



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

5086

RCB

FEB 28 1983

Hummer
Dodd

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

File: PP# 3G 2787

MEMORANDUM

DATE: December 16, 1982

SUBJECT: ROVRAL. *FOOD ADDITIVE PETITION 3H5379*
EPA Registration No. 359-685

TO: Henry Jacoby
Product Manager (21)
Registration Division (TS-769)

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

Applicant Rhone-Poulenc Inc.
St. Joseph, MO

Request: Proposed Tolerances for Residues of the Fungicide Iprodione, its isomer and metabolite in or on the raw agricultural commodity grapes and raisins as follows:

Grapes	60 ppm
Raisins	180 ppm

Background information

Recently, an EUP (3G2787) for Iprodione with tolerances of 60 ppm for grapes and 180 ppm for raisins was approved contingent that the requested levels will not be exceeded. (Copy attached.) This request is for the same commodity, same tolerances.

Recommendation: This request is supported contingent that the same limitations as in the EUP are followed.

Alyson Ace
Dec 17 82
W. Butler

DEC 3 1982

Caswell No(s): 470A - CFR

To: Henry Jacoby

Area

Registration No(s): 359-685

Pesticide Petition No(s): 362787 EXPERIMENTAL USE PERM.

Chemical(s): ROVAAL - IPRODIONE (CHIPCO 26019) 150%

IF ILLEGAL RESIDUES ARE PRESENT, FOOD OR FEED WILL NOT BE USE FOR
CONSULT

Requested Action(s): EXPERIMENTAL USE PERMIT - TEMPORARY TOLERANCE

RAC(S) - TOLERANCE(S) GRAPES 60PPM; RAISINS 180PPM CI

Recommendation: This action is supported since the

GRAPES or RAISINS WILL NOT BE UTILIZED FOR FOOD OR

FEED IF THE RESIDUE LEVELS ARE EXCEEDED

Inert(s) cleared 180.1001: YES

% of ADI occupied: Existing: 3.63 Resulting: 7.07

Resulting % increase in TMRC: 0.5449 - 1.0600 = 94.7%

Data considered in setting the ADI: RAT REPRODUCTION, 3 GENERATION

STUDY - NOEL = 500PPM

Attached (?): ADI printout: YES/NO; TOX "one-liner": YES/NO; DER: YES/NO

Existing regulatory actions against registration: NONE

RPAR status: IS NOT IN THE RPAR LIST

New Data: NONE SUBMITTED

Data gaps: THE 3 FOLLOWING STUDIES HAVE BEEN CLASSIFIED SUPPLE

MENTARY DATA: ACUTE ^{DERMAL} TOXICITY, SECOND-GENERATION, MUTAGE-

NICITY OTHER TESTS (TECH MATERIAL

Comments: LABEL - ACCEPTABLE -

A ONE YEAR DOG FEEDING HAS BEEN INITIATED

Reviewer: [Signature] Date: Nov 30-82

Section Head: [Signature] 12/2/82 Branch Chief: [Signature] 12/3/82 2

File last updated, 12/1/82

ESTIMABLE DAILY INTAKE DATA

ADI, Older Child	S.F.	ADI	ADI	
mg/kg		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)	10.00	0.03	0.00450

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

Unpublished, FCC Approved 8G2067, 0G2402, 2F2596, 2F2722

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Almonds(1)	0.050	0.03	0.00002
Apricots(3)	10.000	0.11	0.01636
Plums, inc prunes(125)	10.000	0.13	0.01993
Cherries(30)	20.000	0.16	0.03066
Nectarines(100)	20.000	0.03	0.00900
Peaches(114)	20.000	0.90	0.26980
Almonds(1)	0.00	0.03	0.00000
Nest, red(90)	0.000	10.81	0.12975
Milk&Dairy Products(93)	0.150	23.02	0.06438

ADI	THRC	% ADI
15.0000 mg/day (60kg)	0.5449 mg/day (1.5kg)	3.63

Current Action 332787

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Grapes, not raisins(67)	60.000	0.45	0.40470
Raisins(134)	180.000	0.04	0.11037

