



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PC Code 392201
DP Barcode D345275

MEMORANDUM

DATE: January 22, 2008

SUBJECT: Tier I Drinking Water Concentrations of the New Chemical Spirotetramat and Its Transformation Products for the Use in the Human Health Risk Assessment for the Registration of the Food Uses on Citrus Fruits (Crop Group 10), Grapes and Small Fruit Climbing (except kiwifruit), Pome Fruits (Crop Group 11), Stone Fruits (Crop Group 12), Tree Nuts (Crop Group 14 plus Pistachio), Hops, Christmas Trees, Cucurbit Vegetables (Crop Group 9), Fruiting Vegetables (Crop Group 8 plus Okra), Leafy Vegetables (Crop Group 4), Brassica (Cole) Leafy Vegetables (Crop Group 5), and Potatoes and Other Tuberosus and Corm Vegetables (Crop Subgroup 1C)

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This memo presents the Tier I Estimated Drinking Water Concentrations (EDWCs) for spirotetramat (CAS No. 203313-25-1), and for two of its major transformation products spirotetramat-enol and spirotetramat-ketohydroxy, calculated using the Tier I aquatic models FIRST (surface water) and SCI-GROW (groundwater) for use in the human health risk assessment. The registrant seeks registration for the new uses of the chemical

on several food crops as mentioned in the Subject Line above.

Exposure to surface water is possible through surface water runoff, soil erosion and/ or off-target spray drift. The mobility of spirotetramat is relatively high [K_d range 3.58-5.52 mL/g, K_{OC} range 184-437 mL/g_{OC} (moderately mobile)]; however, spirotetramat is labile under many conditions (especially, under aerobic soil metabolism conditions). The Tier I Estimated Drinking Water Concentrations (EDWCs) for spirotetramat and for its major transformation products spirotetramat-enol and spirotetramat-ketohydroxy (as requested by the HED Risk Assessment Team), calculated using FIRST (surface water, applications to Christmas trees) and SCI-GROW (groundwater, applications to pome fruits) for use in the human health risk assessment were as follows: For spirotetramat surface water, the acute value is 0.208 ppb and the chronic value is 1.1×10^{-3} ppb. The groundwater screening concentration for both acute and chronic is 2.25×10^{-5} ppb. For spirotetramat-enol surface water, the acute value is 8.0×10^{-5} ppb and the chronic value is 1.7×10^{-5} ppb. The groundwater screening concentration for both acute and chronic is 1.64×10^{-5} ppb. For spirotetramat-ketohydroxy surface water, the acute value is 3.60×10^{-3} ppb and the chronic value is 2.50×10^{-4} ppb. The groundwater screening concentration for both acute and chronic is 3.57×10^{-4} ppb. For the total residues (spirotetramat and transformation products of concern), in surface water, the acute value is 0.212 ppb and the chronic value is 1.37×10^{-3} ppb. The groundwater screening concentration for both acute and chronic is 3.96×10^{-4} ppb.

A more definitive assessment could be performed, using Tier II aquatic models PRZM/ EXAMS. Should any questions arise, please, contact José Meléndez at 787-977-5856 (T & Th) or at melendez.jose@epa.gov.

Identification of specific data gaps:

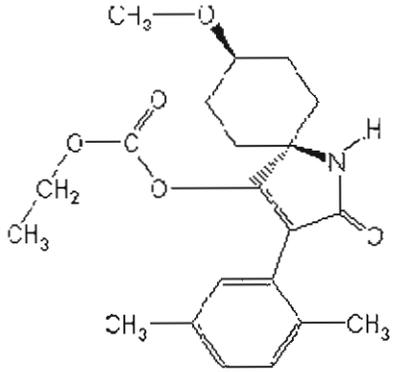
There are important uncertainties about the role of soil photodegradation on spirotetramat and its transformation products. A new study should be conducted to dissipate those uncertainties.

EXECUTIVE SUMMARY

Spirotetramat (PC Code 392201) is a new systemic broad spectrum insecticide intended for the control of sucking pests. Spirotetramat belongs to the chemical class of tetramic acid derivates (ketoenoles). According to the label, it is active primarily by ingestion against immature insect life stages and fertility of adult female insects may be reduced. Spirotetramat moves “through phloem and xylem to all plant tissues including new shoot, leaf and leaf growth...” This active ingredient is advised to be used as “a preventative treatment or timed to coincide with early threshold level in developing populations.”

Two stereo isomers of spirotetramat, cis- and trans-isomer, are possible. The cis-isomer is the active substance.

Table 1: Structure of spirotetramat.

Structure	Mass [g/mol]	Chemical name
	373.45	IUPAC: cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl carbonate CA _{index} : Carbonic acid, cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl ester

This drinking water assessment is related to a Section 3 (new chemical) for spirotetramat. The products MOVENTO™, BYI 8330 150 OD and ULTOR™ are formulated as a suspension concentrate or as an oil dispersion containing 1.25 lb a.i. per gallon or 2 lb a.i. per gallon. The maximum total application rate in a season is 0.4 lb a.i./A. The chemical may be applied by air, ground equipment, airblast or through chemigation. The proposed labels include uses on citrus fruits (Crop Group 10), grapes and small fruit climbing (except kiwifruit), pome fruits (Crop Group 11), stone fruits (Crop Group 12), tree nuts (Crop Group 14 plus Pistachio), hops, Christmas trees, cucurbit vegetables (Crop Group 9), fruiting vegetables (Crop Group 8 plus okra), leafy vegetables (Crop Group 4), brassica (cole) leafy vegetables (Crop Group 5), and potatoes and other tuberous and corm vegetables (Crop Subgroup 1C).

The models used for this Tier 1 screening level drinking waters assessment are FIRST (surface water) and SCI-GROW (groundwater), with the crop with the maximum application rate (pome fruits), the crop with the maximum individual single application rate (Christmas trees) and the maximum PCA (0.87, or national default in both cases). Two degradates were modeled along with the parent spirotetramat: spirotetramat-enol {cis-3-(2,5-Dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro [4.5]dec-3-en-2-one} and spirotetramat-ketohydroxy {cis-3-(2,5-Dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2,4-dione} (as requested by the HED Risk Assessment Team). The total residues approach was not utilized to estimate the exposure to these transformation products because it was found that the mobility characteristics of the metabolites were different than those of the parent, (refer to a summary of the results in Table 2, and structures in Table 4)

For this DWA, it has been assumed that at a given time, the maximum amount of spirotetramat has been applied to the field, and, at the same time, certain amounts of spirotetramat-enol and spirotetramat-ketohydroxy (according to the results of the aerobic soil metabolism studies) are applied by granular method (no drift). The EFED acknowledges that this approach may not achieve mass balance, that is, the amount of

pesticide plus transformation products applied exceeds the maximum application rate. However, the Division believes that the results obtained are suitable for a screening level assessment and are conservative.

There is uncertainty about the role of the soil photodegradation as a route of dissipation on the fate of spirotetramat and/ or its transformation products. Results of the available study were deemed marginally supplemental. A new study is required.

A more definitive assessment could be conducted, using the more refined Tier II aquatic surface water models PRZM/EXAMS if the HED requested it. A summary of the results obtained of Tier I modeled drinking water concentrations, is tabulated below (Table 2).

Table 2. Maximum Tier I Estimated Drinking Water Concentrations (EDWCs) for drinking water risk assessment based on aerial application of spirotetramat on pome fruits (for ground waters) or Christmas Trees (for surface waters), at 0.4 or 0.32 lb a.i./A/season, respectively.

Drinking Water Source (Model)	Type of Risk\ (Units)	Estimated Drinking Water Concentration (EDWC)			
		Spirotetramat	Spirotetramat-enol	Spirotetramat-ketohydroxy	Maximum Total Residues
		(ppb)	(ppb)	(ppb)	(ppb)
Ground-water (SCI-GROW)	Acute and Chronic	2.25×10^{-5}	1.64×10^{-5}	3.57×10^{-4}	3.96×10^{-4}
Surface Water (FIRST)	Acute	0.208	8.0×10^{-5}	3.60×10^{-3}	0.212
	Chronic	1.1×10^{-3}	1.7×10^{-5}	2.50×10^{-4}	1.37×10^{-3}

The acute and chronic EDWCs in groundwater were obtained from spirotetramat's use on pome fruits. The acute and the chronic EDWCs in surface waters were obtained from the use of spirotetramat on Christmas trees. It appears that a higher individual application rate generally yields a higher value of surface waters.

PROBLEM FORMULATION

This is a Tier I drinking water assessment that uses modeling and monitoring data, if available, to estimate the ground water and surface water concentrations of pesticides in drinking water source water (pre-treatment) resulting from pesticide use on sites that are highly vulnerable. This initial tier screens out chemicals with low potential risk and provides estimated exposure concentrations for the human health dietary risk assessment.

ANALYSIS

Use Characterization

A summary table of all new use patterns, highlighting Tier I modeled uses, is provided below (Table 3).

Table 3. Summary use information for spirotetramat, based on BYI 8330 150 OD Insecticide (oil dispersion) and MOVENTO™ (suspension concentrate) labels (Reg. No. 264-XXX, proposed in both cases). Modeled use is bolded and highlighted.

USE	SINGLE APP. RATE (lbs. a.i./A)	NUMBER OF APPS.	SEASONAL APP. RATE (lb. a.i./A)	INTERVAL BETWEEN APPS. (days)	APP. METHOD	PHI (days)
Citrus Fruit (Crop Group 10, including calamondin, citrus citron, citrus hybrids like chironja, tangelo and tangor, grapefruit, kumquat, lemon, lime, mandarin or tangelo, sweet and sour orange, pummelo, Satsuma mandarin, and others)	0.16	2	0.32	21	G*, A, Airblast	1
Grape (including American bunch grape, muscadine grape and vinifera grape)	0.125	2	0.2	30	G*, A, Airblast	7
Grape and Small Fruit Vine Climbing (except kiwifruit) (including American bunch grape, muscadine grape and vinifera grape)	0.12	2	0.2	30	G*, A, Airblast	7
Pome Fruit (Crop Group 11, including apple, crabapple, loquat, mayhaw, pear, oriental pear, quince)	0.14	3	0.4	7	G*, A, Airblast	7
Stone Fruit (Crop Group 12, including apricot, sweet and tart cherry, nectarine, peach, plum-various kinds, plumcot and fresh and dried prune)	0.14	2	0.24	14	G*, A, Airblast	7
Tree Nuts (Crop Group 14 plus pistachio, including almond, beechnut, Brazil nut, butternut, cashew, chestnut, chinquapin, filbert-hazelnut, hickory nut, macadamia nut-bush nut, pecan, pistachio, walnut-black and English)	0.14	3	0.34	14	G*, A, Airblast	7
Hops	0.10	2	0.2	14	G*, A, Airblast	7
Christmas Trees	0.16	2	0.32	14	G*, A, Airblast	N/A

Table 3. Summary use information for spirotetramat, based on BYI 8330 150 OD Insecticide (oil dispersion) and MOVENTO™ (suspension concentrate) labels (Reg. No. 264-XXX, proposed in both cases). Modeled use is bolded and highlighted.

