

US EPA ARCHIVE DOCUMENT




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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Memorandum

DATE: January 7, 2008

SUBJECT: Transmission of Review and Reference Materials for the February 5 – 8, 2008 Session of the FIFRA Scientific Advisory Panel (SAP) Entitled “Scientific Issues Associated with the Agency's Proposed Action Under FIFRA 6 (b) Notice of Intent to Cancel Carbofuran”

FROM: Steven Bradbury, PhD., Director 
Special Review and Reregistration Division
Office of Pesticide Programs (7508P)

TO: Sharlene Matten, PhD., Designated Federal Official
FIFRA Scientific Advisory Panel
Office of Science Coordination and Policy (7201M)

Attached are two transmittal memoranda and associated compact discs. The memoranda are from Dr. Donald Brady, Acting Director of the Environmental Fate and Effects Division, and Dr. Tina Levine, Director of the Health Effects Division. The compact discs contain the documents for the February 5 – 8, 2008 Session of the FIFRA Scientific Advisory Panel (SAP) Entitled “Scientific Issues Associated with the Agency's Proposed Action Under FIFRA 6 (b) Notice of Intent to Cancel Carbofuran”. The documents transmitted through these memoranda concern both the human health and ecological risk assessments conducted for carbofuran.

These documents include “review documents” identified in the tables in the individual HED and EFED transmittal memoranda, provided for the Panel's review as the principal basis for the charge to the Panel. In addition, reference materials are provided. Should the Panel wish to review any additional references that are not included, we can provide them at a later date, assuming all of the necessary clearances are obtained.

These documents do not contain any information protected under the statute as Confidential Business Information (CBI). However, some of the documents do contain information protected from disclosure to foreign and multi-national pesticide producers under FIFRA Section 10(g).

The CDs and hard copies attached contain the documents identified in the table below. Please feel free to call upon us if you have any questions.

| Disc Label | Disc Contents | Contains FIFRA 10(g) Protected Material |
|---------------------------|---|--|
| CD # I | Transmittal memos (This cover memo, EFED transmittal memo, and HED transmittal memo) Draft NOIC Charge Questions to the Panel | No |
| EPA Disk 1 | Environmental Fate and Effects Division Review Documents | No |
| Carbofuran CD 1 Ref. Disk | Environmental Fate and Effects Division Review Documents | Yes |
| CD # 3 | Health Effects Division Review Documents & References | Yes |
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FROM: Donald Brady, Acting Director
Environmental Fate and Effects Division
Office of Pesticide Programs (7507P)

A handwritten signature in black ink, appearing to read "D. Brady", written over the typed name and title.

TO: Sharlene Matten, Designated Federal Official
FIFRA Scientific Advisory Panel
Office of Science Coordination and Policy (7201M)

Attached are compact discs containing the documents for the February 5 – 8, 2008 Session of the FIFRA Scientific Advisory Panel (SAP) Entitled “Scientific Issues Associated with the Agency's Proposed Action Under FIFRA 6 (b) Notice of Intent to Cancel Carbofuran”. The documents transmitted through this memorandum concern the ecological risk assessments conducted for carbofuran.

These documents include the “review documents” identified in the table below. These documents are being provided for the Panel's review and form the basis for the charge to the Panel. In addition, reference materials are provided as well. Should the Panel wish to review any additional references that are not included, such as the avian field studies conducted for carbofuran, we can provide them at a later date, assuming all of the necessary clearances are obtained.

These documents do not contain any information protected under the statute as Confidential Business Information (CBI). However, some of the documents do contain information protected from disclosure to foreign and multi-national pesticide producers under FIFRA Section 10(g).