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

Data requiredClassification

Acute oral -rat	3,700 mg/kg	m
Acute dermal -rabbit	30,000mg/kg male -5,000 mg/kg female	s
Acute inhalation-rat	3.29mg/l/4h	m
Primary eye-skin-rabbit	Not an irritant	m
90 day feeding -dog	NOEL 2,400 ppm - LEL 7,200 ppm	m
Teratology - rat	NOEL 400 mg/kg /day	m
Teratogenicity - rabbit	NOEL 400 mg/kg/day	s
Chronic oncogenicity -rat 24 month feeding	NOEL 1,000 ppm	m
18 months oncogenicity -mouse	NOEL 1,250 ppm	m
Mutagenicity , dominant lethal - mouse -	No evidence of mutagenicity at 1,500 or at 6,000 ppm	m
Three generations reproduction study -rat	NOEL 500 ppm	m

Justification for using the 3 generation reproduction study -rat instead of the
3 month dog feeding study, to find the A D I

The NOEL in the 3 months feeding study -(dog) was found at the 2,400 ppm dose level. The LEL was 7,200 ppm and the symptom observed was muscular atony , no other signs of toxicity were reported

The three generation reproduction study (rat) with a NOEL of 500 ppm and with no toxic signs observed in the parent animals, will give a better indication of the potential toxicity of the material . The only adverse effect observed during the 3 generations study was the post natal pup growth for group 1V that was reduced in a minor percent as compared with group 1.

Tox Chem No. 470A Iprodione (Rovral)File Last Updated 2-3-81Current Date 7-11-81

EPA

Accession

Results:

TOX

CONE Grade/
USE. NO.

Study	Accession	Results:	TOX	CONE Grade/ USE. NO.
Acute oral LD ₅₀ , mice	232701	LD ₅₀ = 3050 mg/kg ✓ (2630-3540)	III	Minimum
Acute oral LD ₅₀ , mice	232701	LD ₅₀ = 4.0 (3.3-4.8) g/kg - M ✓ 4.4 (3.3-5.9) g/kg - F ✓	III	Minimum
Acute oral LD ₅₀ , rat	232701	LD ₅₀ = 3700 ± 300 mg/kg - M = 4400 (3200-6100) mg/kg - F]	III	Minimum
Acute oral LD ₅₀ , dog	232701	Atoxic at 2000 mg/kg —	III	Supplementary
Acute dermal LD ₅₀ , rat	232701	Atoxic at 2.5 g/kg —	III	Supplementary
Acute dermal LD ₅₀ , rabbit	232701	Atoxic at 1 g/kg —	IV	Supplementary
Primary dermal irritation - rabbit	232701	LD ₅₀ > 30,000 mg/kg - M > 5,000 mg/kg - F	IV	Supplementary
Primary dermal irritation - rabbit	232701	Not irritating at 1 g/kg —	IV	Supplementary
Primary dermal irritation - rabbit	232701	Not an irritant —	IV	Minimum
Primary dermal irritation - rabbit	232701	Not an irritant (Summary) —	IV	Supplementary
Primary eye irritation - rabbit	232701	Not an irritant —	IV	Minimum
Acute inhalation LD ₅₀ , rat	232701	LC ₅₀ = > 3.29 mg/L/4 hr. —	IV	Minimum
Sensitization dermal - guinea pig	232701	Negative ✓	IV	Supplementary
28-Day Oral - mice	232701	NOEL = 1,900 ppm —		Supplementary

Tox Chem No. 470A

EPA

File Last Updated 2-3-81

Current Date 7-11-81

Study/Lab/Study #/Date

Material

Accession No.

Results: 1 mg, 10 mg, 100 mg, 1 g

TOX Category

CORE Grade/Score

Mutagenicity dominant lethal - mice

TECH

232712

No evidence of mutagenicity or adverse effects on fertility at 1500 or 6000 ppm dose males

Minimum

Mutagenicity - micro-biologic

TECH

232712

Negative

Supplementary

3-Generation reproduction - rat

TECH

232712

NOEL = 500 ppm

Minimum

Tox Chem No. 470A

File Last Updated 2-3-81

Current Date 7-11-81

Study/Lab/Study #/Date

Material

EPA
Accession
No.

Results:

Def. ICR. PIS. NOEL. LEL

TOX
Category

CORE Grade/
Proc. No.

Supplementarity

90-Day feeding, dog

TECH

232701

NOEL = 2,400 ppm
LEL = 7,200 ppm

Minimum

5-Month feeding, rat

TECH

232701

NOEL $\geq$ 1,000 ppm (highest dose tested)

Minimum

24-Month feeding, rat

TECH

097201

NOEL $\geq$ 1,000 ppm (highest dose tested)

Minimum

18-Month feeding -
oncogenicity, mice

TECH

097201

NOEL $\geq$ 1,250 ppm (highest dose tested)

Minimum

Not carcinogenic.

