

January 18, 2011

Docket ID No. EPA-HQ-OPP-2007-0935

**SUPPLEMENT TO  
NATURAL RESOURCES DEFENSE COUNCIL'S  
PETITION TO CANCEL PET COLLAR USES  
FOR THE PESTICIDE PROPOXUR**

On November 26, 2007, the Natural Resources Defense Council (NRDC) filed a petition to the U.S. Environmental Protection Agency (EPA) to, among other things, cancel all pet collar uses for the pesticide propoxur because of the unnecessary dangers posed by exposure to this toxic chemical, particularly in light of the alternatives available. To date, EPA has not responded. In April, 2009, NRDC supplemented its petition to EPA with its report "Poison on Pets II" showing unacceptably high residues from touching pets wearing propoxur-impregnated flea collars. This document incorporates the arguments from the original petition, the supplement to the original petition, and provides additional evidence of elevated risks to children from propoxur formulated pet collars.

Since the filing of the two previous petitions, EPA has initiated a Registration Review for propoxur. As part of this review, new documents detailing exposure and risk information for pet collar uses of propoxur have been posted to the docket. These include a residential exposure and risk assessment for propoxur-formulated pet collars performed by EPA, and information provided by Sergeant's Pet Care Products (one of the manufacturers of propoxur-formulated pet collars and EPA registrant) contesting the agency assessment and providing their own assessment.<sup>1 2 3</sup> Our analysis of the EPA documents and those provided by the manufacturer demonstrates evidence of an elevated risk to children from use of propoxur formulated pet collars.

EPA's assessment of children's exposure to propoxur-formulated pet collars found unacceptably high risks. However, EPA's assessment significantly underestimates risks from propoxur-formulated collars by failing to assess dermal exposures, using inadequate estimates of children's hand-to mouth behavior, and ignoring cancer risks. Furthermore, using the alternative residue levels submitted to EPA by Sergeant's to calculate the risk also identifies elevated risks to children.

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<sup>1</sup> EPA Memorandum dated April 7, 2010 Subject: Propoxur: Occupational and Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars Docket Number: EPA-HQ-OPP-2009-0806

<sup>2</sup> EPA Memorandum dated July 12, 2010 Subject: Issues for Consideration Related to Propoxur: Occupational and Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars Docket Number: EPA-HQ-OPP-2009-0806

<sup>3</sup> Johnston, Jason E. 2010. Residential Risk Assessment for Post-application Exposures Associated with Pet Collars Containing Propoxur Using Rate of Release Data from Historical On-Animal Studies Docket Number: EPA-HQ-OPP-2009-0806

All the evidence before the Agency provides EPA with ample reason to cancel pet uses for propoxur. EPA should immediately take action on their own assessment and the evidence presented here to protect children from these dangerous products and cancel pet uses of propoxur.

### **EPA's Assessment of Children's Exposure to Propoxur Formulated Pet Collars Found Unacceptable Risks.**

In a memorandum dated April 7, 2010, EPA detailed the results of its most recent occupational and residential exposure and risk assessment for propoxur formulated pet collars.<sup>4</sup> This assessment found Margins of Exposure (MOEs)<sup>5</sup> ranging from 20 to 62 for child incidental oral ingestion risk. These values are significantly less than the Agency's threshold for safety of 1000 and the document concluded that the "risks are of concern to the Agency".<sup>6</sup> The calculations in this assessment were refined in a follow-up memorandum, dated July 12, 2010, and the new MOEs ranged from 55 to 82.<sup>7</sup> Together the calculations presented in these two memos are hereinafter referred to as the "2010 risk assessment". (See Table 1 for exposure parameters and Appendix A for relevant exposure algorithm and calculation method).

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<sup>4</sup> EPA Memorandum dated April 7, 2010 Subject: Propoxur: Occupational and Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars Docket Number: EPA-HQ-OPP-2009-0806

<sup>5</sup> The Margin of Exposure (MOE) is the ratio of the estimated dose to the level of safe exposure. The lower the MOE the higher the risk.

