Rev. 4/14/82

D-7659 /linuron SR 7-19-82

Ca

JUL 19 1982

To: Hoyt Jamerson, Minor Use Officer, Registration Division PM #43

Registration No(s).: none given by RD

Pesticide Petition No(s).: 2E 2705 and 2H 5354 Sponsor = IR 4 for AZ, CA, NM states.

Chemical(s): a.i. = linuron formulation = Lorox manufacturer = Dupont

Requested Action(s): Incremental Risk Analysis, i.e. the increase in TMRC

Recommendation: NONE

Inert(s) cleared 180.1001: yes

% of ADI occupied: Existing: 90.05 % Resulting: 90.25 %

Resulting % increase in TMRC: 0.2 %

Data considered in setting the ADI: Dog study reviewed by M. Quaife in 1963 re-viewed again in 1982 by J.W. Holder- O.K. ADI = .0063 mg/kg/day MPI = 0.3750 mg/day

Attachment(s): three ADI printout: YES (NO); TOX "one-liner": YES (NO); DER: YES (NO)

Existing regulatory actions against registration: none, but has been refered to RPAR

RPAR status: pre-RPAR

New Data: NONE

Data gaps: MOUSE 2 year Oncology Studies

Comments: see attachments # 2 and #3.

Reviewer: J.W. Holder 7/16/82

Date: 7/16/82

Section Head: C.F. Chaisson 7/16/82

Branch Chief: [signature] 7/19/82

Attachment
No. 1

Calculations for Increase in TMRC

	Proposed Tolerance		Average Consumption per diem		Food Factor		
Beet roots:	$0.2X10^{-6}$	X	$1.5X10^{6}$ mg/day	X	.0017	=	0.00051
Beet tops:	$1.0X10^{-6}$	X	$1.5X10^{6}$ mg/day	X	.0003	=	0.00045
Beet pulp:	$1.0X10^{-6}$	X	$1.5X10^{6}$ mg/day	X	.0017	=	0.00255
						Sum =	.00351 mg/day

Percent U.S. Crop Treated (PCI) in the States of Arizona(308,000 tons), California (4,778,000 tons), and New Mexico (37,000 tons)

is: Total US Production in tons $\frac{308,000 + 4,778,000 + 37,000}{25,868,000} = .1965 = PCT$

	Sum contribution of Linuron from consumption of beet products:		PCT:
increase in Linuron intake	= 0.00351 mg/day	X	0.1965 = .0006897 mg/day

present		increase
TMRC =	.3377 mg/day	in TMRC = .0006897 mg/kg

% increase in TMRC = 0.2%

q.e.d.

2

Attachment

No.2

Comments

A positive oncology trigger has been independently identified by B. Dykstra, Mitre, and J. Holder. The trigger, in my opinion, is testicular interstitial adenomas in Charles River CD-1 rats. This may indicate a problem to the U.S. populace. These findings, howeever, must be reviewed by Dr. Paynter (see Attached No. 3) before they become the official Toxicology Branch position. A risk assessment is being planned on Linuron in order to assess the level of risk due to currently registered uses of Linuron in the U.S. When this risk analysis is performed, I will forward you the results along with Dr. Paynter's decision.

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

14 JUL 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TO: All Toxicology Branch Staff
Hazard Evaluation Division (TS-769)

SUBJECT: Evaluation of Carcinogenicity/Oncogenicity Data

Many issues pertinent to the proper evaluation of data relevant to carcinogenicity/oncogenicity are presently under consideration. Because our reviews must reflect a unified and defensible approach to these issues, I will personally review the Branch work on such studies. All reviews addressing the finding of evidence of carcinogenicity of a chemical must be submitted to me before the review can be considered final.

This is effective immediately.

Orville E. Paynter

Orville E. Paynter, Chief
Toxicology Branch
Hazard Evaluation Division (TS-769)

4