Exhibit 73

STUDY TITLE

Proposed Waiver for Dacthal (DCPA) Chronic Study Testing on *Leptocheirus plumulosus*

Response to EPA's Generic Data Call-In

Order Number: GDCI-0798701-1140

Chemical #PC Code: 078701

CAS #: 1861-32-1

TEST GUIDELINE:

None

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EXECUTIVE SUMMARY

On January 31, 2013, EPA issued the Generic Data Call-In (Order Number: GDCI-0798701-1140; Chemical #PC Code: 078701; CAS #: 1861-32-1; 90-Day Response) for Dacthal (DCPA). One of the study requirements was for conducting chronic sediment testing on the estuarine/marine invertebrate species *Leptocheirus plumulosus.* Since the DCI was issued, the initiation of this study has been significantly delayed because of study validation issues of which AMVAC has notified and updated EPA. Since our last update, we have received new information that justifies the granting of a waiver for this requirement.

Within this document, we provide information that DCPA only manifests toxicological effects on aquatic invertebrates at water concentrations that are unlikely to occur in the environment. It can also be established that sediment-dwelling organisms are only minimally impacted at DCPA concentrations that approach its solubility limit. Testing of additional sediment-dwelling organisms is unlikely to change that profile.

Further, sediment-dwelling aquatic organisms (i.e., *Hyalella azteca, Chironomus dilutes*) have been shown to display a much lower level of sensitivity to DCPA compared to water column-dwelling organisms (i.e., *Daphnia magna, Americamysis bahia*). Amongst these sediment-dwelling organisms, amphipods (*H. azteca)* appear to be less sensitive to DCPA than midges (*C. dilutes).* This further substantiates the validity of a waiver for *L. plumulosus,* a second sediment-dwelling amphipod, as this additional testing would not change the risk profile for aquatic invertebrates.

Recognizing that testing of *L. plumulosus* has proven difficult and that there is now a solid line of evidence that indicates testing of this species would be of minimal value, AMVAC proposes that a waiver be granted from this study requirement.

Table of Contents

1.0 Background

DCPA is a herbicide that has a water solubility of approximately 0.5 ppm at 25°C. Overall, the compound is not considered very toxic to most aquatic animals even at concentrations that approach this solubility limit. DCPA strongly adsorbs to soils with Kocs in silty loam, loamy sand, sandy loam, and silty clay loam ranging from 2185 to 4444 and desorption Kocs in these soils ranging from 2760 -6292 (Shelby 1995). Therefore, predicted runoff concentrations would typically be at levels far below the solubility limits of the compound. Spray drift has the potential for loading the aquatic ecosystem; but again DCPA water concentrations are unlikely to reach levels associated with aquatic effects.

Fish are especially insensitive to DCPA. Acute testing at levels that exceeds the solubility limit does not elicit any toxicological effects. By exceeding the solubility limit, these tests provide a worse case situation, as over-saturation better ensures that testing of the active is at its water solubility limit. These studies demonstrate that DCPA is not acutely toxic. The EC_{50}s are not reached at its solubility limit for Bluegill sunfish (*Lepomis macrochirus*), Rainbow trout (*Oncorhynchus mykiss*) and Sheepshead minnow (*Cyprinodon variegatus*). Similarly, acute toxicity to aquatic invertebrates *D. magna* (freshwater amphipod), *A. bahia* (estuarine/marine midge), *Crassostrea virginica* (Eastern oyster), and *Penaeus aztecus* (Brown shrimp) only occurs at higher environmental concentrations.

Information herein provides for the assessment of the relative sensitivity to DCPA between sediment-dwelling invertebrates (*C. dilutus* and *H. azteca*) and water column-dwelling invertebrates (*D. magna* and *M. bahia*). This information provides a basis for establishing whether EPA's risk assessment for DCPA on aquatic invertebrates would likely be based on data associated with sediment-dwelling organisms; and whether expanding that dataset to include testing on a third sediment-dwelling organism is appropriate.

