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

**OFFICE OF
 PREVENTION, PESTICIDES AND
 TOXIC SUBSTANCES**

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Memorandum

SUBJECT: Etofenprox: Occupational and Residential Exposure Assessment for Proposed Section 3 Registration on Domestic Pets. (DP# D327844)

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DP Barcode:	PC Code:	Trade Name:	EPA Reg#	MRID#	Decision#	Class
D327844	128965	SPI #8208-55D Etofenprox Spot-On	69332-3	45869402 46082301 46082302	363726	Insecticide

Pet Logic, LLC has requested the registration of a product containing the active ingredient (ai) etofenprox for use on domestic pets (i.e., cats). An occupational and residential exposure/risk assessment for the requested use is presented in this document. A document entitled, "Etofenprox Spot-On Treatment for Cats: Residential Non-Dietary Risk Assessment," (MRID# 46082301, C. Walls, completion date 09/03/03) was submitted by Sergeant's Pet Products, Inc. in support of this registration request. Results from the above document were considered, however, due to deficiencies in the studies upon which the submitted assessment was based, as well as differences between certain standard assumptions in the submitted document and those used by HED, the submission was not used in the development of this HED assessment.

Executive Summary

HED is conducting an occupational and residential exposure/risk assessment in support of the proposed registration of the active ingredient, etofenprox (2-[ethoxyphenyl]-2-methylpropyl-3-phenoxy benzyl ether), for insecticidal use. Etofenprox is proposed for use as an insecticide on companion animals (cats) to control fleas, ticks and mosquito pests. The active ingredient (ai), etofenprox (55%), is formulated with pyriproxyfen (2.2%) in a ready-to-use (RTU) product (SPI #8208-55D Etofenprox Spot-On) which is applied topically to pets by a syringe-type applicator tube (referred to as a "spot-on" treatment). Pyriproxyfen, the other ai in this proposed formulation, has been assessed previously for its use as the sole ai in pet collars, sprays and spot-on treatments (DP# 281982, T. Swackhammer, 05/02/02). Estimated risks from these uses, where the percent of pyriproxyfen was higher than in the formulation being assessed here, did not exceed HED's level of concern. Therefore, it is assumed that the presence of pyriproxyfen in formulation being assessed here, also will not exceed HED's level of concern.

Etofenprox is a synthetic pyrethroid-like substance. Its mode of action against insects is very similar to that of pyrethroids, and its main action site is the neuronal axon. However, its toxicity and its chemical structure are somewhat different from that of a pyrethroid. It differs in structure from pyrethroids in that it lacks a carbonyl group. Etofenprox contains an ether moiety; pyrethroids contain ester moieties.

There are no existing tolerances for etofenprox in the United States. The labeled product subject to this petition is proposed for a nonfood use in residential settings.

Occupational Handler Exposure/Risks

While dermal exposure may be possible, no dermal toxicity endpoint was identified, and therefore, an occupational handler exposure/risk assessment was not performed.

Occupational Postapplication Exposure/Risks

While dermal exposure may be possible, no dermal toxicity endpoint was identified, and therefore, an occupational handler exposure/risk assessment was not performed.

Non-Occupational (Residential) Handler Exposure/Risks

While dermal exposure may be possible, no dermal toxicity endpoint was identified, and therefore, a residential handler exposure/risk assessment was not performed.

Non-Occupational (Residential) Postapplication Exposure/Risks

Incidental oral (hand-to-mouth) exposures of children from contact with pets that have been treated with the proposed etofenprox spot-on product result in MOEs \geq 100, and therefore, do not exceed HED's level of concern. Combined risks from exposure to co-occurring etofenprox flea treatment uses (i.e., from use of the indoor total-release fogger and the cat spot-on product) all result in MOEs that do not exceed HED's level of concern except for the combined risk that includes the high application rate spot-on product assessed with a 20% transferability factor.