The compact disks are enclosed and include the documents identified in the table below. It should be noted that we will be providing an additional document, which provides the context for this SAP, at a later date. Please feel free to call upon us if you have any questions.

| REVIEW DOCUMENTS | Source | File Name | Author(s) | Date | FIFRA 10(g) Protected |
|--|---------------------------|--|---|-------------------|------------------------------|
| Reregistration Eligibility Science Chapter for Carbofuran, Environmental Fate and Effects Chapter. | EPA Disk 1 | EFED Chapter Mar 2006 | US EPA | March 7, 2006 | --- |
| Summary Evaluation of Recently Submitted FMC Avian Studies (D347778) | EPA Disk 1 | EPA Review of FMC avian studies | US EPA | December 19, 2007 | --- |
| Impact of 2007 Avian Data on EPA's Probabilistic Risk Assessment on Carbofuran (D347916) | EPA Disk 1 | EPA Review of Impact of 2007 FMC Avian Data on EPA's PRA | US EPA | January 4, 2008 | --- |
| Avian Incident Monitoring System Final Report. EPA Agreement X-82908201-0. | EPA Disk 1 | File Folder: ABC Avian Incident Report (2007) | American Bird Conservancy | February 28, 2007 | --- |
| Brief analysis of within field pesticide residue variability (D348020) | EPA Disk 1 | EPA Analysis – Residue Variability | US EPA | January 7, 2008 | --- |
| REFERENCE MATERIALS | Source | File Name | Author(s) | Date | FIFRA 10(g) Protected |
| Determination of the Time Course of Brain Cholinesterase (ChE) Activity Depression and Recovery in Northern Bobwhite (<i>Colinus virginianus</i>) Following Scheduled Oral Dosing with Furadan 4F. Springborn Smithers Laboratories, 2900 Quakenbush Rd., Snow Camp, North Carolina 27349. Springborn Smithers Study Number 282.4110 and FMC Study Number A2007-6201. FMC Corporation, P.O. Box 8, Route 1 and Plainsboro Rd. Princeton, NJ 08543. June 7, 2007. Unpublished report. MRID 47107601 | Carbofuran CD 1 Ref. Disk | Final Report. 282.4110f | Brewer, L.W., Stafford, J.M., and Moore, D. | April 16, 2007 | Yes |
| Assessment of Mallard Duck (<i>Anas platyrhynchos</i>) avoidance to feed containing Furadan 4F. Springborn Smithers Laboratories, 2900 Quakenbush | Carbofuran CD 1 Ref. Disk | 282.4111fi | Stafford, J.M. | May 15, 2007 | Yes |

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|--|---|--|--|-----------------------|---------------------|------------|
| <p>Rd., Snow Camp, North Carolina 27349. Springborn Smithers Study Number 282.4111 and FMC Study Number A2007-6202. FMC Corporation, P.O. Box 8, Route 1 and Plainsboro Rd. Princeton, NJ 08543. May 15, 2007. Unpublished report. MRID 47128701</p> | <p>Assessment of the Differential Toxicity of Carbofuran to Northern Bobwhite When Dosed With a Single Aqueous Bolus Versus the Same Dose Mixed in Feed, Springborn Smithers Laboratories Protocol No.: 0907/comparative/tox/ bobwhite/Furadan 4F. Springborn Smithers Laboratories, 2900 Quakenbush Rd., Snow Camp, North Carolina 27349. Springborn Smithers Study Number 282.4113 and FMC Study Number A2007-6204-01. FMC Corporation, P.O. Box 8, Route 1 and Plainsboro Rd. Princeton, NJ 08543. May 15, 2007. Unpublished report. MRID 47152901</p> | <p>Carbofuran CD 1 Ref. Disk</p> | <p>A2007-6204-01 Final BWQ Feed Matrix</p> | <p>Stafford, J.M.</p> | <p>June 7, 2007</p> | <p>Yes</p> |
| | | <p>Carbofuran CD 1 Ref. Disk</p> | <p>Avian Food Matrix</p> | <p>Stafford, J.M.</p> | <p>May 31, 2007</p> | <p>Yes</p> |