USE	SINGLE APP. RATE (lbs. a.i./A)	NUMBER OF APPS.	SEASONAL APP. RATE (lb. a.i./A)	INTERVAL BETWEEN APPS. (days)	APP. METHOD	PHI (days)
Cucurbit Vegetables [Crop Group 9, including chayote, Chinese waxgourd-Chinese preserving melon, citron melon, cucumber, gherkin, gourd-various kinds, <i>Momordica spp.</i> -includes various kinds, muskmelon (various kinds like eantaloupe, casaba, Crenshaw melon, melon, honeydew melon, Persian melon, pineapple melon, snake melon, and others), pumpkin, squash (includes summer type squash like scallop squash, zucchini and others, and winter type squash like acorn squash, calabaza and others), and watermelon (includes hybrids)]	0.08	2	0.16	7	G, A, Chemigation	1
Fruiting Vegetables (Crop Group 8 plus okra including eggplant, groundcherry, okra, pepinos, pepper-various kinds, tomatillo and tomato)	0.08	2	0.16	7	G, A, Chemigation	1
Leafy Vegetables (Crop Group 4 including amaranth-various kinds, arugula-roquette, cardoon, celery, celtuce, chervil, Chinese celery, chrysanthemum, corn salad, garden cress, cress-various kinds, dandelion, sorrel dock, endive, Florence fennel, lettuce-head and leaf, orach, parsley, garden and winter purslane, radicchio-red chicory, rhubarb, spinach-various kinds, Swiss chard)	0.08	2	0.16	7	G, A, Chemigation	3
Brassica (Cole) Leafy Vegetables (Crop Group 5 including broccoli raab, Brussels sprouts, cabbage, cauliflower, cavalo broccolo, Chinese broccoli, Chinese cabbage, Chinese mustard cabbage, collards, kale, kohlrabi, mizuna, mustard greens, mustard spinach, rape greens, tumip greens)	0.08	2	0.16	7	G, A, Chemigation	1

Table 3. Summary use information for spirotetramat, based on BYI 8330 150 OD Insecticide (oil dispersion) and MOVENTO™ (suspension concentrate) labels (Reg. No. 264-XXX, proposed in both cases). Modeled use is bolded and highlighted.

USE	SINGLE APP. RATE (lbs. a.i./A)	NUMBER OF APPS.	SEASONAL APP. RATE (lb. a.i./A)	INTERVAL BETWEEN APPS. (days)	APP. METHOD	PHI (days)
Potato and Other Tuberous and Corm Vegetables (Crop Subgroup 1C including arracacha, arrowroot, artichoke-Chinese and Jerusalem, edible canna, bitter and sweet cassava, chayote-root, chufa, dasheen-taro, ginger, leren, potato, sweetpotato, tanier, turmeric, yam bean, true yam)	0.08	2	0.16	7	G, A, Chemigation	7

*High air velocity, low volume or air curtain sprayers.

Spirotetramat may be applied via conventional ground airblast; high air velocity, low volume or air curtain sprayers; chemigation; or aerially. The proposed label does not have a designated buffer zone; however, there is the advice that a level well maintained vegetative buffer strip between areas to which the product is applied and surface water bodies such like ponds, streams and springs could reduce contamination of water from rainfall runoff. It is noted, though, that such buffer strip is not mandatory.

The use pattern selected for modeling was pome fruits. It has the highest seasonal application rate (0.4 lb a.i./A), the minimum application interval (7 days), and the highest percent crop area (PCA of 0.87 or national default). In addition, the use on Christmas trees was modeled because it has the maximum single application rate (0.16 lb a.i./A), the highest PCA (0.87 or national default) at a minimum interval between applications of 14 days.

Fate and Transport Characterization

A detailed summary table of physical/ chemical and environmental fate/ transport properties of spirotetramat (and transformation products), including measured parameters, values, data sources, and comments, is provided below (Table 3).

Table 3. Summary of physical/ chemical and environmental fate and transport properties of spirotetramat (and its transformation products).

PARAMETER	VALUE(S) (units)	SOURCE	COMMENT
Chemical Name	IUPAC: cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl carbonate CA _{index} : Carbonic acid, cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl ester	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	-

Table 3. Summary of physical/ chemical and environmental fate and transport properties of Spirotetramat (and its transformation products).			
PARAMETER	VALUE(S) (units)	SOURCE	COMMENT
Molecular Weight	373.45 g/mol	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	–
Solubility (20°C)	At pH 4, 7 and 9, 33.5, 29.9 and 19.1 mg/L, respectively; in distilled water (pH 6.0-6.3), 33.4 mg/L	OECD Monograph Annex B. Spirotetramat. B.2 Physical and chemical properties	–
Solubility of Spirotetramat in Organic Solvents (20 °C)	Ethanol = 44 g/L; n-hexane = 0.055 g/L; toluene = 60 g/L; dichloromethane = >600 g/L; acetone = 100-120 g/L; ethylacetate = 67 g/L; dimethyl sulfoxide = 200-300 g/L	OECD Monograph Annex B. Spirotetramat. B.2 Physical and chemical properties	–
Vapor Pressure (20°C)	5.6×10^{-9} Pa = 4.2×10^{-11} mm Hg	OECD Monograph Annex B. Spirotetramat. B.2 Physical and chemical properties	–
Henry's Law constant	6.99×10^{-8} Pa·m ³ /mol = 5.24×10^{-10} atm·m ³ /mol	OECD Monograph Annex B. Spirotetramat. B.2 Physical and chemical properties	At 20°C and pH 7, estimated from vapor pressure and water solubility.
pKa Spirotetramat	10.7	OECD Monograph Annex B. Spirotetramat. B.2 Physical and chemical properties	Loss of the H attached to the nitrogen in spirotetramat
Octanol-Water Partition Coefficient Spirotetramat (K _{ow} , at 20 °C)	324	OECD Monograph Annex B. Spirotetramat. B.2 Physical and chemical properties	–
Spirotetramat-enol Solubility K _{ow} and log K _{ow} pK _a	Solubility at 20°C, pH 5 = 0.09 g/L, pH 7 = 2.7 g/L, pH 8 = 28 g/L; K _{ow} and log K _{ow} at pH 5 = 109 and 2.0, respectively, at pH 7 = 2.1 and 0.3, respectively, at pH 9 = 0.06 and -1.3, respectively; pK _a 5.2	OECD Monograph Annex B. Spirotetramat. B.2 Physical and chemical properties	
Spirotetramat-ketohydroxy Solubility K _{ow} and log K _{ow} pK _a	Solubility = 0.228 g/L K _{ow} and log K _{ow} = 20 and 1.3, respectively at pH 7 pK _a = 11.0	OECD Monograph Annex B. Spirotetramat. B.2 Physical and chemical properties	
Hydrolysis Half-life Spirotetramat [pH 4, 7, 9; (20 and 25°C)]	SFO; r ² = 1.00 in all cases: pH 4, 25°C, t _{1/2} = 32.5 days pH 4, 20°C, t _{1/2} = 47.6 days pH 7, 25°C, t _{1/2} = 8.6 days pH 7, 20°C, t_{1/2} = 13.1 days pH 9, 25°C, t _{1/2} = 0.32 days	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	Major metabolite – spirotetramat-enol.

Table 3. Summary of physical/ chemical and environmental fate and transport properties of spirotetramat (and its transformation products).			
PARAMETER	VALUE(S) (units)	SOURCE	COMMENT
Hydrolysis Half-life of spirotetramat-enol (pH 4, 7, 9; 50 °C)	No time-dependent degradation of <u>spirotetramat-enol was observed.</u> (STABLE) The study was conducted for 5 days at 50 °C. Spirotetramat-enol is hydrolytically stable under abiotic environmental conditions. Hydrolysis is not expected to contribute to the degradation of spirotetramat-enol in the environment.	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	-
Aqueous Photolysis Half-life (pH 5.0) vs. [natural water at pH 7.9]	$t_{1/2} = 3.0$ days ($r^2 = 0.98$ for irradiated samples; $r^2 = 0.89$ for dark control; SFO) vs. $t_{1/2} = 14.4$ Phoenix, AZ days vs. [$t_{1/2} = 0.22$ days ($r^2 = 1.00$ for both the irradiated and the dark control samples; SFO) $t_{1/2} = 0.74$ Phoenix, AZ days]	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	All values are corrected for dark control. Different metabolites were observed in buffered solution and natural water.
Soil Photolysis Half-life	Supplemental study, useful to identify possible photodegradates. A fine SL and a L; Degradates observed in irradiated samples only: dimethyl benzoic acid, methoxycyclohexanone, ROI 9, ROI 11, ROI 17	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	The dark control degraded faster than the irradiated samples.
Aerobic Soil Metabolism Half-life of parent spirotetramat	<u>Half-lives for spirotetramat (SFO)</u> FL sandy loam; $t_{1/2} = 0.327$ days Sandy loam; $t_{1/2} = 0.210$ days Silt loam; $t_{1/2} = 0.232$ days Silt; $t_{1/2} = 0.083$ days <u>Half-lives for spirotetramat (DFOP-best fit)</u> FL sandy loam; $t_{1/2} = 0.30$ days Sandy loam; $t_{1/2} = 0.24$ days Silt loam; $t_{1/2} = 0.26$ days Silt; $t_{1/2} = 0.09$ days 90th percentile = 0.298 days	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	DT₉₀ (for DFOP kinetics) = 1.26, 0.89, 0.97 and 0.34, respectively. Bolded item is the best fit kinetics. SFO data provided FIO.
Aerobic Soil Metabolism Half-life of spirotetramat-enol	<u>SFO Half-lives for spirotetramat-enol</u> FL sandy loam; $t_{1/2} = 0.098$ days Sandy loam; $t_{1/2} = 0.022$ days Silt loam; $t_{1/2} = 0.22$ days Silt; $t_{1/2} = 0.020$ days <u>SFORB (best fit) Half-lives for spirotetramat-enol</u> FL sandy loam; $t_{1/2} = 0.05$ days Sandy loam; $t_{1/2} = 0.02$ days Silt loam; $t_{1/2} = 0.16$ days Silt; $t_{1/2} = 0.02$ days 90th percentile = 0.117 days	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	DT₉₀ (SFORB kinetics) = 0.17, 0.07, 0.53 and 0.06 days, respectively. Bolded item is the best fit kinetics. SFO data provided FIO.
Aerobic Soil Metabolism Half-life of spirotetramat-ketohydroxy derived from study performed with spirotetramat-enol	<u>Half-lives for spirotetramat-ketohydroxy (SFO)</u> FL sandy loam; $t_{1/2} = 16.7$ days Sandy loam; $t_{1/2} = 4.2$ days Silt loam; $t_{1/2} = 5.1$ days Silt; $t_{1/2} = 1.5$ days 90th percentile = 12.38 days	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	Respective DT ₉₀ = 55.6, 13.9, 16.9 and 5.1 days – SFORB-SFO
Aerobic Soil Metabolism Half-life of spirotetramat-MA-amide derived from study performed with spirotetramat-enol	<u>Half-lives for spirotetramat-MA-amide (SFO)</u> FL sandy loam; $t_{1/2} = 5.4$ days Sandy loam; $t_{1/2} = 1.1$ days Silt loam; $t_{1/2} = 1.8$ days Silt; $t_{1/2} = 0.3$ days 90th percentile = 3.99 days	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	Respective DT ₉₀ = 18.1, 3.6, 6.3 and 1 days

