Rev. 4/14/82 Toxicology Branch/HED Review CASWELL FILE

OCT 3 1985

Caswell No(s).: 160

To: Hoyt Jamerson PM 43 TS-767

Registration No(s).: 264-316 (80%)

Pesticide Petition No(s).: 5E3391

Chemical(s): Carbaryl (1-naphthylmethylcarbamate)

40 CFR 180.169

Requested Action(s): IR-4 pome fruit at 10ppm

Recommendation: Establish the tolerance

Inert(s) cleared 180.1001: Yes

% of ADI occupied: Existing: 91.57 % Resulting: 91.80 %

Resulting % increase in TMRC: 99.8%

Data considered in setting the ADI: 2-year rat feeding-NOEL 200ppm(10mg/kg), rat reproduction 3 generation NOEL 200mg/kg, mouse 18mo oncogenic NOEL 400ppm(60mg/kg) monkey(Rhesus) teratogenic NOEL 20mg/kg

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

Existing regulatory actions against registration:

RPAR status: None

New Data: None

Data gaps: One year dog feeding and dog metabolism study

Comments:

OCT 3 1985

David Rutta 10-2-85

File last updated 9/30/05

ACCEPTABLE DAILY INTAKE DATA

MAL,Older NOEL		S.F.	cDI	cAI
mg/kg	ppm		mg/kg/day	mg/day/60kg
10.000	200.00	100	0.1000	6.0000

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Published Tolerances

Crop	Tolerance	Food Factor	mg/day/1.5kg
Blackberries(15)	12.000	0.03	0.00540
Boysenberries(17)	12.000	0.03	0.00540
Collards(37)	12.000	0.08	0.01472
Dewberries(52)	12.000	0.03	0.00540
Beet greens(15)	12.000	0.03	0.00540
Kale(75)	12.000	0.03	0.00540
Loganberries(86)	12.000	0.03	0.00540
Mustard greens(99)	12.000	0.06	0.01104
Parsley(110)	12.000	0.03	0.00540
Raspberries(135)	12.000	0.03	0.00540
Spinach(150)	12.000	0.05	0.00920
Swiss Chard(156)	12.000	0.03	0.00540
Turnip Greens(166)	12.000	0.03	0.00540
Apples(2)	10.000	2.53	0.37950
Apricots(3)	10.000	0.11	0.01686
Asparagus(5)	10.000	0.14	0.02146
Bananas(7)	10.000	1.42	0.21300
Beans(9)	10.000	2.04	0.30600
Blueberries(16)	10.000	0.03	0.00450
Broccoli(19)	10.000	0.10	0.01533
Brussel Sprouts(20)	10.000	0.03	0.00450
Cabbage,sauerkraut(22)	10.000	0.74	0.11037
Carrots(24)	10.000	0.48	0.07205
Cauliflower(27)	10.000	0.07	0.01073
Cherries(30)	10.000	0.10	0.01533
Chinese Cabbage(177)	10.000	0.03	0.00450
Citrus Fruits(33)	10.000	3.81	0.57179
Cranberries(44)	10.000	0.03	0.00450
Cucumbers,inc pickl(46)	10.000	0.73	0.10984
Eggplant(53)	10.000	0.03	0.00450
Escarole/endive(56)	10.000	0.03	0.00450
Grapes, inc raisins(60)	10.000	0.49	0.07358
Kohlrabi(76)	10.000	0.03	0.00450
Lettuce(84)	10.000	1.31	0.19622
Melons(92)	10.000	2.00	0.30046
Nectarines(100)	10.000	0.03	0.00450
Okra(103)	10.000	0.07	0.01073
Olives(104)	10.000	0.06	0.00920
Peaches(114)	10.000	0.90	0.13490
Pears(116)	10.000	0.26	0.03832
Peas(117)	10.000	0.69	0.10424
Peppers(120)	10.000	0.12	0.01840
Plums,inc prunes(125)	10.000	0.13	0.01993
Pumpkin,inc squash(131)	10.000	0.11	0.01686
Salisfy(142)	10.000	0.03	0.00450
Sorghum(147)	10.000	0.03	0.00450

Cranberries(152)	10.000	0.18	0.02755
Summer Squash(155)	10.000	0.03	0.00450
Tomatoes(163)	10.000	2.87	0.43122
Corn,all types(38)	5.000	2.51	0.18825
Cottonseed (oil)(41)	5.000	0.15	0.01125
Beets(14)	5.000	0.17	0.01303
Horseradish(77)	5.000	0.03	0.00225
Poultry(128)	5.000	2.94	0.22075
Parsnips(111)	5.000	0.03	0.00225
Peanuts(115)	5.000	0.36	0.02683
Radishes(133)	5.000	0.03	0.00225
Rice(137)	5.000	0.55	0.04139
Rutabagas(139)	5.000	0.03	0.00225
Salisfy(142)	5.000	0.03	0.00225
Soybeans (oil)(148)	5.000	0.92	0.06886
Turnips(165)	5.000	0.05	0.00383
Almonds(1)	1.000	0.03	0.00045
Filberts(58)	1.000	0.03	0.00045
Pecans(118)	1.000	0.03	0.00045
Walnuts(167)	1.000	0.03	0.00045
Eggs(54)	0.500	2.77	0.02078
Sweet Potatoes(157)	0.200	0.40	0.00120
Chestnuts(153)	1.000	0.03	0.00045
Celery(28)	10.000	0.29	0.04292
Maple syrup(201)	0.500	0.03	0.00023
Lentils(83)	10.000	0.04	0.00613
Dandelion(194)	12.000	0.03	0.00540
Wintersquash(171)	10.000	0.03	0.00450
Pistachio nuts(210)	1.000	0.03	0.00045
Wheat(170)	3.000	10.36	0.46633
Cattle(26)	0.100	7.18	0.01078
Goats(62)	0.100	0.03	0.00005
Hogs(69)	0.100	3.43	0.00515
Sheep(145)	0.100	0.19	0.00029
Horses(208)	0.100	0.03	0.00005
Kidney(203)	1.000	0.03	0.00045
Liver(211)	1.000	0.03	0.00045
Dairy Products(93)	0.500	28.62	0.12877
Potatoes(127)	0.200	5.43	0.01628
Sunflower(156)	1.000	0.03	0.00045
Millet(94)	3.000	0.03	0.00135
Flax Seed(182)	5.000	0.03	0.00225
ckly pear cactus (214)	12.000	0.03	0.00540

