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MEMORANDUM

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SUBJECT: **Carbaryl:** Updated Carbaryl Pet Collar Risk Assessment.

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The purpose of this document is to provide a required update to the Agency's carbaryl pet collar residential human health risk assessment based upon the review of the study, *Determination of Dislodgeable Residues of Carbaryl from the Hair of Dogs Wearing Collars Impregnated with Carbaryl* (MRID 47739402). The study was submitted by the carbaryl pet collar primary registrant, Wellmark International, in response to a March 2005 Generic Data Call In (DCI) resulting from to the February 2003 residential risk assessment conducted to support the Interim Reregistration Eligibility Decision (IRED) for Carbaryl (J. Dawson., D287251). Wellmark International also submitted a human health risk assessment, *Exposure and Risk Assessment for Carbaryl Dog Collars Using Data from a Clipping Study* (MRID 47739401), in conjunction with the study. The Agency determined that study is acceptable for use in quantifying estimated exposure/risk; however, the submitted risk assessment has issues which preclude its use to

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inform the updated risk assessment. The submitted study and risk assessment were reviewed in the document, *Carbaryl: Data Evaluation Record for the Study "Determination of Dislodgeable Residues of Carbaryl from the Hair of Dogs Wearing Collars Impregnated with Carbaryl* (W. Britton, D364767).

The study, *Transferable Residues from Dogs Treated with 16% Carbaryl Collar* (MRID 457922-01), was submitted by Zoecon Industries in support of reregistration of carbaryl. The study was determined to lack quality control procedures; however, since the results were chemical-specific and significantly different from Agency standard values, it was used for comparative rangefinder purposes in the February 2003 risk assessment (J. Dawson, D287251). Additional pet collar studies, *Rate of Release Evaluation of a Four Month Carbaryl Dog Collar* (MRID 460756-01), and addendum, *Determination of the Quantity of Carbaryl Removed by Petting Dogs Wearing 16% Carbaryl Dog Collars* (MRID 460150-01), were submitted in the past by Wellmark International because of the Agency's requirement for confirmatory data. MRID 460150-01 was submitted as an addendum to MRID 457922-01 in an effort to provide clarification and improve quality control analysis. In addition, MRID 460756-01 was conducted to determine the rate of release of carbaryl from dogs' collars. Both of the submitted studies were reviewed by HED (S. Tadayon, D320047) and it was determined that the quality assurance and quality control (QA/QC) aspects were inadequate, nor was adequate documentation included for all data generated both in the laboratory and the field. Therefore, the studies did not address the Agency's requirement for quality assurance and it was determined that these data would not be used for quantitative risk assessment purposes.

The Agency assessed human exposure from the application of treated carbaryl collars, as well as, from contact with previously treated dogs in the February 2003 risk assessment (J. Dawson, D287251) and the subsequent June 2007 risk assessment, *Carbaryl: Revisions to Residential Exposure and Risk Assessment* (W. Britton, D334862). The assessments were performed using the *Draft 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.* Due to the absence of data, the Agency assumed a default percent residue for transfer from the fur of the treated pet to an exposed toddler. The submitted study (MRID 47739402) measured the amount of carbaryl transferred from a dog's fur (mg ai/cm^2) while wearing a carbaryl impregnated collar. This updated assessment is conducted in a manner similar to the February 2003 and June 2007 risk assessments, with the application of measured residue transfer from the submitted study.

The noncancer assessment of the carbaryl pet collar using the data from the submitted study results in an estimate of toddler residential postapplication dermal exposure of concern to the Agency (i.e., an MOE < 180). Toddler incidental ingestion (hand-to-mouth) exposure from contacting a treated pet is not of concern to the Agency (i.e., an MOE > 100). While it is likely that the dermal and hand-to-mouth routes of exposure could occur simultaneously from toddler activity/contact with a treated pet, these have not been combined since dermal exposure estimates are of concern. Adult residential postapplication dermal exposure resulting from contact with a treated pet is of concern to the Agency for 2 of the 3 scenarios considered (i.e., an MOE < 100).

The cancer residential postapplication assessment for adults exposed to dogs treated with a carbaryl collar results in a risk estimate of 3×10^{-7} (based on an annual exposure frequency of 1 day per year for 50 years). The allowable number of days of carbaryl collar exposure per year required to get a $1x10^{-6}$ cancer risk is 4 days. An increased cancer risk of $1x10^{-6}$ is generally not of concern to the Agency.

Hazard Concerns

Carbaryl is an *N*-methyl carbamate (NMC) insecticide in which the mode of action is carbamylation of acetylcholinesterase. Additional studies in adult and juvenile rats which describe the time-course and dose-response for brain and red blood cell (RBC) cholinesterase inhibition were received since the 2003 carbaryl IRED. The occupational and residential assessments for carbaryl were, therefore, updated to reflect the recent cholinesterase data and resulting PoDs and FQPA safety factor. The Reregistration Eligibility Decision (RED) for Carbaryl (September 2007) can be referenced for a full description of the dose-response assessment, including changes occurring since the 2003 IRED.

Dose-Response Assessment

Points of Departure (PoDs) required to assess occupational and residential exposure/risk include short- and intermediate-term incidental oral (toddler) and short- and intermediate-term dermal (adult and toddler/youth).

Incidental Oral: For short-term incidental oral, the 2003 IRED relied on the developmental neurotoxicity study in the rat with NOAEL of 1 mg/kg/day to define the PoD. The LOAEL of 10 mg/kg/day was based on an increased incidence of functional observational battery (FOB) changes and decreases in RBC, whole blood, plasma and brain cholinesterase. For intermediate-term incidental oral in 2003, the PoD was established based on the subchronic neurotoxicity rat study. The NOAEL was 1 mg/kg with LOAEL of 10 mg/kg/day, based on increased incidences of FOB changes, decrease in RBC, whole blood, plasma and brain cholinesterase.