1.0 Hazard and Toxicity Profile

On Jan. 30, 2001, the Health Effects Division (HED) Hazard Identification Assessment Review Committee (HIARC) reviewed the toxicology database for etofenprox, selected acute and chronic dietary endpoints and toxicological endpoints for use as appropriate in occupational/residential exposure risk assessments. Subsequently, the RAB3 Toxicology Team met on February 28, 2006, to evaluate the results of new studies on acute and subchronic neurotoxicity and to re-evaluate dermal toxicity and potential for increased susceptibility of infants and children. Because this petition is not subject to the requirements of the Food Quality Protection Act (FQPA) of 1996 (because there are no current food tolerances) the susceptibility findings are not discussed in this assessment. Findings from a re-evaluation of dermal toxicity resulted in no changes to the previous assessment, including the need for a cautionary statement on the label regarding dermal irritation from repeated contact. A re-evaluation by the Carcinogen Assessment Review Committee resulted in a change of etofenprox's classification of carcinogenic potential to, "Not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis." Table 1 below, contains the current toxicity doses and endpoints for use in etofenprox risk assessments. Table 2 contains acute toxicity categories for technical grade etofenprox.

Table 1. Doses and Toxicological Endpoints for Etofenprox			
Exposure Scenario	Dose Used in Risk Assessment, Interspecies, Intraspecies and any Traditional UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (females 13-49 years of age)	NA	NA	No acute dietary endpoint was selected.
Acute Dietary (General population including infants and children)	NA	NA	No acute dietary endpoint was selected.
Chronic Dietary (All populations)	NOAEL = 3.7 mg/kg/day Chronic RfD = 0.037 mg/kg/day	FQPA SF = 1x cPAD = <u>Chronic RfD</u> Special FQPA SF = 0.037 mg/kg/day	Combined Chronic Toxicity /Carcinogenicity Study in Rat (MRID No. 40449707) LOAEL = 25.5 mg/kg/day based on increased thyroid weights. Related to increased liver weights and histopathology changes in liver and thyroid that occurred at the higher dose.
Incidental Oral Short-Term (1 - 30 days)	NOAEL = 100 mg/kg/day UF = 100	LOC for MOE = 100	Developmental Toxicity in Rabbit (MRID No. 45210602) LOAEL = 300 mg/kg/day based on decreased body weights, body weight gains, and food consumption (maternal toxicity).
Incidental Oral Intermediate-Term (1 - 6 months)	NOAEL = 20 mg/kg/day UF = 100	LOC for MOE = 100	Subchronic Oral Toxicity in Rat (MRID No. 40449703) LOAEL = 120 mg/kg/day based on decreased body weight gain, increased liver and thyroid weights with corresponding histopathology, changes in hematology and clinical chemistry.
Dermal (All durations)	NA	NA	No systemic toxicity was identified in the dermal 28-day study; Highest Dose Tested was 1000 mg/kg/day.
Inhalation (All durations)	NOAEL = 10.6 mg/kg/day UF = 100	LOC for MOE = 100 Residential LOC for MOE = 100 Occupational	13-Week Inhalation Toxicity in Rat (MRID No. 40449705) LOAEL = 52.3 mg/kg/day based on organ weight changes and histopathological changes in liver, adrenals and thyroid.
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis."		

UF = uncertainty factor, FQPA SF = Any additional safety factor retained due to concerns unique to the FQPA, 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

Table 2. Acute Toxicity of Etofenprox Technical

Guideline #	Study Type	MRIDs #	Results	Toxicity Category
870.1000	Acute Oral - Dog	40449724	LD ₅₀ = > 5000 mg/kg	IV
870.1200	Acute Dermal-Rabbit	40237710	LD ₅₀ = > 2100 mg/kg	III
870.1300	Acute Inhalation - Rat	40237705	LC ₅₀ = > 5.9 mg/L	IV
870.2400	Primary Eye Irritation -Rabbit	40237706	PIS for Conjunctival redness/edema at 24 hrs < 0.8; at 72 hrs = 0; reversible	IV
870.2500	Primary Dermal Irritation - Rabbit	40237707	PIS = 0.1 to 0.5, minimal irritation	IV
870.2600	Dermal Sensitization - Guinea Pig	40237708	Negative	NA

2.0 Use Profile

Etofenprox is a relatively new active ingredient. Currently, etofenprox products, including pressurized foggers, an emulsifiable concentrate (EC), and aerosols, have registrations for uses in the U.S. to control insects infesting commercial and public establishments, homes, and transport vehicles.