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| 8, Route 1 and Plainsboro Rd. Princeton, NJ 08543. May 31, 2007. Unpublished report. MRID 47143706 | | | | | | | | |
| A Discussion with the FIFRA Scientific Advisory Panel Regarding the Terrestrial and Aquatic Level II refined Risk Assessment Models (Version 2.0) | EPA Disk 1 | File folder: A Discussion with the FIFRA SAP: Terrestrial and Aquatic Level II Refined Risk Assessment Models | US EPA | March 4, 2004 | --- | | | |
| Refined (Level II) Terrestrial and Aquatic Models, Probabilistic Ecological Assessments for Pesticides: Level II Aquatic Model Session. SAP Report No. 2004-01. | EPA Disk 1 | SAP Report March 2004 Aquatic | FIFRA SAP | 2004 | --- | | | |
| Refined (Level II) Terrestrial and Aquatic Models, Probabilistic Ecological Assessments for Pesticides: Terrestrial. SAP Report No. 2004-03. | EPA Disk 1 | SAP Report March 2004 Terrestrial | FIFRA SAP | July 20, 2004 | --- | | | |
| Probabilistic Models and Methodologies: Advancing the Ecological Risk Assessment Process in the EPA Office of Pesticide Programs. SAP Report No. 2001-06. | EPA Disk 1 | SAP Report 2001 | FIFRA SAP | 2001 | --- | | | |
| A Probabilistic Model and Process to Assess Risks to Aquatic Organisms | EPA Disk 1 | EPA Document for 2001 SAP Aquatic | US EPA | February 19, 2001 | --- | | | |
| A Probabilistic Model and Process to Assess Acute Lethal Risks to Birds | EPA Disk 1 | EPA Document for 2001 SAP Terrestrial | US EPA | February 16, 2001 | --- | | | |
| Summary Evaluation of Recently Submitted FMC Water Exposure Studies | Carbofuran CD 1 Ref. Disk | EPA's Evaluation of Recently Submitted Water Exposure Studies | US EPA | December 26, 2007 | --- | | | |
| Watershed Regressions for Pesticides (WARP) Model Estimates for Carbofuran in Illinois Watershed. Performed by | Carbofuran CD 1 Ref. Disk | FMC Watershed Regressions | Trask, Jennifer R., and Joshua Amos. | August 15, 2005 | Yes | | | |

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|--|---------------------------|--|--|------------------|-----|
| Waterborne Environmental, Inc., Leesburg, VA. WEI 362.07. Submitted by FMC Corporation, Philadelphia, PA. Report No. P-3786. MRID 46688915. | Carbofuran CD 1 Ref. Disk | Study on the Potential for Carbofuran Leaching to GW | Fawcett, Richard S., Bernard Engel, and W. Martin Williams. | August 24, 2007 | Yes |
| An Investigation into the Potential for Carbofuran Leaching to Ground Water Based on Historical and Current Use Practices. Submitted by FMC Corporation, Philadelphia, PA. Report No. PC-0363. MRID 47221602. | Carbofuran CD 1 Ref. Disk | FMC Study to Estimate SW Concentrations in IN | Williams, W. M., B. Engel, S. Dasgupta, and C. G. Hoogeweg. | August 29, 2007 | Yes |
| An In-Depth Investigation to Estimate Surface Water Concentrations of Carbofuran within Indiana Community Water Supplies. Performed by Waterborne Environmental, Inc., Leesburg, VA, Engel Consulting, and Fawcett Consulting. Submitted by FMC Corporation, Philadelphia, PA. WEI No 528.01, FMC Report No. PC-0378. MRID 47221603. | Carbofuran CD 1 Ref. Disk | FMC National Assessment SW IL | Williams, Martin W., Bernard Engel, Josh J. Amos, and Cornelis Hoogeweg. | November 2, 2007 | Yes |
| National Assessment of the Relative Vulnerability of Community Water Supply Reservoirs in Carbofuran Use Areas. Performed by Waterborne Environmental Inc., Leesburg, VA and Engel Consulting, West Lafayette, IN. Submitted by FMC Corporation, Philadelphia, PA. WEI Report No. 528.01-B, FMC Report No. PC-0387. MRID 47272301. | Carbofuran CD 1 Ref. Disk | Supplemental Carbofuran GW Report FINAL | Fawcett, Richard S., Bernard Engel, and W. Martin Williams. | October 1, 2007 | yes |
| An Investigation into the Potential for Carbofuran Leaching to Ground Water Based on Historical and Current Use Practices: Supplemental Report on Twenty-one Additional States. Submitted by FMC Corporation, Philadelphia, PA. Report No. PC-0383. MRID 47244901. | Carbofuran CD 1 Ref. Disk | | | | |

