

US EPA ARCHIVE DOCUMENT



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

2,4-D/TOX (49)

5-14-81

Releasable

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

~~MAY 21 1981~~

MEMORANDUM

Casual No (315)

DATE: MAY 14 1981

SUBJECT: The use of 2,4-D on apricots as a plant growth regulator.
PP #2E1293 at 5 ppm in or on the fruits.

FROM: Henry Spencer, Ph.D. *HES 5/7/81*
Review Section #1
Toxicology Branch/HED (TS-769)

D. M. ... 5/18/81

TO: Clinton Fletcher, PM #43
Registration Division (TS-767)

WFB

THRU: William L. Burnam, Deputy Chief
Toxicology Branch/HED (TS-769)

Conclusions and Recommendation:

1. Toxicology Branch finds the use of 2,4-D dimethylamine on apricots with a tolerance of 5 ppm is toxicologically supportable.
2. Neither the ADI the MPI will be exceeded by this proposed use.

Comments:

1. Data gaps exist for:
 - a. a second species oncogenicity study.
 - b. a new reproduction study.
2. Studies which are desirable but absent:
 - a. a dermal absorption study with the dimethyl amine salt.
 - b. a teratology study with the 2,4-D metabolite, D,C-phenol.

Toxicology Branch notes that the spray solution is very weak (proposed 25 ppm). Exposure to 1 liter of spray and total absorption would result in 25 mg/60 kg person or 0.42 mg/kg (a highly unlikely situation).

The TMRC is increased on an average intake basis of 0.9%. The ADI is utilized 12.16% and both are considered insignificant increases per F.R. Notice 44:93 dated 5/11/79.

Note:

Though the 2,4-D acid and several esters have been shown to be teratogenic at fairly high dose levels, a margin of safety exists (MOS) for the proposed use on this food intake of approximately 2400. This is assuming the individual eats this 0.2 kg of fresh fruit at 5 ppm tolerance.

A summary of TOX data pertinent to this petition follows as taken from the memo of H. Spencer dated 5/29/80 in regards to PP #OG2301 and FAP OH 5252.

Toxicity Data Summary:

Route	Species	Sex	Value
Acute Oral 2,4-D acid	Rat	Mixed	LD50 = 375 mg/kg Core-minimum
NOTE: LD50 values vary from about 375 - 1000 mg/kg in different species.			
Chronic feeding - 2 year rat - NOEL = 1250 ppm (62.5 mg/kg/day) for systemic effects.	2,4-D		Supplemental (being repeated)
Chronic feeding - 2 year dog - NOEL = 500 ppm (12.5 mg/kg/day) LEL = 1000	2,4-D acid		Core-minimum
Reproduction - 2,4-D acid Rat - equivocally positive for reduced viability to weanling age at 100 ppm (5 mg/kg) (No NOEL) Not acceptable by today's standards			Supplemental (being repeated)
Teratology Rat - LEL = 150 mg/kg 2,4-D acid NOEL = 50 mg/kg			Core-minimum
Mouse LEL only = 147-221 mg/kg, 2,4-D acid (1 test dose)			Core-minimum
Hamster LEL = 60 mg/kg NOEL = 40 mg/kg			Core-minimum

NOTE: Most long term studies have been performed on the 2,4-D acid.

8-13-80
mch

SUBMISSION REVIEW RECORD

1. Chemical Name 2,4-D
 2. Identifying Number 2 E 1293
 3. Action Code 202
 4. Accession Number —

5. *Record Number 12862
 5. *Reference No. 2
 6. Date Received (EPA) 9/23/75
 7. Date Sent to HED 8/13/80
 (to be completed by PCB)
 8. Statutory Due Date
 (45 days) (90 days) (120 days)
(34)

12. CHECK THE FOLLOWING IF APPLICABLE:

- Public Health/Quarantine
- Substitute Chemical
- Seasonal Concern
- Request Requires Less than 4 Hrs Review
- Minor Use
- Part of IPM

(ms) 9. Projected Return Date 55 days 10/3/80
 10. Product Manager C. Fletcher
 11. Product Manager Team Number 43

3. INSTRUCTIONS TO HED REVIEWER

- Total Assessment - 3(c) (5)
- Incremental Risk Assessment - 3(c) (7) and/or E.L. Johnson memo of May 12, 1977.
- Other - (Explained below)

Provide incremental risk assessment based on known data gaps relative to conversations with H. Spencer, TTB, HED

4. Related Actions:

15. 3(c) (2) (B)
 Use any or all available information. Use only attached data.
 Use only the attached data for formulation and any or all available information on the technical or manufacturing chemical.

