Exhibit 78

STUDY TITLE

Tetrachlorophthalic Acid (TPA)

Anaerobic Terrestrial and Aquatic Metabolism Waiver Request

TEST GUIDELINE:

None

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STUDY COMPLETION DATE:

December 11, 2020

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PROJECT NUMBER:

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GOOD LABORATORY PRACTICE COMPLIANCE

This study does not fall under EPA FIFRA Good Laboratory Practice (GLP) Standards set forth in Title 40, Part 160 of the Code of Federal Regulations.

Submitter:

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EXECUTIVE SUMMARY

The anaerobic metabolism of the primary dacthal (DCPA) degradate tetrachlorophthalic acid (TPA) has not been observed in studies of the compound. Also, such metabolism has not been evident under aerobic conditions. For this reason, TPA appears persistent and can migrate to lower depths in the soil and ultimately in the groundwater.

EPA study guidelines for studying the anaerobic fate of pesticides and their degradates specifies a test duration that should not normally exceed 100 days. Because the robustness of microbial populations in a laboratory environment are difficult to maintain, such a specification is appropriate. Within this period, EPA states that half-lives, DT50, DT75, and DT90 values should be determined, but that these values should not be calculated using extrapolative procedures far past the study period. In the case of TPA, this is too short a time for the development of kinetics for such a persistent chemical.

Although studies that first investigated the anaerobic fate of DCPA and TPA were conducted long ago and did not meet the stringent standards used with current testing, those findings need only be considered from a simple qualitative perspective in a situation where no degradation is evident. This was definitively demonstrated in several sediment systems under anaerobic conditions for 60 days, which attests to the highly stable nature of TPA. On this basis, there is no need to consider the ability of the study to provide for a kinetic assessment that would require a more rigorous data set.

The finding that TPA is persistent under anaerobic conditions is not surprising and literature information is herein provided that demonstrates the limit to which normal anaerobic behavior may act on a molecule such as TPA that contains a polychlorinated benzoate structure. Even if an effective microbiological culture could be developed within the sediment system, anaerobic conditions that might lead to reductive dehalogenation or decarboxylation would not be capable of degrading the aromaticity of TPA as that requires an aerobic environment.

Although TPA has been shown to be highly persistent, the chemical itself is rather innocuous and does not share the toxicological considerations of the diester parent compound DCPA. For example, exposure to the sensitive freshwater aquatic invertebrate *Daphnia magna* for a 48-hour period yielded no effects on mobility at the highest tested dose of 100 mg/L (Manson, 2003a). Testing on the higher-level aquatic species, *Oncorhynchus mykiss* not surprisingly yielded these same results (Manson, 2003b). As a diacid, TPA did not present the same phytotoxicity effects as DCPA. Its effect on the growth of a unicellular green alga, *Selenastrum capricornutum* supports an EC50 of greater than 100 mg/L (Manson, 2003c). The health effects of TPA on terrestrial mammals is also quite limited and provides again a clear distinction between it and its parent molecule DCPA.

TPA is not lipophilic and has a low binding potential to soil and plant material. Unlike DCPA it is not volatile; thus its behavior in the environment is simple being that TPA simply leaches through the soil stratum. Ultimately, TPA with sufficient buildup would likely present a suitable substrate for some microbial community, which could then act upon it through both anaerobic and aerobic processes to degrade the chemical. TPA is not unique in being a polychlorinated aromatic compound as many pesticides share some of its common chemistry within an anaerobic environment. What is unique about TPA is the simplicity of its structure that makes it easily studied and the fact that its polychlorinated phthalate structure likely makes it more impervious to degradation in the environment than a polychlorobenzoate.

Based on the fact that TPA is persistent (though relatively innocuous) and that there are study data and literature references that attest to this stability under anaerobic conditions, there would be no value in conducting new anaerobic soil metabolism or anaerobic aquatic metabolism studies for this compound. On this basis, we ask that EPA waive the requirement for further work in this area.

