UNITT ST TES ENVIRONMENTAL PROTE(O' GENCY (9-17-79)

CASWELL FILE

DATE: September 17, 1979

SUBJECT: Section 18, Exemption: Use of Allethrin in Milk Storage and Milking Areas/All States

FROM: John Doherty John Doherty 9/24/79
Toxicology Branch/HED (TS-769)

Bdd 9/27/79

Caswell #25

TO: D. Stubbs
RD, (TS-767)

Conclusion:

1. This Section 18 cannot be toxicologically supported in the absence of the normal battery of tests required for use of a product on commodities used as human food.

   However, a special case may exist here because Allethrin is so similar to the naturally occuring pyrethrin and is thought to be one of the active ingredients of the natural product. Previous government policy has been to consider the toxicity of Allethrin to be essentially the same as the natural product (O. G. Fitzhugh memo, dated July 13, 1955, Pesticide Petition No. 20 copy enclosed). Depending upon EPA's willingness to continue this policy, this Section 18 can be approved as far as a limited use of Allethrin is concerned.

2. The low quantity of Allethrin requested (15-20 lbs. in Mississippi and up to 6000 lbs. nationwide) and the short time span for the remainder of the fly season, (until Dec. 31, 1979) indicate that exposure to this pesticide will not be excessive. Proper care in applying this pesticide further reduces the human exposure.

3. The product (FLYS OFF) is not registered for use by EPA and this problem will have to be further resolved (see review).

Section 18 Review

1. Naturally occuring pyrethrins are currently being used to control flies in milking areas of dairy barns and milk storage areas, however, there is currently a critical shortage of the natural product. Allethrin, a synthetic chemical that is thought to be at least one of the naturally occuring components of pyrethrins, has been suggested as a substitute.

   It is requested that Allethrin be used in any state where there is a critical fly problem and natural pyrethins are not available. It is estimated that 6000 lbs. of Allethrin will be used during the remainder of the 1979 fly season (Dec. 31, 1979).

An aerosol or space spray will be used, cows will not be sprayed directly and all equipment must be kept covered. The frequency of the application was not stated.

One particular Section 18 exemption is to use Allethrin (15-20 lbs.) in 1306 dairies in the state of Mississippi.

2. The formulation to be used for this Section 18 exemption (in Mississippi) is:

Flys-Off (EPA file No. 499-ENU)
(Not yet registered for use by EPA)

Active ingredient
Allethrin .56%
Piperonyl Butoxide 4%

Inerts [redacted]

This ingredient statement does not add up to 100%.

An alternate formulation consists of [redacted] are cleared under 40 CFR 180.1001. [redacted] will need more precise description for clearance.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

There is no record of acute toxicology data for this product. The registrant was previously informed of this deficiency (see F.D.R. Gee letter of June 29, 1979).

Piperonyl Butoxide is currently an RPAR chemical. However, as per conversation with Homer Hall, SPRD, it is expected to be returned to Registration Division without serious adverse action requested.

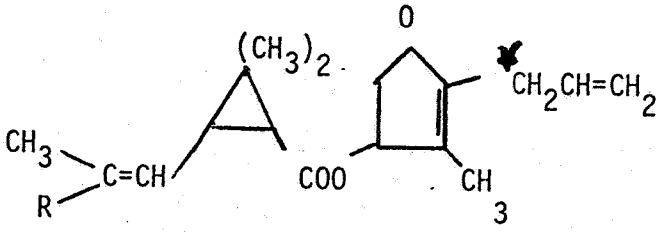
3. Chemistry Branch has determined the residues will not be expected to exceed 0.1 ppm (E. Zager).

4. Allethrin has tolerances of 4.0 ppm resulting from postharvest use on various fruits and vegtables and 2.0 ppm on various grains (40 CFR 180.113). Allethrin is exempted from a tolerance when used before harvest on various fruits and vegtables (40 CFR 180.1002). See computer printout.

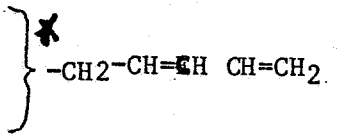
5. Current tolerances occupy 44.92% of the ADI (see computer printout). The TMRC will be 1.0535 mg/day/1.5 kg. Rat 90-day study with a NOEL of 1500 ppm and a safety factor of 2000 were used. Use of Allethrin on milk areas will change the ADI to 46.82% (or an increase of 1.9%).