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| <p><i>Best Management Practices to Reduce Carbofuran Losses to Ground And Surface Water. Submitted by FMC. Corporation, Philadelphia, PA. Report No. PC-0362. MRID 47279201.</i></p> | <p>Carbofuran CD 1 Ref. Disk</p> | <p>FMC BMPs for GW and SW</p> | <p>Fawcett, Richard S., Bernard Engel, and W. Martin Williams.</p> | <p>November 9, 2007</p> | <p>yes</p> |
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From: Jack E. Housenger, Associate Director
Office of Pesticide Programs,
Health Effects Division (7509P)

Jack E. Housenger
1-7-08

Through: Tina Levine, PhD., Director
Office of Pesticide Programs,
Health Effects Division (7509P)

Tina E. Levine
1-7-08

TO: Sharlene Matten, PhD., Designated Federal Official
FIFRA Scientific Advisory Panel
Office of Science Coordination and Policy (7201M)

Attached are compact discs (CD) containing the documents for the February 5 – 8, 2008 Session of the FIFRA Scientific Advisory Panel (SAP) Entitled “Scientific Issues Associated with the Agency’s Proposed Action Under FIFRA 6 (b) Notice of Intent to Cancel Carbofuran”. The documents transmitted through this memorandum concern the human health risks from exposure to carbofuran and can be found on CD # 3. The charge questions are provided along with the Notice of Intent to Cancel on CD # 1.

The documents listed below and found on CD #3 are being provided for the Panel’s review and form the basis for the charge to the Panel. In addition, reference materials are provided as well.

These documents do not contain any information protected under the statute as Confidential Business Information (CBI). However, some of the documents do contain information protected from disclosure to foreign and multi-national pesticide producers under FIFRA section 10(g).

| Documents | File Name | FIFRA 10(g) Protected |
|--|----------------------------|--------------------------------------|
| Risk Assessment and Supporting Documents | | |
| Carbofuran. HED Revised Risk Assessment for the Notice of Intent to Cancel PC 090601. DP#347038. | HumanHlt RA 1-3-08 | NA |
| Issue Paper for the FIFRA SAP Meeting on Carbofuran: Human Health Risk Assessment | HumanHlt_Issuepaper_1-3-08 | NA |
| Carbofuran Acute Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Reregistration Eligibility Decision | D344607.drs.doc | NA |
| Review of Carbofuran Incident Update Reports. DP Barcode 306793, PC Code 090601 | Incident memo 1-3.doc | NA |
| May 2-3, 2006 EPA Human Studies Review Board Meeting Report (July 7, 2006) | HSRB report May 06 | NA |
| Data Evaluation Records¹ Benchmark Dose Analyses and Spreadsheets | | |
| Acute dose-response study of carbofuran technical administered by gavage to adult and postnatal day 11 male and female CD®(Sprague-Dawley) rats. MRID 46688914 | 46688914.der | NA |
| Cholinesterase depression in juvenile (day 11) and adult rats following acute oral (gavage) dose of carbofuran technical. MRID 47143705 | 47143705.der | NA |
| 21-Day dermal toxicity study of Carbofuran Technical in Crl:CD (SD) rats.MRID 47143702 and 47143701 | MRID47143701.DER | NA |
| Dose-time response modeling of rat brain AChE activity: carbofuran gavage dosing 10/5/07 | Carbofuran-RatBrainDR.pdf | NA |
| Dose-time response modeling of rat RBC-AChE activity: carbofuran gavage dosing 10/23/07 | RatRBC_DR.pdf | NA |
| PND17 BMDs and BMDLs and recovery half-lives for the effects of carbofuran on brain and blood AChE | PND17_DR.pdf | NA |
| AggData.xls | AggData.xls | NA |
| New Data.xls | New Data.xls | NA |
| PadillaData.xls | PadillaData.xls | NA |