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I. INTRODUCTION

Background:

EPA issued a Data Call-In for DCPA on January 31, 2013. At that time, AMVAC commenced with the conduct of certain required studies and submitted rationale for waiver requests for other studies, including the anaerobic soil metabolism and anaerobic aquatic metabolism study requirements for TPA. AMVAC's initial response to EPA occurred on April 13, 2013. Included in that submission was a request to waive the requirement for additional studies on the basis that the there was sufficient information for assessing the anaerobic fate of TPA. Through the consideration of information contained within this report, it can be readily established that TPA is impervious to anaerobic metabolism within the confines of a laboratory-based study.

On March 21, 2014, EPA responded to our waiver request, but that memorandum was not received by AMVAC until March 17, 2017. The Agency's rationale for the denial was based on a desire to confirm its already established contention as stated within its EPA's February 19, 2009 document, "Risks of DCPA Use to Federally Threatened California Red-legged Frog (*Rana aurora draytonii*) Pesticide Effects Determination" that TPA is stable to both aerobic and anaerobic soil metabolism studies. The Agency's response is provided in full below:

> EFED Response: Since EFED has designated TPA as stable for both aerobic and anaerobic soil metabolism studies, EFED accepts AMVAC's proposal to provide a new study data to verify this finding for the aerobic soil metabolism of TPA. Previously, the DCPA anaerobic soil metabolism study has been classified as supplemental due to the limited data with only three data points, EFED does not believe that the results can be applied to TPA; therefore, EFED believes that a reliable anaerobic soil metabolism study for TPA is still needed for risk assessment, but will assume stability in the absence of a study.

The Agency has similarly denied the initial waiver request for conducting an anaerobic aquatic metabolism study within this same time period. Here the EPA expressed concern that because of the high conversion of this compound, an understanding as to its dissipation in the environment was of critical need. The Agency's response is provided in full below:

> EFED Response: TPA, a major degradate, has up to a 100% conversion rate and forms as a major degradate in aerobic and anaerobic metabolism studies. As stated in the problem formulation, TPA will be included as a residue of concern with the parent DCPA for the ecological risk assessment. Given that the formation rate of TPA is up to 100%, it is critical to understand its dissipation pathways. **EFED recommends that PRD *deny the waiver request to defer the data collection of TPA until DCPA studies are completed.***

In response, on February 22, 2018, AMVAC provided additional information to support our waiver position but had not received response to this letter. Therefore, the purpose of this document is to present this information again but with additional lines of evidence that can be used by the Agency in fulfilling this requirement.

II. Anaerobic Metabolism Study for Deducing the Fate of TPA

1. Anaerobic Soil Metabolism of Dacthal® by Duane, W. C.

An anaerobic metabolism study was conducted in 1976 for the purpose of supporting the registration of DCPA. Although the study was conducted prior to the development of current EPA guidelines, it serves an important purpose of qualitatively demonstrating that TPA is stable under anaerobic conditions in soil. The study is also recognized as having certain deficiencies that would normally preclude its ability to provide a quantitative description of the kinetics within the three soil systems, but that need is lacking in this instance. The study is quite definitive in its use of radiolabeled material to demonstrate the lack of any metabolism of TPA under anaerobic conditions within a 60-day period. The study findings are summarized below.

The anaerobic soil metabolism of DCPA has been studied in three different soil systems using C-14 radiolabeled material. The initial concentration of DCPA was 10.5 ppm. The three soils were diverse in texture and physicochemical properties. The test systems included a silty clay and two sandy loams. One of the sandy loams was acidic and one was basic. Organic matter content ranged between 1.3 and 1.6%. Soils were first incubated aerobically for a 28-day period and then the oxygenated atmosphere was replaced with nitrogen to obtain anaerobic conditions. The systems were subsequently monitored for an additional 60 days. Under these conditions by the end of the experiment, mass recoveries exceeded 90% for all soils. The concentrations of TPA in the three test systems ranged from 83.1 to 89%. Although some conversion of DCPA to TPA would have occurred during the incubation period under aerobic conditions, the study indicates that the transformation could occur at a similar rate under anaerobic conditions. This was accomplished by the study author through a comparison of the results of the aerobic soil metabolism study, which used the same test systems. The study also demonstrated that there was no measurable transformation of TPA. Potential reactivity through decarboxylation or reductive dehalogenation was not observed during the study.