Since the time of the 2003 IRED, the comparative cholinesterase study has become available. This study provides the appropriate duration of exposure (acute) and endpoint of concern (ChE inhibition). Therefore, the comparative cholinesterase study with $BMDL_{10}$ of 1.1 mg/kg/day based on the more sensitive subpopulation is appropriate for the PoD of both short-term and intermediate-term incidental oral scenarios. The 10x intraspecies and 10x interspecies factors are applicable, however, the 10x FQPA factor is reduced to 1x since cholinesterase data from the most sensitive subpopulation (PND 11) is the basis of the point of departure (PoD). A margin of exposure (MOE) of 100 defines HED's level of concern (LOC).

Dermal: The 4-week dermal toxicity rat study with NOAEL of 20 mg/kg/day established the PoD for both the short- and intermediate-term dermal scenarios in the 2003 IRED. The LOAEL of 50 mg/kg/day was based on significant decreases in RBC cholinesterase in males and females and brain cholinesterase in males.

Since the 2003 IRED, a BMD analysis from the same 4-week dermal adult rat study has

provided the central estimate (BMD_{10}) and lower limit ($BMDL_{10}$) of the cholinesterase data. This BMD analysis is the same methodology that is being used in the NMC cumulative risk assessment for the dermal exposure scenario. The power of the BMD analysis allows for the refinement of the true NOAEL based on dose-response. The BMD_{10} is 49 mg/kg, which corresponds with the brain and RBC cholinesterase inhibition observed at that LOAEL of 50 mg/kg. As in the NMC cumulative risk assessment, the $BMDL_{10}$ is used as the PoD. Therefore, the $BMDL_{10}$ of 30.56 mg/kg is the PoD for adults in the dermal short- and intermediate-term scenarios. The 10x intraspecies and 10x interspecies factors are both applicable and an MOE of 100 defines HED's level of concern. The FQPA factor is not applicable to the adult dermal scenarios.

Juvenile rat dermal data are not available to compare with the adult dermal data for the dermal risk assessment. However, based on the oral comparative cholinesterase study in rats, juvenile rats are 1.8x more sensitive than adults. An FQPA factor of 1.8x, therefore, is appropriate and health protective for children scenarios in the dermal risk assessment. An MOE of 180 defines HEDs level of concern. This extrapolation of adult to the young is also supported biologically by applying the 13% dermal absorption factor to the PND11 oral derived PoD of 1.1 mg/kg. This would lead to a PoD of 14 mg/kg for children. This 14 mg/kg is essentially the same as applying the 1.8x FQPA to the adult BMDL of 30.56 mg/kg (17 mg/kg).

An *in vitro* dermal absorption study was also evaluated. The study showed that carbaryl was slowly absorbed through rat and human skin *in vitro* and that rat skin was about 2.8 times more permeable than the human skin at the low and mid dose. Therefore, the dermal PoD was adjusted by 2.8X to account for the differences between human and rat skin.

FQPA Considerations: Since the time of the 2003 IRED, the comparative cholinesterase study has become available. Similar to results in comparative cholinesterase studies with other *N*-methyl carbamates, this comparative cholinesterase study revealed that PND11 pups are more sensitive to carbaryl than adult rats. The FQPA factor is based on the ratio of the adult BMD_{10} to PND11 BMD_{10}. Cholinesterase data from this one comparative cholinesterase study indicates that the PND11 pups were 1.8 fold more sensitive than adult rats to brain cholinesterase inhibition. For the single chemical risk assessment for carbaryl, the FQPA factor is only necessary when relying on the adult rat data (i.e., adult dermal rat study). A common toxicological endpoint exists for the dermal, inhalation, and incidental oral routes. Therefore, MOEs can be combined for aggregate residential risk assessments. However, since LOCs for toddler routes of exposure are not the same (an MOE of 100 defines incidental oral while dermal is defined by an MOE of 180) an aggregate risk index (ARI) was required to combine or aggregate estimated MOEs.

Cancer: Carbaryl was classified as a Class C carcinogen and was assessed for carcinogenic risk from exposure using a linear, low dose extrapolation approach with a Q_1^* of 8.75×10^{-4} $(mg/kg/day)^{-1}$. A dermal absorption factor of 12.7 percent was selected from a rat dermal absorption study using radiolabeled ^{14}C and should be used for all chronic duration dermal calculations.

Occupational Handler and Postapplication Exposure/ Risks

HED determined there is potential for short-term exposure in occupational settings during the application of the pet collar product. No assessment of exposure/risk from pet collar application (handling) in occupational settings was performed in either the February 2003 or June 2007 risk assessments. An assessment was performed, however, for residential handling of pet collars and this exposure scenario was determined not to be of concern (i.e., an MOE $\geq$ 100). Since the algorithms and inputs for the application of pet collars are the same whether handled occupationally or residentially, the result is identical.

Postapplication exposure from occupational application of pet collars is anticipated to be negligible since minimal involvement with the animal is anticipated to occur post-treatment. Furthermore, if contact with the animal did occur, it is assumed that a greater potential for exposure exists from the direct occupational application of the pet collar product.

Residential Handler Exposure/Risks

HED has determined that there is potential for short-term exposure in residential settings during the application of the pet collar product. An assessment of residential application of a carbaryl pet collar was performed as a part of the February 2003 and June 2007 residential risk assessments and was determined not to be of concern to the Agency. No confirmatory data was required for the assessment of residential handler exposure/risk.

Residential Postapplication Exposure/Risks

HED has determined that exposure to carbaryl is likely following residential pet collars use. Adults and toddlers are likely to contact a previously treated pet and, therefore, risk estimates were updated for each. Transfer measures resulting from the submitted study (MRID 47739402) were used to estimate adult and toddler postapplication exposure.

