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

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Jay Ellenberger (12)
Registration Division (TS-767)
and
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Larvin; EPA Reg. ~~#264-GUE; 264-GUR~~; PP#0F2413, 0H5275; ~~Larvin~~ in/on Cotton and Soybeans; Recalculation of the ADI

Recommendation:

The recalculation ADI is 0.03 mg/kg/day.

Review:

1) Toxicity Data considered in Setting the ADI

°Rat Oral LD_{50} = 325 mg/kg

°Rat Teratology: Negative at 30 mg/kg/day; fetotoxic NOEL = 3.0 mg/kg/day

°Mouse Teratology: Negative at 200 mg/kg/day; fetotoxic NOEL = 200 mg/kg/day

°Acute Delayed Neurotoxicity: Negative at 660 mg/kg

°Rat Dominant Lethal: Negative at 10 mg/kg/day

°Ames Salmonella/Microsome Plate Test: Negative

°Micronucleus Test: Negative

°Reverse Mutation in Saccharomyces cerevisiae: Negative

°Mitotic Crossing Over in Saccharomyces cerevisiae: Negative

°Mitotic Gene Conversion in Escherichia coli: Positive

°Primary DNA Damage in Escherichia coli: Negative

°3-Generation Rat Reproduction: NOEL = 10 mg/kg/day (HDT)

°Mouse Oncogenicity: oncogenic potential: negative at 10 mg/kg/day (HDT)

°Six-Month Dog Feeding: ChE NOEL = 15 mg/kg/day; Subchronic toxicity NOEL = 15 mg/kg/day

°2-Year Chronic/Oncogenic Rat Feeding Study: ChE NOEL = 10 mg/kg/day; chronic toxicity NOEL = 3.0 mg/kg/day; oncogenic potential: negative at 10 mg/kg/day (HDT)

2) Calculation of the ADI

The ADI is based on the NOEL of 3.0 mg/kg/day in the 2-year rat feeding studing. This is the most sensitive species for which chronic toxicity data are available. A 100 fold safety factor was used to calculate the ADI.

$$\text{ADI} = 3.0 \text{ mg/kg/day} \times \frac{1}{100}$$

$$\text{ADI} = 0.03 \text{ mg/kg/day}$$

The MPI for a 60 kg person is 1:8 mg/day.

3) Permanent tolerances utilize 0.13% of the ADI.

William Dykstra, Ph.D
Toxicology Branch
Hazard Evaluation Division (TS-769)

5/12/82

Attachment

TS-769:th:TOX/HED:WDykstra:5-12-82:Rm. 820:77395:card 4

NO CFR NUMBER Larvin 5/12/82

File last updated 4/30/82

ACCEPTABLE DAILY INTAKE DATA

RAT,Older	NOEL	S.F.	ADI	MPI
mg/kg	ppm		mg/kg/day	mg/day(60kg)
3.000	60.00	100	0.0300	1.8000

Unpublished,Tox Approved 2G2581

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Cottonseed (oil)(41)	0.000	0.15	0.00000
Soybeans (oil)(148)	0.000	0.92	0.00000

MPI	TMRC	% ADI
1.8000 mg/day(60kg)	0.0000 mg/day(1.5kg)	0.00

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Current Action PP 0F2413

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Cottonseed (oil)(41)	0.400	0.15	0.00090
Soybeans (oil)(148)	0.100	0.92	0.00138

MPI	TMRC	% ADI
1.8000 mg/day(60kg)	0.0023 mg/day(1.5kg)	0.13

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No CFR Number Lar in 2/17/83

Appendix G

File last updated 2/17/83

ACCEPTABLE DAILY INTAKE DATA

RAT,Older	NOEL	S.F.	ADI	MPI
mg/kg	ppm		mg/kg/day	mg/day(60kg)
3.000	60.00	100	0.0300	1.8000

Unpublished,Tox Approved 2G2581,0F2413

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Cottonseed (oil)(41)	0.000	0.15	0.00000
Soybeans (oil)(148)	0.000	0.92	0.00000
Cottonseed (oil)(41)	0.400	0.15	0.00090
Soybeans (oil)(148)	0.100	0.92	0.00138

MPI	TMRC	% ADI
1.8000 mg/day(60kg)	0.0023 mg/day(1.5kg)	0.13

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Current Action 3G2782

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Corn,grain(68)	0.050	1.00	0.00075
Corn,sweet(40)	1.500	1.43	0.03218

MPI	TMRC	% ADI
1.8000 mg/day(60kg)	0.0352 mg/day(1.5kg)	1.96

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