



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

RCB
1-25-83

Hammond
Dodd

File: PAK 3G 2801

JAN 25 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

DATE: January 10, 1983

SUBJECT: Gylcophene/Lettuce
Petition # 3G2801, Caswell # 470A
CFR # 180.399

TO: Henry Jacoby, PM (21)
R.D. (TS-769)

THRU: W. Butler, W. Burnam
Tox Branch (TS-767)

W. Butler 1-13-83

Registrant: Rhone Poulenc Inc., Agrochemical
Division, New Jersey.

- Request:
- a. Application for an EUP for Testing
Rovral, Registration No. 359-685, on
lettuce.
 - b. Petition for a temporary tolerance on
raw agricultural commodity *lettuce*

SECTION F

a. PROPOSED TEMPORARY TOLERANCES FOR RESIDUES OF THE FUNGICIDE
IPRODIONE, ITS ISOMER AND METABOLITE IN OR ON LETTUCE

It is hereby proposed a tolerance for the combined residues of iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer [3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboxamide], and its metabolite [3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide] in and/or on the raw agricultural commodity lettuce.

Lettuce

7.0 ppm

359-EUP
Fungicide.

The EUP is for Rovral

Active Ingredient

PRODIONE: 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide 50.0%
Inert Ingredients 50.0%
(Inert ingredients has been cleared).

The label is acceptable. The precautionary statement "Caution" is correct. This wettable powder formulation will be used to control Bottom Rot, Botrytis and Lettuce Drop on Lettuce at the rate of 50-100 gallons per acre (1.5 to 2.0 lbs/acre), by sprayers.

Previously submitted data (Refer to attached "one liner") is sufficient to approve these requests for an EUP and a Temporary Tolerance. The 3 studies classified as supplementary data; acute dermal toxicity, second teratology - rabbit and mutagenicity other tests must be upgraded, or new tests submitted at the most earliest convenience. The attached printout explains that the percentage of ADI, existing 7.07%, will be increased resulting in 7.98%.

The increase in the T.M.R.C. is from 1.0600 to 1.1973 mg/day/1.5 kg of food. The product is not in the RPAR list.

Recommendation

This EUP and Temporary Tolerance is acceptable for the 10,000 acres in the five states of Arizona, California, Florida, New York and Wisconsin for the use of a total of 38,000 lbs./ai.

apl
Don- 13-1983
10/25/83

TOX:Alex Arce:jad:DCR#26334:TOX10:Rm.815:1/10/83

File last updated 1/10/83

ACCEPTABLE DAILY INTAKE DATA

FAI, Older NOEL	S.F.	ADI	NPI
mg/kg ppm		mg/kg/day	mg/day (60kg)
25.000 500.00	100	0.2500	15.0000

Published tolerances

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Kiwi Fruit (204)	10.000	0.03	0.00450

NPI	THRC	% ADI
15.0000 mg/day (60kg)	0.0045 mg/day (1.5kg)	0.03

Unpublished, Tox Approved 8G2087, 0G2402, 2F2596, 2F2728, 3G2737

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Almonds (1)	0.050	0.05	0.00002
Apricots (3)	10.000	0.11	0.01665
Plums, inc. prunes (125)	10.000	0.13	0.01993
Cherries (30)	20.000	0.10	0.03066
Nectarines (100)	20.000	0.03	0.00900
Peaches (114)	20.000	0.90	0.21980
Almonds (1)	0.050	0.03	0.00000
Meat, red (90)	0.800	10.81	0.12975
Milk & Dairy Products (93)	0.150	28.62	0.06438
Grapes, not raisins (67)	60.000	0.45	0.40470
Raisins (134)	180.000	0.04	0.11037

NPI	THRC	% ADI
15.0000 mg/day (60kg)	1.0600 mg/day (1.5kg)	7.07

Current Action 3G2801

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Lettuce (34)	7.000	1.31	0.15735

NPI	THRC	% ADI
15.0000 mg/day (60kg)	1.1973 mg/day (1.5kg)	7.98

EPA

Accession

Results:

TOX

CORE Grade/

Doc. No.