Table 3. Summary of physical/ chemical and environmental fate and transport properties of spirotetramat (and its transformation products).			
PARAMETER	VALUE(S) (units)	SOURCE	COMMENT
Aerobic Soil Metabolism Half-life of 4-methoxycyclohexanone	<u>Half-lives for 4-methoxycyclohexanone (SFO)</u> <1day (obs.), <1day (obs.) and 0.6 days, for Silt Loam, Loam and FL Loamy Sand, respectively	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	DT ₉₀ = 1.8 days for LS; DT ₉₀ could not be calculated for SiL and L.
Anaerobic Soil Metabolism Half-life	SL; t _{1/2} = 0.06 days (χ ² error 5.27-lowest; best fit, R ² of 0.993, FOMC) The spirotetramat-enol reached a maximum amount at the last test interval; spirotetramat-ketohydroxy was a maximum at 1 day interval.	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	DT ₉₀ = 1.33 days.
Anaerobic Aquatic Metabolism Half-life	KS CL sediment; t _{1/2} = 2.8 days (SFO)	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	DT ₉₀ = 9.3 days
Aerobic Aquatic Metabolism Half-life	<u>Parent spirotetramat,*</u> SFO, total system: L sediment; t _{1/2} = 1.06 days LS sediment; t _{1/2} = 1.05 days 90 th percentile = 1.070 days <u>Rates for spirotetramat-enol, SFO**</u> four compartment model: L sediment; t _{1/2} = 59.0 days LS sediment; t _{1/2} = 37.9 days 90 th percentile = 80.92 days <u>Rates for spirotetramat-ketohydroxy:</u> could not be evaluated, there is no decline or last test interval with maximum value; these data are not required for the DWA	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	*Respective spirotetramat DT ₉₀ 's = 3.52 and 3.50 days **Respective spirotetramat-enol DT ₉₀ 's = 196 and 126 days
Organic Carbon Partition Coefficient (K _{OC}) – parent spirotetramat	184, 437, 201, 385, 237 L/Kg _{OC} Ave = 289 L/Kg _{OC}	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	LS, SL, SiL, Mo SL and L, respectively
Soil Partition Coefficient (K _d) – parent spirotetramat	4.38, 3.80, 4.69, 3.58, 5.52 L/Kg Ave = 4.39 L/Kg	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	LS, SL, SiL, Mo SL and L, respectively
Organic Carbon Partition Coefficient (K _{FOC}) – parent spirotetramat (mg/kg)/(mg/L) ^{1/n}	201, 435, 176, 435, 159	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	LS, SL, SiL, Mo SL and L, respectively
Soil Partition Coefficient (K _F) – parent spirotetramat (mg/kg _{OC})/(mg/L) ^{1/n}	4.79, 3.78, 4.10, 4.05, 3.70	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	LS, SL, SiL, Mo SL and L, respectively
Organic Carbon Partition Coefficient (K _{OC}) – spirotetramat-enol	27, 65, 29 and 99; mean K _{OC} = 55 L/Kg _{OC} (mobile)	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	SL, L, SiL and SL, respectively. Estimated K _{OC} values from the soil column leaching study:

Table 3. Summary of physical/ chemical and environmental fate and transport properties of spirotetramat (and its transformation products).			
PARAMETER	VALUE(S) (units)	SOURCE	COMMENT
Soil Partition Coefficient (K_d) Organic Carbon Partition Coefficient (K_{oc}) For spirotetramat-ketohydroxy	0.560, 0.529, 1.10, 0.867, 2.28 L/Kg 43.1, 48.1, 42.0, 99.7, 93.7 L/Kg $_{oc}$	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	SL, SiL, SiL, SL and CL, respectively
Soil Partition Coefficient (K_d) Organic Carbon Partition Coefficient (K_{oc}) For spirotetramat-MA-amide	0.071, 0.064, 0.116, 0.119, 0.126 L/Kg 4.2, 7.0, 5.0, 25.6, 5.6 L/Kg $_{oc}$	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	SL, SiL, SiL, LS and L, respectively
Organic Carbon Partition Coefficient (K_{oc}), obtained using HPLC method For spirotetramat-enol dimer 1	At pHs 6.0 and 1.7, 1771 and 1477 L/Kg $_{oc}$, respectively; a mean of 1624 L/Kg $_{oc}$ (slightly mobile)	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	–
Organic Carbon Partition Coefficient (K_{oc}), obtained using HPLC method For spirotetramat-enol dimer 2	At pHs 6.0 and 1.7, 3115 and 3301 L/Kg $_{oc}$, respectively; a mean of 3208 L/Kg $_{oc}$ (slightly mobile)	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	–
Terrestrial Field Dissipation Half-life for parent spirotetramat	<u>SFO</u> NY LS; bg; $t_{1/2}$ = 0.5 days FL S; bg; $t_{1/2}$ = 0.9 days FL S; Cropped; $t_{1/2}$ = 1.0 days CA SL; bg; $t_{1/2}$ = 1.0 days CA SL; Cropped; $t_{1/2}$ = 1.0 days WA SL; bg; $t_{1/2}$ = 0.4 days WA LS; Cropped; $t_{1/2}$ = 0.3 days	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	bg = bareground
Terrestrial Field Dissipation Half-life for total residues of spirotetramat-enol + spirotetramat-ketohydroxy	<u>All SFO in series</u> NY LS; bg; $t_{1/2}$ = 31.6 days FL S; bg; $t_{1/2}$ = 6.6 days FL S; Cropped; $t_{1/2}$ = 4.8 days CA SL; bg; $t_{1/2}$ = 7.6 days CA SL; Cropped; $t_{1/2}$ = 8.7 days WA SL; bg; $t_{1/2}$ = 5.2 days WA LS; Cropped; $t_{1/2}$ = 4.6 days	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	bg = bareground FL S; Cropped; bush beans 'Blue Lake'; CA SL; Cropped; tomatoes 'Germain's Seed'; WA LS; Cropped; yellow sweet Spanish onions.
Terrestrial Field Dissipation Half-life for total residues of spirotetramat + spirotetramat-enol + spirotetramat-ketohydroxy	<u>SFO</u> NY LS; bg; $t_{1/2}$ = 23.4 days FL S; bg; $t_{1/2}$ = 7.6 days FL S; Cropped; $t_{1/2}$ = 5.7 days CA SL; bg; $t_{1/2}$ = 8.4 days CA SL; Cropped; $t_{1/2}$ = 10.2 days WA SL; bg; $t_{1/2}$ = 6.3 days WA LS; Cropped; $t_{1/2}$ = 5.0 days	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	bg = bareground Note same as above.

All the following appear to be important routes of degradation/ transformation for spirotetramat: hydrolysis in basic media, photolysis in sterile natural water and biodegradation in aerobic and anaerobic environments (DT50's range <1-2.8 days). Hydrolysis in neutral and acidic environments and photolysis in sterile buffered solution (half-lives 8.6-32.5 days) appear to be routes of transformation of relatively low importance for spirotetramat. The chemical degrades to spirotetramat-enol (product of cleavage of the ester link), which also degrades relatively rapidly in aerobic environments and under photolytic conditions, and subsequently forms numerous degradates most of which have the basic backbone structure of spirotetramat. It appears that spirotetramat's

metabolites spirotetramat-enol and spirotetramat-ketohydroxy are of high concern in soils, sediments and water. The parent spirotetramat appears to be labile in most environments (particularly in aerobic media). Spirotetramat's total residues (spirotetramat + spirotetramat-enol + spirotetramat-ketohydroxy) have a potential to contaminate surface waters for a period of weeks to months posttreatment, and a potential to move subsurface and contaminate groundwaters. Spirotetramat and/ or its residues are incorporated into the targeted crop/ canopy and translocated into it. The chemical and/ or its residues are available for periods of weeks to months, when the chewing insects will take them. There is also the chance that the chemical would be deposited off-target by spray drift (the chemical may be applied by ground and aerial methods or via airblast). In addition, given the relatively high solubility of spirotetramat-enol and spirotetramat-ketohydroxy and their relatively low level of binding, these particular transformation products could be released via plant wash-off to soils in large rain events, specially if they occur shortly after application. It appears that the residues could reach adjacent bodies of water in runoff events both via dissolution or bound to the soils (high levels of bound residue were observed in most laboratory studies).

Spirotetramat has a moderately low solubility in distilled water (33.4 mg/L at pH 6.0-6.3, and 29.9 at pH 7 @ 20°C) and a high solubility in various common organic solvents (*e.g.* ethanol, toluene and acetone). Spirotetramat has a low vapor pressure and Henry's Law constant (4.2×10^{-11} mm Hg at 20°C and 6.90 atm-m³/mol at 20°C and pH 7, respectively). It is not likely to volatilize substantially. Spirotetramat's 1-octanol/water partition coefficient is 324, indicating a low tendency to bioaccumulate/ bioconcentrate.

The hydrolysis behaviour of spirotetramat is strongly pH and temperature dependent. The rate of reaction increased with increasing pH. At 25°C, the experimental half-lives for the chemical were 32.5, 8.6 and 0.32 days at pH's of 4, 7 and 9, respectively. In addition, hydrolysis rates increased with increasing temperature. The major hydrolysate is spirotetramat-enol, which appeared to be stable to hydrolysis in this and in a separate study conducted on the metabolite at pH's 4, 7 and 9 and 50°C for 5 days.

Spirotetramat photolyzes relatively rapidly. Spirotetramat photolyzes with hydrolysis-corrected half-lives (DT50's) of 3.0 and 0.22 days, in sterile buffer (pH 5) solution and natural water (pH 7.9), respectively. These half-lives (DT50's) correspond to 14.4 and 0.74 days, respectively, under environmental conditions (summer light in Phoenix, AZ). In sterilized natural water the major products observed were spirotetramat-enol (81.9% at 1 day), methoxycyclohexanone (17.5% at 8 days) and methoxy-cyclohexylamino carboxylic acid (11.3 % at 10 days). In sterile buffer solution (pH 5), the major transformation products were spirotetramat-photo-cyclopentyl (maximum 42.9% at 7 days), spirotetramat-photo-methyl (maximum 22.9% at 6 days), spirotetramat-photo-formyl (maximum 11.5% at 3 days) and spirotetramat-photo-methyl (maximum 19.3% at 6 days). All the latter metabolites are the result of rearrangement of the parent.