An assessment is also provided on the relative sensitivity between sediment-dwelling amphipods (*H. azteca*) and sediment-dwelling midges (*C. dilutus*). This information can further support the need or lack thereof for further testing on a second sediment-dwelling midge for purposes of improving the aquatic risk assessment for invertebrates.

2.0 Chronic Study Results for DCPA and Sediment-Dwelling Organisms

2.1 DCPA Testing on *H. azteca*

Past DCPA testing has been conducted on the sediment-dwelling, freshwater amphipod, *H. azteca* under static-renewal conditions for a period of 42 days (Picard 2014a). The primary endpoints used for determination of significant effects include survival and growth of adult amphipods. Reproductive effects were also assessed during the study, which include cumulative young produced per female on day 28 through day 42 and male:female ratio.

Study observations for these endpoints provide for mean measured sediment and pore water No-Observed-Effect Concentrations (NOECs) of 92 mg/kg and 0.34 mg/L., respectively. These concentrations are near the solubility limit of the DCPA; therefore it can be concluded that sediment-dwelling amphipods are highly unlikely to be affected in the environment.

2.2 DCPA Testing on *C. dilutes*

Past DCPA testing has been conducted on the sediment-dwelling, freshwater dipteran midge *C. dilutus* under static-renewal conditions for a period of 60 days (Picard 2014b). The primary endpoints used for determination of significant effects include survival and growth. Reproductive effects were also assessed during the study, which include number of egg masses, eggs per mass, eggs per mated female, percent hatch and days until oviposition.

Although there were statistical differences in the percent emergence among midges associated with the 12 mg/kg sediment treatment level, this reduction is not considered to be toxicant related due to the lack of an observed effect at the two higher dose levels. There were also statistical differences observed in the mean number of days to death for exposed females associated with the 30 mg/kg treatment level. This finding is also not considered to be toxicant related due to the lack of an observed effect at the highest dose level, and because there was no effect associated with this endpoint for exposed males.

Statistical analysis determined a significant difference in the mean number of eggs per egg mass in the 12 and 86 mg/kg treatment levels. The reduction at the 12 mg/kg is not considered to be toxicant related due to the lack of a clear dose response as there was no statistical difference noted at the 30 mg/kg treatment level. At the 86 mg/kg dose level, the observed effect was <10% of the control value. The NOEC for this effect was at the 30 mg/kg treatment level.

Statistical analysis determined a significant difference in the mean number of eggs per mated female in the 4.8, 12 and 86 mg/kg treatment. The reduction at the 4.8 mg/kg and 12 mg/kg level were not considered to be toxicant related due to the lack of a clear dose response as there was no statistical difference noted at the 30 mg/kg treatment level. At the 86 mg/kg dose level, the observed effect was <5% of the control value. The NOEC for this effect was at the 30 mg/kg treatment level.

Overall, none of the tested endpoints yielded EC_{50} values, which indicates that acute environmental effects are unlikely to occur. Minor though statistically significant effects were noted for two of the reproductive parameters, which occurred at the highest dose rate; therefore the mean measured sediment and pore water NOECs were at 30 mg/kg and 0.21. mg/L, respectively.

2.3 DCPA Testing on *D. magna*

The most recent acute study on the amphipod species *D. magna* employed static test conditions for a period of 48 hours (Shaw 2013a). The primary endpoint used for determination of significant effects by statistical evaluation was immobilization (i.e., survival).

Since none of the test concentration resulted in amphipod immobilization, the NOEC was determined to be 0.55 mg/L, the highest concentration tested. Previous studies that did not fully meet current guidelines yielded comparable results.

Chronic testing of DCPA was conducted on *D. magna* under static renewal conditions for a period of 21 days (Shaw 2013b). The primary endpoints used for determination of significant effects by statistical evaluation were immobilization (i.e., survival), reproduction, and growth. The 21-day NOEC for immobilization was at a concentration of 0.54 mg/L, which was the highest tested concentration and reflects the solubility limit of DCPA. The 21-day NOECs for total body length and dry body weight were established at the lower dose concentration of 0.27 mg/L. The magnitudes of these effects were approximately a 10% and 30% reduction, respectively. Similarly, there was a reproductive effect at the 0.54 mg/L test concentration. The 21-day NOEC was established at 0.27 mg/L. This was the most sensitive indication of DCPA toxicity as the magnitude of the effect at the highest dose level was approximately a 60% reduction.