<sup>6</sup> EPA Memorandum dated April 7, 2010 Subject: Propoxur: Occupational and Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars Docket Number: EPA-HQ-OPP-2009-0806

<sup>7</sup> EPA Memorandum dated July 12, 2010 Subject: Issues for Consideration Related to Propoxur: Occupational and Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars Docket Number: EPA-HQ-OPP-2009-0806

**Table 1:** Residential post application for **only** hand-to- mouth exposures using EPA (2010) transferable residue calculations and unrealistic exposure assumptions from EPA’s (2010) residential exposure and risk assessment.

Variable	Source	Wellmark Dog Collar	Wellmark Cat Collar	Sergeant’s Dog Collar	Sergeant’s Cat Collar
Weight of the collar (g)	EPA (2010) Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars	34	10.5	30	14
AR* (Wellmark 10% - Sergeant’s 9%) (g)		3.4	1.05	2.7	1.26
F(AR)		0.2	0.2	0.2	0.2
SA(pet) (cm2)		5986	2737	5986	2737
SAL		0.5	0.5	0.5	0.5
SA(hands) (cm2)		20	20	20	20
Freq (events/day)		1	1	1	1
BW (kg)		15	15	15	15
Daily Transferable residue (mg/cm2-day)		0.008	0.005	0.006	0.006
Dose (mg/kg) - ingestion			0.005	0.003	0.004
NOAEL (mg/kg-day)		0.28	0.28	0.28	0.28
MOE		55	82	70	68

\* See Appendix A for abbreviations and calculation algorithms.

Although these refined MOEs are higher, they are still well below 1000 and thus still represent an inadequate margin of safety. Due to the unacceptable risks determined in this assessment, EPA should immediately cancel pet uses of the pesticide propoxur.

**EPA’s Residential Exposure and Risk Assessment Significantly Underestimates Health Risks From Propoxur In Pet Collars.**

The most recent risk assessment conducted by EPA continues to be flawed, as has EPA’s past risk assessments for propoxur. In the 2010 risk assessment, EPA failed to consider the risks from dermal exposure to propoxur in pet collars. Furthermore, as NRDC has mentioned time and again, EPA makes faulty assumptions about toddlers.<sup>8</sup> Specifically, EPA either makes unrealistic assumptions about, or completely ignores aspects of, toddlers’ mouthing behavior. And finally, EPA completely ignores the cancer risk associated with this pesticide. These deficiencies in the risk assessment make a pesticide that EPA has already identified as of concern even more problematic.

<sup>8</sup> NRDC comments on the EPA *Organophosphate Cumulative Risk Assessment* (October 2, 2006) EPA docket EPA-HQ-OPP-2006-0618. Supplement to Natural Resources Defense Council Petition To Cancel Pet Collar Uses For The Pesticide Propoxur (April 23, 2009) EPA docket EPA-HQ-OPP-2009-0207-0003.

### *Failure to Assess Dermal Exposures*

EPA's 2010 residential risk assessment of exposure to propoxur-formulated flea collars ignored the risks associated with absorbing propoxur through the skin. EPA incorrectly claims in the occupational and residential risk assessment that there are no data on rates of dermal absorption for propoxur.<sup>9</sup> However, the 1997 Reregistration Eligibility Determination for propoxur cites a human study that found a 20% dermal absorption rate.<sup>10</sup> Normal activity with a pet, including petting and hugging, would be expected to result in dermal contact ranging from the surface of the hands to a significantly larger skin surface area. This exposure pattern was included in the risk assessment performed for pet uses of the pesticide dichlorvos (DDVP), in which EPA calculated dermal exposures based on one pet hug per day. Given this evidence, risk assessments for pet uses of propoxur must include calculation of dermal exposure.