The soil photodegradation study available on spirotetramat was found to have certain deficiencies and cannot be upgraded. Definite conclusions on the rate of photodegradation could not be derived from it. However, useful information on the

identity of the degradates in the study may be obtained from the study. The following degradates were identified ($\geq 4.8\%$): spiro tetramat-enol, spiro tetramat-ketohydroxy, methoxycyclohexanone and dimethylbenzoic acid. Methoxycyclohexanone and dimethyl-benzoic acid were observed only in the irradiated samples.

Spirotetramat degraded under aerobic conditions relatively quickly, with half-lives (DT50's) of <1 day in four soils. Furthermore, spiro tetramat-enol also degraded relatively quickly, with calculated half-lives (DT50's) of <1 day, in four soils. In the course of the spiro tetramat-enol degradation study, spiro tetramat-enol showed a biphasic kinetic behaviour, whereas in the first phase (during one day) more than 80 % of AR "has degraded." In the second phase a much slower degradation was shown (during 118 days from 10.7 – 17.2 % of AR to 2.7 – 6.1 % of AR, mean of both labels). Half-lives (DT50's) for spiro tetramat-ketohydroxy (maximum 24.0% of the applied, range of DT50's 1.5-16.7 days) and spiro tetramat-amide (maximum 5.2% of the applied, range of DT50's 0.03-5.4 days) were derived from the results obtained in the study conducted on spiro tetramat-enol. Carbon dioxide formation was 9.7-19.4% by 50 days in the study conducted with spiro tetramat and 10.9-34.9 by 60 days in the study conducted with spiro tetramat-enol. Volatiles were insignificant while non-extractable residues were important (both cases). In an outdoor metabolism study spiro tetramat degraded with calculated half-lives (DT50's) of 1.2 and 2.9 days. Spiro tetramat-enol was a maximum of 7.8%. The degradates spiro tetramat-glyoxylic amide and dimethyl-benzoic acid were observed besides the aerobic soil metabolites observed in the laboratory. The latter two compounds were also observed in the soil photodegradation studies.

In aquatic environment, under aerobic aquatic conditions, spiro tetramat degraded with calculated half-lives (DT50's) of 0.7 and 0.9 days in the total system. Spiro tetramat was initially mostly associated with the aqueous phase. The metabolite spiro tetramat-enol reached a maximum at 14 days at 99.0%, and decreased to <LOQ to 21.0% at 120 days. The degradate spiro tetramat-ketohydroxy was a maximum of 50.8% at study termination. It appeared to be relatively stable in the aerobic aquatic system. Minor transformation products included spiro tetramat-MA-amide, spiro tetramat-oxo-enol and spiro tetramat-dihydroxy ($\leq 8.7\%$ in total system). Non-extractable residues increased throughout the study to a maximum of 33.9% at 120 days. Mineralization was a maximum of 13.5-24.0% at 120 days.

In the anaerobic soil metabolism study, the metabolites observed were also generally consistent with the ones for the aerobic soil metabolism studies for spiro tetramat and spiro tetramat-enol, with respect to the metabolites observed. Under anaerobic soil conditions, spiro tetramat dissipated quickly with a calculated half-life of $\ll 1$ day. The major degradates were spiro tetramat-enol, which increased throughout the study (maximum 54.6% at 180 days) and spiro tetramat-ketohydroxy (maximum 19.3% at 1 day). Mineralization was very low. Non-extractable residues were a maximum of 17.5% at 0.6 days. In contrast, in an anaerobic aquatic metabolism system, spiro tetramat completely degraded to spiro tetramat-enol, which was found to be stable thereafter. The half-life for (DT50) the transformation of spiro tetramat was calculated to be 2.8 days in the total anaerobic system.

Spirotetramat is moderately mobile in five sterilized soils, with K_d values ranging from 3.58-5.52 L/Kg, K_{OC} values between 184-437 L/Kg $_{OC}$ (mean 289 L/Kg $_{OC}$), K_F values ranging from 3.70-4.79 (mg/Kg $_{OC}$)/(mg/L) $^{1/n}$, K_{FOC} values ranging from 159-435 (mg/Kg $_{OC}$)/(mg/L) $^{1/n}$ [mean 281 (mg/Kg $_{OC}$)/(mg/L) $^{1/n}$], ranging from 0.823 to 1.042 [mean 0.941 (mg/Kg $_{OC}$)/(mg/L) $^{1/n}$].

Spirotetramat, at approximately 0.39 lb a.i./A, formulated as an oil dispersion, was applied once to four plots (most of which included bareground and planted, total of 7 trials), located in the USA (FL, CA, NY and WA), dissipated rapidly with calculated half-lives of 0.3-1.0 days. These half-lives are consistent with the ones observed in laboratory trials. No carryover from year to year is expected for spirotetramat. Due to the low storage stability of spirotetramat-enol, which degraded to spirotetramat-ketohydroxy during storage, individual quantification of these metabolites is not possible. Instead, the combined residues of spirotetramat-enol and spirotetramat-ketohydroxy were calculated. Those residues presented calculated half-lives ($DT_{50,S}$) of 4.6-31.6 days. In addition, the combined residues of spirotetramat, spirotetramat-enol and spirotetramat-ketohydroxy were found to degrade at moderate rates with half-lives ($DT_{50,S}$) ranging from 5.0-23.4 days. Spirotetramat and its residues remained in the top 0-15 cm soil layer, except for detections in the 15-30 cm soil layer at the Florida site; the chemicals observed above the LOQ in 15-30 cm soil layer were spirotetramat-enol and spirotetramat-ketohydroxy at days 1 and 7. The residues went below the LOD and the LOQ by the next test interval.

Spirotetramat is not readily biodegradable.

There is uncertainty about the role of soil photodegradation on the fate of spirotetramat and/ or its transformation products. Results of the available study were deemed marginally supplemental.

A summary of the various degradation products formed by each process in the studies reviewed is provided in tabular form below (Table 4).

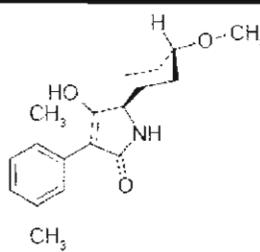
Table 4: Chemical name, structure, molecule mass and occurrence of investigated and/or observed metabolites of spirotetramat.				
Substance	Chemical name	Structure	Mole mass (g/mol)	Occurrence (maximum amounts based on mean of replicates) [% of AR]**
Spirotetramat-enol	CAS: cis-3-(2,5-Dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one		301.39	Aerobic soil: 100.0 (0 d) (most conservative assumption) Aerobic outdoor: 7.8 (7 d) Anaerobic soil: 54.6 (180 d) Field soil: na ^a Soil photolysis: 10.1 (1 d) Hydrolysis (pH 7): 91.8 (29 d) Photolysis water: 81.9 (1 d) Aerobic water/sed.: 79.7 / 41.2

Table 4: Chemical name, structure, molecule mass and occurrence of investigated and/or observed metabolites of spirotetramat.

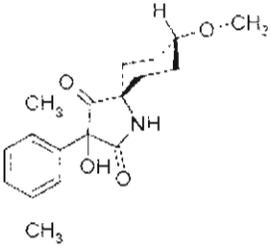
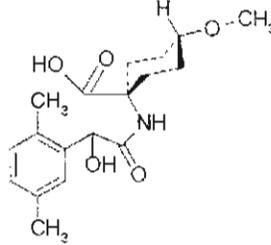
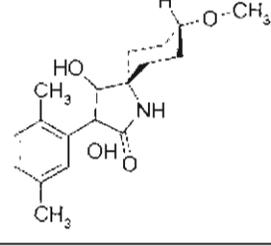
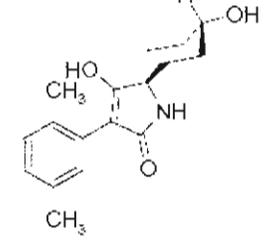
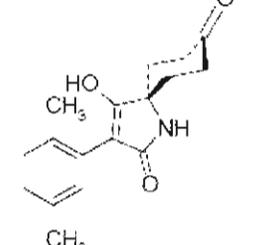
Substance	Chemical name	Structure	Mole mass (g/mol)	Occurrence (maximum amounts based on mean of replicates) [% of AR]**
Spirotetramat-ketohydroxy	CAS: cis-3-(2,5-Dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2,4-dione		317.39	Aerobic soil: 24.0 (1 d) Aerobic outdoor: 25.3 (14 d) Anaerobic soil: 19.3 (1 d) Field soil: na ^a Soil photolysis: 20.9 (2 d) Hydrolysis: - Photolysis water: - Aerobic water/sed.: 17.4 / 42.8
Spirotetramat-MA-amide	IUPAC: 2 cis-1-[[[(2,5-Dimethylphenyl)hydroxyacetyl]amino]-4-methoxycyclohexanecarboxylic acid		335.40	Aerobic soil: 5.2 (4 d) Aerobic outdoor: 6.2 (28 d) Anaerobic soil: 7.2 (180 d) Field soil: 4.5 Soil photolysis: - Hydrolysis: - Photolysis water: - Aerobic water/sed.: 7.8 / 2.1
Spirotetramat-di-hydroxy	IUPAC: (5s,8s)-3-(2,5-dimethylphenyl)-3,4-dihydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one		319.40	Aerobic soil: - Aerobic outdoor: - Anaerobic soil: 3.2 (90 d) Field soil: - Soil photolysis: - Hydrolysis: - Photolysis water: - Aerobic water/sed.: 4.3 / 5.5
Spirotetramat-desmethyl-enol	IUPAC: (5s,8s)-3-(2,5-dimethylphenyl)-4,8-dihydroxy-1-azaspiro[4.5]dec-3-en-2-one		287.36	Aerobic soil: 2.0 (4 d) Aerobic outdoor: - Anaerobic soil: - Field soil: - Soil photolysis: - Hydrolysis: - Photolysis water: - Aerobic water/sed.: -
Spirotetramat-oxo-enol	IUPAC: 3-(2,5-dimethylphenyl)-4-hydroxy-1-azaspiro[4.5]dec-3-ene-2,8-dione		285.35	Aerobic soil: 1.1 (7 d) Aerobic outdoor: - Anaerobic soil: - Field soil: - Soil photolysis: - Hydrolysis: - Photolysis water: - Aerobic water/sed.: 6.0 / 2.3

Table 4: Chemical name, structure, molecule mass and occurrence of investigated and/or observed metabolites of spirotetramat.

