



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCESOPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361MEMORANDUM

DATE: 1/14/2009

SUBJECT: **Current Guidance for Residential Exposure Risk Assessment for Pet Insecticide Treatments**

PC Code: NA

DP Barcode: 350531

MRID No.: NA

Registration No.: NA

Petition No.: NA

Regulatory Action: General Correspondence

Assessment Type: NA

Reregistration Case No.: NA

TXR No.: NA

CAS No.: NA

FROM: Wade Britton, Industrial Hygienist
Risk Assessment Branch V
Health Effects Division (7509P)
Office of Pesticide Programs

THROUGH: William Donovan, Acting Branch Chief
Risk Assessment Branch V
Health Effects Division (7509P)
Office of Pesticide Programs

TO: Venus Eagle, Product Manager (01)
Insecticide-Rodenticide Branch
Registration Division (7505P)
Office of Pesticide Programs

The purpose of this document is to respond to a request for guidance on the risk assessment of residential exposure from pet insecticidal spot-on formulations. The attached memorandum, "Draft Interim Guidance for the Assessment of Human Health Exposure and Risk from Pet Insecticide Treatments" represents current, established algorithms and assumptions for the assessment of pet products. The memo does not address the SOP revisions which are currently under development for residential pet exposure assessment. Furthermore, this document will remain in draft format until all revised residential SOPs are finalized. When finalized, the pet risk assessment SOP will supersede this draft guidance.

Approved
1/23/2009
CWC

Science Advisory Council for Exposure

Draft Interim Guidance for the Assessment of Human Health Exposure and Risk from Pet Insecticide Treatments

The purpose of this draft memorandum is to provide interim guidance for risk assessors when estimating human health risk from exposure to pet insecticides. The residential SOP concerning exposure to treated pets is currently under revision. Until the completion of this process, the following assumptions and algorithms regarding exposure to treated pets should be used for risk assessment purposes. Deterministic and probabilistic methods of assessing risk from pet exposure are described and either has been deemed appropriate for use during the period of transition.

Unless chemical-specific data is available, please refrain from the use/reference of any previously performed pet exposure assessment or any pet study data which does not coincide with the following directive.

Deterministic Risk Assessment Method

Handler Inhalation and Dermal Dose from Treating Pets

Data and Assumptions for Residential Handler (Applicator) Exposure Scenarios

The series of assumptions and exposure factors which serve as the basis for estimating the dermal and inhalation exposures from all product formulations are derived from the "HED Standard Operating Procedures (SOPs) for Residential Exposure Assessments (December 19, 1997)."

- Daily dose is based upon the amount of active ingredient handled on the day of treatment (i.e., a single pet treatment). The Agency always considers the maximum application rates allowed by product labeling. The maximum rate for a single pet treatment is determined using a representative (average) animal, or a medium-sized (30 lb) dog. Estimated risks are based on an even loading of residues across the entire surface of a 30 lb dog, where Surface Area (cm²) = $((12.3 * ((BW (lb) * 454)^{0.65}))$ from HED's 1993 Wildlife Exposure Factors Handbook. Treatments intended for cats are defined separately, using product labels to determine a representative weight and the above algorithm to estimate surface area.
- Ten percent (0.1) of the active ingredient applied to the pet is assumed to be the amount the homeowner is exposed to during dipping, dusting, and shampooing. This assumption is based on the professional judgment of the OPP/HED staff and assumed to be an upper-percentile value.

- One percent (0.01) of the active ingredient applied to the pet is assumed to be available for dermal and inhalation exposure from handling flea collars. This assumption is based on the professional judgment of the OPP/HED staff and assumed to be an upper-percentile value.
- If the product is a spray formulation, it is assumed that the handler is applying one-half can of spray. Unit exposure values for the application of a typical pesticide product from an aerosol can are similar to that of a pet spray and will be used for this formulation. These can be obtained from the "Pesticide Handlers Exposure Database (PHED) Surrogate Exposure Guideline, V1.1. Health Effects Division, Office of Pesticide Programs (August 1998)."
- HED assumes handler contact during application with a spot-on product to be negligible. These products are designed to be self-contained, as it is applied directly from the tube to the pet with the tip of the applicator used to part the pet's hair.
- Adults are assumed to weigh 70 kg (use 60 kg for females when the selected endpoint is from a reproductive or developmental study). A body weight of 70 kg represents the mean body weight for all adults (i.e., male and female, ages 18 years and older) and is the value recommended in U.S. EPA (1996). A body weight of 60 kg represents the average body weight for females between ages 13 and 54 years (U.S. EPA, 1996).

