ppm)
vii.	18-month oncogenesis, mice	NOEL = 500 ppm, no oncogenic effects

1 of 3

viii.	2-year chronic feeding/ oncogenesis, rats	NOEL = 100 ppm, no oncogenic effects
ix.	3-generation reproduction, rats ✓	NOEL = 500 ppm
x.	Dominant Lethal Study ✓	No effect at 2500 ppm (highest dose)
xi.	Effect on male mammary glands ✓	No effect at 5000 ppm (highest dose)
xii.	Teratology, rats (Hazelton study)	Not teratogenic or fetotoxic at doses up to 500 mg/kg/day.
xiii.	Cataractogenic study (IBT Study)	Negative at 3000 ppm
xiv.	Ames Mutagenicity Assay	Negative at levels up to 1000 ug/ plate
xv.	Host Mediated Assay, mice	Negative at doses up to 16.6 mg/ mouse

2. Data considered desireable but currently lacking:

   i. Teratology study in a second species.

3. Toxicology Branch has received a 2-year dog study and review is pending. Robert Taylor (PM #23) has informed TOX that the company has taken action to conduct the required teratology study.

4. See attached computer printout for summary of other tolerances granted for this pesticide.

5. The % ADI used up will increase to 1.06% from 1.05% if this tolerance (rice grain) is established.

6. The MPI is 3.00 mg/day/60 kg person. The 2-year rat chronic feeding/oncogenicity study with a NOEL of 100 ppm was used to calculate the ADI. The ADI is 0.05 mg/kg/day. A safety factor of 100 was used.

7. This reviewer is unaware of any pending regulatory actions against this pesticide.

8. There are apparently no other relevant considerations operative at this time.

OPP:HED:TOX: J.DOHERTY:sb 2/27/81 X73711 Rm. 814 CM 2 5L

R 165.361 pendimethalin(Prowl) 2/25/81

File last updated 2/25/81

000344

ACCEPTABLE DAILY INTAKE DATA

RAT,Older NOEL mg/kg	ppm	S.F.	ADI mg/kg/day	MPI mg/day(60kg)
5.000	100.00	100	0.0500	3.0000

CBRC

361

Published Tolerances

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Corn,grain(68)	0.100	1.00	0.00150
Cottonseed(41)	0.100	0.15	0.00022
Soybeans(148)	0.100	0.92	0.00138

MPI	TMRC	% ADI
3.0000 mg/day(60kg)	0.0031 mg/day(1.5kg)	0.10

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Unpublished,Tox Approved PP#0F1741,0G1740&1739,7G1923,9F2134&2246,0G2275,et

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Peanuts(115)	0.100	0.36	0.00054
Beans(9)	0.100	2.04	0.00306
Peas(117)	0.100	0.69	0.00104
Potatoes(127)	0.100	5.43	0.00814
Sorghum(147)	0.100	0.03	0.00005
Wheat(176)	0.100	10.36	0.01554
Sunflower(150)	0.100	0.03	0.00005

Remove 9/3/82

MPI	TMRC	% ADI
3.0000 mg/day(60kg)	0.0315 mg/day(1.5kg)	1.05

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BEST AVAILABLE COPY

Current Action PP#0F2401

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Rice(137)	0.050	0.55	0.00041

MPI	TMRC	% ADI
3.0000 mg/day(60kg)	0.0319 mg/day(1.5kg)	1.06

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Have the same meal schedule (no detailed document) dated 2/25/81 by Sue Edelman. Potatoes and soybeans have been published and made permanent.

3