LD₅₀, LC₅₀, PIS, NOEL, LEL

Category

Material

Study/Lab/Study #/Date

No.

Teratology (Oral) - Rabbit, DREB, #730925, 2/5/76	Technical 1% CMC (Carboxymethyl cellulose)	232712	Maternal NOEL = < 100 mg/kg (decrease body weight) Terat NOEL => 400 mg/kg (HDT) Fetotoxic NOEL = < 100 mg/kg (Ossi- fication retardation)		Supplementary 000614
Teratology (gastric) intubation) - Rat DREB, #731016, 2/5/76	Technical 1% CMC	232712	Teratogenic NOEL = > 400 mg/kg (HDT) Maternal NOEL = 200 mg/kg Maternal LEL = 400 mg/kg (reduced body weight and food consumption rate and implantation sites)		Minimum 000614
Acute Oral LD ₅₀ - Mouse	Technical	232701	LD ₅₀ = 3050 mg/kg (Male) (2630-3540)	III	Minimum 001519
Acute Oral LD ₅₀ - Mouse	Technical	232701	LD ₅₀ = 4 g/kg (Male) (3.3-4.8) LD ₅₀ = 4.4 g/kg (Female) (3.3-5.9)	III	Minimum 001519
Acute Oral LD ₅₀ - Rat	Technical	232701	LD ₅₀ > 2 g/kg (Male & Female)	III	Supplemen- tary 001519
Acute Oral LD ₅₀ - Dog	Technical	232701	LD ₅₀ > 2 g/kg (Male & Female)	III	Supplemen- tary 001519
Acute Dermal LD ₅₀ - Rat	Technical	232701	LD ₅₀ > 2.5 g/kg (Male & Female)	III	Supplemen- tary 001519

Acute Dermal LD ₅₀ - Rabbit	Technical	232701	LD ₅₀ > 1 g/kg (Male & Female)	II	Supplementary 001519
Primary Dermal Irritation Rabbit	Technical	232701	Not an irritant at 1 g/kg (Male & Female)	IV	Supplementary 001519
Primary Dermal Irritation Rabbit	Technical	232701	Not an irritant	IV	Minimum 001519
Primary Dermal Irritation Rabbit	Technical	232701	Not an irritant		Supplementary 001519
Primary Eye Irritant - Rabbit	Technical	232701	Not an irritant		Minimum 001519
Acute Inhalation, LC ₅₀ - Rat	Technical	232701	LC ₅₀ > 3.29 g/l/4 hr.		Minimum 001519
Dermal Sensitization - Guinea Pig	Technical	232701	No evidence of sensitization		Supplementary 001519
28 Day Oral - Mouse	Technical	232702	NOEL = 1,900 ppm (Male & Female) Stripped liver above 6000 ppm		Supplementary 001519
28 Day Feeding - Mouse	Technical	232702	NOEL = 1,900 ppm, white foci Stripped liver above 6000 ppm		Supplementary 001519
90 Days Feeding - Dog	Technical	232702	NOEL = 2400 ppm LEL = 7200 ppm		Minimum 001519

Study/Lab/Study #/Date	Material	EPA Accession		Results:		TOX Category	CORE Grade/ Doc. No.
		No.		LD50, LC50, PIS, NOEL, LEL			
5 Month Feeding - Rat	Technical	232702		NOEL > 1000 ppm (HDT) (Male & Female)			Minimum 001519
24 Month Feeding - Rat	Technical	097201		NOEL > 1000 ppm (HDT)			Minimum 001519
18 Month Toxicity and Oncogenicity - Mouse	Technical	097201		NOEL > 1250 ppm (HDT) (Male & Female) Not carcinogenic			Minimum 001519
Mutagenicity - Mouse	Technical	232712		No evidence of mutagenicity or adverse effect on fertility at 1500 and 6000 ppm			Minimum 001519
3 Generation Reproduction Rat	Technical	232712		Reproductive NOEL = 500 ppm Reproductive LEL = 2000 ppm (HDT) decreased fetal weight Systemic NOEL > 2000 ppm (HDT)			Minimum 001519
Mutagenicity, Microbio- logic	Technical	232712		All tests performed were negative			Supplemen- tary 001519