United States
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
(7505P)

Pesticide Fact Sheet

Name of Chemical: **Spirotetramat**
Reason for Issuance: **Conditional Registration**
Date Issued: **June 2008**

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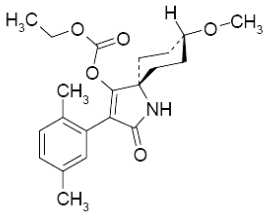
1. DESCRIPTION OF THE CHEMICAL

Chemical Name:	cis-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl-ethyl carbonate
Empirical Formula	$C_{21}H_{27}NO_5$
Common Name:	Spirotetramat
Experimental Name:	BYI 08330
EPA PC Code:	392201

Chemical Class:	Tetramic acid derivative (ketoenole)
Mode of Action:	Inhibition of lipogenesis in treated insects, resulting in decreased lipid contents, growth inhibition of younger insects, and reduced ability of adult insects to reproduce.
Pesticide Type:	Insecticide
U.S. Technical Registrant:	Bayer CropScience 2 T.W. Alexander Drive NC 27709
Chemical Structure:	

2. USE PATTERNS AND FORMULATIONS

Registered Uses:	Citrus (Crop Group 10); Cucurbit Vegetables (Crop Group 9); Fruiting Vegetables (Crop Group 8); Grape (Crop Subgroup 13F); Hops; Leafy *Brassica* Vegetables (Crop Group 5); Leafy Non-*Brassica* Vegetables (Crop Group 4); Pome Fruit (Crop Group 11); Potato and Other Tuberous and Corm Vegetables (Crop Subgroup 1C); Stone Fruit (Crop Group 12); Tree Nuts (Crop Group 14); Onions; Strawberries; Livestock Commodities; and Greenhouses/Nurseries.
Pests/Application Sites:	aphids, whiteflies, scales, mealybugs, psylla, phylloxera, thrips, and mites.
Application Rates:	Seasonal Maximum: Food Crops - 0.4 lb a.i./acre Greenhouse/Nursery - 0.39 lb a.i./acre
Types of Formulations/ Product Names:	<u>Technical</u>: Spirotetramat Technical

(97.37% a.i.)

End Use (Agricultural Uses):
Movento
(22.4% a.i.; suspension concentrate)

Ultor
(14.5% a.i. suspension concentrate)

BYI 8330 OD Insecticide
(15.3% a.i.; oil dispersion)

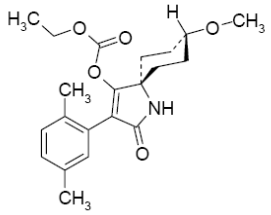
End Use (Nuresry/Greenhouse/Interior Plantscapes Uses):
Spirotetramat 240 SC Greenhouse and Nursery Insecticide
(22.4% a.i.; suspension concentrate)

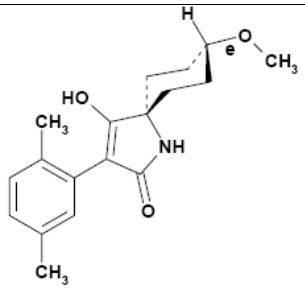
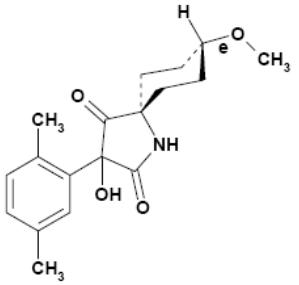
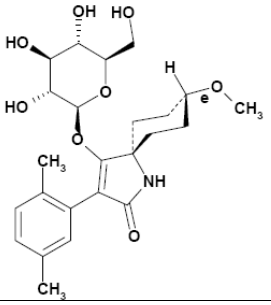
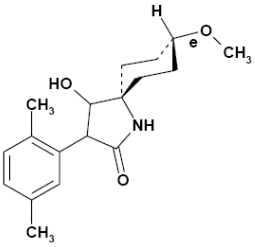
3. SCIENCE FINDINGS

Physical and Chemical Characteristics:

The test compound nomenclature of spirotatramat and its metabolites, and the physical and chemical properties of the technical are set forth below in Tables 1 and 2 respectively:

Table 1. Test Compound Nomenclature.

Compound	Chemical Structure 
Common name	Spirotetramat
Company experimental name	BYI 08330
IUPAC name	*cis*-4-(ethoxycarbonyloxy)-8-methoxy-3-(2,5-xylyl)-1-azaspiro[4.5]dec-3-en-2-one
CAS name	*cis*-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl carbonate
CAS #	382608-10-8
End-use product/EP	Movento™, Ultor™, BYI 8330 OD
Compound: BYI08330-enol	Chemical Structure

	
Common name	BYI08330-enol
Company experimental name	BYI08330-enol
IUPAC name	None provided
CAS name	*cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one
CAS #	None provided
Compound: BYI08830-ketohydroxy	Chemical Structure 
Common name	BYI08830-ketohydroxy
Company experimental name	BYI08830-ketohydroxy
IUPAC name	None provided
CAS name	*cis*-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione
CAS #	None provided
Compound: BYI08330-enol-Glc	Chemical Structure 
Common name	BYI08330-enol-Glc
Company experimental name	BYI08330-enol-Glc
IUPAC name	None provided
CAS name	*cis*-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl beta-D-glucopyranoside
CAS #	None provided
Compound: BYI 08330-mono-hydroxy	Chemical Structure 
Common name	BYI 08330-mono-hydroxy
Company experimental name	BYI 08330-mono-hydroxy
IUPAC name	None provided

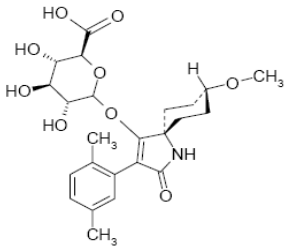
CAS name	*cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one
CAS #	None provided
Compound: BYI 08330-enol-GA	Chemical Structure 
Common name	BYI 08330-enol-GA
Company experimental name	BYI 08330-enol-GA
IUPAC name	None provided
CAS name	*cis*-3-(2,5-dimethylphenyl)-4-(β-D-glucopyranosyloxy)-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one
CAS #	None provided

Table 2. Physicochemical Properties of Technical Grade Spirotetramat.