III. Studies in the Scientific Literature on the Anaerobic Metabolism of Chlorobenzoates and Phthalates in the Environment

The general scientific literature provides evidence that microbial processes can degrade simple chloro-aromatic acids and chloro-phthalic acids under anaerobic conditions; but this process is limited and entails a lag period in order for suitable microbial populations to develop. Once an amenable microbial population is established, the polychlorinated aromatic substrate may serve as an electron donor or acceptor and with subsequent addition of oxygen the chemical can be fully mineralized to chloride and carbon dioxide. Degradation mediated by specially adapted microbes that can operate under anaerobic conditions would likely occur through the primary mechanisms of reductive halogenation or decarboxylation.

However, the dissipation of TPA is not governed by these reactions because of the considerable lag period between chemical introduction and microbial degradation. For this reason, the fate of TPA in the environment simply results in the leaching of the highly mobile chemical prior to any notable metabolism.

In a laboratory setting where leaching is precluded, TPA buildup has been shown to occur with no evident degradation. Literature studies that consider the fate of polychloro-aromatic carboxylates validate this finding, reporting that lag periods in anaerobic aquatic sediments can be as long as one year.

Because there is no regulatory value in considering the kinetics of such transformation, conducting further studies in this area is not well justified. Although TPA is persistent under anaerobic conditions, long-term buildup is precluded by the fact that sediments and deep soil layers have at least a theoretical capability to eventually develop appropriate microbial populations that could degrade such compounds efficiently. Also, buildup is precluded because leaching behavior reduces potential for concentration increases on the soil surface.

In general, polychlorinated benzoates tend to be persistent in the environment and are not easily transformed under aerobic conditions, especially for chemicals with the structural elements of TPA that contain two ortho-substituted chlorines (MacRae, 1965; Sheets, 1968; DiGeronimo, 1979). For effective biotransformation of such compounds, certain anaerobic bacterial cultures can be leveraged for removal of one of the *ortho*-chlorines. However, such polychlorinated benzoates still require aerobic conditions in order to degrade the benzene ring. As example, the compound 1,3,6-trichlorobenzoate has been demonstrated to be stoichiometrically reduced to 2,5-dichlorbenzoate and chloride under anaerobic conditions by a microbial population grown with *P. aeruginosa* JB2 in continuous culture (Gerritse, 1992). Further degradation and mineralization, however, requires the introduction of oxygen to present aerobic conditions.

Polychloro-benzoates or phthalates can be reductively dechlorinated by acting as an electron acceptor. The degree of chlorination dramatically affects the biodegradability potential under

different redox conditions as higher chlorinated aromatics are more susceptible to anaerobic, rather than aerobic biotransformation. The metabolism of polychlorinated benzoates in ecological water bodies and sediments requires the development of a suitable microbial population. For example, when 3-chlorobenzoate fortified at 16-125 mg/L was incubated with freshwater river, pond lake, or marsh sediments, there was a lag period for biodegradation of 2.5 to 8 months (Horowitz, 1983; Gibson, 1986; Genther, 1989a, Haggblom, 1993, vanderWoude, 1996). Similarly, 3-chlorobenzoate biodegradation required 3-4 months within anaerobic aquifer sediments (Gibson, 1986; Kazumi, 1995a; Townsend, 1997). Within estuarine and salt marsh sediments biodegradation required 6-7 months (Genthner, 1989a), Haggblom, 1993).