Adjusting EPA's risk calculation from the residential exposure assessment to include the dermal exposure resulting from one pet hug per day results in an estimated dose for dog and cat collars ranging from 0.194 to 0.158 mg/kg-day and MOEs of 1 or 2. This represents up to a 40 fold increase in the risk compared to EPA's 2010 risk assessment. (See Table 2 for exposure parameters and Appendix A for relevant exposure algorithm and calculation method).

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<sup>9</sup> EPA Memorandum dated April 7, 2010 Subject: Propoxur: Occupational and Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars Docket Number: EPA-HQ-OPP-2009-0806

<sup>10</sup> US EPA 1997. Reregistration Eligibility Decision (RED) Propoxur. EPA-738-R-97-009. page 20.

**Table 2:** Residential post application for **hand-to- mouth and dermal exposures** using EPA (2010) transferable residue calculations and keeping EPA (2010) unrealistic exposure assumptions for hand-to-mouth and adding a conservative estimate of dermal exposures following EPA guidance.

Variable	Source	Wellmark Dog Collar	Wellmark Cat Collar	Sergeant's Dog Collar	Sergeant's Cat Collar
Weight of the collar (g)	EPA (2010) Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars	34	10.5	30	14
AR (Wellmark 10% - Sergeant's 9%) (g)		3.4	1.05	2.7	1.26
F(AR)		0.2	0.2	0.2	0.2
SA(pet) (cm2)		5986	2737	5986	2737
SAL		0.5	0.5	0.5	0.5
SA(hands) (cm2)		20	20	20	20
Freq (events/day)		1	1	1	1
BW (kg)		15	15	15	15
SA(hug)		1875	1875	1875	1875
Freq (events/day)	1 hug per day scenario	1	1	1	1
Fraction absorbed	EPA (1997) Propoxur RED	0.2	0.2	0.2	0.2
Daily transferable residue (mg/cm2-day)		0.008	0.005	0.006	0.006
Dose (mg/kg-day) - ingestion		0.005	0.003	0.004	0.004
Dose (mg/kg-day)-dermal		0.189	0.128	0.150	0.153
Total Dose (mg/kg-day)		0.194	0.131	0.154	0.158
NOAEL (mg/kg-day)		0.28	0.28	0.28	0.28
MOE		1	2	2	2

*Underestimation of Children's Hand-to-Mouth Behavior*

In the 2010 residential risk assessment, EPA assumed that a child would have only one hand-to-mouth event per day after exposure to a treated pet. This assumption is not substantiated by either the available literature or by EPA's own previous risk assessments for pet products. A meta-analysis performed by Xue et al. (2007) reported a mean hand-to-mouth activity for 1-2 year olds of 19.6 events per hour.<sup>11</sup> Residential post-application exposure to pesticides in flea collars in the Organophosphate Cumulative Risk Assessment (2006) uses a "most likely" value of nine events per hour.<sup>12</sup> EPA's assessment of DDVP, which had been used in pet collars,

<sup>11</sup> Xue, J., Zaratarian, V., Moya, J., Freeman, N., Beamer, P., Black, K., Tolve, N., and Shalat, S. 2007 "A Meta-Analysis of Children's Hand-to-Mouth Frequency Data for Estimating Nondietary Ingestion Exposure." *Risk Analysis*, 27:2

<sup>12</sup> EPA. 2006. Organophosphate Cumulative Risk Assessment

assumed that toddlers were exposed for 2 hours per day.<sup>13</sup> The assumptions in the 2010 propoxur risk assessment are unrealistic, inconsistent with previous agency findings, and significantly underestimate actual risk to toddlers.