Parameter	Value	
Melting Point (°C)	142	
pH	6.3	
Density	$D_4^{20} = 1.22$	
Solubility in water at 20ºC	pH 4 - 33.5 mg/L pH 7 - 29.9 mg/L pH9 - 19.1 mg/L	
Solubility in organic solvent at 20ºC	Solvent	g/L
	n-hexane	0.055
	Dichloromethane	>600
	Dimethyl Sulfoxide	200-300
	Toluene	60
	Acetone	100–120
	Ethyl acetate	67
	Ethanol	44
Partition Coefficient n-octanol/water (log K_{ow})	pH 4 - 2.51 pH 7 - 2.51 pH 9 - 2.50	
Vapor pressure (Pa)	Extrapolated Values: 5.6×10^{-9} (20ºC) 1.5×10^{-8} (25ºC) 1.5×10^{-6} (50ºC)	
UV/Visible Absorption Spectra	Peak Maxima (nm)	Molar Absorptivity (1000 cm^2/ mol)
	211	22.0×10^3
	276	0.8×10^3

Metabolism Assessment:

Metabolism in Primary Crops

The submitted metabolism data for apple, lettuce, cotton and potato are adequate to elucidate the nature of the residue in plants. Major metabolic reaction involved the hydrolytic cleavage of the carbonate ester parent bond of the parent compound to form BYI 08330-enol. Further reduction of the double bond in the tetramic acid moiety of BYI 08330-enol occurred to form the BYI 08330-mono-hydroxy metabolite. Hydroxylation in the tetramic acid moiety resulted in BYI 08330-ketohydroxy. Demethylation of the

methoxy group of the cyclohexyl ring resulted via a proposed intermediate (BYI 08330-desmethyl-enol) in BYI 08330-desmethyl-ketohydroxy (after the corresponding hydroxylation). Oxidation of the methoxy group resulted in BYI 08330-ketohydroxy-formiate. Partly, metabolites bearing a hydroxy group were conjugated with glucose.

Metabolism in Rotational Crops

It appears that two major metabolic routes in rotational crops start with the soil metabolites BYI 08330-ketohydroxy and BYI 08330-enol. The first metabolic route proceeds by demethylation of the cyclohexyl ring or hydroxylation of one methyl group of the xylol ring. Another metabolic route starts with the addition of water to the tetramic acid ring of BYI 08330-enol resulting in the formation of BYI 08330-di-hydroxy, followed by the demethylation of the metabolite. Additionally, hydroxylation of one methyl group of the xylol ring of BYI 08330-enol followed by demethylation of the cyclohexyl ring results in BYI 08330-desmethyl-enol-alcohol, which was detected in all matrices. Most of the metabolites were rapidly conjugated. Glucosides and/or glucosyl malonic acid conjugates were detected for BYI 08330-enol, BYI 08330-desmethyl-di-hydroxy, BYI 08330-desmethyl-ketohydroxy and BYI 08330-ketohydroxy-alcohol. The percentage of conjugates increased from the 30-day to the 260-day rotation.

Metabolism in Livestock

The submitted goat and poultry metabolism data are adequate to satisfy data requirements. The biodegradation of spirotetramat in livestock can be characterized as cleavage of the carbonate ester group to the primary metabolite BYI 08330-enol followed by conjugation of the enol hydroxy group with glucuronic acid to BYI 08330-enol-GA. Oxidation of the azaspirodecenyl moiety to BYI 08330-ketohydroxy and demethylation of the methoxy group to BYI 08330-desmethyl-enol were minor metabolic reactions in ruminants as well as reduction of the azaspirodecenyl moiety to BYI 08330-monohydroxy.

Analytical Methodology

The registrant has submitted several HPLC-MS/MS residue analytical methods for the determination of residues of the parent and its metabolites in/on plant and livestock commodities. Analytical method 00857 was developed for the determination of residues of spirotetramat, the metabolites BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-mono-hydroxy and BYI 08330-enol-Glc in plant matrices by HPLC-MS/MS. The analytical method 00966 was developed for the determination of residues of spirotetramat and the metabolites BYI 08330-enol and BYI 08330-enol-GA in livestock matrices by HPLC-MS/MS. These methods were used as the data-collection methods in the analysis of samples for residues of concern from the various studies associated with the current petition. Each method has been adequately validated by the petitioner as well as by independent laboratories. Methods 00857 and 00966 were also adequately radiovalidated using weathered samples obtained from metabolism studies. Methods 00857 and 00966 are suitable enforcement methods for plant and livestock commodities, respectively, since the methods passed a successful PMV by Agency chemists at ACL/BEAD.