MPI	TMRC	% ADI
6.0000 mg/day/60kg	4.6688 mg/day/1.5kg	77.81

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Unpublished,Tox Approved 6E1874,1848,2554,2667,8G1036,5E3208

CROP	Tolerance	Food Factor	mg/day/1.5kg
Rye(140)	3.000	0.03	0.00135
Oats(102)	3.000	1.36	0.01610
Barley(8)	3.000	0.03	0.00135
Potatoes(127)	9.800	5.43	0.79772
oysters (214)	0.250	0.03	0.00011
Pineapple(123)	2.000	.30	0.00889

MPI	TMRC	% ADI
6.0000 mg/day/60kg	5.4943 mg/day/1.5kg	91.57

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File last updated 9/30/05

DRAFT

ACCEPTABLE DAILY INTAKE DATA

Rat,Older NOEL		F.F.	ADI	MPI
mg/kg	ppm		mg/kg/day	mg/day(60kg)
10.00	200.0	100	0.1000	6.0000

Current Action 5L3291

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Apples(2)	0.000	2.53	0.00000
Crabapples(42)	10.000	0.03	0.00450
Pears(116)	0.000	0.26	0.00000
Quinces(152)	10.000	0.03	0.0450
rest of pome fruits (214)	10.000	0.03	0.0450

TMRC	% ADI
0.0135 mg/day(1.5kg)	0.23

TMRC 0.0000 mg/day(60kg)

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AUG 9

TO: Reviewer

Toxicology Branch ~~Branch~~, HED

CASWELL FILE

FROM: Jim Tompkins

RSERB, RD

RE: Registration Status of Pesticide Uses with Pending Emergency Exemption Requests

The purpose of this form is to identify the outstanding data requirements (in accordance with 40 CFR Part 158) necessary to secure the registration of this use. Other data gaps may be identified during the course of future petition or registration standard reviews.

After reviewing the attached emergency exemption, EE I.D. No. 85-CA-15, please complete the following using additional sheets if necessary. If a registration standard is available, RSERB/PM will identify data gaps to the extent possible for this particular use pattern. Reg Standard

___ ... ___ ... ___ ... ___ ... ___

TO: ____________________

RSERB, RD

Complete numbers 1, 2, and 3.

1. Data gaps in accordance with 40 CFR 164 Part 135 for the use described in the attached emergency exemption are: (RCB and TB please circle appropriate studies on attached sheet.)

2. Data listed in Number 1, above, are currently under review in HED and projected review completion dates are as follows:

Data listed in number 1, have not been received by Tox.

3. Data listed in Number 1, above, not required for previous uses. Minimum length of time to submit studies is:

Not applicable

Additional Comments:

Date: July 25 1985 Signed: [signature], HED Reviewer

Date: 7/25/85 Signed: [signature], Section Head

Date: 8/1/85 Signed: C Frick for B Burnam, Branch Chief

Return to ____________________, RSERB, Room 716, 557-1192.

Attachment

TOXICOLOGICAL DATA REQUIREMENTS

Instructions: Please circle data gaps applicable to the use described in the cover sheet.

Oral LD50 - Rat

Dermal LD50 - Rabbit

Inhalation LC50 - Rat

Primary Eye Irritation - Rabbit

Primary Dermal Irritation - Rabbit

Dermal Sensitization - Guinea Pig

Neurotoxicity - Hen

90-Day Feeding: Rodent
Non-Rodent

21-Day Dermal - Rabbit

90-Day Dermal

90 Day Inhalation

90 Day Neurotoxicity - Hen, Mammal

Chronic Feeding: Rodent
Non-Rodent

Oncogenicity: Rat
Mouse

Teratogenicity: Rat
(2 species) Mouse
Hamster
Rabbit

Reproduction (2 Generation): Rat or
Other

Gene Mutation

Chromosomal Aberration

Other Mechanisms of Mutagenicity

General Metabolism - ~~Rat~~ Dog

Dermal Penetration

Domestic Animal Safety (Variable)

Additional Comments:

With reference to the memo of R. Landolt dated April 14, 1985
to Jay Ellenberger, the condition for a dog teratology study
has been satisfied.