The effect of this low assumption for hand-to-mouth events in the 2010 propoxur risk assessment is that EPA significantly underestimates the potential dose to a child from exposure to a pet collar. This is illustrated by adjusting EPA’s risk calculation from the residential exposure assessment to use more reasonable hand-to-mouth variable exposure parameters from other EPA risk assessments. For example, using EPA’s “most likely” assumption of nine hand-to-mouth events from the OP Cumulative Risk Assessment and the two hours per day exposure from the DDVP risk assessment, would result in dose estimates ranging from 0.061 to 0.091 mg/kg - day for dog and cat collars and corresponding MOEs from 3 to 5. (See Table 3 for exposure parameters and Appendix A for relevant exposure algorithm and calculation method.) This represents up to a 20 fold increase in the dose compared to EPA’s 2010 risk assessment.

**Table 3:** Residential post application for *only hand-to- mouth exposures* using EPA (2010) transferable residue calculations and more realistic hand-to-mouth exposure parameters from other EPA risk assessments for pet collars.

Variable	Source	Wellmark Dog Collar	Wellmark Cat Collar	Sergeant’s Dog Collar	Sergeant’s Cat Collar
Weight of the collar (g)	EPA (2010) Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars	34	10.5	30	14
AR (Wellmark 10% - Sergeant’s 9%) (g)		3.4	1.05	2.7	1.26
F(AR)		0.2	0.2	0.2	0.2
SA(pet) (cm2)		5986	2737	5986	2737
SAL		0.5	0.5	0.5	0.5
SA(hands) (cm2)		20	20	20	20
BW (kg)		15	15	15	15
Mouthing events (events/hr)	EPA (2006) CRA for Organophosphates	9	9	9	9
Duration of exposure (hrs/day)	EPA (2006) RED DDVP	2	2	2	2
Freq (events/day) = events/hour * hours/day	= events/hour * hours/day	18	18	18	18
Daily transferable residue (mg/cm2-day)		0.008	0.005	0.006	0.006
Dose (mg/kg- day) - ingestion		0.091	0.061	0.072	0.074
NOAEL (mg/kg-day)		0.28	0.28	0.28	0.28
MOE		3	5	4	4

<sup>13</sup> EPA (2006) Reregistration Eligibility Determination for Dichlorovos (DDVP) EPA-738-R-06-013

The exposure calculation in Table 3 assumes that a toddler's hand is equally replenished with pesticide residue after each mouthing event. Wellmark International contends that this assumption is incorrect. Specifically, in comments submitted to EPA in opposition to NRDC's petition to cancel pet uses of propoxur, Wellmark claimed that a child's hands would not be replenished with the same residue level each time because pesticide residues would be concentrated near the collar and, once removed due to petting activity, would not be replaced right away. Wellmark also claimed that it would be unrealistic to assume that a child would fully replenish their fingers multiple times an hour.<sup>14</sup> However, as explained below, there is sufficient evidence to support retaining this assumption when assessing exposures from propoxur formulated pet collars.

A child actively playing with a pet is in regular contact with the pet's fur. The EPA risk calculation assumes that the palmar surface of three fingers, equivalent to 20 cm<sup>2</sup> of finger surface area, are inserted in the mouth per mouthing event. However, regular petting behavior involves contact of the whole hand with the fur and pesticide residues, meaning a larger area than just three fingers would pick up residue during each petting event. If each petting event transfers pesticide residue to the palmar surface of both hands of a child this equals 66.7 cm<sup>2</sup> of contaminated finger surface area and 176 cm<sup>2</sup> of the total hand surface area.<sup>15 16</sup> Therefore, the exposure scenario of nine mouthing events per hour consisting of an equal, and maximal, level of residue, from other EPA risk assessments for pet products, can be achieved a number of ways. This includes nine separate petting and mouthing events or, if the child were to mouth different fingers during each event, both hands would only need to be replenished (through petting) about three times (every 20 minutes).<sup>17</sup> If the child were to mouth the palmar surface of the fingers and the palm following a petting event, the same level of exposure would be achieved after just one hand replenishment per hour.<sup>18</sup> Therefore, this exposure scenario can be understood to represent a range from one to nine petting events per hour (or every 7 to 60 minutes) where the hands are replenished with pesticide residue, which is not inconsistent with normal child/pet interactions.