The noncancer assessment of the carbaryl pet collar using the data from the submitted study results in an estimate of toddler residential postapplication dermal exposure of concern to the Agency (i.e., an MOE < 180). Toddler incidental ingestion (hand-to-mouth) exposure from contacting a treated pet is not of concern to the Agency (i.e., an MOE > 100). While it is likely that the dermal and hand-to-mouth routes of exposure could occur simultaneously from toddler activity/contact with a treated pet, these have not been combined since dermal exposure estimates are of concern. Adult residential postapplication dermal exposure resulting from contact with a treated pet is of concern to the Agency for 2 of the 3 scenarios considered (i.e., an MOE < 100).

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1.0 Toxicological Endpoints

A hazard summary detailing the updates required to reflect the recent cholinesterase data are summarized above and are outlined in Table 1, below.

Table 1. Summary of Toxicological Dose and Endpoints for Carbaryl for Use in Human Risk Assessment[1]

Exposure Scenario	Point of Departure (mg/kg/day)	Uncertainty/FQPA Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Short- (1-30 days) and Intermediate -Term (1-6 mos) Incidental Oral	1.1	UF_A=10x UF_H=10x FQPA SF=1x	MOE = 100	Comparative Cholinesterase Study- (47007001) BMD_{10}= 1.5mg/kg and $BMDL_{10}$= 1.1 mg/kg, based on brain ChE inhibition in post-natal day 11 (PND11) pups
Short- (1-30 days) and Intermediate -Term (1-6 mos) Dermal	85.56[2]	UF_A=10x UF_H=10x FQPA SF=1.8x (children only)	MOE = 100 (adult) MOE= 180 (children)	Rat Adult Dermal Study (45630601), Brain ChE inhibition most sensitive, BMD_{10}= 49.35 mg/kg and $BMDL_{10}$= 30.56 mg/kg
Dermal Long-Term (>6 mos)	Due to the rapid recovery of ChE activity, the acute exposure from carbaryl is the main duration of concern and therefore a long-term assessment is not appropriate for carbaryl.			
Inhalation Short-Term (1-30 days) Inhalation Intermediate -Term (1-6 mos)	1.1	UF_A=10x UF_H=10x FQPA SF=1	MOE = 100	Comparative Cholinesterase Study- (47007001/ MRID pending) BMD_{10}= 1.5mg/kg and $BMDL_{10}$= 1.1 mg/kg, based on brain ChE inhibition in post-natal day 11 (PND11) pups
Inhalation Long-Term (>6 mos)	Due to the rapid recovery of ChE activity, the acute exposure from carbaryl is the main duration of concern and therefore a long-term assessment is not appropriate for carbaryl.			
Cancer (oral, dermal, inhalation)	Classification: C $Q^*_1 = 8.75 \times 4^{-4}$ $(mg/kg/day)^{-1}$			
Dermal	12.7 %			Rat Dermal Absorption

Table 1. Summary of Toxicological Dose and Endpoints for Carbaryl for Use in Human Risk Assessment[1]				
Exposure Scenario	Point of Departure (mg/kg/day)	Uncertainty/FQPA Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Absorption – Chronic				Study

[1] **Explanation of Abbreviations:** UF = uncertainty factor. UF_A = extrapolation from animal to human (intraspecies). UF_H = potential variation in sensitivity among members of the human population (interspecies). FQPA SF = FQPA Safety Factor. aPAD = population adjusted dose. RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.
[2] **Dermal Point of Departure:** 85.56 mg/kg/day = 30.56 mg/kg/day x 2.8 (differences between rat and human skin))

1.1 Use Profile

Carbaryl [1-napthyl methylcarbamate] is one of the most widely used broad spectrum insecticides in agriculture, professional turf management, professional ornamental production, and in the residential pet, lawn and garden markets. The carbaryl pet collar product was reregistered in 2003 under the condition of the submission of confirmatory data. The collar is a 17.7 % ai ready to use (RTU) product formulated for residential use to control of fleas and ticks. The application rate per collar is 0.011 pounds, or 5 grams ai.

2.0 Residential Exposure/ Risk Assessment

It has been determined there is a potential for exposure in residential settings during the application process for homeowners who purchase and use the carbaryl pet collar. There is also potential for postapplication exposure from contacting a companion animal previously treated with the pet collar.

Residential risks are typically calculated for short- and intermediate-term exposures because repeated exposures are likely. Since peak inhibition of cholinesterase occurs rapidly with recovery occurring within hours, the daily exposure to carbaryl is the main duration of concern. Therefore, toxicological dose and endpoints selected for short- and intermediate-terms routes of exposure are the same.

2.1 Residential Handler Exposure/Risks

The Agency uses the term "handlers" to describe those individuals who are involved in the pesticide application process. The Agency believes that there are distinct tasks related to applications and that exposures can vary depending on the specifics of each task. The amount of chemical to be used in an application, the kinds of equipment used and the target being treated can cause exposure levels to differ in a manner specific to each application event.

An assessment of residential application (handling) of a carbaryl pet collar was performed as a part of the February 2003 and June 2007 residential risk assessments and was determined not to be of concern to the Agency. No confirmatory data was required for the assessment of residential handler exposure/risk

2.2 Residential Postapplication Exposure/ Risks

The Agency uses the term "postapplication" to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Carbaryl can be used in many areas that can be frequented by the general population including residential areas (e.g., home lawns and gardens), parks, athletic fields, and golf courses. As a result, individuals can be exposed by entering these areas if they have been previously treated. The use of a carbaryl pet collar can result in exposure through contact with a previously treated animal and is, therefore, subject to postapplication assessment.

2.2.1 Residential Postapplication Noncancer Exposure/Risk Estimates

The residential postapplication exposure/risk calculations are presented in this section. Noncancer risks were calculated using the Margin of Exposure (MOE) approach which is a ratio of the body burden to the toxicological endpoint of concern. Adults and toddlers are likely to contact a pet previously treated with a carbaryl collar and, therefore, risk estimates were updated for each.

The Agency combines or aggregates risks resulting from exposures to individual chemicals when it is likely they can occur simultaneously based on the use pattern and the behavior associated with the exposed population. Toddlers can be exposed to a previously treated dog through either dermal or hand-to-mouth routes of exposure. These routes of exposure are typically added together because it is logical they can co-occur.

