



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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Memorandum

DATE: August 1, 2017

SUBJECT: Transmission of Background Materials on the Physiologically Based Pharmacokinetic/Pharmacodynamic (PBPK/PD) Model on Carbaryl 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", is written over the "FROM:" line.

Transmitted with this memo are copies of all background documents and model files for the physiologically based pharmacokinetic/pharmacodynamic (PBPK/PD) model of carbaryl from TKI 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 background materials on the physiologically based pharmacokinetic/pharmacodynamic (PBPK/PD) model for Carbaryl 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)*
TKI_SAP_White_Paper_072817_FINAL_B.DOCX	ScitoVation	8-1-2017	Waived	X	N/A
Supplemental-July.docx	ScitoVation	7-24-2017	Waived	X	N/A

*If applicable

Table 2: Transmission of files related to the physiologically based pharmacokinetic/pharmacodynamic (PBPK/PD) model for Carbaryl 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
Rinstall_run_instruction.docx	ScitoVation	7-24-2017	Waived	X	N/A	Instruction for renaming file names, setting up directories, and running model simulations
Life stage parameters_Female_SAP- July.xlsx	ScitoVation	07.24.17	Waived	X	N/A	
Life stage parameters_Male_SAP- July.xlsx	ScitoVation	07.24.17	Waived	X	N/A	
MC parameters_Female-SAP-July.xlsx	ScitoVation	07.24.17	Waived	X	N/A	
MC parameters_Male-SAP-July.xlsx	ScitoVation	07.24.17	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_Carbaryl.xlsx	ScitoVation	07.24.17	Waived	X	N/A	
model-new-annotated.txt	ScitoVation	07.24.17	Waived	X	N/A	This is the model to run scenarios with specific scenario files designated below
params_F_1Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for female age 1Y
params_F_3Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for female age 3Y
params_F_6M.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for female age 6M
params_F_6Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for female age 6Y
params_F_13Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for female age 16Y
params_F_16_R_Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for female age 16Y with resting phase respiratory parameter values
params_F_16Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for female age 16Y
params_F_19Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for female age 19Y
params_F_20Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for female age 20Y
params_F_25Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for female age 25Y
params_F_49Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for female age 49Y
params_F_60Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for female age 60Y

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params_M_1Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for male age 1Y
params_M_3Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for male age 3Y
params_M_6M.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for male age 6 months
params_M_6Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for male age 6Y
params_M_13Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for male age 13Y
params_M_16Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for male age 16Y
params_M_19Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for male age 19Y
params_M_20Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for male age 20Y
params_M_25_R_Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for male age 25Y with Resting phase respiratory parameter values
params_M_25M.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for standard male age 25Y used to validate the model with May et al data.
params_M_25Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for male age 25Y
params_M_49Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for male age 49Y
params_M_60Y.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide parameter values for male age 60Y

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params_match Acslx.txt	ScitoVation	07.24.17	Waived	X	N/A	This is a file to provide comparison between parameter annotation in Acslx to R
Dermal-Residential Handler-80kg-half SKcontact-1hr.txt	ScitoVation	07.24.17	Waived	X	N/A	
Dermal-Residential post-app-11kg-half SKcontact-1_5hr.txt	ScitoVation	07.24.17	Waived	X	N/A	
Dermal-Residential post-app-32kg-half SKcontact-1_5hr.txt	ScitoVation	07.24.17	Waived	X	N/A	
Dermal-Residential post-app-57kg-half SKcontact-1_5hr.txt	ScitoVation	07.24.17	Waived	X	N/A	
Dermal-Residential post-app-80kg-half SKcontact-1_1hr.txt	ScitoVation	07.24.17	Waived	X	N/A	
Dermal-Residential post-app-80kg-half SKcontact-1_5hr.txt	ScitoVation	07.24.17	Waived	X	N/A	
Dermal-Residential post-app-80kg-half SKcontact-2_2hr.txt	ScitoVation	07.24.17	Waived	X	N/A	
Dermal-Worker-Applicator-80kg-full SKcontact-8hr.txt	ScitoVation	07.24.17	Waived	X	N/A	
Dermal-Worker-mix loader-80kg-full SKcontact-8hr.txt	ScitoVation	07.24.17	Waived	X	N/A	
Dermal-Worker-PHED-80kg-full SKcontact-8hr.txt	ScitoVation	07.24.17	Waived	X	N/A	
Drinking water-4_8Kg-6 doses.txt	ScitoVation	07.24.17	Waived	X	N/A	
Drinking water-12_6Kg-6 doses.txt	ScitoVation	07.24.17	Waived	X	N/A	
Drinking water-18_7Kg-6 doses.txt	ScitoVation	07.24.17	Waived	X	N/A	
Drinking water-37_1Kg-6 doses.txt	ScitoVation	07.24.17	Waived	X	N/A	
Drinking water-67_3Kg-4 doses.txt	ScitoVation	07.24.17	Waived	X	N/A	
Drinking water-81_2Kg-60Y-4 doses.txt	ScitoVation	07.24.17	Waived	X	N/A	
Drinking water-81_5Kg-4 doses.txt	ScitoVation	07.24.17	Waived	X	N/A	
Food-Single-4_8Kg.txt	ScitoVation	07.24.17	Waived	X	N/A	
Food-Single-12_6 kg.txt	ScitoVation	07.24.17	Waived	X	N/A	

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Food-Single-18_7 kg.txt	ScitoVation	07.24.17	Waived	X	N/A	
Food-Single-37_1 kg.txt	ScitoVation	07.24.17	Waived	X	N/A	
Food-Single-67_3 kg.txt	ScitoVation	07.24.17	Waived	X	N/A	
Food-Single-81_2 kg - 60Y.txt	ScitoVation	07.24.17	Waived	X	N/A	
Food-Single-81_5 kg.txt	ScitoVation	07.24.17	Waived	X	N/A	
Inhalation-Worker-Applicator-80kg- 1730RESPR-8hr.txt	ScitoVation	07.24.17	Waived	X	N/A	
Inhalation-Worker-Loader-80kg- 1730RESPR-8hr.txt	ScitoVation	07.24.17	Waived	X	N/A	
Inhalation-Worker-PHED-80kg- 640RESPR-1hr.txt	ScitoVation	07.24.17	Waived	X	N/A	
Inhalation-Worker-PHED-80kg- 1730RESPR-8hr.txt	ScitoVation	07.24.17	Waived	X	N/A	
Oral turf-Residential Post-app-11kg.txt	ScitoVation	07.24.17	Waived	X	N/A	
Oral-ParaHuman-standard.txt	ScitoVation	07.24.17	Waived	X	N/A	

*If applicable