Spirotetramat and five metabolites BYI 08330-enol, BYI 08330-ketohydroxy, BYI 08330-

mono-hydroxy, BYI 08330-enol-Glc, and BYI 08330-enol-GA were screened through multiresidue methods described in the U.S. Food and Drug Administration (FDA) Pesticide Analytical Manual, Vol. I (PAM I). The multiresidue methods (MRMs) are not suitable for the analysis of spirotetramat or its metabolites. The multiresidue methods testing data will be forwarded to FDA for further evaluation and inclusion of results in PAM Vol. I.

A tabular summary of metabolites and degradates of Spirotetramat is presented in Table 3 below:

Table 3 Tabular Summary of Metabolites and Degradates

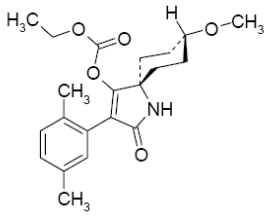
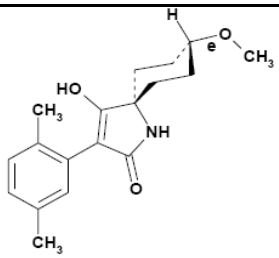
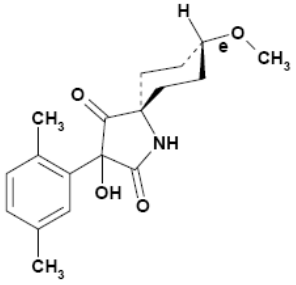
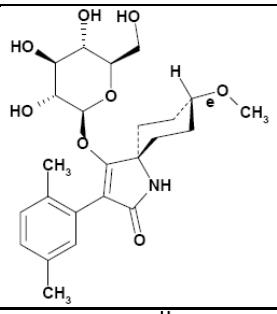
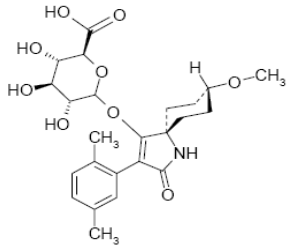
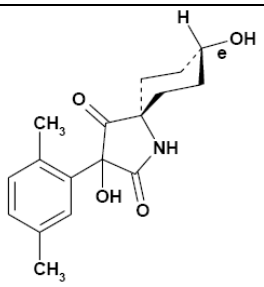
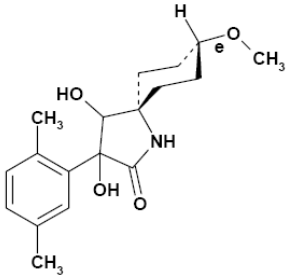
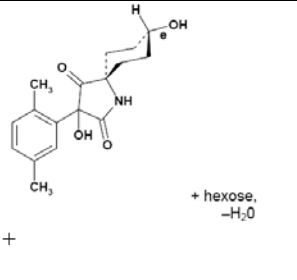
Chemical Name (other names in parenthesis)	Matrix	Percent TRR (PPM)[1]		Structure
		Matrices - Major Residue (>10%TRR)	Matrices - Minor Residue (<10%TRR)	
Spirotetramat (*cis*-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl carbonate)	Plants	Apple Fruit & Leaves; Lettuce; Cotton Gin Trash & Lint; Potato Tops	Cotton Seed	
	Rotational Crops	-	-	
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	
	Water	-	-	
BYI08330-enol (*cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one)	Plants	Apple Leaves; Lettuce; Cotton Gin Trash & Seed	Apple Fruit, Cotton Lint, Potato Tops	
	Rotational Crops		Wheat Grain	
	Ruminant	Muscle, Fat, Liver, Kidney, Milk		
	Poultry	Muscle, Eggs, Fat, Liver		
	Rat	Liver, Kidney, Excreta, Plasma		
	Water	Aerobic Soil, Aerobic Outdoor		
BYI08830-ketohydroxy (*cis*-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione)	Plants	Cotton Gin Trash& Lint; Potato Tops	Apple Fruit & Leaves, Lettuce, Cotton Seed	
	Rotational Crops	Wheat Forage; Chard; Turnip Roots	Wheat Straw, Hay; Turnip Leaves	
	Ruminant		Muscle, Liver, Kidney, Milk	
	Poultry	-	-	
	Rat	Kidney, Liver	Excreta, Plasma	
	Water	Aerobic Soil, Aerobic Outdoor		
BYI08330-enol-Glc (*cis*-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl beta-D-glucopyranoside)	Plants	Lettuce	Apple Fruit, Potato Tops	
	Rotational Crops		Wheat Hay, Straw	
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	
	Water	-	-	
BYI 08330-	Plants	Apple Fruit	-	

Table 3 Tabular Summary of Metabolites and Degradates

Chemical Name (other names in parenthesis)	Matrix	Percent TRR (PPM)[1]		Structure
		Matrices - Major Residue (>10%TRR)	Matrices - Minor Residue (<10%TRR)	
mono-hydroxy (*cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one*)	Rotational Crops	-	-	
	Ruminant		Liver, Milk	
	Poultry	-	-	
	Rat	-	-	
	Water	-	-	
BYI 08330-enol-GA (*cis*-3-(*cis*-3-(2,5-dimethylphenyl)-4-(β-D-glucopyranosyloxy)-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one)	Plants	-	-	
	Rotational Crops			
	Ruminant	Fat, Liver, Kidney, Milk		
	Poultry	Liver,	Muscle, Eggs	
	Rat		Liver, Kidney, Excreta	
	Water	-	-	
BYI 08330-desmethyl-ketohydroxy (*cis-3-(2,5-dimethylphenyl)-3,8-dihydroxy-1-azaspiro[4.5]decane-2,4-dione*)	Plants		Apple Fruit, Cotton Gin Trash	
	Rotational Crops		Wheat Forage, Straw, Hay; Chard, Turnip Leaves, Roots	
	Ruminant	-	-	
	Poultry	-	-	
	Rat		Liver, Kidney, Excreta	
	Water	-	-	
BYI 08330-di-hydroxy (*cis*-3-(2,5-dimethylphenyl)-3,4-dihydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one)	Plants	-	Apple Fruit	
	Rotational Crops	Wheat Straw, Chard	Wheat Forage, Hay, Grain; Turnip Leaves, Roots	
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	
	Water	-	-	
BYI 08330-desmethyl-ketohydroxy-glucoside (isomers), in leaves also +BYI 08330-ketohydroxy-formiate-	Plants	-	Apple Fruit & Leaves; Cotton Gin Trash & Lint	
	Rotational Crops	Wheat Forage, Hay, Straw; Chard	Wheat Grain; Turnip Leaves	
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	