Furthermore, Wellmark's concern that there would be insufficient residue on the pet's fur to support this exposure scenario is without merit. EPA's exposure scenario of nine mouthing events consisting of the palmar surface of three fingers equals contact with 180 cm<sup>2</sup> of residue contaminated fur per hour, or 3% of the surface area of the default sized dog.<sup>19</sup> On a treated pet there is likely to be at least this amount of fur with the maximal pesticide residue available for a child to fully replenish his or her hands. Therefore, the same level of residue would be available for potential ingestion for each mouthing event and this assumption should be conserved in the risk assessment.

<sup>14</sup> Wellmark International. 2009. Comments Submitted in Response to: Petition Requesting Cancellation of Propoxur Pet Collar Uses; Notice of Availability. April 9, 2009. FR 74 (66): 15980-15981. Docket ID No.: EPA-HQ-OPP-2009-0207.

<sup>15</sup> (20cm<sup>2</sup>/3 fingers) \* 10 fingers = 66.7 cm<sup>2</sup>.

<sup>16</sup> Palmar surface of both hands is assumed to equal half the total surface area of a child's hands (350cm<sup>2</sup>/2 = 176 cm<sup>2</sup>). EPA.1997. Standard Operating Procedure for Residential Exposure Assessment.

<sup>17</sup> Nine mouthing events \*20 cm<sup>2</sup> = 180cm<sup>2</sup> of mouthed area per hour. 180 cm<sup>2</sup>/66.7 cm<sup>2</sup> per petting event = 2.69 or 3 petting events per hour.

<sup>18</sup> 180 cm<sup>2</sup>/176 cm<sup>2</sup> per petting event = 1.02 or 1 petting event per hour.

<sup>19</sup> 180 cm<sup>2</sup> per hour /5986 cm<sup>2</sup> per dog = 3% per hour for contact with one dog.

EPA also ignored “indirect” hand-to-mouth activity, which is the exposure from toddlers who touch an object or food with pesticide-contaminated hands and then put that object or food into their mouths. However, published studies show that there is actually noticeable indirect hand to mouth activity in infants and children. In fact, one study found that, on average, a toddler will touch an object and then put that object into his or her mouth 15 times in one hour. At the high end of the study’s distribution (90th percentile), that rate rises to 66 times per hour.<sup>20</sup> This same study found a statistically significant positive correlation between the frequency of object or food in mouth activity and blood lead levels.

Taken together, this evidence demonstrates that the risk to children from pet collar uses is substantially greater than EPA calculated in its 2010 risk assessment due to significant underestimates in hand-to-mouth exposures stemming from inadequate assumptions of hand-to-mouth frequency and failure to include indirect hand-to-mouth exposures.

In total, when a conservative estimate of dermal exposure is added to the more realistic estimates of children’s hand-to-mouth exposures used in previous EPA risk assessments, the estimated dose is about 56 times greater than what is described in EPA’s 2010 risk assessment.<sup>21</sup> These calculations demonstrate the degree to which the exposure calculations used in the 2010 risk assessment are inadequate and result in a significant underestimate of risks to children from propoxur formulated pet collars.

#### *Failure to Consider Cancer Risks*

Propoxur is classified as a Group B2 Probable Human Carcinogen with a unit risk  $Q_1^*$  of  $3.7 \times 10^{-3}$ .<sup>22</sup> It is also listed as a chemical known to the state of California to cause cancer under California’s Safe Drinking Water and Toxic Enforcement Act.<sup>23</sup> As of December 2010, all propoxur-formulated flea collars sold in California carry the required warning label indicating that propoxur is a known carcinogen. Despite this evidence of propoxur’s carcinogenicity, EPA failed to include a cancer risk assessment in the 2010 risk assessment based on the stated explanation that the cancer determination was based on exposures “orders of magnitude greater than what is currently allowable for propoxur”.<sup>24</sup> However, as explained below, EPA’s justification is both insufficient and inaccurate.