The current request is for registration of SPI #8208-55D Etofenprox Spot-On, a 55% ai RTU product formulated in a syringe-type applicator tube with pyriproxyfen (2.2% ai) for use on cats. This proposed etofenprox product is further described in Table 3.

Table 3. Etofenprox Use Profile Summary for Homeowner Spot-on Treatment of Cats

Product	Use Site	Max. Application Rate	Handler Scenario	Use Instructions
Spot-On Treatments				
SP1 88208-55D Etofenprox Spot-On	Cats	<ul style="list-style-type: none"> * For cats weighing > 2.2 lbs. and < 5 lbs: 0.385 ml at/treatment. (385 mg at/treatment) * For cats weighing > 5 lbs: 0.77 ml at/treatment (770 mg at/treatment) 	Apply Liquid, R111 applicator tube	<ul style="list-style-type: none"> * Invert the tube and use the narrow end to part the animal's hair while gently squeezing to apply to the animal's skin. Apply contents of tube as a spot high on the back of the cat's neck behind its head, or for large cats, extending as a stripe down to in front of the shoulder blades. * Do not get product in pet's eyes or mouth. * Reapply monthly. * Best when used year round. * Do not use on pets under 12 weeks of age. * Do not use on cats under 2.2 pounds.

* based on 1 ml of water weighing 1 gram.

3.0 Occupational Exposure/Risk Assessment

While dermal exposure may be possible, no dermal toxicity endpoint was identified. Also, inhalation exposure to handlers and postapplication workers is considered to be minimal. Therefore, occupational handler and postapplication exposure assessments were not performed.

4.0 Residential (Non-Occupational) Exposures and Risks

4.1 Residential Handler Exposure Scenarios

While dermal exposure may be possible, no dermal toxicity endpoint was identified. Also, inhalation exposure to handlers is considered to be minimal. Therefore, a residential handler exposure assessment was not performed.

4.2 Residential Postapplication Exposures and Risks

The proposed etofenprox residential use is for spot-on treatment of companion animals (i.e., cats). As a result, individuals of varying ages can potentially be exposed from contact with treated companion animals. Potential routes of exposure include dermal and incidental ingestion (toddlers only). Because no dermal toxicity endpoint was identified, only incidental oral exposures to toddlers were assessed. While it is assumed that most residential uses of etofenprox will result in short-term (1 to 30 days) postapplication exposures, it is also believed that intermediate-term (> 30 days to 180 days) exposures are possible.

4.2.1 Data and Assumptions for Residential Postapplication Exposure/Risk From Pets

4.2.1.1 Data from Study Submissions

An important input parameter to the hand-to-mouth exposure calculation for cat spot-on products is the amount of applied pesticide that is assumed to be available to transfer to human skin from handling a treated animal. Two studies regarding transferable residues following the application of an etofenprox cat spot-on product were submitted in support of this registration request. Reviews of these studies by HED are summarized below.

Review of "Validation Study Comparing Dose Residue Recoverability of Etofenprox from Cotton and Latex Gloves Analysis of Data and Conclusions." (DP Barcode 298228; MRID# 45869402; March 6, 2006)

The purpose of the validation study was to compare dose residue recoverability of etofenprox from cotton and latex gloves.

Both cotton and latex gloves were spiked at the following levels: 307.32 mg; 144.14 mg; 66.89 mg; 32.12 mg; 15.74 mg; 7.86 mg; 3.99 mg; 2 mg; 0.98 mg; 0.49 mg; and 0.25 mg. Six samples

(gloves) of each type and at each fortification level were analyzed 4 hours following spiking. The same was done on samples shipped overnight, where they were extracted and analyzed within 30 hours of spiking.

Sampling and Analyses

No description was given for the method of extraction, detection method, or limits of quantification (LOQ). Details regarding the preparation and handling of solvents and untreated controls were not given.