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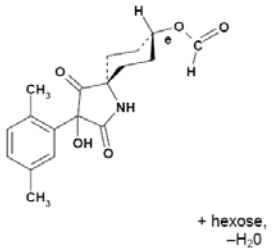
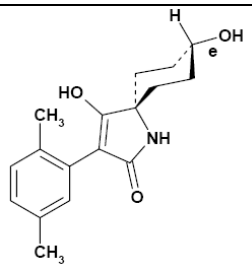
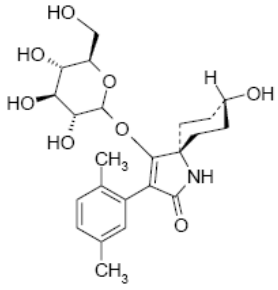
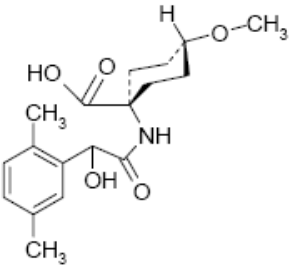
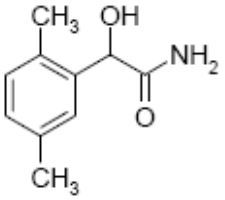
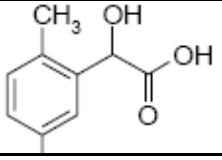
Chemical Name (other names in parenthesis)	Matrix	Percent TRR (PPM)[1]		Structure
		Matrices - Major Residue (>10%TRR)	Matrices - Minor Residue (<10%TRR)	
glycoside	Water	-	-	
BYI 08330-desmethyl-enol Or BYI 08330-4-hydroxy-enol (*cis-3-(2,5-dimethylphenyl)-4,8-dihydroxy-1-azaspiro[4.5]dec-3-en-2-one*)	Plants	-	Potato Tops	
	Rotational Crops	-	-	
	Ruminant		Goat Muscle, Liver, Kidney, Milk;	
	Poultry	-	-	
	Rat	Excreta	Liver, Kidney, Plasma	
	Water		Aerobic Soil	
BYI 08330-desmethyl-enol-Glc (Glucoside of 3-(2,5-dimethylphenyl)-4,8-dihydroxy-1-azaspiro[4.5]dec-3-en-2-one)	Plants		Cotton Gin Trash & Seed; Potato Tops	
	Rotational Crops	-	-	
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	
	Water	-	-	
BYI 08330-MA-amide (1-{[(2,5-dimethylphenyl)(hydroxy)acetyl]amino}-4-methoxycyclohexanecarboxylicacid)	Plants	-	Cotton Gin Trash Cotton Lint	
	Rotational Crops	-	-	
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	
	Water		Aerobic Soil, Aerobic Outdoor	
BYI 08330-mandelic acid amide (2-(2,5-dimethylphenyl)-2-hydroxyacetamide)	Plants	Cotton Lint	Cotton Gin Trash Cotton Seed	
	Rotational Crops	-	-	
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	
	Water	-	-	
BYI 08330-mandelic acid ((2,5-dimethylphenyl)(hydroxy)	Plants	-	Cotton Lint	
	Rotational Crops	-	-	
	Ruminant	-	-	
	Poultry	-	-	