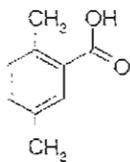
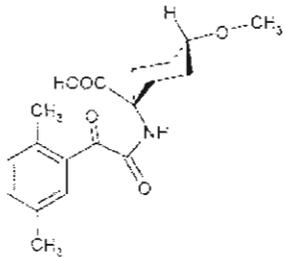
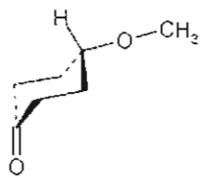
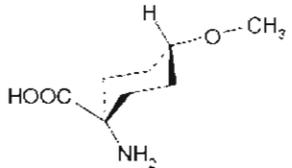
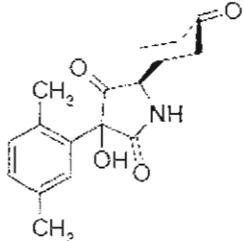
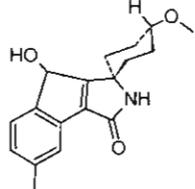
Substance	Chemical name	Structure	Mole mass (g/mol)	Occurrence (maximum amounts based on mean of replicates) [% of AR]**
Dimethyl-benzoic acid	IUPAC: 2,5-Dimethyl-benzoic acid		150.18	Aerobic soil: - Aerobic outdoor: 3.3 (7 d) Anaerobic soil: - Field soil: - Soil photolysis: 21.8 ^b (7 d) Hydrolysis: - Photolysis water: - Aerobic water/sed.: -
Spirotetramat-glyoxylic amide	IUPAC: (1s,4s)-1-(((2,5-dimethylphenyl)(oxo)acetyl)amino)-4-methoxycyclohexanecarboxylic acid		333.39	Aerobic soil: - Aerobic outdoor: 2.3 (7 d) Anaerobic soil: - Field soil: - Soil photolysis: 4.1 (2 d) Hydrolysis: - Photolysis water: - Aerobic water/sed.: -
Methoxy-cyclohexanone	CAS: 4-methoxy-cyclohexanone		128.17	Aerobic soil: - Aerobic outdoor: - Anaerobic soil: - Field soil: - Soil photolysis: 10.0 (2 d) Hydrolysis: - Photolysis water: 17.5 (8 d) Aerobic water/sed.: -
Methoxy-cyclohexylamino-carboxylic acid	CAS: Cyclohexanecarboxylic acid		173.21	Aerobic soil: - Aerobic outdoor: - Anaerobic soil: - Field soil: - Soil photolysis: - Hydrolysis: - Photolysis water: 11.3 (10 d) Aerobic water/sed.: -
Spirotetramat-oxo-ketohydroxy	IUPAC: 3-(2,5-dimethylphenyl)-3-hydroxy-1-azaspiro[4,5]decane-2,4,8-trione		301.35	Aerobic soil: << 0.5 Aerobic outdoor: - Anaerobic soil: - Field soil: - Soil photolysis: - Hydrolysis: - Photolysis water: - Aerobic water/sed.: -
Spirotetramat-photo-cyclopentyl	IUPAC: (1s,4s)-8'-hydroxy-4-methoxy-5'-methyl-2'H-spiro[cyclohexane-1,1'-indeno[1,2-c]pyrrol]-3'(8'H)-one		299.4	Aerobic soil: - Aerobic outdoor: - Anaerobic soil: - Field soil: - Soil photolysis: - Hydrolysis: - Photolysis water: 42.9 ^c (7 d)

Table 4: Chemical name, structure, molecule mass and occurrence of investigated and/or observed metabolites of spirotetramat.

Substance	Chemical name	Structure	Mole mass (g/mol)	Occurrence (maximum amounts based on mean of replicates) [% of AR]**
				Aerobic water/sed.: -
Spirotetramat-photo-2-methylcarbonate	IUPAC: ethyl 2-[(5s,8s)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-3-yl]-4-methylbenzyl carbonate		373.4	Aerobic soil: - Aerobic outdoor: - Anaerobic soil: - Field soil: - Soil photolysis: - Hydrolysis: - Photolysis water: 19.3^c (6 d) Aerobic water/sed.: -
Spirotetramat-photo-2-hydroxymethyl	IUPAC: (5s,8s)-3-[2-(hydroxymethyl)-5-methylphenyl]-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one		301.4	Aerobic soil: - Aerobic outdoor: - Anaerobic soil: - Field soil: - Soil photolysis: - Hydrolysis: - Photolysis water: 22.9^c (6 d) Aerobic water/sed.: -
Spirotetramat-photo-2-formyl	IUPAC: 2-[(5s,8s)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-yl]-4-methylbenzaldehyde		299.4	Aerobic soil: - Aerobic outdoor: - Anaerobic soil: - Field soil: - Soil photolysis: - Hydrolysis: - Photolysis water: 11.5^c (3 d) Aerobic water/sed.: -
Spirotetramat-enol-dimer 1^d	Not available		600	Aerobic soil: 5.0 (60 d) Aerobic outdoor: 1.5 (28 d) Anaerobic soil: 7.0 (6 d) Field soil: < 0.2 Soil photolysis: 2.3 (2 d) Hydrolysis: - Photolysis water: - Aerobic water/sed.: -
Spirotetramat-enol-dimer 2^d	Not available		600	Aerobic soil: 3.6 (14 d) Aerobic outdoor: 0.9 (7 d) Anaerobic soil: 4.6 (180 d) Field soil: < 0.2 Photolysis water: - Soil photolysis: - Hydrolysis: - Aerobic water/sed.: -

^a Not applicable owing to distinct storage instability of spirotetramat-enol (degrading to spirotetramat-ketohydroxy during frozen storage).

^b In an outdoor metabolism study, conducted with the formulation on bare soil including natural sunlight, dimethyl-benzoic acid was shown not to exceed 3.3 % of AR.

^c Photo-rearrangement products produced in sterile buffer solution.

^d Possible artefacts owing to hot-spot application in the laboratory; formation was low under environmental conditions (formulated a.i.).

** Bolded values at or above 10% of the applied.

Major degradates observed were spirotetramat-enol, spirotetramat-ketohydroxy, dimethyl-benzoic acid, methoxy-cyclohexanone, methoxy-cyclohexylaminocarboxylic acid, spirotetramat-photocyclopentyl, spirotetramat-photo-2-methylcarbonate, spirotetramat-2-hydroxymethyl, spirotetramat-2-formyl. The first two of the listed major metabolites were observed under metabolism conditions, while the other ones were observed under photolytic conditions (on soil and/ or in water).

Spirotetramat-enol degraded relatively quickly, with calculated half-lives (DT50's) of <1 day in aerobic soil metabolism studies, in four soils. The half-lives (DT50's) for spirotetramat-ketohydroxy in aerobic soil metabolism study were moderate (range 1.5-16.7 days) and smaller for spirotetramat-amide (range 0.03-5.4 days); they were calculated from the results obtained in a study conducted with spirotetramat-enol. Carbon dioxide formation was 10.9-34.9% by 60 days. Volatiles were insignificant while non-extractable residues were important. The major degradation pathway for spirotetramat under aerobic soil condition is hydrolytic cleavage of the ester bond, yielding spirotetramat-enol (presumed to be quantitative). The latter is oxidized at the benzylic carbon to spirotetramat-ketohydroxy (maximum 24.0% at 1 day), which is hydrolytically opened to spirotetramat-MA-amide (maximum 5.2% at 1 day, one sample). In another possible pathway, demethylation of spirotetramat-enol occurs to yield spirotetramat-desmethyl-enol and subsequently spirotetramat-oxo-enol. Furthermore, oxidative spirotetramat-enol dimerization may occur to yield spirotetramat-enol dimer 1 and spirotetramat-enol dimer 2. The degradation products in most soil and water/ sediment studies were consistent with these degradation pathways. The soil photodegradation study was deemed supplemental. Even though there is information on the presence of the degradates, there is uncertainty on the results. In addition to the metabolites mentioned above, dimethyl benzoic acid, spirotetramat-glyoxylic amide and methoxy cyclohexanone were observed in the soil photolysis study.

Spirotetramat-enol, spirotetramat-ketohydroxy and spirotetramat-MA-amide were found to be more mobile than the parent, spirotetramat. There is the possibility of offsite transport for these metabolites due to runoff. The mobility of spirotetramat-enol was assessed using a soil column leaching study. The chemical was found mostly in the 0-6 cm soil depth (9.6-16.5%) and at low levels in the 6-12 cm soil depth (0.1-1.4%). In the leachate fractions, spirotetramat-enol was a total of 0.1-2.8%. The estimated K_{OC} values for spirotetramat-enol were between 27-99 mL/g_{OC} (mean 55 mL/g_{OC}) over four soil types (mobile). No definitive batch equilibrium test could be conducted on spirotetramat-enol because the chemical was labile during the adsorption phase. The degrade spirotetramat-ketohydroxy is mobile in five sterilized soils, with K_d values ranging from 0.529-2.28 mL/g, K_{OC} values ranging from 43.1-99.7 mL/g_{OC} (mean 65.3 mL/g_{OC}), K_F values ranging from 0.516-2.21 ($\mu\text{g/g}/(\mu\text{g/mL})^{1/n}$), K_{FOC} values between 41.0-99.1 ($\mu\text{g/g}_{OC}/(\mu\text{g/mL})^{1/n}$) [mean 63.7 ($\mu\text{g/g}_{OC}/(\mu\text{g/mL})^{1/n}$)] and 1/n values close to unity (range 0.915-0.929, mean 0.922). The K_{OC} values were similar to the Freundlich adsorption constants K_{FOC} . The degrade spirotetramat-MA-amide is mobile to highly mobile in five viable soils, with K_d values ranging from 0.064-0.179 mL/g, K_{OC} results ranging from 4.2-25.6 mL/g_{OC} (mean 9.6 mL/g_{OC}), K_F values ranging from 0.075-0.179

$(\mu\text{g/g})/(\mu\text{g/mL})^{1/n}$, K_{FOC} values 4.4-25.5 $(\mu\text{g/gOC})/(\mu\text{g/mL})^{1/n}$ [mean 9.3 $(\mu\text{g/gOC})/(\mu\text{g/mL})^{1/n}$] and $1/n$ results from 0.80-1.07 (mean 0.95, for four of the five soils the range 0.93-1.07).