16. Reviews Sent to: TOX EEB PCB EFB

To	Type of Review	Number of Actions				
		Perms.	Petition	EOP	SNM	Sec. 13
<input checked="" type="checkbox"/>	Toxicology		1			
	Ecological Effects					
	Residue Chemistry					
	Environmental Fate					

18. Label Submitted with Application Attached. 20. Confidential Statement of Formula Attached
 19. Representative Labels Showing Accepted Uses Attached.
 21. Date Returned to PD (to be completed by HED) _____
 22. Include an original and 3 copies of this completed form for each Branch checked for review.
 *For use by PM only.

File last updated 5/3/81

ACCEPTABLE DAILY INTAKE DATA

Dog	NOEL	S.F.	DI	MPI
mg/kg	ppm		mg/kg/day	mg/day/60kg
12.500	500.00	100	0.1250	7.5000

Published tolerances

CROP	Tolerance	Food Factor	mg/day/1.5kg
Apples(2)	5.000	2.53	0.13975
Citrus Fruits(33)	5.000	3.31	0.23590
Cucurbits(49)	0.100	2.34	0.00425
Pears(110)	5.000	3.26	0.01916
Quinces(132)	5.000	0.93	0.00225
Potatoes(127)	0.500	5.43	0.01628
Sugar, cane&beet(154)	2.000	3.64	0.10915
Barley(5)	0.500	0.03	0.00023
Oats(102)	0.500	0.35	0.00258
Rye(140)	0.500	0.03	0.00023
Wheat(170)	0.500	10.36	0.07772
Corn, all types(30)	0.500	2.51	0.01883
Cranberries(44)	0.500	0.03	0.00023
Grapes, inc raisins(60)	0.500	0.49	0.00368
Sorghum(147)	0.500	0.03	0.00023
Blueberries(18)	0.100	0.03	0.00005
Rice(137)	0.100	0.55	0.00083
Citrus Fruits(33)	0.100	3.31	0.00572
Fruiting Vegetables(60)	0.100	2.99	0.00449
Grain Crops(64)	0.100	13.79	0.02069
Leafy vegetables(60)	0.100	2.76	0.00414
Nuts(101)	0.100	0.10	0.00015
Pome fruits(126)	0.100	2.79	0.00418
Root Crop veg(133)	0.100	11.00	0.01649
Seed&Pod veg(143)	0.100	3.56	0.00549
Small fruit, berries(146)	0.100	0.83	0.00125
Stone Fruits(151)	0.100	1.25	0.00187
Avocados(6)	0.100	0.03	0.00005
Cottonseed(41)	0.100	0.15	0.00022
Hops(73)	0.100	0.03	0.00005
Strawberries(152)	0.100	0.18	0.00023
Asparagus(5)	5.000	0.14	0.01073
Fish, shellfish(59)	1.000	1.03	0.01625
Meat, red(90)	0.200	10.81	0.03244
Milk&Dairy Products(93)	0.100	23.62	0.04292
Poultry(123)	0.050	2.94	0.00221
Eggs(54)	0.050	2.77	0.00208
Millet(94)	0.500	0.03	0.00023

MPI	TMRC	% ADI
7.5000 mg/day/60kg	0.9033 mg/day/1.5kg	12.04

Current Action PP# 2E1293

CROP	Tolerance	Food Factor	mg/day/1.5kg
Apricots(3)	5.000	0.11	0.00843

MPI	TMRC	% ADI
7.5000 mg/day/60kg	0.9113 mg/day/1.5kg	12.16