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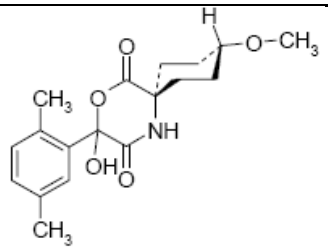
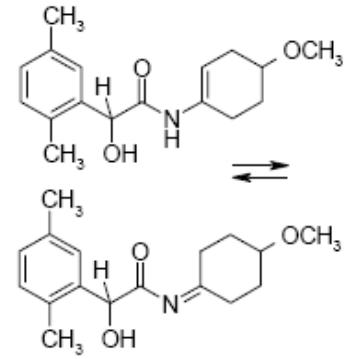
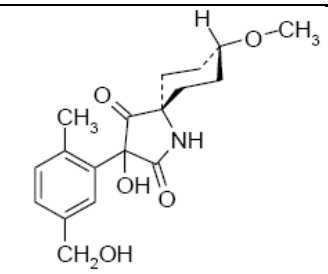
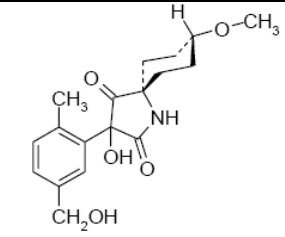
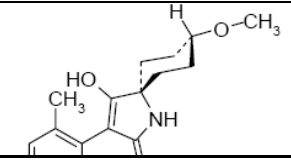
Chemical Name (other names in parenthesis)	Matrix	Percent TRR (PPM)[1]		Structure
		Matrices - Major Residue (>10%TRR)	Matrices - Minor Residue (<10%TRR)	
acetic acid)	Rat	-	-	
	Water	-	-	
BYI 08330-hydroxymorpholinedion (3-(2,5-dimethylphenyl)-3-hydroxy-9-methoxy-4-oxa-1-azaspiro[5.5]undecane-2,5-dione)	Plants		Cotton Gin Trash	
	Rotational Crops	-	-	
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	
	Water	-	-	
BYI 08330-olefine (2-(2,5-dimethylphenyl)-2-hydroxy-N-(4-methoxycyclohex-1-en-1-yl)acetamide or 2-(2,5-dimethylphenyl)-2-hydroxy-N-(4-methoxycyclohexylidene) acetamide)	Plants	-	Cotton Gin Trash Cotton Lint	
	Rotational Crops	-	-	
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	
	Water	-	-	
BYI 08330-ketohydroxy-alcohol (*cis*-3-hydroxy-3-[5-(hydroxymethyl)-2-methylphenyl]-8-methoxy-1-azaspiro[4.5]decane-2,4-dione)	Plants	-	-	
	Rotational Crops	Wheat Straw, Hay, Grain; Chard, Turnip Leaves		
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	
	Water	-	-	
BYI 08330-ketohydroxy-alcohol-glycoside (glycoside of cis-3-hydroxy-3-[5-(hydroxymethyl)-2-methylphenyl]-8-methoxy-1-azaspiro[4.5]decane-2,4-dione)	Plants	-	-	 + $C_6H_{12}O_6 - H_2O$
	Rotational Crops		Wheat Forage, Straw, Hay, Grain; Turnip Leaves	
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	
	Water	-	-	
BYI 08330-enol-alcohol (*cis*-4-hydroxy-3-[5-(hydroxymethyl)-2-methylphenyl]-8-	Plants	-	Potato Tops	
	Rotational Crops	-	-	
	Ruminant	-	-	
	Poultry	-	-	

Table 3 Tabular Summary of Metabolites and Degradates

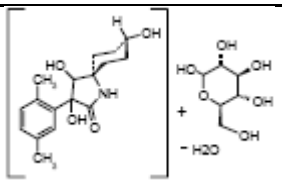
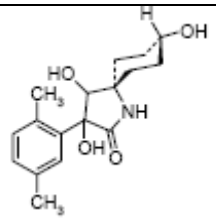
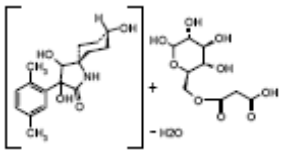
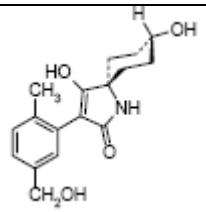
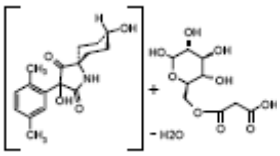
Chemical Name (other names in parenthesis)	Matrix	Percent TRR (PPM)[1]		Structure
		Matrices - Major Residue (>10%TRR)	Matrices - Minor Residue (<10%TRR)	
methoxy-1-azaspiro[4.5]dec-3-en-2-one)	Rat		Liver, Kidney, Excreta	
	Water	-	-	
BYI 08330-desmethyl-di-hydroxy-Glc (glucoside of (5s,8s)-3-(2,5-dimethylphenyl)-3,4,8-trihydroxy-1-azaspiro[4.5]decan-2-one)	Plants	-	-	
	Rotational Crops	Wheat Straw, Forage, Hay	Wheat Grain; Chard, Turnip Leaves	
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	
	Water	-	-	
BYI 08330-desmethyl-di-hydroxy ((5s,8s)-3-(2,5-dimethylphenyl)-3,4,8-trihydroxy-1-azaspiro[4.5]decan-2-one)	Plants	-	-	
	Rotational Crops		Wheat Straw, Hay, Grain, Turnip Leaves	
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	
	Water	-	-	
BYI 08330-desmethyl-dihydroxy-Glc-MA (glucosyl-malonic acid conjugate of (5s,8s)-3-(2,5-dimethylphenyl)-3,4,8-trihydroxy-1-azaspiro[4.5]decan-2-one)	Plants	-	-	
	Rotational Crops	Wheat Hay	Wheat Straw, Grain; Chard, Turnip Leaves, Roots	
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	
	Water	-	-	
BYI 08330-desmethyl-enol - alcohol ((5s,8s)-4,8-dihydroxy-3-[5-(hydroxymethyl)-2-methylphenyl]-1-azaspiro[4.5]dec-3-en-2-one)	Plants	-	-	
	Rotational Crops		Wheat Forage, Straw, Hay, Grain; Chard, Turnip Leaves, Roots	
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	
	Water	-	-	
BYI 08330-desmethyl-ketohydroxy-Glc-MA (isomer 1 & isomer 2) (glucosyl-malonic acid conjugate of	Plants	-	-	
	Rotational Crops	Wheat Forage, Hay, Straw	Wheat Grain; Turnip Leaves	
	Ruminant	-	-	
	Poultry	-	-	
	Rat	-	-	