Since the carbaryl IRED, additional studies with time-course, dose-response, and half-life cholinesterase data have been submitted and were reviewed by HED. As a result, the level of concern (LOC) for toddler/youth dermal postapplication exposure is expressed as an MOE = 180 (i.e., an MOE $\geq$ 180 is considered not of concern to HED). The LOC for the incidental oral routes of toddler postapplication exposure is an MOE = 100. An aggregate risk index (ARI) is required to combine or aggregate toddler postapplication risk from dermal and incidental oral routes of exposure when the LOCs are not the same. However, while it is likely that dermal and hand-to-mouth routes of exposure could occur simultaneously from toddler activity with a treated pet, these were not combined since dermal exposure estimates alone are of concern.

Data and Assumptions

A series of assumptions and factors served as the basis for completing the residential postapplication risk assessment of adult and toddler exposure to carbaryl pet collars. The assumptions and factors used in this risk assessment are consistent with current Agency policy for completing residential exposure assessments (i.e., *Draft HED SOPs for Residential Exposure Assessment* and 1999 Draft Policy 13, *Postapplication Exposure Assessment for Children from Treated Pets*). The assumptions and factors used in the risk calculations include:

- the Agency always considers the maximum application rates allowed by labels in its risk assessments to consider what is legally possible based on the label;

- In the absence of chemical-specific data, it may be assumed that on the day of application 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).

  Since a chemical-specific postapplication exposure study has been submitted, the percent transfer assumption is unnecessary. The submitted data was used as a surrogate for transferable residue (TR). Results from the day of application (Day 0) should be used in place of the default transferable residue fraction assumption; however, an average of all days sampled (28) has also been presented for the purposes of risk characterization.

- 3 year old toddlers are expected to weigh 15 kilograms (representing an average weight from years one to six).

- Adults are assumed to weigh 70 kg. A body weight of 70 kg represents the mean body weight for all adults (i.e., male and female, ages 18 years and older).

- 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., $20cm^2$/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 dermal absorption factor is 100% as determined by HED;

- the chronic (cancer) dermal absorption factor is 12.7% as determined by HED;

- hand surface area per event is 20 cm^2, which represents the palmar surfaces of three fingers;

- saliva extraction efficiency is 50 percent meaning that every time the hand goes in the mouth approximately ½ of the residues on the hand are removed;

- HED default for the surface area of an adult hug is 5625 cm^2, a toddler hug is 1875 cm^2 (US EPA, 1999 SAP).

Postapplication Exposure Study

The postapplication exposure study, *Determination of Dislodgeable Residues of Carbaryl from the Hair of Dogs Wearing Collars Impregnated with Carbaryl* (MRID 47739402) was submitted to the Agency by Wellmark International in response to a March 2005 Generic Data Call In (DCI). Wellmark International also submitted a human health risk assessment, *Exposure and Risk Assessment for Carbaryl Dog Collars Using Data from a Clipping Study* (MRID 47739401), in conjunction with the study. Both submissions were reviewed by the Agency in the document, *Carbaryl: Data Evaluation Record for the Study "Determination of Dislodgeable Residues of Carbaryl from the Hair of Dogs Wearing Collars Impregnated with Carbaryl* (D364767). The Agency determined that study is acceptable for use in quantifying estimated exposure/risk; however, the submitted risk assessment had issues which preclude its use to inform this updated assessment. The following is a citation and summary review for the submitted postapplication carbaryl pet collar study:

Determination of Dislodgeable Residues of Carbaryl From the Hair of Dogs Wearing Collars Impregnated with Carbaryl. Brian D. Lange (2009). EPA MRID 47739402. Unpublished study prepared by Wellmark International.

This study measured the amount of carbaryl that may be dislodged from dog's hair while the dog is wearing a Zodiac FleaTrol® Flea Collar for Dogs, a carbaryl impregnated collar. One collar, containing 17.71% carbaryl was placed around the neck of each of ten dogs, following label instructions. The test product was formulated as a slow release product intended for 120-day use. There were two control dogs without collars. The dogs were of varying breeds. Half of the dogs had long hair and half of the dogs had medium length hair. According to the study author, the sampling technique precluded the use of short-haired dogs. The dogs had not been exposed to carbaryl for at least 30 days prior to application of the collars and were bathed with a non-pesticidal shampoo 5 days prior to the study. The dogs were housed individually and handled minimally during the study.

Hair samples were collected from five locations on each dog: neck (above the collar), middle of back, lumbar (top of tail), left thorax, and right thorax. Sampling took place on Days 0 (5 hrs), 1, 4, 7, 14, and 28 after application of the collar. Samples were also collected one day prior to application. Hair samples were collected using clippers and hair was clipped down to the skin level.

The hair samples were dislodged on the same day as collection using 0.01% Aerosol OT Solution. After dislodging, the hair and the OT solution samples were stored frozen until analysis. Both OT solution samples and dislodged hair extract samples were analyzed. Total extraction of hair residues were performed using the dislodged hair samples mixed with methylene chloride. An aliquot was collected and evaporated to dryness. The sample was reconstituted with 1:1 methanol mixture and transferred to a vial for analysis.

Residues of carbaryl in each sample (µg) were converted to µg per cm^2 of skin surface area from which the sample was collected. The residues were not corrected for field fortification recoveries, concurrent recoveries, or storage stability recoveries because the field fortification

recoveries were greater than 90%, recoveries from laboratory fortified recoveries were not reported, and storage stability recoveries were acceptable. For calculation purposes, ½ limit of quantitation (LOQ) values were used for residues less than the LOQ.