Results

Mean recovery from cotton gloves ranged from 11.51% to 16.54%, while mean recovery of etofenprox from latex gloves ranged from 54.47% to 67.56%. Neither the level of fortification nor the time to extraction (4 hours up to 30 hours) impacted the dose extracted for either cotton or latex gloves. Although etofenprox recovery from latex gloves is higher than from cotton gloves, both fall outside the acceptable spike recovery range of 70-120%.

Study Limitations

Information missing from the study includes details regarding fortification methods, storage condition of samples during shipping, exact time from spike fortification to sample analysis (the study mentions up to 30 hours) and specific analytical methods used. Other information missing from the study includes the LOQ and the sample preparation and handling of the controls.

The information gaps associated with this study severely limit the confidence that can be placed in its results and precludes use of the study for risk assessment purposes.

Review of "Dislodgeability of Etofenprox from the Haircoat of Cats Treated with a Spot-On Formulation." (March 6, 2006; DP Barcode 298228; MRID# 46082302)

The purpose of the study was to measure the dislodgeability of the test substance from the haircoats of cats treated with a spot-on formulation containing etofenprox.

Study Design

Eight cats were separated into two groups according to body weight. Four cats weighed ≤ 2.6 kg (Group I), and four cats weighed > 4.0 kg (Group II). The test substance was applied per container label instruction. Each animal was stroked with a latex gloved hand at 4 hours, 24 hours, 2 days and 3 days after application. Glove residue levels were then measured.

Sampling and Analyses

A cat spot-on formulation containing 56.03% etofenprox was administered to each cat according to label dosage recommendations and technique (i.e., parting the animal's haircoat with a syringe applicator and syringing the tube contents on the skin on the back of the neck behind the head. Cats in both groups were given 330 mg/kg of test formulation. With a gloved hand (latex glove) each cat was stroked once down its back, on each side and ventrally, from under the cats chin to the pelvis. Each stroking routine was conducted at 4 hours, 24 hours, 2 days and 3 days after application. Each of the 8 samples (gloves) was immediately removed, placed in a separate container and shipped overnight for analysis within 30 hours of the sampling procedure.

Samples were extracted by a solvent from the gloves and analyzed by gas chromatography. No other details were given.

Method validation was conducted by assessing etofenprox residues recovered from gloves that were spiked with serial dilutions of the spot-on product containing 0.5 mL of etofenprox. Recoveries ranged from 47 to 54%.

Results

Analysis of the gloves found that no etofenprox was recovered from any of the gloves used for sampling at 4 hours, 24 hours or 2 days after dosing. Day 3 samples were not analyzed following the low recovery results from the previous days' samples.

The fractional recovery rates of etofenprox in the validation spikes were used to derive correction factors to be applied to the recovered dislodged residues of etofenprox from the gloves used to stroke the cats. The mean correction factor was 1.97; however, since etofenprox was not recovered from any of the glove extractions, the correction factor from the validation spikes could not be applied.

Study Limitations

There are no applicable OPPTS Guidelines for this type of study. However, OPPTS Series 875 Part B, Guideline 875.2400: Dermal Exposure, Postapplication and Part C Guidelines were used as a guide for assessing the study. The following are limitations of the study:

1. The LOQ values for etofenprox were not provided and residues detected below the LOQ were reported as zero;
2. Detailed information regarding the analytical methodology including the extraction procedures of etofenprox from the gloves and HPLC detection methods were not provided;
3. Laboratory and field fortifications spikes were not utilized in the study;

4. Information regarding the storage stability of the samples was not provided;
5. Method validation results indicate that the recovery of etofenprox from spiked glove samples was very low (i.e., 47 to 54%); and
6. Latex gloves were used in the study to monitor residue transfer from cats' fur to human hands. Typically cotton gloves are used for residue transfer studies because they are more absorbent. Also, the stroking regimen used in the study, may have caused residues from the first stroke (i.e., head to tail) to be transferred to other parts of the cat (sides) on subsequent strokes. Thus, no residues were detected on the gloves.

Due to the above listed limitations, some of which may have resulted in findings of no residues on the cat's haircoat, results of this study should not be used for quantitative risk assessment purposes.

