



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 (PBPK) Models on Deltamethrin and cis-Permethrin 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, likely belonging to Dana Vogel, is positioned to the right of the "FROM:" line. The signature is stylized and fluid.

Transmitted with this memo are copies of all background documents and model files for the physiologically based pharmacokinetic (PBPK) models of deltamethrin and cis-permethrin from the Council for the Advancement of Pyrethroid Human Health Risk Assessment (CAHRA) 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, some of these materials include information protected by copyright, and CAHRA has obtained permission from the publishers to reproduce the distribution these copyrighted materials for purposes of the FIFRA SAP review and in the electronic form attached to this memorandum. The attached documents have completed QA/QC review and are listed below in the attached Tables 1 and 2.

Attachment

cc:

Table 1: Transmission of background materials on the physiologically based pharmacokinetic (PBPK) models for Deltamethrin and cis-Permethrin 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)*
CAPHRA_July_Submission_FINAL.DOCX	ScitoVation	7-24-2017	Waived	X	N/A
DMD34-389_YOON_170510.pdf	Dodenhoff R.	5-10-2017	Waived	X	N/A

*If applicable

Table 2: Transmission of files related to the physiologically based pharmacokinetic (PBPK) models for Deltamethrin and cis-Permethrin 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. Both file names and file extensions for files with a .txt extension need to be changed as indicated in the readme_CAPHRA_human.docx and readme_CAPHRA_rat.docx in order for these model files to run in R.

Document Title	Author(s)	Date	FIFRA 10(g) or © Protected (designate as)	QA/QC (mark w/ X)	Master Record Identification Number (MRID)*	Additional Instruction
readme_CAPHRA_human.docx	ScitoVation	7-24-2017	Waived	X	N/A	Instruction for renaming file names, setting up directories, and running the human model simulations
readme_CAPHRA_rat.docx	ScitoVation	7-24-2017	Waived	X	N/A	Instruction for renaming file names, setting up directories, and running the rat model simulations
Rats_PYR_clearance_calculation.xlsx	ScitoVation	7-24-2017	Waived	X	N/A	

Document Title	Author(s)	Date	FIFRA 10(g) or © Protected (designate as)	QA/QC (mark w/ X)	Master Record Identification Number (MRID)*	Additional Instruction
Sensitivity_analysis_DLM_CPM_TPM_ Rat.xlsx	ScitoVation	7-24-2017	Waived	X	N/A	
PYR_Clearance_calculationfinal.xlsx	ScitoVation	7-24-2017	Waived	X	N/A	
MC parameters_PER_male.xlsx	ScitoVation	7-24-2017	Waived	X	N/A	
MC parameters_PER_Female.xlsx	ScitoVation	7-24-2017	Waived	X	N/A	
MC parameters_Male_DLM.xlsx	ScitoVation	7-24-2017	Waived	X	N/A	
MC parameters_Female_DLM.xlsx	ScitoVation	7-24-2017	Waived	X	N/A	
Life stage parameters_Male.xlsx	ScitoVation	7-24-2017	Waived	X	N/A	
Life stage parameters_Female.xlsx	ScitoVation	7-24-2017	Waived	X	N/A	
Sensitivity_analysis_DLM_CPM_final.xlsx	ScitoVation	7-24-2017	Waived	X	N/A	
Supplemental_Caphra project.docs	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_CPM_Exposure_scenarios.xlsx	ScitoVation	7-24-2017	Waived	X	N/A	
model_rat.txt	ScitoVation	7-24-2017	Waived	X	N/A	
main_rat.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_IV_90d_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_Oral_15d_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_Oral_90d_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_pub_10d_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_pub_90d_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_Oral_15d_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_oral_90d_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_Oral_15d_TPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_Oral_90d_TPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	

Document Title	Author(s)	Date	FIFRA 10(g) or © Protected (designate as)	QA/QC (mark w/ X)	Master Record Identification Number (MRID)*	Additional Instruction
CPM_Oral_POD_15d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Oral_POD_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Oral_Scenario1_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Oral_Scenario2_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Oral_Scenario3_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Oral_Scenario4_15d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Oral_Scenario5_15d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Oral_Scenario6_15d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_IV_Scenario1_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_IV_Scenario2_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Oral_POD_15d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Oral_POD_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Oral_Scenario_PUB1_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Oral_Scenario_PUB2_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Oral_Scenario_PUB3_10d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Oral_Scenario_PUB4_10d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Oral_Scenario_PUB5_10d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Oral_Scenario1_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Oral_Scenario2_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Oral_Scenario3_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Oral_Scenario4_15d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Oral_Scenario5_15d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Oral_Scenario6_15d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
TPM_Oral_POD_15d.txt	ScitoVation	7-24-2017	Waived	X	N/A	

Document Title	Author(s)	Date	FIFRA 10(g) or © Protected (designate as)	QA/QC (mark w/ X)	Master Record Identification Number (MRID)*	Additional Instruction
TPM_Oral_POD_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
TPM_Oral_Scenario1_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
TPM_Oral_Scenario2_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
TPM_Oral_Scenario3_90d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
TPM_Oral_Scenario4_15d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
TPM_Oral_Scenario5_15d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
TPM_Oral_Scenario6_15d.txt	ScitoVation	7-24-2017	Waived	X	N/A	
model_human.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_1Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_2Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_5Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_6M_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_10Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_12Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_13Y_DLM.txt						
params_F_19Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_20Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_25Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_49Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_1Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_1Y5_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_2Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_3Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_4Y5_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	