Taking into account the revised hand-to-mouth frequency and dermal exposure adjustments to the dose calculation used above for children’s exposures, and assuming adult exposure is limited to dermal exposure from one pet hug per day, the lifetime cancer risk is around  $5.01 \times 10^{-4}$  or

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<sup>20</sup> Ko,S., Schaefer, P.D., Vicario, C.M., and Binns, H.J. 2007. “Relationship of Video Assessments of Touching and Mouthing Behaviors During Outdoor Play in Urban Residential Yards to Parental Perceptions of Child Behaviors and Blood Lead Levels.” *Journal of Exposure Science and Environmental Epidemiology*.

<sup>21</sup> Sum of dermal dose plus revised hand to mouth for Wellmark Dog collar (0.189 mg/kg-day + 0.091mg/kg-day = 0.28 mg/kg-day). Revised dose compared to EPA estimate from 2010 risk assessment =  $0.28/0.005 = 56$ .

<sup>22</sup> US EPA 1997. Reregistration Eligibility Decision (RED) Propoxur. EPA-738-R-97-009

<sup>23</sup> California Health and Safety Code Section 25249.6 (commonly referred to as “Proposition 65.”)

<sup>24</sup> EPA Memorandum dated April 7, 2010 Subject: Propoxur: Occupational and Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars Docket Number: EPA-HQ-OPP-2009-0806



about 500 per million exposed.<sup>25</sup> (See Appendix B for calculation) This cancer risk exceeds EPA's acceptable risk range of 1 to 100 per million exposed.<sup>26</sup> In addition, it is likely an underestimate because it does not account for increased early life susceptibility, adult hand-to-mouth exposures, and relies on low-end estimates of dermal exposures. This calculation demonstrates that there is a significant cancer risk associated with exposures from propoxur formulated pet collars that should be included as part of the residential exposure assessment.

### **Even the Registrant's Transferable Residue Calculations Result in Unacceptable Risks to Children.**

In study dated June 22, 2010, registrant Sergeant's Pet Care Products claimed that the EPA 2010 risk assessment overestimated the levels of pesticide residue to be expected 15 days following application of the pet collar. Instead, Sergeant's proposed two alternate mechanisms for calculating the amount of pesticide residue likely to be transferred to the hand of a child and then calculated the dose and MOE associated with those adjusted residues using EPA's 2010 risk assessment assumptions.

Based on Sergeant's first adjustment to the rate of propoxur released from the collar, the dose calculated using EPA's exposure assessment assumption for a medium dog was 0.000770 mg/kg-day with a MOE of 466, which is less than EPA's safety margin (MOE of 1000) and therefore represents an unacceptable risk. Sergeant's made an additional adjustment to the amount of residue expected to transfer to a child's hand. Based on that second adjustment, Sergeant's calculated the dose to be 0.0000932 mg/kg-day and the MOE to be 3,000.

However, as we discussed above, EPA's assessment (and by extension, Sergeant's calculations) uses unrealistically low estimates of hand-to-mouth activity and fails to include dermal exposures. A calculation using a more comprehensive exposure assessment (as in the examples given above) and using both of Sergeant's adjustments for the residue that would be transferred onto a child's hand, results in dose estimates ranging from 0.005 to 0.007 mg/kg-day and MOEs between 42 and 54 for Sergeant's products. (See Figure 4, for exposure parameters and Appendix A for relevant exposure algorithm and calculation method.) These MOEs are far less than EPA's safety margin (MOE of 1000) and represent an unacceptable risk to children.

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<sup>25</sup> As per EPA guidance, children's exposure pattern was used up to age 5. Cancer risk was calculated as the weighted average exposure over a 70 year lifetime.