¹ A DER is an EPA summary and review document of a study. In the case of carbofuran, EPA has written DERs for only FMC-supported studies

| Documents | File Name | FIFRA 10(g) Protected |
|---|---|------------------------------|
| Carbofuranpnd17che.xls | Carbofuranpnd17che.xls | NA |
| Repeatedacute.xls | Repeatedacute.xls | NA |
| FMC Carbo CCA 5_2007_v2.xls.DBW | FMC Carbo CCA 5_2007_v2.xls.DBW | NA |
| Pnd11-carbofuran ages.xls | Pnd11-carbofuran ages.xls | NA |
| Repeated_acute.xls | Repeated_acute.xls | NA |
| DRUtils_Documentation_1.2.pdf | DRUtils_Documentation_1.2.pdf | NA |
| DRUtilsSourceCode_1.2.pdf | DRUtilsSourceCode_1.2.pdf | NA |
| DRUtils_1.2.tar (zip file) | DRUtils_1.2.tar | NA |
| DRUtils_1.2. | DRUtils_1.2. | NA |
| Toxicity Studies conducted with Carbofuran | | |
| Report on cholinesterase sensitivity study of carbofuran: Adult and PND11 MRID 47289001 | EPA-ORD pnd11 and adult rats | NA |
| Final report on cholinesterase inhibition study of carbofuran: PND17 rats. MRID 47167801 | EPA-ORD pnd 17 rats | NA |
| Acute oral (gavage) dose range-finding study of cholinesterase depression from carbofuran technical in juvenile (day 11) rats. MRID 47143703 | A2006-6135 KZH00140 Draft Report Feb 9 2007 | Yes |
| Acute oral (gavage) time course study of cholinesterase depression from carbofuran technical in adult and juvenile (day 11 postpartum) rats. MRID 47143704 | A2006-6136 KZH00141 Time Course Merged Document | Yes |
| Cholinesterase depression in juvenile (day 11) and adult rats following acute oral (gavage) dose of carbofuran technical. MRID 47143705 | A2006-6137 KZH00142 Merged Document | Yes |
| 21-Day Dermal Toxicity Study of Carbofuran Technical in Crl:CD(SD) Rats. MRID 47143702. | A2006-6148 KZH00154 Merged Document | Yes |
| 7-Day Dermal Toxicity Study of Carbofuran Technical in Crl:CD(SD) Rats MRID 47143701. | A2006-6198 KZH00165 Draft Final Report | Yes |
| References | | |
| Padilla S, Marshall RS, Hunter DL, and Lowit A (2007). Time course of cholinesterase inhibition in adult treated acutely with carbaryl, carbofuran, formetanate, methomyl, methiocarb, oxamyl, or propoxur. Toxicology and Applied Pharmacology 219: 202-209. | Padilla et al 2007 | copyright |

| Documents | File Name | FIFRA 10(g) Protected |
|---|-------------------------------|--------------------------------------|
| McDaniel KL, Padilla S, Marshall RS, Phillips PM, Podhorniak L, Qian Y, and Moser V (2007). Comparison of acute neurobehavioral and cholinesterase inhibitory effects of N-methylcarbamates in rat. <i>Toxicological Sciences</i> 98(2), 552-560. | McDaniel ToxSci 07 carbamates | copyright |
| Shah, PV, Fisher ML Month NJ, Sunler, MR and Hall LL.. (1987). Dermal penetration of carbofuran in young and adult Fischer 344 rats. <i>Journal of Toxicology and Environmental Health</i> 22:207- 22 | Shah 1987 | copyright |