Document Title	Author(s)	Date	FIFRA 10(g) or © Protected (designate as)	QA/QC (mark w/ X)	Master Record Identification Number (MRID)*	Additional Instruction
params_M_5Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_6M_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_6Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_10Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_10Y5_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_12Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_13Y_DLM.txt						
params_M_16Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_17Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_19Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_20Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_25Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_49Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_50Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_60Y_DLM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_1Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_2Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_5Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_6M_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_10Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_12Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_13Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_19Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	

Document Title	Author(s)	Date	FIFRA 10(g) or © Protected (designate as)	QA/QC (mark w/ X)	Master Record Identification Number (MRID)*	Additional Instruction
params_F_20Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_25Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_F_49Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_1Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_1Y5_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_2Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_3Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_4Y5_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_5Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_6M_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_6Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_10Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_10Y5_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_12Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_13Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_16Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_17Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_19Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_20Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_25Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_49Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_50Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
params_M_60Y_CPM.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Human_Inh.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Human_Oral.txt	ScitoVation	7-24-2017	Waived	X	N/A	

Document Title	Author(s)	Date	FIFRA 10(g) or © Protected (designate as)	QA/QC (mark w/ X)	Master Record Identification Number (MRID)*	Additional Instruction
CPM_Scenario1_Food_male_20Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario2_Drinking_male_6M.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario3_WorkerMixerLoader_ Inh_male_60.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario4_WorkerApplicator_Inh_ male_60Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario5_WorkerPHEDcombo_I nh_male_60Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario6_ResidentialHandler_Inh _male_60Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario7_ResidentialPostAppl_O ral_male_2Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario8_ResidentialPostAppl_O ral_male_6Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario9_ResidentialPostAppl(in doorcarpet)_Oral_male_2Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario10_ResidentialPostAppl(i ndoorhardsurf)_Oral_male_2Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario11_ResidentialPostAppl(p aints)_Oral_male_2Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario12_ResidentialPostAppl(p ets)Oral_male_2Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario13_ResidentialPostAppl(I ndoorspacespray)_Inh_male_60Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario14_ResidentialPostAppl(I ndoorspacespray)_Inh_male_1Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario15_ResidentialPostAppl(Outdoorspacespray)_Inh_male_60Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	

Document Title	Author(s)	Date	FIFRA 10(g) or © Protected (designate as)	QA/QC (mark w/ X)	Master Record Identification Number (MRID)*	Additional Instruction
CPM_Scenario16_ResidentialPostAppl(Outdoorspacespray)_Inh_male_1Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario17_ResidentialPostAppl(Outdoorspacespray)_Inh_male_4Y5.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario18_ResidentialPostAppl(Mosquitocide)_Inh_male_60Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_Scenario19_ResidentialPostAppl(Mosquitocide)_Inh_male_1Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_ScenarioO1_Food_male_6M.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_ScenarioO2_Drinking_male_6M.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_ScenarioO3_Food_male_1-2Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_ScenarioO4_Drinking_male_1-2Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_ScenarioO5_Food_male_3-5Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_ScenarioO6_Drinking_male_3-5Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_ScenarioO7_Food_male_6-12Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_ScenarioO8_Drinking_male_6-12Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_ScenarioO9_Food_male_13-19Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_ScenarioO10_Drinking_male_13-19Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_ScenarioO11_Food_male_20-49Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_ScenarioO12_Drinking_male_20-49Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	

Document Title	Author(s)	Date	FIFRA 10(g) or © Protected (designate as)	QA/QC (mark w/ X)	Master Record Identification Number (MRID)*	Additional Instruction
CPM_ScenarioO13_Food_male_50-60Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_ScenarioO14_Drinking_male_50-60Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_ScenarioO15_Food_female_13-49Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
CPM_ScenarioO16_Drinking_female_13-49Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Human_Inh.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Human_Oral.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Scenario1_Food_male_20Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Scenario2_Drinking_male_6M.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Scenario3_Worker_Inh_male_60Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Scenario4_ResidentialHandler_Inh_male_60Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Scenario5_ResidentialPostAppl_Inh_male_60Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Scenario6_ResidentialAppl_Inh_male_1Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Scenario7_ResidentialPostAppl_Oral_male_2Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Scenario8_IndoorCarpet_Oral_male_2Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Scenario9_IndoorHardSurface_Oral_male_2Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Scenario10_Turf_Oral_male_2Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
DLM_Scenario11_SurfaceDirectSpray_	ScitoVation	7-24-2017	Waived	X	N/A	

Document Title	Author(s)	Date	FIFRA 10(g) or © Protected (designate as)	QA/QC (mark w/ X)	Master Record Identification Number (MRID)*	Additional Instruction
Oral_male_2Y.txt						
DLM_Scenario12_PetCollar_Oral_male_2Y.txt	ScitoVation	7-24-2017	Waived	X	N/A	
main_human.txt	ScitoVation	7-24-2017	Waived	X	N/A	

*If applicable