Drinking Water Exposure Modeling

Models

SCI-GROW v. 2.3 dated 07/29/2003 (Screening Concentration in Ground Water) is a regression model used as a screening tool to estimate pesticide concentrations found in ground water used as drinking water. SCI-GROW was developed by fitting a linear model to groundwater concentrations with the Relative Index of Leaching Potential (RILP) as the independent variable. Groundwater concentrations were taken from 90-day average high concentrations from Prospective Ground Water studies; the RILP is a function of aerobic soil metabolism and the soil-water partition coefficient. The output of SCI-GROW represents the concentrations that might be expected in shallow unconfined aquifers under sandy soils, which is representative of the ground water most vulnerable to pesticide contamination likely to serve as a drinking water source. (Ref. 2)

FIRST v. 1.1.0, 12/12/2005 (FQPA Index Reservoir Screening Tool) is a metamodel of PRZM and EXAMS used as a screening tool to estimate pesticide concentrations found in surface water used as drinking water. FIRST was developed by making multiple runs of PRZM using varying sorption coefficients and determining the concentration in the EXAMS index reservoir scenario after a two-inch single storm event. (The Index Reservoir is a standard water body used by the Office of Pesticide Programs to assess drinking water exposure, Office of Pesticide Programs, 2002). It is based on a real reservoir (albeit not currently in active use as a drinking water supply), Shipman City Lake in Illinois, that is known to be vulnerable to pesticide contamination.) The single runoff event moves a maximum of 8% of the applied pesticide into the reservoir. This amount can be reduced by degradation or effects of binding to soil in the field. Additionally, FIRST can account for spray drift and adjusts for the area within a watershed that is planted with the modeled crop (Percent Cropped Area). Spray drift (modeled as direct deposition of the pesticide into the reservoir) is assumed to be 16% of the applied active ingredient for aerial application, 6.3% for orchard air blast application, and 6.4% for other ground spray application. Despite being a single event model, FIRST can account for spray drift from multiple applications. The default agricultural Percent Cropped Area (PCA) is 87%. The PRZM scenario used for FIRST development was among the most vulnerable, and thus resulting surface water concentrations represent the upper bound values on the concentrations that might be found in drinking water from the use of a pesticide. (Ref. 3 and 4)

For volatile and semi-volatile compounds, Tier I modeling will tend to over-estimate surface water EDWCs because there are no parameters in FIRST that

explicitly take into account volatility (i.e., no vapor pressure or Henry's Law inputs). Therefore, in reality, more of the compound will be volatilizing than Tier I can account for. If drinking water levels of concern are exceeded for over-estimated Tier I surface water EDWCs, Tier II modeling will be able to refine these EDWCs by including volatility, Henry's Law, diffusion in air, and enthalpy considerations. Since SCIGROW is a regression model developed from actual pesticide data with a range of volatilities, systematic conclusions cannot be drawn about over or underestimation of groundwater EDWCs at Tier I.

Modeling Approach and Input Parameters

In order to determine which transformation products or metabolites would be included in the expression of the drinking water analysis, the EFED issued on 12/03/07 a final draft of a memorandum RE: Drinking Waters Degradates Identification Memorandum for Spirotetramat (PC Code 392201). The decision of which metabolites to include in the expression for the DWA was made as a result of conversations with HED Risk Assessment Team (in a meeting held on 12/03/07), and depended on: the prevalence of the transformation products in laboratory or field dissipation studies. (for example, metabolites at $\geq 10\%$ of applied in parent equivalents were flagged for further scrutiny) and the degree of toxicity (potential acute or chronic risk to humans). The HED Risk Assessment Team selected the following Residues of Concern (ROCs): parent, spirotetramat, and metabolites spirotetramat-enol and spirotetramat-ketohydroxy as the compounds to include in the drinking water assessment.

Tables 5, 6 and 7 provide the modeling parameter input values for SCI-GROW, for the compounds spirotetramat, spirotetramat-enol and spirotetramat-ketohydroxy, respectively. Tables 8, 9 and 10 provide the modeling parameter input values for FIRST, for the compounds spirotetramat, spirotetramat-enol and spirotetramat-ketohydroxy, respectively. These values were based on the current Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides (*Ref. 5*). It is noted here that in all instances, in SCI-GROW, only pome fruits were modeled, because they have the higher seasonal application rate. In addition, it is noted that in all cases, in FIRST, the maximum possible application rate was presumed, with the maximum number of applications and the minimum retreatment interval. In all cases, the percent crop area (PCA) was 0.87 or 87%, which is the national default, since there are no specific PCA's developed for pome fruits and Christmas trees.

For spirotetramat, in SCI-GROW, the median was used for both, the organic carbon partition coefficient (K_{OC}) and the aerobic soil metabolism because there were five K_{OC} values (but they did not show greater than three-fold variation), and four aerobic soil metabolism values. In FIRST, the lowest non-sand K_d was utilized because the K_d model represented the mobility better than the K_{OC} (the relative standard deviation was smaller for the K_{OC}). The aerobic soil metabolism input value in FIRST represented the 90th percentile of the upper confidence bound on the mean of four half-life values. In many instances, it has been found that sometimes there is no aerobic aquatic metabolism study available for a given chemical; however, for this study, there is a substantial database,

and an aerobic aquatic metabolism study, conducted in two sediments is available. The 90th percentile of the upper confidence bound on the mean of the two values was 1.07 days. [It is noted that the value that would have been derived from the input of the aerobic soil metabolism study is less conservative than the one utilized (2X the input for the aerobic soil metabolism value is 0.596 days vs. the actual input value of 1.07 days).]

To calculate the maximum application rate of the transformation products spirotetramat-enol and spirotetramat-ketohydroxy, the maximum concentration observed in the aerobic soil metabolism study (written as a fraction) was multiplied by the application rate of spirotetramat by the appropriate mole ratio. The maximum concentrations observed in the aerobic soil metabolism study (written as a fraction) are 100.0% or 1.000 for spirotetramat-enol (assumed the most conservative scenario) and 24.0% or 0.24 for spirotetramat-ketohydroxy.

Sample Calculation – for Spirotetramat-Ketohydroxy Use on Pome Fruits

Maximum percentage observed in the aerobic soil metabolism study, expressed as a fraction (unitless) by application rate by mole ratio =

$$\text{App Rate} = \frac{(0.240)(0.133 \text{ lb a.i./A})(317.39 \text{ g/mol})}{373.45 \text{ g/mol}} = 0.0271 \text{ lb a.i./mol}$$

For spirotetramat-enol, in SCI-GROW, the K_{OC} selected was the lowest one because there was greater than three-fold variation among values. The median value was selected for the aerobic soil metabolism; however, it is noted that there is more than a five-fold difference among values. The soil partition coefficient utilized in FIRST was the lowest non-sand K_{OC} because the K_{OC} model represents the mobility better than the K_d. The aerobic soil metabolism and the aerobic aquatic metabolism input half lives were the 90th percentiles of the upper confidence bound on the mean of four and two half-lives, respectively. The resulting input value for the aerobic aquatic metabolism was 80.92 days (as opposed to twice the aerobic soil metabolism input value which is 0.234 days). It is noted that the aquatic metabolism of spirotetramat-enol is much slower than the terrestrial metabolism (the chemical is stable under anaerobic aquatic metabolism conditions). The hydrolysis is known to be stable at all pH levels, and the aqueous photolysis is presumed to be stable in the absence of data. The method of application is granular. This method of application yields a spray drift equal to zero (appropriate for a metabolite), and is suitable for a Tier 1 level screening analysis.

In the case of spirotetramat-ketohydroxy the organic carbon partition coefficient (K_{OC}) and the aerobic soil metabolism half-life input parameters for SCI-GROW were the median of five and four values, respectively. The values of K_{OC} show less than a three-fold variation among themselves, while there is more than a five-fold difference among the aerobic soil metabolism half-lives. In the case of FIRST, the soil partition coefficient input parameter is the lowest non-sand K_{OC}. The K_{OC} model represents the mobility better than the K_d. In addition, the aerobic soil metabolism input parameter is the 90th percentile of the upper confidence bound on the mean of four half-life values. As for the

transformation product spirotetramat-enol, the method of application is granular for the same reasons. For this chemical, the input parameter for the aerobic aquatic metabolism was twice the input for the aerobic soil metabolism.

Table 5. SCI-GROW (v2.3) input parameter values for spirotetramat use on pome fruits¹.

PARAMETER (units)	VALUE(S)	SOURCE	COMMENT
Maximum Application Rate (lb a.i./A)	0.133 for pome fruit	Proposed label.	Even though the maximum single application rate is 0.14 lb a.i./A, the value selected represents most-conservative scenario in which the total maximum rate per year is applied in three applications.
Number of Applications per Year	3	Proposed label.	–
Organic Carbon Partition Coefficient (K _{oc} ; mL/g)	237	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	Represents the median value of five values as follows: 184, 437, 201, 385, 237 mL/g _{oc} for the parent compound (K _{oc} does not show more than a three-fold variation among values).
Aerobic Soil Metabolism Half-life (days)	0.25		Represents the median value, since there are four or more values (FL SL; t _{1/2} = 0.30 days, SL; t _{1/2} = 0.24 days, SiL; t _{1/2} = 0.26 days, Si; t _{1/2} = 0.09 days).

¹ Parameters are selected as per Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides; Version II, February 28, 2002.

Table 6. SCI-GROW (v2.3) input parameter values for transformation product spirotetramat-enol use on pome fruits¹.

PARAMETER (units)	VALUE(S)	SOURCE	COMMENT
Maximum Application Rate (lb a.i./A)	0.107	Proposed label.	It is assumed that the transformation is quantitative in the aerobic soil metabolism study. Maximum concentration observed in the aerobic soil metabolism study or 100% by application rate by mole ratio = (1.00)(0.133)(301.39/373.45) = 0.107 lb a.i./mol for pome fruit
Number of Applications per Year	3	Proposed label.	–
Organic Carbon Partition Coefficient (K _{oc} ; mL/g)	27	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	Represents the lowest one of four values as follows: 27, 65, 29 and 99, mL/g _{oc} for the parent compound (there is greater than a three-fold variation among values).
Aerobic Soil Metabolism Half-life (days)	0.035		Represents the median value, since there are four or more values (FL SL; t _{1/2} = 0.30 days, SL; t _{1/2} = 0.02 days, SiL; t _{1/2} = 0.16 days, Si; t _{1/2} = 0.02 days). It is noted that there is more than 5-fold difference from the lowest to the highest values.

¹ Parameters are selected as per Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides; Version II, February 28, 2002.

PARAMETER (units)	VALUE(S)	SOURCE	COMMENT
Maximum Application Rate (lb a.i./A)	0.0271	Proposed label.	Maximum concentration observed in the aerobic soil metabolism study by application rate by mole ratio = $(0.240)(0.133)(317.39/373.45) = 0.0271$ lb a.i./mol for pome fruit
Number of Applications per Year	3	Proposed label.	–
Organic Carbon Partition Coefficient (K_{oc} ; mL/g)	48.1	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	Represents the median value of five values as follows: 43.1, 48.1, 42.0, 99.7, 93.7 mL/g _{OC} for the parent compound. (there is less than a three-fold variation among values).
Aerobic Soil Metabolism Half-life (days)	4.65		Represents the median value, since there are four or more values (FL sandy loam; $t_{1/2} = 16.7$ days, Sandy loam; $t_{1/2} = 4.2$ days, Silt loam; $t_{1/2} = 5.1$ days, Silt; $t_{1/2} = 1.5$ days). There is more than 5-fold difference from the lowest to the highest values.

¹ Parameters are selected as per Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides; Version I, February 28, 2002.

