

US EPA ARCHIVE DOCUMENT

CASWELL FILE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: December 17, 1979

SUBJECT: PP#0E2278; Request for ~~Propachlor~~ tolerances of 3 ppm on flax seed and 11 ppm flax straw. CASWELL#194 Acc.#099032

FROM: Gary Burin ^{GB}
Toxicology Branch (TS-769) *RFJ 12/28/79*

TO: Clint Fletcher
ERS, RD (TS-769)

THRU: Dr. Adrian Gross, Chief *William Butler for M. Adrian Gross*
Toxicology Branch (TS-769)

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS

PC 019101

Applicant: G.M. Markle
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Action Requested

Establishment of tolerances of 3 ppm and 11 ppm for propachlor on flax seed and straw, respectively, resulting from use the Ramrod 4 flowable formulation in the control of foxtail in the states of South Dakota, North Dakota and Minnesota.

Recommendations

1. This action is not toxicologically supported by the available data. Tolerances can not be based on data submitted by Industrial Biotest Laboratories without proper validation.

(See Review of Data for list of IBT Studies). In addition to validation and our acceptance of the IBT studies, the following studies will be required on the technical ingredient:

1. Teratology in 2 species
 2. A two generation reproduction study
 3. Oncogenic potential
2. The effect of this proposed tolerance on existing tolerances for meat and milk can not be assessed prior to RCB review. However, it should be noted that flax is an important component of cattle feed.

(2)

- Existing tolerances are shown on the attached computer printout. These tolerances are based on IBT data and, unless these IBT studies are validated and accepted, it is suggested by this reviewer that existing tolerances be reassessed.

Review of Data

- The following data has been recently submitted by Monsanto and was performed by Younger Laboratories with the Ramrod $\frac{4}{7}$ flowable formulation (See memo of September 24, 1979 from S.A. Sterling):

Oral LD ₅₀ , Rat	4.7 g/kg
Dermal LD ₅₀ , Rabbit	3.16 g/kg
Eye Irritation, Rabbit	TOX Category II
Skin Irritation, Rabbit	TOX Category II

- The following testing was performed by Industrial Biotest Laboratories and can not be considered in support of this application without validation:

Acute Oral, Rat
Acute Dermal, Rabbit
Skin Irritation, Rabbit
Acute Inhalation, Rat
Subacute Dermal, Rabbit
90-Day Oral, Rat
90-Day Oral, Dog
Eye Irritation, Rabbit

TOX/HED:th:RD Initial WWOODROW:11-26-79



CFR 180.21

2C1Nipropylacetanilide

11/22/78

File last updated 11/22/78

ACCEPTABLE DAILY INTAKE DATA

RAT, Older	NOEL	S.F.	PADI	MPI
mg/kg	ppm		mg/kg/day	mg/day/60kg
13,300	266.00	2000	0.0067	0.3990

Published Tolerances

CROP	Tolerance	Food Factor	mg/day/1.5kg
Sorghum (147)	0.250	0.03	0.00011
Corn, grain (68)	0.100	1.00	0.00150
Cottonseed (41)	0.100	0.15	0.00022
Corn, sweet (40)	0.100	1.43	0.00215
Eggs (54)	0.020	2.77	0.00083
Milk & Dairy products (93)	0.020	28.62	0.00858
Meat, inc poultry (89)	0.020	13.85	0.00415
Peas (117)	0.200	0.69	0.00208

MPI	TMRC	% ADI
0.3990 mg/day/60kg	0.0196 mg/day/1.5kg	4.92

Current Action 9E2140

CROP	Tolerance	Food Factor	mg/day/1.5kg
Pumpkin, inc squash (131)	0.100	0.11	0.00017

MPI	TMRC	% ADI
0.3990 mg/day/60kg	0.0198 mg/day/1.5kg	4.96



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