UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1
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BOSTON, MA 02114-2023

Memorandum

Date: January 9, 2007

Subject: Evaluation of Risk Associated with PCB in Clariant Pigments

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To: Marianne Milette, PCB Enforcement Coordinator (SEP)
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BACKGROUND

On September 23, 2003 Clariant notified EPA Headquarters that elevated PCB concentrations had been identified in two pigment products manufactured at its Coventry, Rhode Island facility. Subsequently, EPA Headquarters provided this information to Region 1 for follow-up. Following an October 3, 2003 meeting between Clariant and Region 1 and an October 15, 2003 letter to Clariant from Region 1, Clariant submitted additional information in December 2003.

In January, 2004 EPA Region 1 and EPA Headquarters held a joint meeting with Clariant in Washington. During that meeting, EPA identified the steps that Clariant would need to follow to evaluate the risks associated with products which may have been manufactured with the pigments that exceeded allowable concentrations under 40 CFR Part 761. Numerous products were identified by Clariant and conservative estimates on the PCB concentrations in those products needed to be evaluated to determine if a product recall would be necessary based on unacceptable exposures to PCB products by end-users. Based on this discussion, the following information was provided to Region 1. {EPA's responses to the information provided by Clariant are also noted}.

- Clariant Corporation to EPA, letter dated April 30, 2004 with proposed approach for assessing exposure risks {EPA response June 2, 2004}

- *Conceptual Exposure Model and Preliminary Assessment for End User of Pigment Red 144 and 214, August 31, 2004 with Appendix 1, Volumes 1 and 2* {Versar comments October 25, 2004}

- *Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214, December 6, 2004* {Versar comments January 23, 2005}

- *Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214, February 21, 2005* {Versar comments March 18, 2005}

- *Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214, April 11, 2005* {Versar comments June 6, 2005 and June 20, 2005}

- Clariant July 8 and July 11, 2005 Responses to EPA June 20, 2005 comments {Versar comments August 1, 2005}

- *Addenda to the Conceptual Exposure Model Report (August 2004) and Exposure and Screening-Level Risk Assessment Report (August 11, 2005), Red Pigment Project, September 16, 2005* {Versar comments December 16, 2005}

- *Addendum II To Report: Exposure and Screening Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214 April 11, 2005 Revision, August 18, 2006* {Versar comments October 13, 2006}

- *Addendum II To Report: Exposure and Screening Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214 April 11, 2005 Revision, Step-By-Step Calculations Guide November 14, 2006* {Versar had no comments on this final package finding all information provided to be reasonable and the calculations to support the findings}

CONCLUSIONS

As part of the initial evaluation of products potentially remaining in use, EPA agreed that it was reasonable to look at the products that would have the highest potential exposure for end-users: carpet fiber and food wrap. The exposure and screening level risk assessments considered work-case scenarios, including highest concentrations of PCBs in products.

No risks were identified in the food wrap scenario. In the carpet fiber scenario, only 1 risk exceedence was identified. The Child Non-Cancer and Cancer Risk Scenarios, which considered completed volatilization of PCBs from the Carpet Surface (Table 4 of Addendum II), found an exceedence of the non-cancer hazard index of 1. This exceedence occurred using the highest exposures and highest PCB concentration found in the carpet. Based on ATSDR guidance, the oral bioavailability is likely to be lower than 1.0 (worst-case scenario) and therefore under actual conditions, the hazard index is likely

to be less than 1.0, which would fall within acceptable risk guidelines. The cancer risk end point of 1×10^{-6} was never exceeded in the carpet fiber evaluation.

Based on the information provided, the exposure and risk evaluations provided by Clariant appear reasonable. Given that the products representing the highest potential exposures have been evaluated and that the risk evaluations appear to support that there is no unacceptable risk to PCBs for the end-user, it does not appear that evaluation of further products is necessary. However, in the event Clariant should determine that information provided to support its evaluations is not accurate, re-evaluation of the exposures and risk determinations may be needed.