Although anaerobic degradation more readily occurs for simpler compounds such as 3-chlorobenzoate and 2-chlorobenzoate, more halogenated aromatics show great resistance to degradation (Horowtitz, 1983; Genthner, 1989a; Haggblom, 1993; vanderWoude, 1996). Even in the presence of an iron reducing sediment, these compounds may resist degradation for a period as long as 6 months. The compound 4-chlorobenzoate also demonstrates resistance to degradation and under methanogenic conditions, it is not significantly reduced (Horowitz, 1983; Gibson, 1986; Genthner, 1989a; Haggblom, 1993). In other sediments, degradation occurs after a lag period of up to 12 months (Genthner, 1989a; van der Woude, 1996).

The reduction of the trichlorinated benzoate 3,4,5-trichlorobenzoate has been reported in anaerobic sediments. The dehalogenation of 3,4-dichlorobenzoate to 3-and 4-chlorobenzoate and of 3,5-dichlorobenzoate to 3-chlorobenzoate in pond and aquifer sediments required several weeks of incubation time (Gibson 1986). Similar behavior has been observed for the dehalogenation of 3,5-dichloro-4-aminobenzoate to 3-chloro-4-aminobenzoate and subsequently to 3-chlorobenzoate, with each phase requiring several weeks (Horowitz, 1983). These studied sediments required a much longer activation phase for degradation of 2,3,6-trichlorobenzoate to 2,6-dichlorobenzoate, taking from 1 to 12 months.

Chlorobenzoates are also degraded with alternative electron acceptors under anaerobic conditions such as the mineralization of 3-chlorobenzoate under denitrifying, sulfate reducing and iron reducing conditions (Kazumi, 1995b). In certain enrichment studies, the responsible bacterium has been identified.

Literature studies relating to the degradation of phthalates under anaerobic conditions also provide insight into the environmental fate of TPA. When methanogenic enrichment cultures grown on terephthalate are compared with cultures grown on benzoates, the effect of a second aromatic carboxylate group on degradation can be assessed (Kleerebezam, 1999a). The finding is that the initial reaction results in decarboxylation of phthalates to form benzoate. In this study, however, only low-level reactivity was noted. A Gibbs free energy assessment indicates that the reaction rate was likely retarded as molecular hydrogen and substrates combined in

amounts where reduction and oxidation processes were of comparable energy. Such cultures when enriched with terephthalate still demonstrate preference for benzoate reduction (Kleerebezam, 1999b).

Enzyme specificity also plays a role in the degradation of phthalates, and in some systems, such as that of the nitrate-reducing bacterium *Azoarcus* sp. strain PA01, the putative CoA-transferases and a UbiD-like decarboxylase that were assigned to be specifically involved in the initial steps of anaerobic o-phthalate degradation were shown not to be operative for terephthalate (Junghare, 2016). This provides some evidence on the impervious nature of phthalate metabolism.

The relevance of these studies to TPA yields several general conclusions. First, there is a need for appropriate microbial enrichment of the soil for anaerobic metabolic processes to be effective. Second, such reactions are typically limited as degradation of aromaticity requires aerobic conditions. Ecological studies suggest that polychloro-aromatic compounds in general are of similar toxicity such that the overall polychloro-benzoate load would not change through anaerobic metabolism when assessing effects to terrestrial and aquatic organisms.

IV. CONCLUSIONS

In summary, TPA has been shown to be impervious to metabolism in three different sediment systems for a 60-day anaerobic period. This finding is consistent with the fact that polychorobenzoates are resistant to anaerobic degradation and that there is a considerable lag period before metabolism becomes evident. The fate of TPA in the environment is easily understood based on its propensity to leach through the soil profile. However, the chemical has been shown to be relatively innocuous to mammalian and aquatic life and would not pose an undue burden in the environment. Although the chemical may buildup in certain compartments, it has also been demonstrated that over time, anaerobic and aerobic processes are capable of degrading compounds such as TPA fully producing both chloride and carbon dioxide.

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