PARAMETER (units)	VALUE(S)	SOURCE	COMMENT
Application Rate (lb a.i./A)	0.133 for pome fruit 0.16 for Christmas tree	Proposed label.	Pome fruit - even though the maximum single application rate is 0.14 lb a.i./A, the value selected represents most-conservative scenario in which the total maximum rate per year is applied in three applications.
Number of Applications	3 for pome fruit, 2 for Christmas tree	Proposed label.	–
Interval between Applications (days)	7 for pome fruit, 14 for Christmas tree	Proposed label.	–
Percent Cropped Area (decimal)	0.87 for both crops	Proposed label.	National default.
Soil Partition Coefficient (K_d ; (mL/g) or K_{oc} (mL/g _{OC}))	3.58	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	Represents the lowest non-sand K_d value among five values: 4.38, 3.80, 4.69, 3.58, 5.52 mL/g for LS, SL, SiL, SL and L, respectively. The K_d value represents better the mobility of spirotetramat (relative standard deviation is smaller)
Aerobic Soil Metabolism Half-life (days)	0.298		Represents the 90 th percentile of the upper confidence bound on the mean of four half-life values (FL SL; $t_{1/2} = 0.30$ days, SL; $t_{1/2} = 0.24$ days, SiL; $t_{1/2} = 0.26$ days, Si; $t_{1/2} = 0.09$ days)

Table 8. FIRST (v1.0) input parameter values for spirotetramat use on pome fruits or Christmas trees¹.

PARAMETER (units)	VALUE(S)	SOURCE	COMMENT
Wetted in?	No	Proposed label.	-
Depth of Incorporation (inches)	0	Proposed label.	-
Method of Application	Aerial	Proposed label.	-
Solubility in Water @ 20 °C, unbuffered (mg/L)	33.5	OECD Monograph Annex B. Spirotetramat. B.2 Physical and chemical properties	At pH 4, 7 and 9, 33.5, 29.9 and 19.1 mg/L, respectively; in distilled water (pH 6.0-6.3), 33.4 mg/L; input parameter is the maximum available value at 20 or 25°C.
Aerobic Aquatic Metabolism Half-life (days)	1.07	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	Represents the 90 th percentile of the upper confidence bound on the mean of two half-life values (L sediment; t _{1/2} =1.06 days, LS sediment; t _{1/2} =1.05 days
Hydrolysis Half-life @ pH 7 (days)	13.1		pH 7, 20°C, t _{1/2} =13.1 days – use the maximum available value at 20- 25°C.
Aquatic Photolysis Half-life @ pH 7 (days)	14.4		t _{1/2} = 14.4 Phoenix, AZ days, maximum dark-controlled available value
¹ Parameters are selected as per Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides; Version II, February 28, 2002			

Table 9. FIRST (v1.0) input parameter values for transformation product spirotetramat-enol use on pome fruits or Christmas trees¹.

PARAMETER (units)	VALUE(S)	SOURCE	COMMENT
Application Rate (lb a.i./A)	0.107 for pome fruit and 0.129 for Christmas tree	Proposed label.	It is assumed that the transformation is quantitative in the aerobic soil metabolism study. Maximum concentration observed in the aerobic soil metabolism study or 100% by application rate by mole ratio = $(1.00)(0.133)(301.39/373.45) = 0.107 \text{ lb a.i./mol}$ for pome fruit and $(1.00)(0.16)(301.39/373.45) = 0.129 \text{ lb a.i./mol}$ for Christmas trees
Number of Applications	3 for pome fruit, 2 for Christmas tree	Proposed label.	-
Interval between Applications (days)	7 for pome fruit, 14 for Christmas tree	Proposed label.	-
Percent Cropped Area (decimal)	0.87	Proposed label.	National default.
Soil Partition Coefficient K _{OC} (mL/g _{OC})	27	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	Represents the lowest non-sand K _{OC} value among four values: 27, 65, 29 and 99 mL/g _{OC} for SL, L, SiL and SL, respectively. The K _{OC} is the only available value.

Table 9. FIRST (v1.0) input parameter values for transformation product spirotetramat-enol use on pome fruits or Christmas trees¹.

PARAMETER (units)	VALUE(S)	SOURCE	COMMENT
Aerobic Soil Metabolism Half-life (days)	0.117		Represents the 90 th percentile of the upper confidence bound on the mean of four half-life values (FL SL; t _{1/2} = 0.05 days, SL; t _{1/2} = 0.02 days, SiL; t _{1/2} = 0.16 days, Si; t _{1/2} = 0.02 days).
Wetted in?	No	Proposed label.	—
Depth of Incorporation (inches)	0	Proposed label.	—
Method of Application	Granular	Proposed label.	This method of application is selected because the value of spray drift is 0%.
Solubility in Water @ 20 °C, buffered solution pH 7 (mg/L)	2700	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	—
Aerobic Aquatic Metabolism Half-life (days)	80.92		Represents the 90 th percentile of the upper confidence bound on the mean of two half-life values (L sediment; t _{1/2} = 59.0 days, LS sediment; t _{1/2} = 37.9 days)
Hydrolysis Half-life @ pH 7 (days)	0		Test substance is stable to hydrolysis.
Aquatic Photolysis Half-life @ pH 7 (days)	0		No data available, it is assumed stable.
¹ Parameters are selected as per Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides; Version II, February 28, 2002			

Table 10. FIRST (v1.0) input parameter values for transformation product spirotetramat-ketohydroxy use on pome fruits or Christmas trees¹.

PARAMETER (units)	VALUE(S)	SOURCE	COMMENT
Application Rate (lb a.i./A)	0.0271 for pome fruit and 0.0326 for Christmas tree	Proposed label.	Maximum concentration observed in the aerobic soil metabolism study by application rate by mole ratio = (0.240)(0.133)(317.39/373.45) = 0.0271 lb a.i./mol for pome fruit and (0.240)(0.16)(317.39/373.45) = 0.0326 lb a.i./mol for Christmas trees
Number of Applications	3 for pome fruit, 2 for Christmas tree	Proposed label.	—
Interval between Applications (days)	7 for pome fruit, 14 for Christmas tree	Proposed label.	—
Percent Cropped Area (decimal)	0.87	Proposed label.	National default.

Table 10. FIRST (v1.0) input parameter values for transformation product spirotetramat-ketohydroxy use on pome fruits or Christmas trees¹.

PARAMETER (units)	VALUE(S)	SOURCE	COMMENT
Soil Partition Coefficient K_{oc} (mL/g _{oc})	42.0	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	Represents the lowest non-sand K_{oc} value among five values: 43.1, 48.1, 42.0, 99.7, 93.7 mL/g _{oc} for SL, SiL, SiL, SL and CL, respectively. The K_{oc} value represents better the mobility of spirotetramat-ketohydroxy (rsd is lower)
Aerobic Soil Metabolism Half-life (days)	12.38		Represents the 90 th percentile of the upper confidence bound on the mean of four half-life values (FL sandy loam; $t_{1/2}$ = 16.7 days, Sandy loam; $t_{1/2}$ = 4.2 days, Silt loam; $t_{1/2}$ = 5.1 days, Silt; $t_{1/2}$ = 1.5 days).
Wetted in?	No	Proposed label.	–
Depth of Incorporation (inches)	0	Proposed label.	–
Method of Application	Granular	Proposed label.	–
Solubility in Water @ 20 °C, unbuffered (mg/L)	228	OECD Monograph Annex B. Spirotetramat. B.8 Fate and Behaviour	Distilled water
Aerobic Aquatic Metabolism Half-life (days)	24.76		The value is twice the aerobic soil metabolism half-life.
Hydrolysis Half-life @ pH 7 (days)	0		No data available, it is assumed stable.
Aquatic Photolysis Half-life @ pH 7 (days)	0		No data available, it is assumed stable.
¹ Parameters are selected as per Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides; Version II, February 28, 2002			

The Percent Cropped Area (PCA) used was the national default of 0.87 for both pome fruit and Christmas trees (options for Tier I are national scale cotton, wheat, corn, soybeans, or default; regional PCAs are a Tier II tool intended for refined assessment). (Ref. 6)

Modeling Results

The acute and chronic EDWCs in ground waters were obtained from spirotetramat's use on pome fruits, with the highest seasonal application rate. The acute and the chronic EDWCs in surface waters were obtained from the use of spirotetramat on pome fruits and Christmas trees. However, the surface waters results reported were from the use on Christmas trees because they were higher. It appears that a high individual application rate (like in Christmas trees) generally yields a higher value of concentrations in surface waters (EDWCs). Table 11 and 12 summarize the results obtained for pome fruits and Christmas trees, respectively. The bolded results were the ones reported in Table 2 in the Executive Summary.

Table 11. Maximum Tier I Estimated Drinking Water Concentrations (EDWCs) for drinking water risk assessment based on aerial application on pome fruits at 0.4 lb/A/season.

Drinking Water Source (Model)		ESTIMATED DRINKING WATER CONCENTRATION (EDWC) (ppb)			
		Spirotetramat	Spirotetramat-enol	Spirotetramat-ketohydroxy	Total Residues
Ground-water (SCI-GROW)	Acute and Chronic	2.25x10 ⁻⁵	1.64x10 ⁻⁵	3.57x10 ⁻⁴	3.96x10 ⁻⁴
Surface Water (FIRST)	Acute	1.07x10 ⁻¹	6.7x10 ⁻⁵	4.38x10 ⁻³	0.111
	Chronic	9.18x10 ⁻⁴	1.4x10 ⁻⁵	3.04x10 ⁻⁴	1.23x10 ⁻³

Table 12. Maximum Tier I Estimated Drinking Water Concentrations (EDWCs) for drinking water risk assessment based on aerial application on Christmas trees at 0.32 lb/A/season.

Drinking Water Source (Model)		ESTIMATED DRINKING WATER CONCENTRATION (EDWC) (ppb)			
		Spirotetramat	Spirotetramat-enol	Spirotetramat-ketohydroxy	Total Residues
Ground-water (SCI-GROW)	Acute and Chronic	---	---	---	---
Surface Water (FIRST)	Acute	2.08x10 ⁻¹	8.0x10 ⁻⁵	3.60x10 ⁻³	0.212
	Chronic	1.1x10 ⁻³	1.7x10 ⁻⁵	2.50x10 ⁻⁴	1.37x10 ⁻³

SCI-GROW concentration (ppb) represents the groundwater concentration that might be expected in shallow unconfined aquifers under sandy soils. Output is used for both acute and chronic endpoints.

FIRST concentrations (ppb) represent untreated surface water concentrations. The one-in-10-year peak day concentration is used for acute endpoints and the one-in-10-year annual average concentration is used for chronic endpoints.

The estimated concentrations provided in this assessment are conservative estimates of concentrations in drinking water. If dietary risks require refinement, higher tiered crop-specific and location-specific models and modeling scenarios can be used.

Monitoring Data

Monitoring data provide different kinds of information than modeling estimates. For example, monitoring data consist of actual information from the field, reflecting current use pattern and usually underestimating frequency of occurrence. Monitoring data does not always include peak values, and inputs for monitoring cannot be adjusted as modeled ones can. In addition, monitoring is often conducted for purposes other than characterizing exposure from a particular pesticide, and as a consequence is used to complement modeling rather than to refine it. In general, a useful interpretation of

monitoring values requires in-depth assessment of the data, which is beyond the scope of a Tier I assessment.