4.2.1.2 Assumptions

The standard value for the percent of the application rate initially available to transfer from pet to human is 20%, from HED's Residential Exposure SOPs^{1,2,3}. However, in this assessment the value of 5% also was used. The rationale for using the 5% value includes the following:

- The 20% transferability factor in the SOPs is a bounding value, determined from a study that employed a vigorous rubbing of the treated area for an extended period of time.
- The 20% value was derived from a study on a shampoo product, which is presumed to have more readily available surface residues for transfer to humans than the proposed spot-on treatments which are applied to the animals skin, and thought to migrate more along the skin of the animal (i.e., not the fur).
- The results from a study on the dislogeability of tetrachlovinphos from animals treated by a pump-spray treatment product (MRID 45485501) were used as a surrogate for the etofenprox spot-on product. The dataset for this study includes estimates for the percent of applied dose available on the fur that is transferred to the hand (~5%).
- While HED has used the 5% value in this assessment, the assumption that the proposed pet spot-on product is similar to the tetrachlorvinphos product may, or may not, be true. Further, **there may be data compensation issues involved with the use of this study.** In the event that results from this study are not allowable, the standard 20% factor is also used to estimate risks.

Instructions for pet spot-on treatments include a monthly re-treatment regimen, and therefore short- and intermediate-term incidental oral exposures are possible. However, because "day of treatment" residues are anticipated to dissipate between applications, a 31-day average residue level was used to estimate intermediate-term exposures. The 31-day average is based on a residue dissipation rate of 5% per day, and a re-application on the 31st day. The calculation begins with the day of application, where the amount of residue available on the animal is estimated to be 5% of the application rate (20% was also calculated). On each of the next 30 days this amount is diminished by 5%. On the 31st day, a new application amount is added. Then the residue amounts for each day are added and divided by 31 days to estimate the 31-day average residue on the animal available for transfer to humans. Estimated residues on the day of treatment (day 0) were used for estimating short-term exposures and risk.

The calculations used for the pet use scenario are presented below, with summaries of the estimated exposures and risks presented in Table 4.

Calculations for Hand-to-Mouth

$$D = [(AR/SA_{\text{pet}}) * F_{\text{AR}} * (1 - DR)^t * (SAL) * SA_{\text{hands}} * \text{Freq} * \text{Hr}]/\text{BW}$$

where:

D	=	daily nondietary ingestion dose from treated pets (mg/kg/day);
AR	=	application rate or amount applied to animal in a single treatment (mg ai/animal);
SA _{pet}	=	surface area of a treated animal (standard value of 5986 cm ² /animal);
F _{AR}	=	fraction of the application rate available as transferable residue (0.05 to 0.20);
t	=	time after application (days);
DR	=	dissipation rate per day (5% per day);
SAL	=	saliva extraction factor (50%);
SA _{hands}	=	surface area of the hands (20 cm ²);
Freq	=	frequency of hand-to-mouth events (20 events/hour for short-term; 9.5 events/hour for intermediate-term);
Hr	=	exposure duration (2 hours); and
BW	=	body weight (15 kg).

Table 4. Hand-to-Mouth Exposure and Risk to Children from Treated Cats

AR	Γ_{AR}	SA _{pet}	Ave. 31-day Residue [day "0" residue] ¹	SAL	SA _{hands}	Freq (events/hour)	ET (hours)	S-T Dose (mg/kg/day)	I-T Dose (mg/kg/day)	S-T MOE ²	I-T MOE ²
385 mg ai per cat of > 2.2 lbs and < 5 lbs	0.2	5986 cm ²	0.00688 mg/cm ² [0.0129 mg/cm ²]	0.5	20 cm ²	20 (S-T)	2	0.344	0.087	290	230
	0.05		0.00172 mg/cm ² [0.00322 mg/cm ²]					0.0859	0.022	1200	900
770 mg ai per cat of > 5 lbs	0.2	5986 cm ²	0.0138 mg/cm ² [0.0244 mg/cm ²]	0.5	20 cm ²	20 (S-T)	2	0.681	0.175	150	110
	0.05		0.00344 mg/cm ² [0.00643 mg/cm ²]					0.171	0.0436	580	460