The results of this study indicate that carbaryl residues spread from the impregnated collar to the neck, back, lumbar, and thorax of the dog. Carbaryl residues were detected in the majority of the dislodging OT solution samples and the dislodged hair extract samples at all sampling intervals (Day 0 through Day 28) and all sampling locations. The carbaryl residues remained relatively constant from Day 0 through Day 28, with an exception of the neck residues in the hair extract samples which increased significantly over time and the residues were 4.9X higher on Day 28 than Day 0 based on the average of all replicates. Carbaryl residues were significantly higher in the neck region than the other regions sampled (back, lumbar, and thorax). Additionally, the other regions all showed similar levels of carbaryl. From highest to lowest, average carbaryl residues in the OT solution samples were 44.4 $\mu g/cm^2$ for the neck, 2.49 $\mu g/cm^2$ for the back, 1.20 $\mu g/cm^2$ for the lumbar and the left thorax, and 1.08 $\mu g/cm^2$ for the right thorax. The overall average for the OT solution samples was 10.1 $\mu g/cm^2$. The average carbaryl residues in the hair extract samples, from highest to lowest, were 6.10 $\mu g/cm^2$ for the neck, 0.51 $\mu g/cm^2$ for the back, 0.37 $\mu g/cm^2$ for the left and right thorax, and 0.34 $\mu g/cm^2$ for the lumbar. The overall average for the hair extract samples was 1.54 $\mu g/cm^2$.

Carbaryl residues were higher in the OT solution samples than the hair extract samples. According to the study author, the extracted hair samples may be more reflective of the solubility of carbaryl in the aqueous OT solution than the availability of carbaryl for transfer to a person handling the dog.

The Agency did not perform a regression analysis because in general, the residue pattern did not show steady increase or decrease in residues. Additionally, residues were highly variable between replicates. When calculating the average residues for each sampling location, the standard deviation values were often at a similar level or higher than the average values. Unfortunately, the data (average residues) is limited and not conducive for regression tests. Additionally, the plot of average residues vs. time follows a sinusoidal pattern which makes it very difficult to conduct a simple regression analysis.

Table 2 and 3 present summary tables of carbaryl residue measured in dislodging OT solution and in hair extracts (all replicates combined). Residues measured for each sampling interval (days) represent an average of all the five locations sampled per dog (neck (above the collar), middle of back, lumbar (top of tail), left thorax, and right thorax) and the average across all dogs sampled (N=10) for that particular day.

Table 2. Summary of Carbaryl Residue (µg/cm²) in OT Solution (All Replicates Combined)								
Sample Location	Statistic	Sampling Interval (Day) Residue in µg/cm²						Average Residue µg/cm²
		0	1	4	7	14	28	
neck	Average	67.4	47.9	32.7	45.6	31.8	41.2	44.4
	Standard Deviation	119.6	51.5	29.8	65.3	35.6	42.3	37.9
	Geometric Mean	20.5	24.5	22.3	23.9	20.3	28.3	32.0
back	Average	1.6	1.0	1.8	2.3	5.3	3.0	2.5
	Standard Deviation	1.7	0.77	0.92	2.7	11.2	6.8	3.5
	Geometric Mean	1.2	0.83	1.6	1.4	1.7	0.9	1.5
lumbar	Average	3.6	0.85	0.72	0.56	0.68	0.73	1.2
	Standard Deviation	6.8	0.62	0.34	0.39	0.65	0.90	1.2
	Geometric Mean	1.3	0.68	0.65	0.44	0.45	0.40	0.91
thorax left	Average	0.38	0.55	0.83	1.1	2.7	1.6	1.2
	Standard Deviation	0.24	0.24	0.32	1.7	5.9	2.3	1.6
	Geometric Mean	0.31	0.50	0.77	0.66	1.0	0.80	0.76
thorax right	Average	0.53	1.0	1.4	0.91	1.4	1.3	1.1
	Standard Deviation	0.58	1.4	2.6	1.5	2.7	2.0	1.5
	Geometric Mean	0.33	0.61	0.64	0.49	0.58	0.66	0.66
All Locations	**Average**	**14.7**	**10.3**	**7.5**	**10.1**	**8.4**	**9.5**	**10.1**
	Standard Deviation	23.9	10.4	6.2	13.5	9.2	8.8	7.6
	Geometric Mean	5.9	5.9	5.5	5.6	5.3	6.8	7.7

Table 3. Summary of Carbaryl Residue (µg/cm²) in Hair Extracts (All Replicates Combined)								
Sample Location	Statistic	Sampling Interval (Day) Residues in µg/cm²						Average Residue µg/cm²
		0 (5 hours after application)	1	4	7	14	28	
neck	Average	2.5	3.3	4.6	4.8	9.1	12.2	6.1
	Standard Deviation	3.0	3.0	3.8	2.9	8.0	10.5	4.5
	Geometric Mean	1.3	2.2	3.5	4.1	6.7	9.7	5.0
back	Average	0.25	0.25	0.46	0.44	0.89	0.74	0.51
	Standard Deviation	0.15	0.15	0.29	0.24	0.88	1.06	0.34
	Geometric Mean	0.20	0.21	0.38	0.38	0.61	0.41	0.42
lumbar	Average	0.34	0.27	0.54	0.18	0.36	0.36	0.34
	Standard Deviation	0.33	0.21	0.96	0.10	0.42	0.24	0.32
	Geometric Mean	0.28	0.21	0.27	0.16	0.24	0.27	0.27
thorax left	Average	0.068	0.18	0.26	0.31	0.67	0.74	0.37

Table 3. Summary of Carbaryl Residue (µg/cm²) in Hair Extracts (All Replicates Combined)								
Sample Location	Statistic	Sampling Interval (Day) Residues in µg/cm²						Average Residue µg/cm²
		0 (5 hours after application)	1	4	7	14	28	
	Standard Deviation	0.038	0.13	0.17	0.21	0.52	0.54	0.21
	Geometric Mean	0.052	0.15	0.23	0.25	0.51	0.55	0.32
thorax right	Average	0.066	0.17	0.29	0.26	0.49	0.94	0.37
	Standard Deviation	0.030	0.12	0.20	0.24	0.41	1.16	0.32
	Geometric Mean	0.054	0.14	0.23	0.19	0.36	0.58	0.28
All Locations	**Average**	**0.65**	**0.84**	**1.2**	**1.2**	**2.3**	**3.0**	**1.5**
	Standard Deviation	0.60	0.63	0.74	0.60	1.6	2.1	0.90
	Geometric Mean	0.47	0.6	1.1	1.1	1.8	2.5	1.3