**Figure 4:** Residential post application for **hand-to- mouth and dermal exposures** using **Sergeant’s transferable residue calculations and exposure parameters from EPA risk assessments for other pet collars.**

Variable	Source	Sergeant’s Dog Collar (medium)	Sergeant’s Dog Collar (large)	Sergeant’s Cat Collar
Weight of the collar (g)	Sergeant’s 2010 Comments submitted to EPA	25	32	14
AR-Total ( 9%) (g)		2.25	2.88	1.26
AR - 15 days (18%) (g)		0.405	0.5184	0.2268
F(AR) - adjusted		0.031	0.031	0.031
SA(pet) (cm2)	EPA (2010) Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars	5986	5986	2737
SAL		0.5	0.5	0.5
SA(hands) (cm2)		20	20	20
BW (kg)		15	15	15
SA(hug)		1875	1875	1875
Mouthing events (events/hr)	EPA (2006) CRA for Organophosphates	9	9	9
Duration of exposure (hrs/day)	EPA (2006) RED DDVP	2	2	2
Freq (mouthing events/day)	= events/hour * hours/day	18	18	18
Freq (events/day)	1 hug per day scenario	1	1	1
Fraction absorbed	EPA (1997) Propoxur RED	0.2	0.2	0.2
Daily transferable residue (mg/cm2-day)		0.0001	0.0002	0.0002
Dose (mg/kg-day) - ingestion		0.002	0.002	0.002
Dose (mg/kg-day)- dermal		0.003	0.004	0.004
Total Dose (mg/kg-day)		0.005	0.007	0.006
NOAEL (mg/kg-day)		0.28	0.28	0.28
MOE		54	42	44

## **Conclusion**

Taken together, the evidence provided here and in previous NRDC submissions demonstrates children can be exposed to levels of propoxur that significantly exceed the reference dose. Therefore, EPA must exercise its statutory obligation to protect children by cancelling all pet collar uses of propoxur.

Respectfully submitted,

Miriam Rotkin-Ellman, MPH  
Gina Solomon, MD, MPH  
Mae Wu, Esq.  
Natural Resources Defense Council

## APPENDIX A: Exposure Assessments Algorithms

### Abbreviations

TR = Transferable Residue

SAL = Saliva Extraction Factor

SA<sub>hands</sub> = Hand Surface Area

SA<sub>pet</sub> = Pet Surface Area

SA<sub>hug</sub> = Child's Hug Surface Area

Freq = Frequency of Events

BW = Body Weight

AR = Application Rate

F<sub>AR</sub> = Fraction available on pet's body

MOE = Margin of Exposure

### Residential Post-application incidental oral ingestion (hand-to-mouth)

$$\text{Dose (mg/kg-day)} = (\text{Transferable residue (TR)} * \text{Saliva extraction factor (SAL)} * \text{Hand surface area (SA}_{\text{hands}}) * \text{Frequency of events (Freq)}) / \text{Body Weight (BW)}$$

$$\text{Transferable residue (mg/cm}^2\text{)} = (\text{Application Rate (AR)} * \text{Fraction available on pet's body (F}_{\text{AR}})) / \text{Surface Area of pet (SA}_{\text{pet}})$$

$$\text{Daily transferable residue (mg/cm}^2\text{-day)} = \text{TR} / 15 \text{ days}$$

$$\text{MOE} = \text{No Observed Adverse Effect Level} / \text{Dose}$$

Source: US EPA (2010). Propoxur: Occupational and Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars

### Residential Post-application dermal exposures

$$\text{Dose (mg/kg-day)} = (\text{Transferable residue (TR)} * \text{Dermal absorption factor} * \text{Surface area of child hug (SA}_{\text{hug}}) * \text{Frequency of events (Freq)}) / \text{Body Weight (BW)}$$

$$\text{Total Dose (mg/kg-day)} = \text{Hand to Mouth} + \text{Dermal}$$

Source: US EPA (2006). Reregistration Eligibility Determination for Dichlorovos (DDVP) EPA 738-R-06-013