Table 3 Tabular Summary of Metabolites and Degradates				
Chemical Name (other names in parenthesis)	Matrix	Percent TRR (PPM)[1]		Structure
		Matrices - Major Residue (>10%TRR)	Matrices - Minor Residue (<10%TRR)	
(5s,8s)-3-(2,5-dimethylphenyl)-3,8-dihydroxy-1-azaspiro[4.5]decane-2,4-dione)	Water	-	-	
Apple, 46904480; 0.982 lb ai/A; 2.5X rate; first application at growth stage 69 BBCH and the second application at growth stage 71; 63 days (fruit & leaves). *Lettuce, 46695529; 0.15 lb ai/A; 0.9X rate; two applications at a 14-day RTI; 7 days.* *Cotton, 46904479; 0.23 lb ai/A; first application at growth stage 15 BBCH and the second application at growth stage 85; 39 days (gin trash, lint and undelinted seed).* *Potato, 46904484; 0.275 lb ai/A; 1.7X rate; three applications at a 21-day RTI; 14 days.* *Cow (PH label); 46695532; 8.01 ppm; 6.8X MTDB; 7 days; 23 hour PSI* *Hen (PH label); 46695534; 11.33 ppm; 470X MTDB; 14 days; 24 hour PSI* *Rotational Crops; 46695612; Swiss chard, turnips, and spring wheat; 1.2X, applied to bare soil;90-day PBI* *Rat Metabolism; 46904504, 46904561; 2, 100, 1000 mg/kg oral dose; Wistar, 2-day depuration.*				

Hazard Characterization:

Toxicology Requirements

The requirements (40 CFR 158.340) for the use of spirotetramat on food at the time of data submission are listed in Table 4.

Table 4. Toxicology Data requirements.

Test		Technical	
		Required	Satisfied
870.1100	Acute Oral Toxicity	yes	yes
870.1200	Acute Dermal Toxicity.....	yes	yes
870.1300	Acute Inhalation Toxicity	yes	yes
870.2400	Primary Eye Irritation	yes	yes
870.2500	Primary Dermal Irritation.....	yes	yes
870.2600	Dermal Sensitization	yes	yes
870.3100	Oral Subchronic (rodent)	yes	yes
870.3150	Oral Subchronic (nonrodent)	yes	yes
870.3200	21-Day Dermal.....	yes	yes
870.3250	90-Day Dermal.....	no	-
870.3465	90-Day Inhalation	no	-
870.3700a	Developmental Toxicity (rodent).....	yes	yes
870.3700b	Developmental Toxicity (nonrodent).....	yes	yes
870.3800	Reproduction.....	yes	yes

Test	Technical	
	Required	Satisfied
870.4100a Chronic Toxicity (rodent)	yes	yes
870.4100b Chronic Toxicity (nonrodent)	yes	yes
870.4200a Oncogenicity (rat)	yes	yes
870.4200b Oncogenicity (mouse)	yes	yes
870.4300 Chronic/Oncogenicity	no	-
870.5100 Mutagenicity—Gene Mutation - bacterial	yes	yes
870.5300 Mutagenicity—Gene Mutation - mammalian	yes	yes
870.5xxx Mutagenicity—Structural Chromosomal Aberrations	yes	yes
870.5xxx Mutagenicity—Other Genotoxic Effects		
870.6100a Acute Delayed Neurotox. (hen)	no	-
870.6100b 90-Day Neurotoxicity (hen)	no	-
870.6200a Acute Neurotox. Screening Battery (rat)	yes	yes
870.6200b 90-Day Neuro. Screening Battery (rat)	no	-
870.6300 Develop. Neuro	no	-
870.7485 General Metabolism	yes	yes
870.7600 Dermal Penetration	yes	yes

Acute Toxicity

Spirotetramat technical demonstrated moderate to low acute toxicity (Toxicity Category III or IV) via the oral, dermal, and inhalation routes. Spirotetramat is non-irritating to the skin (Toxicity Category IV), although it is an irritant to the eyes (Toxicity Category II) and exhibits a skin-sensitization potential in animals and humans. Tables 5 and 6 present acute toxicity profile of technical Spirotetramat and its metabolites.

Table 5. Acute toxicity of Spirotetramat Technical.

Study/Species	MRID No. (year)/	Results	Tox. Cat.
Acute oral toxicity / rat[1]	46904527 (2004)	LD_{50} > 2000 mg/kg (females)	III
Acute dermal toxicity / rat	46904529 (2004)	LD_{50} > 2000 mg/kg (males and females)	III
Acute inhalation toxicity / rat	46904530 (2005)	LC_{50} > 4.183 mg/L (males and females)	IV
Primary eye irritation / rabbit	46904531 (2002)	Corneal opacity & Iritis (grade 1); cleared by day 8.	II

Primary dermal irritation / rabbit	46904532 (2002)	No dermal irritation	IV
Dermal sensitization / guinea pig	46904533 (2002)	Exhibits dermal sensitization potential	---
Dermal sensitization / guinea pig	46904534 (2004)	No dermal sensitization potential	---
Dermal sensitization /LLNA/mouse	46904565 (2004)	Exhibits dermal sensitization potential.	---

Table 6. Acute toxicity of Metabolites.