Postapplication Exposure Assessment Algorithms

The algorithms used for the assessment of residential postapplication dermal and incidental oral (hand-to-mouth) pet exposure scenarios are as follow:

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 an adult or touching a treated companion pet.

$$D\ (mg/kg/day) = \frac{TR * SA_{hug} * DA}{BW\ (kg)}$$

Where:

D	=	daily dose from dermal pet contact (mg/kg/day)
TR	=	amount of residue anticipated to transfer from treated animal to the exposed individual as measured from MRID 47739402 (mg/cm²)
SA_{hug}	=	surface area of a child hug (1875 cm² (toddler), 5625 cm² adult)
DA	=	dermal absorption factor (100 %)
BW	=	body weight (15 kg (toddler), 70 kg (adult))

$$MOE = \frac{NOAEL}{D}$$

Where:

NOAEL	=	No Observed Adverse Effect Level (mg/kg/day)
D	=	daily dose from dermal pet contact (mg/kg/day)

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 toddler touching a treated companion pet and then placing their hands in their mouth.

$$D\ (mg/kg/day) = \frac{TR * SAL * SA_{hands} * Freq}{BW\ (kg)}$$

Where:

D	=	daily nondietary ingestion dose from treated pets (mg/kg/day)
TR	=	amount of residue anticipated to transfer from treated animal to the exposed individual as measured from MRID 47739402 (mg/cm^2)
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)

$$MOE = \frac{NOAEL}{D}$$

Where:

NOAEL	=	No Observed Adverse Effect Level (mg/kg/day)
D	=	daily dose from hand-to-mouth pet contact (mg/kg/day)

Risk Summary

Toddler residential postapplication dermal exposure resulting from contact with a pet treated with a carbaryl collar is of concern to the Agency (i.e., an MOE < 180). Toddler incidental ingestion (hand-to-mouth) exposure from contacting a treated pet is not of concern to the Agency (i.e., an MOE > 100). While it is likely that the dermal and hand-to-mouth routes of exposure could occur simultaneously from toddler activity/contact with a treated pet, these have not been combined since dermal exposure estimates alone are of concern. Adult residential postapplication dermal exposure resulting from contact with a treated pet is of concern to the Agency for 2 of the 3 scenarios considered (i.e., an MOE < 100).

The Agency presented three scenarios for the assessment of adult and toddler postapplication dermal and toddler hand-to-mouth routes of exposure. These scenarios represent the use of study data (carbaryl residue dislodgeable by Aerosol OT solution) for Day 0 residue transfer values, the average day, and lowest day sampled. Day 0 residue values are typically considered since they are often the most conservative; however, this is not always the case for pet collars. Based on the review of the review of pet collar study data, Day 0 values are the highest resulting residue measures.

All data used represent an average of all samples taken across the dog's body (neck (above the collar), middle of back, lumbar (top of tail), left thorax, and right thorax) for all dogs sampled on Day 0, the average and lowest days sampled. For the average day scenario, all days sampled were averaged for all dogs and all body samples taken. Regardless of scenario, all toddler dermal exposure scenarios and 2 of 3 adult scenarios result in a risk of concern. Table 4 presents the results of postapplication adult and toddler dermal and toddler hand-to-mouth exposure/risk assessment.

Table 4. Summary of Postapplication Adult and Toddler Dermal and Toddler Hand-to-Mouth Exposure/Risk from Contacting Pets Wearing Carbaryl Collars - Based on Study Data from (MRID 47739402)

Scenario	TR (mg/cm^2)	Dose (mg/kg/day)	NOAEL (mg/kg/day)	LOC	MOE
Adult Dermal Exposure					
Day 0	0.015	1.2	85.56	100	**72**
Average (All Days)	0.011	0.88			**97**
Lowest Day (4)	0.008	0.60			142
Toddler Dermal Exposure					
Day 0	0.015	1.8	85.56	180	**47**
Average (All Days)	0.011	1.4			**62**
Lowest Day (4)	0.008	0.94			**91**
Toddler Hand-to-Mouth					
Day 0	0.015	0.0098	1.1	100	112
Average (All Days)	0.011	0.0073			150
Lowest Day (4)	0.008	0.0050			220

2.2.2 Postapplication Exposure Risk Characterization

The Agency considered multiple approaches for the assessment of adult and toddler postapplication exposure using the submitted study. In the past, the Agency has typically required a stroking or petting study to determine the amount of pesticide residue available for transfer from the pet to the exposed individual. These studies were conducted using a bare or gloved hand and involved the petting or stroking of a defined area of the animal for either a specific number of repeated motions or for a pre-determined period of time. A measure of the

residue transferred to hand was then determined by means of hand wash, if a bare hand, or by analysis of the glove. The resulting residue values were then either compared to the total amount of ai applied to the animal, resulting in a percent estimate of the amount anticipated to transfer or used directly as a measure of TR. To ensure that adults and toddlers are protected, the Agency assumes the worst case exposure resulting from study results. In the case of a petting or stroking study, this relates to the sampling Day in which the highest transfer value was measured. Typically, but not always, the day of application (Day 0) values reflect the worst case estimate of residue transfer.