Teratogenic - rat

TECH

232712

Teratogenic NOEL $\geq$ 400 mg/kg/day (highest level tested)

Minimum

Fetotoxic NOEL = 200 mg/kg/day

Fetotoxic LEL = 400 mg/kg/day (decrease in mean number of implantation sites)

Maternal NOEL = 200 mg/kg/day

Maternal LEL = 400 mg/kg/day (decrease in conception rate and food consumption)

Teratogenic NOEL $\geq$ 400 mg/kg/day (highest level tested)

Fetotoxic NOEL = undetermined

Maternal LEL = undetermined

Teratogenic - rabbit

TECH

232712

Supple-

mentary

000614

U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (WH-567) WASHINGTON, D.C. 20460		APPLICATION FOR AN EXPERIMENTAL USE PERMIT TO SHIP AND USE A PESTICIDE FOR EXPERIMENTAL PURPOSES ONLY (Please read the instructions on reverse before completing)	
1. TYPE OF APPLICATION ☒ NEW ☐ EXTENSION (Give number below) PERMIT NO. _____		2. EPA COMPANY NUMBER 359-	3. DATE OF APPLICATION November 10, 1982
4. NAME AND ADDRESS OF FIRM/PERSON TO WHOM THE EX- PERIMENTAL USE PERMIT IS TO BE ISSUED (Include ZIP code) Rhone-Poulenc Inc. Agrochemical Division PO Box 125 Monmouth Junction, NJ 08852		5. NAME AND ADDRESS OF SHIPPER (If shipment is intended and if different from applicant) (Include ZIP code) Rhone-Poulenc Inc. Agrochemical Division PO Box 39 St. Joseph, MO 64504	
6. NAME OF PRODUCT ROVRAL		7. IS PRODUCT REGISTERED WITH EPA ☒ YES (If Yes, complete below) ☐ NO EPA REG. NO. 359-685	
8. TOTAL QUANTITY PROPOSED FOR SHIP- MENT/USE PRODUCT: 2490 (1983) 7230 (1984) ACTIVE EQUIVALENT 1245 (1983) POUNDS 3615 (1984)	9. PROPOSED PERIOD OF SHIPMENT/USE April 1983 - December 1984		10. PLACES FROM WHICH SHIPPED Rhone-Poulenc Inc. Agrochemical Division PO Box 39 St. Joseph, MO 64504
11. WILL TECHNICAL MATERIAL BE IMPORTED ☒ YES (Give total quantity below) ☐ NO GALLONS _____ POUNDS 2490 (1983)		12. PLACE WHERE DIRECTIONS FOR USE APPEAR ☐ ON CONTAINER LABEL ☒ IN PRINTED MATTER ACCOMPANYING PRODUCT	
CERTIFICATION This is to certify that food or feed derived from the experimental program will not be used or offered for consumption or sale for consumption except by laboratory or experimental animals if illegal residues are present in or on such food or feed.			
13. SPECIFY THE NAME AND TELEPHONE NUMBER OF THE IN- DIVIDUAL MOST FAMILIAR WITH THIS APPLICATION WHO CAN BE CONTACTED DIRECTLY, IF NECESSARY TO PROCESS THIS APPLICATION David L. Olson 201-297-0100, ext. 598		14. SIGNATURE OF APPLICANT OR AUTHORIZED FIRM REPRESENTATIVE David L. Olson 15. TITLE Registration Specialist 16. DATE SIGNED November 10, 1982	
BELOW FOR U.S. EPA USE ONLY			
In any correspondence on this application, refer to this number:		RECEIVED BY EPA-OPP-REGISTRATION DIVISION, WASHINGTON, D.C. 20460	
Normal review time indicates that processing of this application is expected to be completed by:		Date:	
NAME OF EPA CONTACT		TELEPHONE NO.	

SECTION F

PROPOSED TEMPORARY TOLERANCES FOR RESIDUES OF THE FUNGICIDE
IPRODIONE, ITS ISOMER AND METABOLITE IN OR ON THE RAW
AGRICULTURAL COMMODITY GRAPES AND RAISINS

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-imidazolidinecarboxamide], and its metabolite [3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide] in and/or on the following products:

Grapes	60 ppm
Raisins	180 ppm

*Sent copy
to 7A Section
for notice
of Filing
11-29-82*