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

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 24-AUG-1998

SUBJECT: ID#064248-RU RBF5. **Fipronil: Tolerance Determination and Non-Dietary Exposure Assessment for the Crack and Crevice Application of Gel-Bait Formulation RBF5**. Barcode D239521: Chem# 129121: Submission: S529555.

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TO: Susan Lewis, Product Manager
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Clorox Services Company is seeking a registration of fipronil, formulated as a 0.01% bait-gel to be used as a crack and crevice treatment for controlling cockroaches. The product (RBF5) is packaged in 30 and 60 gram plastic syringes or 30 gram reservoirs to be used with other injector devices such as the Specialty Products Gun or the Maxforce Bait Injector.

CONCLUSION/RECOMMENDATION

A tolerance is not needed for the use of fipronil formulation RBF5 applied as crack and crevice treatment. We believe the use of this product will not result in the contamination of food surfaces based on use directions requiring the placement of the product in small doses inside cracks and crevices. In addition, the paste like consistency and the low volatility of fipronil (2.8E-9 mmHG) make this formulation unlikely to become airborne through evaporation and contaminate food handling surfaces via condensation.

Estimates of occupational exposure result in MOEs greater than 100. Chronic risk for handlers

indicate MOEs greater than 100 (880); risks for short-term and intermediate-term endpoints are also greater than 100 (5000).

DETAILED CONSIDERATIONS

Application activities consist of snapping off the injector tip and applying the gel to cracks and crevices in and around food handling establishments and residential kitchens. Directions include applying the gel into cracks and crevices at a depth of one-half inch, in up to one-half gram amounts per spot. Directions also include removal of the gel from any food handling surfaces that may be the result of any inadvertent treatments to those surfaces. Although there are no applicator exposure data available to assess the use of fipronil applied in the above stated manner, the registrant did submit a gross estimate of exposure. According to the registrant, yearly contact/exposure is to be equal to 1% of the total product use per year. This one percent represents exposure as a result of the application and any potential clean-up activities. It should be noted, this one percent estimate of exposure is equal to or greater than other percents of exposure available in the Pesticide Handlers Exposure Database (PHED).

The registrant has suggested the following algorithm to assess yearly handler exposure to 1000 grams of 0.1% fipronil using the syringes or other similar applicators:

$$\frac{\text{1000 grams RBF5 x 1000 mg/g x 0.01\% fipronil x 0.01 (skin contact) x 0.4 (skin absorption)}}{\text{70 kg (body weight)}} = 0.00057 \text{ mg/kg/year}$$

This algorithm is a reasonable approach to address an applicator's average daily exposure when comparing that exposure to a chronic NOEL (5 mg/kg/day). It is assumed, that pest control operators (PCO's) will use this product on a daily basis. This amortized exposure results in an MOE of 880 ((5 mg/kg/day)/(0.00057 mg/kg/day)). The registrant's approach for calculating a daily exposure for assessing short-term and intermediate-term exposure appears to underestimated the potential dose. That is 0.00057, was divided by 250 work days yielding an estimate of 2.2E-6 mg/kg/day or handling 4 grams of product per day. Based on label directions of ½ gram per application site, and 7 sites per visit (based on example application sites on label) and 20 visits pre day, 70 grams of product may be handled per day. The algorithm is as follows:

$$\frac{\text{70 grams RBF5 x 1000 mg/g x 0.01\% fipronil x 0.01 (skin contact) x 1 (skin absorption*)}}{\text{70 kg (body weight)}} = 0.001 \text{ mg/kg/day}$$

* The short-term and intermediate term endpoint is 5 mg/kg/day and is from a dermal study, thus daily exposure is not adjusted for dermal absorption. The estimated MOE is 5000.

The product RBF5 is registered for use by professional PCO's and not for use by non-professional users in residential settings. Due to the placement of the product (crack and crevice) and the low volatility of fipronil (2.8E-9 mmHG), exposure via the inhalation route in a residential environment is expected to be very unlikely.

To address inadvertent non-dietary ingestion of the product by a child, the registrant proposed using oral ingestion assumptions based on the study "Swallow for MAXFORCE Gel Applicators conducted on behalf of Clorox by the Great Lakes Marketing Associates, Inc."[MRID #443534-03]. In that study, a paste made of cheese was packaged in syringes (similar to the product) and made available to children in a controlled setting. The inference was to determine how much a child may ingest if it were to come by a syringe containing RBF5. It should be noted that both the test material (cheese) and the fipronil product, RBF5 both contained the same amount of bittering agent (Bitrex). Based on the results of the study, which included 68 children, ages 42 to 51 months, an average of 0.376 grams of cheese was ingested. Therefore the registrant proposed the following algorithm:

$$\frac{0.376 \text{ grams of gel ingested} \times 1000 \text{ mg/g} \times 0.01\% \text{ fipronil in gel}}{11.4 \text{ kg (25 pound child)}} = 0.0033 \text{ mg/kg/day}$$

Based on an acute dietary NOEL of 0.5 mg/kg/day, a MOE of 150 is calculated.

Having considered how the bait gel is to be applied (1/2 gram placements), the nature of the product (paste) and considering the low vapor pressure of the active ingredient (2.8E-9, mmHg at 20C), HED concludes that the possibility of detectable residues in foods from the proposed use is so remote that residue data are not required. The requested crack and crevice use in food handling establishments can be considered to be a non-food use. A tolerance or exemption from a tolerance is not required.

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