The algorithms used to assess exposure/risk from residential handler dermal and inhalation pet exposure is presented below.

Spray Formulations:

Where:

$$D \text{ (mg/kg/day)} = (UE * AR * DA) / BW$$

- D = daily dermal/inhalation dose (mg/kg/day)
- UE = unit exposure (mg/lb ai)
- AR = application rate or amount applied to animal (lb ai/ treatment)
- DA = dermal and/or inhalation absorption factor (%)
- BW = adult body weight (kg)

All Other Formulations:

Where:

$$D \text{ (mg/kg/day)} = (AR * DA * F) / BW$$

- D = daily dermal/inhalation dose (mg/kg/day)
- AR = application rate or amount applied to animal (mg ai/ treatment)

DA	=	dermal and/or inhalation absorption factor (%)
F	=	fraction of active ingredient applied which is assumed to be available for dermal or inhalation exposure
BW	=	adult body weight (kg)

Dermal (adult/toddler) and Hand-to-Mouth (toddler only) Postapplication Exposure to Treated Pets

Data and Assumptions for Residential Postapplication Exposure Scenarios

The series of assumptions and exposure factors which serve as the basis for estimating the dermal and incidental oral (hand-to-mouth) exposures from all formulations are derived from the "HED Standard Operating Procedures (SOPs) for Residential Exposure Assessments (December 19, 1997)" and the 1999 Draft Policy 13, "Postapplication Exposure Assessment for Children from Treated Pets."

General assumptions and factors used in the risk calculations include:

- Daily dose is based upon the amount of active ingredient handled on the day of treatment (i.e., a single pet treatment). The Agency always considers the maximum application rates allowed by product labeling. The maximum rate for a single pet treatment is determined using a representative (average) animal, or a medium-sized (30 lb) dog. Estimated risks are based on an even loading of residues across the entire surface of a 30 lb dog, where Surface Area (cm²) = $((12.3 * ((BW \text{ (lb)} * 454)^{0.65})))$ from HED's 1993 Wildlife Exposure Factors Handbook. Treatments intended for cats are defined separately, using product labels to determine a representative weight and the above algorithm to estimate surface area.
- On the day of application, it may be assumed that 20 percent (0.20) of the maximum application rate is available on the pet's body and transferred to the adult/toddler as a dislodgeable residue. This value is based on the professional judgment and experience of the OPP/HED staff from the review of company-submitted data and is believed to be an upper-percentile assumption (US EPA, 1999 SAP).
- If chemical-/use-specific data have been submitted to the Agency (i.e., a petting/stroking study), this data can be used as a surrogate for the fraction of transferable residue. Results from the day of application (Day 0) should be used in place of the default transferable residue fraction assumption.
- Postapplication activities must be assessed on the same day that the pesticide is applied because it is assumed that individuals could handle/touch their pets immediately after application. For subsequent days after application, it may be assumed that residues do not dissipate because it is frequently desirable to maintain a specific level of pesticide on the pet (e.g., flea collars).