¹ Average 31-day residue used for intermediate-term risk estimates; day "0" or "day of treatment" residue used for short-term risk estimates.
² MOE = NOAEL/Dose, where the incidental oral endpoint NOAEL for short-term (S-T) = 100 mg/kg/day; for intermediate-term (I-T) = 20 mg/kg/day.
 Note: Shaded cells indicate that the MOE exceeds HED's level of concern (LOC = 100)

4.2.2 Summary of Residential Postapplication Exposure/Risk From Treated Pets

The MOEs for **postapplication incidental oral hand-to-mouth exposures to children from contact with treated cats** are all > 100 , and therefore **do not exceed HED's level of concern**.

5.0 Combined Exposures/Risk

HED believes that there is a potential for both the etofenprox cat spot-on product and the etofenprox indoor total-release fogger to be used in combination as a comprehensive approach to controlling a household flea problem (Residential exposures/risks from the use of an etofenprox total-release fogger appear in a separate HED risk assessment, ref: D327831, April 6, 2006). For this reason, it is appropriate to assess the exposures/risk from this combined use pattern. Because both short-term (1 to 30 days) and intermediate-term (one month to 180 days) exposures are possible for the indoor fogger and the cat spot-on treatment, short-term, as well as intermediate-term exposure/risks from both flea treatment products are combined.

For short-term exposures, the reciprocal MOE methodology is used to combine all exposures from hand-to-mouth and object-to-mouth, resulting from the use of both the indoor total-release fogger and cat spot-on treatment. Inhalation exposures are not combined because the inhalation toxicity endpoint effect is different than that for incidental oral. **The resulting combined risks when using the 5% transferability factor** is an MOE of 1100 for low-dose application, and an MOE of 570 for the high dose application, both of which **do not exceed HED's level of concern**. Using the 20% transferability factor, the MOEs are 290 for the low dose and 150 for the high dose. These latter MOEs also do not exceed HED's level of concern.

For intermediate-term exposures, the reciprocal MOE methodology also was applied. In this case, inhalation, as well as hand-to-mouth and object-to-mouth exposures can be combined because the toxicity endpoint effect is the same. **The resulting combined risks when using the 5% transferability factor** is an MOE of 240 for low-dose application, and an MOE of 190 for the high dose application, both of which **do not exceed HED's level of concern**. The resulting **combined risks when using the 20% transferability factor** is an MOE of 140 for low-dose application, and **an MOE of 80 for the high dose application, the latter of which exceeds HED's level of concern**.

6.0 Summary/Characterization of Residential Risk and Data Gaps

Most input parameters in the exposure calculations range from central tendency to high end. One exception is the value used in the exposure equation for the surface area of the animal. The surface area used is based on a 30-pound dog, which has a larger surface area than a cat. The result is that there is an element of underestimation of the amount of applied etofenprox per unit area of cat than would actually be the case if a cat surface area were used. A standard cat surface area has not yet been established for use in HED risk assessments.

HED believes that the 5% transferability factor is the most appropriate. An assessment of risks using the SOP value of 20% was only included in the event that the study upon which the 5% factor is based cannot be used because of data compensation issues. While HED has provided a rationale for using the non-SOP value for initial available residue (5%) in a previous section, the most appropriate value for use in this assessment should be determined from a properly conducted residue transferability study with proposed etofenprox pet spot-on treatments. Studies submitted for this purpose were not useable for risk assessment purposes due to numerous study limitations. Because surrogate values have been used in this assessment (i.e., 5% transferability factor and a 5% per day dissipation rate), **HED recommends that this registration be conditional upon submission of a properly conducted residue transferability/dissipation study using the cat spot-on product. Prior to initiation, a study protocol should be submitted to OPP for review and approval.**

References

¹ Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments. (OPP; December 18, 1997)

² Health Effects Division Science Advisory Council for Exposure *SOP 12: Recommended Revisions To The Standard Operating Procedures For Residential Exposure Assessment*, February 22, 2001.

³ Draft: Part B - SOPs, Residential SOPs (Revisions of April 5, 2000)

cc: RAB3 file