6. Allethrin data bank (Specific studies with Allethrin only).

NOTE: The chemical structure of Allethrin and pyrethrin are represented by:



Allethrin

Same as Allethrin 

Pyrethrin

Toxicity studies available in EPA files include:

	Study	Results	CORE Classification
1.	Acute Oral (rats) Procida (France), 1969	630±94 male 774±146 female	Guidelines
2.	Acute Dermal (rat) Welcome Foundation, 1974	5000 mg/kg	Minimum
3.	Intraperitoneal	123 mg/kg	Minimum
4.	90-day subacute -rats Welcome Foundation, Feb. 1972 0,500, 1500, 5000 and 10,000 ppm	NOEL=1500	(only summary available)
5.	24 hour inhalation Welcome Foundation, March 1972 500, 1000, 2000 mg/m^3	NOEL=1000 mg/m^3	Minimum
6.	10-day inhalation Welcome Foundation, March 1972	>125 mg/m^3	Minimum or better

7. A reference (Carpenter et.al., Arch Ind. Hyg. and Occ. Med. 2:420-432, 1950) states no overt or histological effects at 2000 ppm for 1 year.

(See File No. 1021-1217, Acc. No. 051098, dated Sept. 22, 1972).

8. There are restrictions against the use of the pesticide product Flys-Off (EPA File No. 499-ENU) because it is not currently registered with EPA.

9. Allethrin is not an RPAR chemical. However piperonyl butoxide is currently on the list of pre RPAR review chemicals.

per M Butler

CFR 180.113 Allethrin 9/17/79

File last updated 9/14/79

ACCEPTABLE DAILY INTAKE DATA

RAT,Older mg/kg	NOEL ppm	S.F.	PADI mg/kg/day	MPI mg/day/60kg
75.000	1500.00	2000	0.0375	2.2500

Published Tolerances

CROP	Tolerance	Food Factor	mg/day/1.5kg
Apples(2)	4.000	2.53	0.15180
Blackberries(15)	4.000	0.03	0.00180
Blueberries(18)	4.000	0.03	0.00180
Huckleberries(74)	4.000	0.03	0.00180
Boysenberries(17)	4.000	0.03	0.00180
Cherries(30)	4.000	0.10	0.00613
Crabapples(42)	4.000	0.03	0.00180
Currants(48)	4.000	0.03	0.00180
Dewberries(52)	4.000	0.03	0.00180
Figs(57)	4.000	0.03	0.00180
Gooseberries(63)	4.000	0.03	0.00180
Grapes, inc raisins(66)	4.000	0.49	0.02943
Guava(184)	4.000	0.03	0.00180
Loganberries(86)	4.000	0.03	0.00180
Mangoes(88)	4.000	0.03	0.00180
Muskmelons(98)	4.000	0.03	0.00180
Oranges(108)	4.000	2.17	0.12999
Peaches(114)	4.000	0.90	0.05396
Pears(116)	4.000	0.26	0.01533
Pineapple(123)	4.000	0.30	0.01778
Plums,inc prunes(125)	4.000	0.13	0.00797
Raspberries(135)	4.000	0.03	0.00180
Tomatoes(163)	4.000	2.87	0.17249
Barley(8)	2.000	0.03	0.00090
Corn,all types(38)	2.000	2.51	0.07530
Sorgnum(147)	2.000	0.03	0.00090
Milo(95)	2.000	0.03	0.00090
Oats(102)	2.000	0.36	0.01073
Rye(140)	2.000	0.03	0.00090
Wheat(170)	2.000	10.36	0.31088

MPI	TMRC	% ADI
2.2500 mg/day/60kg	1.0106 mg/day/1.5kg	44.92

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Current Action Section 18

CROP	Tolerance	Food Factor	mg/day/1.5kg
Milk&Dairy Products(93)	0.100	28.62	0.04292

MPI	TMRC	% ADI
2.2500 mg/day/60kg	1.0535 mg/day/1.5kg	46.82

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