Since this is a new chemical, there are no monitoring data available.

Drinking Water Treatment

The effects of water treatment on the pesticide and degradates is uncertain. Spirotetramat and its major metabolites, spirotetramat-enol, spirotetramat-ketohydroxy and spirotetramat-MA-amide, were highly mobile to moderately mobile; however, high levels of binding were observed in various of the laboratory metabolism studies. The softening of drinking water generally results in an increase in pH. Since spirotetramat is more susceptible to hydrolysis under alkaline conditions, softening may result in increased dissipation from hydrolysis. (Ref. 9)

CONCLUSIONS

This is a Tier 1 screening level drinking water assessment for the residues of concern (ROCs) of spirotetramat (spirotetramat, spirotetramat-enol and spirotetramat-ketohydroxy). A more definitive drinking surface water assessment may be performed with the use of the Tier 2 aquatic models PRZM/ EXAMS. EDWCs for the total residues, both, acute and chronic in ground waters were obtained from spirotetramat's use on pome fruits. The acute and the chronic EDWCs in surface waters were obtained from the use of spirotetramat on Christmas trees. It appears that a high individual application rate generally yields a higher value of surface waters.

Despite the minor uncertainties found in this assessment, overall, it is considered conservative because no major assumptions were needed to be made in calculations. The following factors make this screening assessment particularly less certain or more certain as it is indicated in each case, for spirotetramat and/ or its residues of concern:

This assessment was based actually on a full data set for the three chemicals whose residues are of concern; this is a major strength of this assessment. Except for the aerobic aquatic metabolism study of spirotetramat-ketohydroxy (in the absence data, the reviewer used 2X the aerobic soil metabolism input value). A full data set gives certainty to the assessment. One weakness of the data set was related to the K_{OC} input values derived from a column leaching study of spirotetramat-enol. These K_{OC} values are relatively uncertain. The arithmetic mean is 55 mL/g_{OC}, while the range of values for four soils (eight replicates) is 26-108 mL/g_{OC}. K_{OC} values derived from a batch equilibrium study could not be taken because spirotetramat-enol was too labile even in sterile soils.

The approach utilized by the EFED in this assessment may not achieve mass balance. The reason is that it was assumed that spirotetramat is transformed to the maximum observed of each transformation product in the aerobic soil metabolism studies (there are four studies available). The transformation products involved are spirotetramat-enol (of which quantitative transformation was assumed) and spirotetramat-ketohydroxy. It appears that this approach is suitable for a screening level assessment and is conservative.

For volatile and semi-volatile compounds, the Tier I modeling for surface waters will tend to over-estimate EDWCs because there are no parameters in FIRST that explicitly take into account volatility (*i.e.*, no vapor pressure or Henry's Law Constant inputs parameters). In reality, more of the compound will be volatilizing than Tier I can account for. If drinking water levels of concern are exceeded for over-estimated Tier I surface water EDWCs, Tier II modeling would be able to refine these EDWCs by including volatility, Henry's Law, diffusion in air, and enthalpy considerations. Since SCI-GROW is a regression model developed from actual pesticide data with a range of volatilities, systematic conclusions cannot be drawn about over or underestimation of groundwater EDWCs at Tier I. It is noted, nevertheless, that the vapor pressure and the Henry's Law constant for spirotetramat are small (4.2×10^{-11} mm Hg and 5.24×10^{-10} atm-m³/mol, respectively).

There is uncertainty related to the use of spirotetramat under soil photolytic conditions. The marginally supplemental study available provides minimal information on the identity of the transformation products of spirotetramat under those conditions. Since the soil photodegradation half-life is not an input value in the aquatic models, this uncertainty has no effect on the input parameters of FIRST or SCI-GROW. It does have effect, however, on the environmental fate assessment.

APPENDIX

SCI-GROW and FIRST model output files.

SCIGROW
VERSION 2.3
ENVIRONMENTAL FATE AND EFFECTS DIVISION
OFFICE OF PESTICIDE PROGRAMS
U.S. ENVIRONMENTAL PROTECTION AGENCY
SCREENING MODEL
FOR AQUATIC PESTICIDE EXPOSURE

SciGrow version 2.3
chemical:Spirotetramat
time is 12/26/2007 12:35:29

Application rate (lb/acre)	Number of applications	Total Use (lb/acre/yr)	Koc (ml/g)	Soil Aerobic metabolism (days)
0.133	3.0	0.399	2.37E+02	0.2

groundwater screening cond (ppb) = 2.25E-05

SCIGROW
VERSION 2.3
ENVIRONMENTAL FATE AND EFFECTS DIVISION
OFFICE OF PESTICIDE PROGRAMS
U.S. ENVIRONMENTAL PROTECTION AGENCY
SCREENING MODEL
FOR AQUATIC PESTICIDE EXPOSURE

SciGrow version 2.3
chemical:Spirotetramat-enol
time is 12/26/2007 12:38:46

Application rate (lb/acre)	Number of applications	Total Use (lb/acre/yr)	Koc (ml/g)	Soil Aerobic metabolism (days)
0.107	3.0	0.321	2.70E+01	0.0

groundwater screening cond (ppb) = 1.64E-05

SCIGROW
 VERSION 2.3
 ENVIRONMENTAL FATE AND EFFECTS DIVISION
 OFFICE OF PESTICIDE PROGRAMS
 U.S. ENVIRONMENTAL PROTECTION AGENCY
 SCREENING MODEL
 FOR AQUATIC PESTICIDE EXPOSURE

SciGrow version 2.3
 chemical:Spirotetramat-ketohydroxy
 time is 12/26/2007 12:41:20

Application rate (lb/acre)	Number of applications	Total Use (lb/acre/yr)	Koc (ml/g)	Soil Aerobic metabolism (days)
0.027	3.0	0.081	4.81E+01	4.7

groundwater screening cond (ppb) = 3.57E-04

RUN No.	1 FOR SPIRO	ON	Pome Fruit	* INPUT VALUES *			
RATE (#/AC)	No.APPS & INTERVAL	SOIL Kd	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	%CROPPED AREA	INCORP (IN)	
.133(.133) 3 7	3.6	33.5	AERIAL(16.0)	87.0	.0	

FIELD AND RESERVOIR HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (RESERVOIR)	PHOTOLYSIS (RES.-EFF)	METABOLIC (RESER.)	COMBINED (RESER.)
.30	2	N/A	14.40- 1785.60	1.07	1.07

UNTREATED WATER CONC (NANOGRAMS/LITER (PPTr)) Ver 1.1.0 JAN 1, 2007

PEAK DAY (ACUTE) CONCENTRATION	ANNUAL AVERAGE (CHRONIC) CONCENTRATION
173.828	.918

RUN No. 2 FOR Spirot ON Xmas tree * INPUT VALUES *

RATE (#/AC) ONE(MULT)	No.APPS & INTERVAL	SOIL Kd	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	%CROPPED AREA	INCRP (IN)
.160(.160)	2 14	3.6	33.5	AERIAL(16.0)	87.0	.0

FIELD AND RESERVOIR HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (RESERVOIR)	PHOTOLYSIS (RES.-EFF)	METABOLIC (RESER.)	COMBINED (RESER.)
.30	2	N/A	14.40- 1785.60	1.07	1.07

UNTREATED WATER CONC (NANOGRAMS/LITER (PPTr)) Ver 1.1.0 JAN 1, 2007

PEAK DAY CONCENTRATION	(ACUTE)	ANNUAL AVERAGE CONCENTRATION	(CHRONIC)
207.798		1.096	

RUN No. 3 FOR Spr-enol ON Pome Fruit * INPUT VALUES *

RATE (#/AC) ONE(MULT)	No.APPS & INTERVAL	SOIL Koc	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	%CROPPED AREA	INCRP (IN)
.107(.107)	3 7	27.0	2700.0	GRANUL(.0)	87.0	.0

FIELD AND RESERVOIR HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (RESERVOIR)	PHOTOLYSIS (RES.-EFF)	METABOLIC (RESER.)	COMBINED (RESER.)
.12	2	N/A	.00- .00	80.92	80.92

UNTREATED WATER CONC (NANOGRAMS/LITER (PPTr)) Ver 1.1.0 JAN 1, 2007

PEAK DAY CONCENTRATION	(ACUTE)	ANNUAL AVERAGE CONCENTRATION	(CHRONIC)
.067		.014	

RUN No. 4 FOR Spr-enol ON Xmas Trees * INPUT VALUES *

RATE (#/AC) ONE (MULT)	No. APPS & INTERVAL	SOIL Koc	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	%CROPPED AREA	INCRP (IN)
.129(.129)	2 14	27.0	2700.0	GRANUL(.0)	87.0	.0

FIELD AND RESERVOIR HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (RESERVOIR)	PHOTOLYSIS (RES.-EFF)	METABOLIC (RESER.)	COMBINED (RESER.)
.12	2	N/A	.00-	.00	80.92

UNTREATED WATER CONC (NANOGRAMS/LITER (PPTr)) Ver 1.1.0 JAN 1, 2007

PEAK DAY (ACUTE) CONCENTRATION	ANNUAL AVERAGE (CHRONIC) CONCENTRATION
.080	.017

RUN No. 6 FOR Spr-keto ON Xmas tree * INPUT VALUES *

RATE (#/AC) ONE (MULT)	No. APPS & INTERVAL	SOIL Koc	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	%CROPPED AREA	INCRP (IN)
.033(.047)	2 14	42.0	228.0	GRANUL(.0)	87.0	.0

FIELD AND RESERVOIR HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (RESERVOIR)	PHOTOLYSIS (RES.-EFF)	METABOLIC (RESER.)	COMBINED (RESER.)
12.38	2	N/A	.00-	.00	24.76

UNTREATED WATER CONC (MICROGRAMS/LITER (PPB)) Ver 1.1.0 JAN 1, 2007

PEAK DAY (ACUTE) CONCENTRATION	ANNUAL AVERAGE (CHRONIC) CONCENTRATION
3.602	.250

RUN No. 7 FOR Spir-keto ON Pome fruit * INPUT VALUES *

RATE (#/AC) ONE(MULT)	No.APPS & INTERVAL	SOIL Koc	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	%CROPPED AREA	INCRP (IN)
.027(.058)	3 7	42.0	228.0	GRANUL(.0)	87.0	.0

FIELD AND RESERVOIR HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (RESERVOIR)	PHOTOLYSIS (RES.-EFF)	METABOLIC (RESER.)	COMBINED (RESER.)	
12.38	2	N/A	.00-	.00	24.76	24.76

UNTREATED WATER CONC (MICROGRAMS/LITER (PPB)) Ver 1.1.0 JAN 1, 2007

PEAK DAY (ACUTE) CONCENTRATION	ANNUAL AVERAGE (CHRONIC) CONCENTRATION
4.383	.304

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