- It is assumed that one pet is contacted per day.
- Adults are assumed to weigh 70 kg (use 60 kg for females when the selected endpoint is from a reproductive or developmental study). A body weight of 70 kg represents the mean body weight for all adults (i.e., male and female, ages 18 years and older) and is the value recommended in U.S. EPA (1996). A body weight of 60 kg represents the average body weight for females between ages 13 and 54 years (U.S. EPA, 1996).
- 3 year old toddlers are expected to weigh 15 kilograms (representing an average weight from years one to six).
- The dermal absorption factor is [insert] % as determined by HED. If a dermal toxicity endpoint is not based on a dermal toxicity study, then a default dermal absorption value must be used. If no chemical-specific dermal absorption data are available, then a default of 100% should be used in the dermal dose calculation.
- HED default for the surface area of an adult hug is 5625 cm², a toddler hug is 1875 cm² (US EPA, 1999 SAP).
- Saliva extraction efficiency is 50 percent (i.e., every time the hand goes in the mouth approximately half of the residues on the hand are removed).
- The approach used to address the hand-to-mouth exposure pathway has been modified since 1999 Draft Policy 13, "Postapplication Exposure Assessment for Children from Treated Pets." In the draft policy, contact with dogs is based on 40 events per day (20 mouthing events/day for 2 hours). For each event, the palmar surface of the hands (i.e., 20cm²/event) is placed in the mouth of the child contributing to non-dietary ingestion exposure. In the revised approach, the frequency term has been modified to an equilibrium approach analogous to the dermal exposure component (i.e., the frequency = 1 event/day). The approach was revised since the data from which the transferable residue concentrations were determined rely on a continuous contact (grooming) technique that would lead to concentrations on the hands which are anticipated to be significantly higher than would result from petting/hugging.

The algorithms used for residential postapplication dermal and incidental oral (hand-to-mouth) pet exposure scenarios are presented below.

Adult and toddler exposure from dermal activity (hug) to treated companion animal:

The following demonstrates the method used to calculate dermal exposures that are attributable to a child touching a treated companion pet.

Where:

$$D \text{ (mg/kg/day)} = \frac{[(AR * F_{AR}) / (SA_{pet}) * (SA_{hug}) * (DA)]}{BW \text{ (kg)}}$$

D	=	daily dose from dermal pet contact (mg/kg/day)
AR	=	application rate or amount applied to animal (mg ai/ treatment)
F _{AR}	=	fraction of the application rate available as transferable residue (0.20), or fraction determined from a chemical-specific petting study
SA _{pet}	=	surface area of a treated dog (5986 cm ² / animal)
SA _{hug}	=	surface area of a child hug (5625 cm ² (adult), 1875 cm ² (toddlers))
DA	=	dermal absorption factor (%)
BW	=	body weight (70 kg (adult), 15 kg (toddler))

Toddler exposure from hand-to-mouth activity to treated companion animal:

The following demonstrates the method used to calculate hand-to-mouth exposures that are attributable to a child touching a treated companion pet and then placing their hands in their mouth.

Where:

$$D \text{ (mg/kg/day)} = \frac{[(AR * F_{AR}) / SA_{pet}) * (SAL) * SA_{hands} * Freq]}{BW \text{ (kg)}}$$

D	=	daily nondietary ingestion dose from treated pets (mg/kg/day)
AR	=	application rate or amount applied to animal (mg ai/ treatment)
F _{AR}	=	fraction of the application rate available as transferable residue (0.20), or fraction determined from a chemical-specific petting study
SA _{pet}	=	surface area of a treated dog (5986 cm ² / animal)
SA _{hands}	=	surface area of a child's hands (20 cm ²)
SAL	=	saliva extraction factor (50%)
Freq	=	frequency of hand-to-mouth events (1 event/day)
BW	=	toddler body weight (15 kg)

Probabilistic Risk Assessment Method

In addition to the deterministic risk assessment method described above, a probabilistic risk assessment method is also appropriate for the assessment of human health risk from exposure to pet insecticides. Until revision of the pet SOP is complete, the assumptions and algorithms as described for the deterministic risk assessment method (handler and postapplication exposure to treated pets) should be used to perform probabilistic risk assessment. In the probabilistic model, the risk assessor should establish, characterize and validate the distributions used for the deterministic data inputs. Current, publicly available models include CARES (Cumulative and Aggregate Risk Evaluation System), Calendex™, and SHEDS (Stochastic Human Exposure and Dose Simulation Model for Pesticides). The Agency will consider probabilistic assessments submitted by registrants under chemical review for use in risk characterization.



13544

R165416

Chemical Name:

PC Code:
HED File Code: 14000 Risk Reviews
Memo Date: 1/14/2009
File ID: 00000000
Accession #: 000-00-0127

HED Records Reference Center
1/30/2009