

CONVERSATION RECORD

DATE: October 13, 2004

TIME: 9:40 AM

CENTER REPRESENTATIVE(S): Keith Olin, Michael Koenig

SPONSOR REPRESENTATIVE(S): Frederick (Rick) Stearns

SPONSOR TELEPHONE NUMBER: 202-434-4288

SPONSOR NAME: Keller and Heckman (on behalf of Clariant GmbH)

SUBJECT: Confidentiality of data to demonstrate safety and effectiveness of piroctone olamine

DISCUSSION

Keith placed a call to Mr. Stearns. We told him we needed to verify that the data submitted to support the safety and effectiveness of piroctone olamine did not contain any confidential information and could be made publicly available in Dockets. Mr. Stearns did not think any of the data was confidential but was going to check with representatives from Clariant GmbH. If Clariant agreed that nothing in the data is confidential, Mr. Stearns indicated that he would send a letter to Div. Dockets Management affirming the data can be made publicly available.

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