When Wellmark International requested input for the conduct of a transferable residue study the Agency was in a period of deliberation. Since the petting/stroking studies involved human subjects who were directly exposed to a pesticide-treated animal, the Agency debated whether this implied intentional human exposure to a pesticide; which, under the Government-wide Common Rule (EPA 40 CFR 26 – Protection of Human Subjects) would not be allowable unless all appropriate criteria pertaining to ethical conduct of the studies were adhered to. Rather than advise Wellmark International to perform a study which could have later been determined unacceptable, HED recommended an alternative transfer study method, pet fur clipping. HED recognizes that the petting/stroking studies and pet fur clipping studies differ and, therefore, the resulting data is subject to interpretation due to the noted differences in the sampling method. The Agency's use of the submitted postapplication exposure pet fur clipping study weighed the following considerations: 1) the use of "dislodged residue" or "extracted residue" data sets to represent transferable residue 2) the use of the Agency default pet residue transfer value (20%) 3) combining locations sampled on the individual dogs 4) combining all dogs sampled per day 5) considering the worst day or exposure only, or averaging all days sampled 6) considering daily residue dissipation and 7) the use/input of resulting data with the Agency's current algorithm for the assessment of exposure/risk from contact with treated pets. The ensuing text lays out the considerations addressed with a description of thought process, selection criteria and resulting approach.

Wellmark International measured residue from fur clipping samples using either a dislodged or extracted residue method. Residues from the dislodged method were measured using a double wash of 0.01% Aerosol OT solution. The extracted method measured the residue remaining from the dislodged sample using methylene chloride to estimate the "total" residue available on the fur clipping sample. The Agency has historically assumed that residue measures resulting from sample surfaces washed in 0.01% Aerosol OT solution represent the amount of residue anticipated to transfer, or dislodge, onto an exposed individual. For example, dislodgeable foliar residue studies, which measure pesticide residues on the surface of sample leaves that are anticipated to transfer onto an exposed individual, frequently use an analytical method that employs 0.01% Aerosol OT. In contrast, the extraction method results in a measure of residue which is designed to observe the total available in the clipped hair. Since the Agency is interested only in the transfer of carbaryl residue, the extracted method data was not used. Therefore, the Agency's assessment of the carbaryl pet collar uses results from the dislodged method as they are believed to be the best representation of transfer.

In the study report, the study author notes that, "Carbaryl residues were higher in the OT solution samples than the hair extract samples. The extracted hair samples may be more reflective of the

solubility of carbaryl in the aqueous OT solution than the availability of carbaryl for transfer to a person handling the dog." It is not possible for the Agency to determine what affect the solubility of carbaryl had on the resulting residue transfer measures and a corrective adjustment is not feasible given the uncertainty of these measures. In order to ensure that the Agency's assessment of adult and toddler exposure/risk is protective of human health, residue transfer measures (collected using the dislodged method) resulting from the submitted study were used with no additional adjustments and/or corrections to account for any potential overestimation of residue transfer based upon the analytical methods used.

The Agency standard default for pesticide transfer from a treated pet, 20%, was not factored into study results. The percent value is based on the professional judgment and experience of the OPP/HED staff from the review of company-submitted data (US EPA, 1999 SAP). It was developed for and only applicable in the absence of chemical-specific data. Since it is the Agency's belief that residue measures using the 0.01% Aerosol OT solution represent a reasonable estimate of that which is anticipated to transfer, the application of the default transfer value would result in an underestimate of adult/toddler exposure from a treated pet. This same rationale was applied to data resulting from a pet fur clipping study conducted for an amitraz spot-on product assessed by the Agency (D341879).

For the purposes of adult/toddler postapplication exposure/risk assessment, the Agency averaged all sample locations (neck (above the collar), middle of back, lumbar (top of tail), left thorax, and right thorax) for each dog. Carbaryl residues were significantly higher in the neck region than the other regions sampled (back, lumbar, and thorax). Additionally, the other regions all showed similar levels of carbaryl. From highest to lowest, average carbaryl residues in the OT solution samples were 44.4 $\mu g/cm^2$ for the neck, 2.49 $\mu g/cm^2$ for the back, 1.20 $\mu g/cm^2$ for the lumbar and the left thorax, and 1.08 $\mu g/cm^2$ for the right thorax. It is possible that an exposed adult/toddler could contact, or hug, only the neck area of the treated dog; however, the Agency determined that is just as likely that the child will contact the dog in other sample locations. To assume toddler exposure would occur from neck contact only is likely an overly conservative estimate of risk and, therefore, was not applied. The concept of the pet hug was introduced as a part of the 1999 SAP meeting which reviewed issues related to standard operating procedures (SOP) for residential exposure assessment.

In addition to averaging all locations sampled, the Agency averaged the results from all dogs on each sample day, as well as, all dogs sampled in the study for all days. Since it is possible that a adult/toddler could be exposed to any dog sampled on a particular day, an assertion could be made that the most health protective estimate would use the highest residue transfer data from all dogs sampled. Such an assumption would likely result in an overestimation of risk since it is more likely that a child would contact a pet represented by an average of all dogs sampled. The Agency typically considers "worst case" residue measures resulting from either Day 0 or the highest day sampled. For the purposes of risk characterization, the worst case (Day 0), average of all days and lowest day sampled were used to estimate adult/toddler postapplication exposure/risk from contacting treated pets. In the February 2003 and June 2007 risk assessments, the Agency adjusted toddler daily dose by dividing the application rate by the active lifetime of the collar (120 days). The submitted study provides a daily measure of residue transfer and, therefore, no adjustment is necessary to estimate adult/toddler daily dose. The

Agency's estimate of adult/toddler risk using the average transferable residues from all days sampled results most closely compares to the approach taken in the prior assessments. Regardless of study day(s) considered, all resulted in an estimated dermal risk of concern for exposed toddlers.

The Agency often considers daily residue dissipation by means of a regression analysis when assessing longer-term durations (i.e., greater than 30 days) or to characterize short-term risk estimates. The Agency did not perform a regression analysis of the submitted postapplication exposure study because in general, the residue pattern did not show steady increase or decrease in residues as would be expected with a collar that is intended to have a steady residue release over its lifetime. Additionally, residues were highly variable between replicates. When calculating the average residues for each sampling location, the standard deviation values were often at a similar level or higher than the average values. Furthermore, since peak inhibition of cholinesterase occurs rapidly with recovery occurring within hours, the daily exposure to carbaryl is the main duration of concern. Therefore, toxicological dose and endpoints selected are the same for short- and intermediate-terms routes of exposure.