2.4 DCPA Testing on *A. bahia*

The most recent acute study on the estuarine midge species *A. bahia* employed static test conditions for a period of 48 hours (Claude 2013). The primary endpoint used for determination of significant effects by statistical evaluation was mortality.

Since none of the test concentration tested resulted in mortality, the NOEC was determined to be 0.391 mg/L, the highest concentration tested. Previous studies that did not fully meet current guidelines yielded comparable results.

Chronic testing of DCPA was conducted on *A. bahia* under flow-through conditions for a period of 28 days (Claude, 2014). Survival, growth, and reproductive parameters were studied on 1st generation organisms for the entire study period and survival of the 2nd generation organisms for approximately 96 hours following the release from the brood pouch.

The mean number of young produced per reproductive day was reduced by approximately 50% at the dose level of 0.076 mg/L. Much more severe effects were noted at the higher dose level of 157 mg/L. Other severe effects that were also noted at this concentration include the percent of surviving females producing young and the mean number of young per surviving female. The 21-day NOEC for these reproductive effects was determined to be 0.039 mg/L. Growth retardation proved to be the most sensitive indicator of toxicity as a statistically significant effect was also noted at 0.039 mg/L. The 21-day NOEC based on growth retardation was determined to be 0.021 mg/L.

3.0 ASSESSMENT

3.1 Relative Sensitivity between Sediment-Dwelling Invertebrates and Water Column-Dwelling Invertebrate Test Species

The chronic studies for the water column-dwelling *D. magna* and *A. bahia test species* demonstrate a much higher level of sensitivity to DCPA than is evident with the sediment-dwelling organisms of *H. azteca* and *C. dilutes*. Significant reproductive effects were also evident for both *D. magna and A. bahia;* whereas effects on *H. azteca* and *C. dilutes* were at most, very minor (i.e., <10% of control) at higher dose levels. Overall the NOECs for these sediment-dwelling organisms could be established at water concentration levels that were greater than 40% the solubility limit of DCPA, indicating that the environmental impact of DCPA on these species would be *de minimus*.

On this basis, we have concluded that DCPA testing of a third sediment-dwelling organism for a compound of such limited toxicity is highly unlikely to yield a noteworthy effect or modify the conclusion of a lack of significant effects relating to sediment-dwelling organisms.

3.2 Relative Sensitivity between Sediment-Dwelling Midges and Amphipods

Although DCPA had no statistically significant effects on *H. azteca*, minor reproductive effects were noted for the midge *C dilutes*. This suggests that sediment-dwelling midges are more sensitive to DCPA than are sediment-dwelling amphipods. Similarly, the 21-day NOEC established at 0.27 mg/L for the water column-dwelling amphipod *D. magna* is approximately 10-fold more sensitive than the 21-day NOEC of 0.021 mg/L established for the water column-dwelling midge *A. bahia.*

These findings support the assertion that there is little value in conducting new testing on *L. plumulosus,* a sediment-dwelling amphipod, that is unlikely to elicit any significant toxicological effects.

4.0 CONCLUSIONS

Based on the assessment provided in this document, chronic testing on *Leptocheirus plumulosus* is not warranted for three reasons.

1. Water column-dwelling invertebrates are much more sensitive to DCPA compared with sediment-dwelling invertebrates and therefore the results from the column-dwelling invertebrates are protective for sediment-dwelling invertebrates. Ecological assessments of invertebrate effects due to possible DCPA exposure should be based on water-column species.

2. Sediment-dwelling amphipods are less sensitive to DCPA than sediment-dwelling midges.

3. Only minor DCPA toxicological effects have been noted for the two sediment-dwelling organisms that have been tested. These effects occur at relatively high concentration

levels that approach the solubility limit of DCPA; and are unlikely to occur in the environment.

5.0 REFERENCES

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