



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Memorandum

DATE: July 25, 2017

SUBJECT: Transmission of Background Materials on the Physiologically Based Pharmacokinetic/Pharmacodynamic (PBPK/PD) Model on Dimethoate to the Panel for the October 24 - 27, 2017 Session of the FIFRA Scientific Advisory Panel (FIFRA SAP) Reviewing PBPK Modeling to Address Pharmacokinetic Differences Between and Within Species

TO: Steven Knott
Acting Executive Secretary
FIFRA Scientific Advisory Panel Staff
Office of Science Coordination and Policy

FROM: Dana Vogel, Director
Health Effects Division
Office of Pesticide Programs

A handwritten signature in blue ink, appearing to read "Dana Vogel", with a long horizontal line extending to the right.

Transmitted with this memo are copies of all background documents and model files for the physiologically based pharmacokinetic/pharmacodynamic model of dimethoate from the FMC to the Panel for the October 24 through 27, 2017 session of the FIFRA SAP reviewing Physiologically Based Pharmacokinetic (PBPK) Modeling to Address Pharmacokinetic Differences Between and Within Species. These documents do not contain any information protected under statute as Confidential Business Information (CBI). These materials do not contain information which may be proprietary in nature and/or are protected from disclosure to foreign and multi-national pesticide producers under FIFRA Section 10(g). In addition, these materials do not include information protected by copyright. The attached documents have completed QA/QC review and are listed below in the attached Tables 1 and 2.

Attachment

Table 1: Transmission of the background materials on the physiologically based pharmacokinetic/pharmacodynamic (PBPK/PD) model for Dimethoate to the panel for the October 24 - 27, 2017 session of the FIFRA Scientific Advisory Panel (FIFRA SAP) reviewing PBPK Modeling to address pharmacokinetic differences between and within species

Document Title	Author(s)	Date	FIFRA 10(g) or © Protected (designate as)	QA/QC (mark w/ X)	Master Record Identification Number (MRID)*
PBPK-PD Models for Dimethoate Final for SAP.pdf	Bogen, K. and R. Reiss	7-20-2017	Waived	X	N/A
(Methylene-(Carbon 14)-) Omethoate: General Metabolism Study in the Rat	Hoshino, T	1989	Waived	X	46099808
(carbon 14)-Dimethoate: The Biokinetics and Metabolism in the Rat	Kirkpatrick, D.	1995	Waived	X	43964001
Omethoate--Acute Oral Neurotoxicity Study in Wistar Rats: Single Administration by Gavage	Mellert, W., K. Deckardt, W. Kaufmann and B. van Ravenzwaay	2003	Waived	X	46167701
Urinary Excretion Profile of Dimethoate and its Metabolites after Single Oral Administration of Dimethoate in Male Volunteers	Meuling, W. and L. Roza	2004	Waived	X	46497601
Dimethoate Effects on Cholinesterase in the CD Rat (Adult and Juvenile) by Oral Gavage Administration	Meyers, D	2001	Waived	X	45529702
Study Protocol: Inhibition kinetics of six organophosphate compounds on human and rat erythrocyte acetylcholinesterase	Chambers, J	2016	Waived	X	N/A

*If applicable

Table 2: Transmission of files related to the physiologically based pharmacokinetic/pharmacodynamic (PBPK/PD) model for Dimethoate to the panel for the October 24 - 27, 2017 session of the FIFRA Scientific Advisory Panel (FIFRA SAP) reviewing PBPK modeling to address pharmacokinetic differences between and within species. The .txt extension of the second file in the table needs to be changed to .m extension in order to run the model file in Mathematica.

Document Title	Author(s)	Date	FIFRA 10(g) or © Protected (designate as)	QA/QC (mark w/ X)	Master Record Identification Number (MRID)*	Simulation Scenarios	Additional Instruction
Exponent Dimethoate Model Primer.pdf	Bogen K.	7-24-2017	Waived	X	N/A	N/A	Instruction for running the model simulations
ExponentDimethoateMod el.txt	Bogen K.	7-24-2017	Waived	X	N/A	Main Mathematica code with all simulations	Need to change the file extension to .m in order to run the model file in Mathematica

*If applicable