

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



OFFICE OF PREVENTION, PESTICIDE
AND TOXIC SUBSTANCES

MEMORANDUM

Date: May 21, 2008

SUBJECT: **d-Phenothrin (Sumithrin®):** Revised Addendum to Residential Exposure Assessment

PC Code: 069005

DP Barcode: D352908

Decision No.: 382326

Registration No.: 2596-150, 2596-151

Petition No.: None

Regulatory Action: Reregistration

Assessment Type: ORE

Reregistration Case No.: 0426

TXR No.: None

CAS No.: 026022-80-2

MRID No.: None

40 CFR: NA

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This document provides an addendum to the Health Effects Division's (HED) assessment of residential exposure and risk for d-Phenothrin to include a pet use scenario that was omitted from the original assessment due to a calculation error. This addendum provides an assessment of residential exposure from use of d-Phenothrin in products EPA Reg. Nos. 2596-150 and 2596-151, which are registered for use as a spot on treatment for dogs and puppies. HED's corrected assessment of these products indicates risks of concern to toddlers from incidental ingestion of residues on pets via hand-to-mouth after pet treatment.

Formulation and Use Pattern

The products assessed, EPA Reg. Nos. 2596-150 and 2596-151, are liquid products containing 87.5% of the active ingredient d-Phenothrin. These products are applied to dogs and puppies to control fleas and ticks. They are packaged and applied in varying amounts based on the weight of the animal. The products are applied by squeezing the contents out of the tube from the dog's shoulder blades along the back to the base of the tail.

Toxicological Endpoint Selection

Endpoints and levels of concern (LOCs) used to complete this assessment are summarized below in Table 1.

Table 1. Summary of Toxicological Doses and Endpoints for Phenothrin for Use in Risk Assessment			
Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Incidental Oral Short-Term (1 - 30 days)	Systemic toxicity NOAEL = 9.3 mg/kg/d UF _A = 10 UF _H = 10 UF _{DB} = 10	Residential LOC for MOE = 1000	26 week oral toxicity study in dogs LOAEL = 32 mg/kg/d based on increased alkaline phosphatase and increased liver weight (absolute and relative) in both sexes
Dermal Short/Intermediate-Term (1 - 30 days/1-6 months)	Dermal toxicity systemic LOAEL = not established 21/28 Dermal toxicity study in rats dermal toxicity systemic LOAEL not established up to 1000 mg/kg/d (HDT)		

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

Residential Exposure Assessment

The exposure scenario assessed for this use is toddler incidental ingestion of residues on pets via hand-to-mouth after pet treatment. A dermal exposure assessment for d-Phenothrin is not required because dermal effects were not observed at the limit dose in animal studies.

Exposure Assumptions

- Average body weight of a toddler is 15 kg.
- Exposure is assessed on day of application (i.e., day zero).
- Exposure duration is short-term.
- Application rate is 2.6 mL per 31 lb dog based on the label.
- Surface area of a treated (30 lb) dog is 6000 cm²
- Transferable residue from a treated pet is assumed to be 2% of the maximum application rate (MRID 45485501)
- Surface portion of hand put in mouth is 20 cm²
- Frequency of hand to mouth events is 20 per hour
- Exposure duration is 2 hours per day

Residential Exposure and Risk Estimates

The target LOC or margin of exposure (MOE) for the residential exposure assessment for d-Phenothrin is 1000. Results of the incidental ingestion scenario for products EPA Reg. Nos. 2596-150 and 2596-151 are presented in Table 2. The estimated MOE for risks to toddlers from incidental ingestion of residues on pets via hand-to-mouth after pet treatment is 46.

Table 2. Estimated Phenothrin Post-application Incidental Ingestion Risks To Toddlers Playing with Pets Treated with Reg. Nos. 2596-150 and 2596-151– Short Term LOC/MOE = 1000				
Application Method	AR (mg ai/animal)	Transferable Residue (%)	Daily Oral Dose (mg/kg/day)	MOE
Spot On	2275	2	0.2018	46

$DOD(mg/kg/day) = \text{Daily Oral Dose} = PDR / BW$
 $PDR_{(t)} (mg/day) = ((AR_{(t)} (mg ai/animal) * F) / SA_{pet}) * SEF * SA_{hands} * Freq (events/hr) * ED (hrs/day)$
 where:
 PDR = Potential Dose Rate - nondietary ingestion dose from contact with treated pets (mg/day)
 AR = Maximum Application Rate or amount applied to animal in a single treatment (mg ai/animal) = 2.6 mL product (85.7% ai) per animal. 2.6 mL/animal x 0.875 (87.5 % ai) x 1L/1000mL x 1 gal/3.8 L x 8.37 lb ai/gal x 454 g/lb x 1000 mg/g = 2275 mg/animal
 F_{AR} = Fraction of Application Rate available contact as dislodgeable residue (2%) based on tetrachlorvinphos study
 SA_{pet} = Surface Area of a treated dog (6000 cm²/animal)
 t = Time After Application (0 days)
 SEF = Saliva Extraction Factor (50%)
 SA_{hands} = Surface Area of the hands (20 cm²)
 Freq = Hand-to-Mouth Events (20 events/day)
 ED = Exposure Duration in hours = 2 hr/day
 BW = 15 kg for toddler
 MOE = Short Term Oral NOAEL (9.3mkd)/Daily Oral Dose (mg/kg/day) MOEs are reported to two significant figures.