The Agency typically required a stroking or petting study to determine the amount of pesticide residue available for transfer from the pet to the exposed individual. Results from these studies were then compared to the total amount of ai applied to the animal, resulting in either a percent estimate of the amount anticipated to transfer or used directly as a measure of TR. In the absence of study data, the transferable residue (TR) input is determined by applying the percent transfer observed in the study (F_{AR}) to the maximum application rate and dividing by the surface area (SA) of an average dog (i.e., 5986 cm^2 for a 30 lb dog).

$$TR\ (mg/cm^2) = \frac{AR * F_{AR}}{SA_{pet}}$$

The pet fur clipping study submitted to the Agency presents residue transfer measures in unit, mg/cm^2, which allows for direct application of measured values into the adult and toddler dermal and toddler hand-to-mouth algorithms. The measures represent what would be typically calculated by the Agency since it provides the residue anticipated to transfer per surface area of the treated animal.

2.2.3 Residential Postapplication Cancer Exposure/Risk Estimates

The residential postapplication exposure and cancer risk calculations are presented in this section. Cancer risks were calculated using a linear, low-dose extrapolation approach (*Q1**) using the formula described below. The carcinogenic risk estimates calculated for the proposed use reflect conservative assumptions regarding prolonged, continuous exposure to a pet treated with a carbaryl collar and exposure (50 years) of an adult to the treated pet. In addition to the cancer risk estimates for an annual frequency of 1 time per year, the number of days of exposure per year required to get a $1x10^{-6}$ cancer risk have been calculated.

Residential handler cancer risk was extrapolated over a 70 year lifetime using high end lifetime expectations for pet exposure (50 years) and employs the following assumptions:

- dogs will be treated with the collar product throughout their lifetimes, assuming continued exposure to the pet owner;

- a dog owner will hug his or her dog on the day of application (Day 0) every year for the lifetime expectation of pet exposure (50 years) over the lifetime of multiple dogs;

The algorithms used for to estimate adult residential postapplication carcinogenic risk are presented below, with a summary of the estimated exposure/risk presented in Table 5.

LADD (mg/kg/day) = D (mg/kg/day) x DE x PO

Where:

LADD = Lifetime Average Daily Dose (mg/kg/day)

D = Daily dose from dermal pet contact (mg/kg/day)

DE = Number of Days Exposed per Year (1 day exposed (Day 0) / 365 days)

PO = Number of Years of Pet Ownership per 70 Year Lifetime (50 years/ 70 year Lifetime)

Carcinogenic Risk = LADD (mg/kg/day) x Q_1*

LADD = Lifetime Average Daily Dose (mg/kg/day)

Q_1* = 8.75×4^{-4} $(mg/kg/day)^{-1}$

Table 5. Residential Postapplication Carcinogenic Risk Estimates (Adult)

Pet Ownership (Years)	TR (mg/cm^2) – Day 0	Dose (mg/kg/day)	LADD (mg/kg/day)	Carcinogenic Risk on Day 0	Days of Exposure Allowed per Year
50	0.015	1.2	0.63	3×10^{-7}	4

Carbaryl Residential Pet Risk Assessment For Toddlers Based On Current Agency Method

Collar Application Rate (g ai/dog):	5	Source of Chronic Dermal Absorption Factor:	Rat DA Study
Saliva Extraction Factor (%/100):	0.5	Short-/Intermediate-term Dermal Abs. (%):	100
Dermal "Hug" Surface Area (cm2):	1875	Source of Short-/Inter-term Dermal Absorption Factor:	Default for use of dermal tox study
Adult "Hug" Surface Area (cm2):	5625		
HTM Frequency (events/day):	1	Short-/Inter-term Uncertainty Factor For Dermal Exposure:	180
Hand (Palmar) Surface Area (cm2):	20	Short-/Inter-term NOAEL (mg/kg/day) For Dermal Exposure:	85.56
Collar Active Lifetime (days):	120	Source of Short-/Inter-term NOAEL For Dermal Exposure:	CRA BMD
Treated Dog Surface Area (cm2):	5986	Short-term Uncertainty Factor For Nondietary Ingestion:	100
Treated Dog Weight (lb):	30	Short-term NOAEL (mg/kg/day) For Nondietary Ingestion:	1.1
Toddler Body Weight (kg):	15	Source of Short-term NOAEL For Nondietary Ingestion:	CCA PND11 Pup BMD
Adult Body Weight (kg):	70	Cancer Q1*	0.00088
Exposure Duration (hrs/day)	1	Years of Exposure (years/lifetime years)	50/70
		Cancer Dermal Absorption (%)	0.127
		Days of Exposure per Year	1/365

Assuming transfer of entire residue measured

	Transerable Residue (Full Body Average) (mg/cm2)	Dermal Exposure Component Dose (mg/kg/day)	MOE (UF ≥180)	Hand to Mouth Exposure Component Dose (mg/kg/day)	MOE (UF≥ 100)	Aggregate Risk Index (ARI)
Toddler						
Highest Day (Day 0)	0.0147	1.8375	**47**	0.0098	112	**0.21**
Lowest Day (Day 4)	0.0075	0.9375	**91**	0.0050	220	**0.41**
Average	0.0110	1.3750	**62**	0.0073	150	**0.28**
Adult						
Highest Day (Day 0)	0.0147	1.1813	**72**			
Lowest Day (Day 4)	0.0075	0.6027	142			
Average	0.0110	0.8839	**97**			

	Transerable Residue (Full Body Average) (mg/cm2)	Dermal Exposure Component Dose (mg/kg/day)	Lifetime Adjusted Daily Dose (mg/kg/day)	Carcinogenic Risk (Day 0)	Days Allowed per Year
Cancer Adult					
Highest Day (Day 0)	0.0147	1.1813	0.00029358	2.57E-07	4

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R175145

Chemical Name: Carbaryl

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