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

JUN 25 1996

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: FIPRONIL: Packaging for Roach and Ant Baits - Risk
Estimates for the Purposes of Child Resistant
Packaging/Labeling

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Registrant: Combat Insect Control Systems

Action Requested: Review labels and formulations to conduct risk estimates pertaining to "COMBAT Roach Bait F1", "MAXFORCE® Roach Bait F1", "COMBAT Ant Bait F1" and "MAXFORCE® Ant Bait F1" in relationship to "Child-resistant packaging and labeling."

Recommendation: The oral ingestion of the Fipronil content of one roach bait station by a 10 kg child would equal the consumption of 1.0 mg to 4.5 mg/kg (i.e. 0.1-0.45 mg/kg body weight) of the active



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ingredient. The oral ingestion of the Fipronil content of one ant bait station by a 10 kg child would equal the consumption of 0.15 mg/kg (i.e. 0.015 mg/kg body weight) of the active ingredient. Based on the acute dietary NOEL of 0.5 mg/kg for neurotoxicity, the Margin of Exposure (MOE) would range from 1.1 to 33 which is considered to be very low and therefore, the child would be at high risk.

The following assumptions are made:

1. The acute dietary NOEL is based on the results observed after a single oral dose in an acute neurotoxicity study in adult rats. The LOEL is based on decreased hind leg splay at 5 mg/kg.
2. It is assumed that a child weighs 10 kg.
3. The child will be exposed to only one bait station (single exposure).

Background:

Combat Insect Control Systems is seeking registration of new roach and ant bait products containing Fipronil as an active ingredient. The products "COMBAT Roach Bait F1" and "MAXFORCE® Roach Bait F1" contain 0.1% of a.i. while "COMBAT Ant Bait F1" and "MAXFORCE® Ant Bait F1" contain 0.01% of a.i. The number of bait stations per package will vary from 3 to 72 and the amount of unit packaging weight will vary from 1 gram to 4.5 grams depending upon the type of pest (Refer to Attachment A for details).

Calculations:

A sample calculation for a roach bait is presented below. The MOE values for various formulations of roach and ant baits are presented in Attachment B).

Amount of formulated bait in one station = 1 gram or 1000 mg

Percent active ingredient in one roach bait station = 0.1

Amount of active ingredient in one bait station = $1000 \text{ mg} \div 1000 = 1.0 \text{ mg}$

For a child weighing 10 kg (22 pounds), the amount per kg body weight = $(1.0 \text{ mg}/10 \text{ kg}) = 0.1 \text{ mg/kg body weight}$

The Margin of Exposure (MOE) is 5 and is based on a NOEL of 0.5 mg/kg (from a single dose in an acute oral neurotoxicity study in rats); $\text{MOE} = 0.5 \text{ mg/kg} \div 0.1 \text{ mg/kg} = 5.0$

Conclusions:

Based upon calculations, the amount of Fipronil as the active ingredient in one bait station orally ingested by a 10 kg child would vary from 0.015 mg/kg to 0.45 mg/kg body weight compared with an acute dietary NOEL of 0.5 mg/kg body weight for neurological effects in adult rats. The Margin of Exposure (MOE) would vary from 1.1 - 33 which is considered to be very low and therefore, the child would be at high risk.

ATTACHMENT A

Packaging Sizes

Percent a.i.	Unit Packaging Wt.	Type of Bait	No. of Bait Stations per Container	Size(s) Retail Container
0.1	1 g, 3g	COMBAT Roach Bait F1	8, 12, 24, 36	12 g, 24 g, 36 g
0.1	1.5 g	MAXFORCE® Roach Bait F1	72	108 g
0.1	4.5 g	MAXFORCE® Roach Bait F1	24	108 g
0.01	1.5 g	COMBAT Roach Bait F1	3, 6	4.5 g, 9 g
0.01	1.5 g	MAXFORCE® Roach Bait F1	24	36 g

ATTACHMENT B

Risk Analyses

Type of Bait	No. of Bait Stations per Package	Amount of Formulated Bait in One Bait Station	Percent a.i. in One Bait Station	Amount of a.i. in One Bait Station	Amount per Kg Body Wt. of Child (10 Kg)	MOE (NOEL/Amount of a.i. in One Bait Station)
COMBAT Roach Bait F1	12-36	1 g	0.1	1 mg	0.1 mg/kg	5
	6	3 g	0.1	3 mg	0.3 mg/kg	1.6
MAXFORCE® Roach Bait F1	72	1.5 g	0.1	1.5 mg	0.15 mg/kg	3.3
	24	4.5 g (for Large Roaches)	0.1	4.5 mg	0.45 mg/kg	1.1
COMBAT Ant Bait F1	3-6	1.5 g	0.01	0.15 mg	0.015 mg/kg	33
MAXFORCE® Ant Bait F1	24	1.5 g	0.01	0.15 mg	0.015 mg/kg	33