**Appendix B: Cancer Risk Assessment**

Cancer Risk = Sum(Cancer potency factor \*dose \*lifetime exposure weighting factor)

Lifetime exposure weighting factor = number of years in group/70

**Table 4:** Residential post application for **hand-to- mouth and dermal** exposures using **EPA (2010)** transferable residue calculations and exposure parameters from EPA risk assessments for other pet collars –CHILD (0 – 5 years)

Variable	Source	Wellmark Dog Collar	Wellmark Cat Collar	Sergeant's Dog Collar	Sergeant's Cat Collar
Weight of the collar (g)	EPA (2010) Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars	34	10.5	30	14
AR (Wellmark 10% - Sergeant's 9%) (g)		3.4	1.05	2.7	1.26
F(AR)		0.2	0.2	0.2	0.2
SA(pet) (cm2)		5986	2737	5986	2737
SAL		0.5	0.5	0.5	0.5
SA(hands) (cm2)		20	20	20	20
BW (kg)		15	15	15	15
SA(hug)		1875	1875	1875	1875
Mouthing events (events/hr)	EPA (2006) CRA for Organophosphates	9	9	9	9
Duration of exposure (hrs/day)	EPA (2006) RED DDVP	2	2	2	2
Freq (mouthing events/day)		18	18	18	18
Freq (events/day)	1 hug per day scenario	1	1	1	1
Fraction absorbed	EPA (1997) Propoxur RED	0.2	0.2	0.2	0.2
Daily Transferable residue (mg/cm2-day)		0.008	0.005	0.006	0.006
Dose (mg/kg-day) - ingestion		0.091	0.061	0.072	0.074
Dose (mg/kg-day)-dermal		0.189	0.128	0.150	0.153
Total Dose (mg/kg-day)		0.280	0.189	0.223	0.227

**Table 5: Residential post application for *only dermal* exposures using EPA’s Transferable Residue Assumptions – and exposure parameters from EPA risk assessments for other pet collars. ADULT (6 – 70 years)**

Variable	Source	Wellmark - Dog Collar	Wellmark Cat Collar	Sergeant’s Dog Collar	Sergeant’s Cat Collar
Weight of the collar (g)	EPA (2010) Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars	34	10.5	30	14
AR (Wellmark 10% - Sergeant’s 9%) (g)		3.4	1.05	2.7	1.26
F(AR)		0.2	0.2	0.2	0.2
SA(pet) (cm <sup>2</sup> )		5986	2737	5986	2737
BW (kg)		70	70	70	70
SA(hug)		5625	5625	5625	5625
Freq (events/day)	1 hug per day scenario	1	1	1	1
Fraction absorbed	EPA (1997) Propoxur RED	0.2	0.2	0.2	0.2
Daily Dislodgeable residue (mg/cm <sup>2</sup> -day)		0.008	0.005	0.006	0.006
Dose (mg/kg-day)-dermal		0.122	0.082	0.097	0.099

**Table 6: Cancer Risk**

Age category	Dose mg/kg-day				Cancer Potency Factor	weighting factor	Risk			
	Wellmark Dog Collar	Wellmark Cat Collar	Sergeant's Dog Collar	Sergeant's Cat Collar			Wellmark Dog Collar	Wellmark Cat Collar	Sergeant's Dog Collar	Sergeant's Cat Collar
0 to <6	0.280	0.189	0.223	0.227	0.0037	0.09	8.89E-05	8.89E-05	8.89E-05	8.89E-05
6 to 70	0.12	0.08	0.10	0.10	0.0037	0.91	4.12E-04	4.12E-04	4.12E-04	4.12E-04
Total - lifetime						1	5.01E-04	5.01E-04	5.01E-04	5.01E-04
Total - lifetime per million							501	501	501	501