Study/Species	MRID	Results	Tox. Cat.
Acute oral toxicity / rat [1]	46904593 (2005)	LD_{50} > 2000 mg/kg (females)	III
Acute oral toxicity / rat [2]	46904596 (2006)	LD_{50} > 2000 mg/kg (females)	III
Acute oral toxicity / rat [3]	46904598 (2006)	LD_{50} > 2000 mg/kg (females)	III
Acute oral toxicity / rat [4]	46904603 (2005)	LD_{50} > 2000 mg/kg (females)	III

[1] BYI 08330-CIS-Ketohydroxy (Purity: 98.7%; Batch No. NL L 7549-7; light yellow solid)
[2] BYI 08330-desmethyl-ketohydroxy (Purity: 94.6%; Batch No. KATH 4726-5-1; light beige powder)
[3] BYI 08330-di-hydroxy (Purity: 94.5%; Batch No. KATH 4727-3-6; light beige powder)
[4] BYI 08330-mono-hydroxy (Purity: 98.41%; Batch No. NLL 7635-2D; white powder)

Subchronic, Chronic and Other Toxicity

The short-term and long-term toxicity of spirotetramat is well understood. The thyroid and thymus glands were target organs in oral subchronic toxicity studies in the dog; whereas, the testes-epididymides were the target organs following subchronic oral treatment of rats. Long-term toxicity studies reflected the short-term toxicological profile of spirotetramat with the thymus and thyroid as target organs following one-year oral exposure of dogs. Chronic exposure of rats to spirotetramat also reflected the subchronic pattern of testicular toxicity. No evidence of tumor formation was found following long-term studies of rodents, and spirotetramat was also negative for mutagenicity and clastogenicity in several standard *in vivo* and *in vitro* assays.

The reproductive and developmental toxicity potential of spirotetramat was tested in rats and rabbits. In addition to testicular histopathology observed following subchronic and chronic exposure of rats to spirotetramat, male reproductive toxicity was recorded in the 2-generation reproductive toxicity study. However, development of the

sexual organs of offspring (balano-preputial separation, vaginal opening) was unaffected. In an investigative study designed to explore the time of onset of testicular toxicity in rats, decreased epididymal sperm counts were noted after 10 days of exposure. Therefore, repeated dosing with spirotetramat is necessary to produce male reproductive toxicity in rats. Similar effects were observed after repeated dosing with the enol metabolite of spirotetramat. Developmental toxicity was not observed with spirotetramat in the absence of maternal toxicity in either the rat or rabbit. The subchronic and chronic toxicity profileof soirotetramat and its metabolites is summarized in Tables 7 & 8.

Table 7. Subchronic, Chronic and Genotoxicity Profile of Spirotetramat.

Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results
870.3100	28-Day oral toxicity (mouse)	46904536 (2001) Acceptable/non-guideline 0, 500 or 5000 ppm (equivalent to 0, 136.5 or 1415 mg/kg bw/day [M])	NOAEL = 5000 ppm (1415 mg/kg/day [M]). LOAEL not observed.
870.3100	90-Day oral toxicity (mouse)	46904539 (2005) Acceptable/guideline 0, 70, 350, 1700, or 7000 ppm (equivalent to 0/0, 12.8/16, 59.6/72.4, 300/389 or 1305/1515 mg/kg bw/day [M/F])	NOAEL = 7000 ppm (1305/1515 mg/kg/day [M/F]). LOAEL not observed.
870.3100	28-Day oral toxicity (rat)	46904537 (1998) Acceptable/non-guideline 0, 500 or 5000 ppm (equivalent to 0, 47.3 or 501.8 mg/kg bw/day [F])	NOAEL = 5000 ppm (501.8 mg/kg/day [F]). LOAEL not observed.
870.3100	90-Day oral toxicity (rat)	46904538 (2005) Acceptable/guideline 0, 150, 600, 2500, or 10000 ppm (equivalent to 0/0, 9/11, 26/46, 148/188 or 616/752 mg/kg bw/day [M/F])	NOAEL = 2500 ppm (148/188 mg/kg/day [M/F]). LOAEL = 10000 ppm (616/752 mg/kg/day [M/F]), based on decreased body weight, abnormal spermatozoa and hypospermia in the epididymis, decreased testicular weight, and testicular degeneration and vacuolation in males; and alveolar macrophages in both sexes.
870.3150	28-Day oral toxicity (dog)	46904572 (2004) Acceptable/non-guideline 0, 100, 400, 1600, or 6400 ppm (equivalent to 0/0, 3/3, 13/12, 42/70, or 104/127 mg/kg/day [M/F])	NOAEL = 1600 ppm (42/70 mg/kg/day [M/F]). LOAEL = 6400 ppm (104/127 mg/kg/day [M/F]) based on decreased thymus size and weight as well as decreased body weight and food consumption, which resulted in emaciation.
870.3150	90-Day oral toxicity (dog)	46904541 (2005) Acceptable/guideline 0, 150, 300, 1200, or 4000/2500 ppm (equivalent to 0/0, 5/6, 9/10, 33/32, or 81/72 mg/kg bw/day)	NOAEL = 1200 (32 mg/kg/day)[F] & 2500 ppm (81 mg/kg/day)[M]. LOAEL = 2500 ppm (72 mg/kg/day)[F] based on decreased body-weight gain and food consumption, depressed RBC parameters (red blood cell count, hemoglobin level and hematocrit), and thymus atrophy.
870.3200	28-Day dermal toxicity (rat)	46904542 (2006) Acceptable/guideline 0, 100, 300, or 1000 mg/kg bw/day (limit dose)	NOAEL = 1000 mg/kg/day. LOAEL not established.

Table 7. Subchronic, Chronic and Genotoxicity Profile of Spirotetramat.

Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results
870.3700a	Prenatal developmental (rat)	46904543 (2004) Acceptable/guideline 0, 20, 140, or 1000 mg/kg bw/day	**Maternal** NOAEL = 140 mg/kg/day. LOAEL = 1000 mg/kg/day based on impaired food consumption, transient body weight loss, impaired body-weight gain, and reduced final body weight. **Developmental** NOAEL = 140 mg/kg/day. LOAEL = 1000 mg/kg/day based on reduced fetal weight and increased incidences of malformations and skeletal variations.
870.3700b	Prenatal developmental (rabbit)	46904544 (2004) Acceptable/guideline 0, 10, 40 or 160 mg/kg bw/day	**Maternal** NOAEL = 10 mg/kg/day. LOAEL = 40 mg/kg/day based on late abortion (≥GD 22), clinical signs, impaired food and water consumption and body weight loss. **Developmental** NOAEL = 160 mg/kg/day. LOAEL not observed.
870.3800	1-gen. reproduction and fertility effects (rat) – range finding	46904571 (2006) Acceptable/non-guideline 0, 200, 500, 6000 or 10000 ppm (equivalent to 0/0, 10.5/12.8, 27.8/31.4, 320.1/384.1, or 537.9/645.7 mg/kg bw/day [M/F])	**Parental/Systemic** NOAEL = 500 ppm (27.8 and 31.4 mg/kg bw/day [M/F]). LOAEL =6,000 ppm (320.1 and 384.1 mg/kg bw/day [M/F]) based on decreased body-weight gain (P females) and terminal body weight (F_1 males). **Reproductive** NOAEL = 500 ppm (27.8 mg/kg bw/day [M]) and 10,000 ppm (645.7 mg/kg/day) [F]. LOAEL = 6,000 ppm (320.1 mg/kg bw/day [M]) based on decreased sperm motility and progression and increased abnormal sperm cells in the F_1 males. **Offspring** NOAEL = 500 ppm (27.8 and 31.4 mg/kg bw/day [M/F]). LOAEL = 6,000 ppm (320.1 and 384.1 mg/kg bw/day [M/F]) based on decreased body weight and body-weight gain during lactation in F_1 pups.

Table 7. Subchronic, Chronic and Genotoxicity Profile of Spirotetramat.

Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results
870.3800	2-gen. reproduction and fertility effects (rat)	46904546 (2006) Acceptable/guideline 0, 250, 1,000 or 6,000 ppm (equivalent to 0/0, 17.2/20, 70.7/82.5 or 419.3/484.7 mg/kg bw/day [M/F])	**Parental/Systemic** NOAEL = 1000 ppm (70.7/82.5 mg/kg/day [M/F]). LOAEL = 6000 ppm (419.3/484.7 mg/kg/day [M/F]) based on decreases in body weight (F_1 males and females), weight gain (P males, F_1 males and females), and food consumption during lactation (P- and F_1-generation females); and kidney histopathology and decreased kidney weights (F_1 males and females). **Reproductive** NOAEL = 1000 ppm (70.7 mg/kg/day)[M] & 6000 ppm (484.7 mg/kg/day)[F]. LOAEL = 6000 ppm (419.3 mg/kg/day)[M] based on abnormal sperm cells and decreased reproductive performance in the F_1 males. **Offspring** NOAEL = 1000 ppm (70.7/82.5 mg/kg/day [M/F]). LOAEL = 6000 ppm (419.3/484.7 mg/kg/day [M/F]) based on decreased body weight and body-weight gain during lactation in both F_1 and F_2 generations.
870.4100	Chronic toxicity (1 year; dog)	46904548 (2006) Acceptable/guideline 0, 200, 600 or 1800 ppm (equivalent to 0/0, 6/5, 20/19, or 55/48 mg/kg/day [M/F])	NOAEL = 200 ppm (6 mg/kg/day)[M] & 1800 ppm (48 mg/kg/day)[F]. LOAEL = 600 ppm (20 mg/kg/day)[M] based on thymus involution [M] and not observed [F]..
870.4100	Chronic toxicity (1 year; rat)	46904547 (2005) Acceptable/guideline 0, 250, 3500, or 7500/12000 ppm (M/F) (equivalent to 0/0, 13.2/18, 189/255, or 414/890 mg/kg bw/day [M/F])	NOAEL = 250 ppm (13.2 mg/kg/day)[M] & 3500 ppm (255 mg/kg/day)[F]. LOAEL = 3500 ppm (189 mg/kg/day)[M] based on dose-dependent increase in alveolar macrophages; & 12000 ppm (890 mg/kg/day)[F] based on decreased body weight and body-weight gain, alveolar macrophages, discoloration of the lung, and yellow/brown staining of the perigenital area and tail.
870.4200	Carcinogenicity (rat)	46904549 (2006) Acceptable/guideline 0, 250, 3500, or 7500/12000 ppm (M/F) (equivalent to 0/0, 12.5/16.8, 169/229, or 373/823 mg/kg bw/day [M/F])	NOAEL = 250 ppm (12.5/16.8 mg/kg/day [M/F]). LOAEL = 3500 ppm (169/229 mg/kg/day [M/F]) based on decreased kidney weight and renal tubular dilation. No evidence of carcinogenicity.

Table 7. Subchronic, Chronic and Genotoxicity Profile of Spirotetramat.

Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results
870.4200	Carcinogenicity (mouse)	46904550 (2006) Acceptable/guideline 0, 70, 1700 or 7000/6000 ppm (M/F) (equivalent to 0/0, 10.9/13.7, 263/331, or 1022/1319 mg/kg/day [M/F])	NOAEL = 7000/6000 ppm (1022/1319 mg/kg/day [M/F]). LOAEL not observed. No evidence of carcinogenicity.
870.5100	Bacterial Gene Mutation	46904551 (2006) Acceptable/guideline 0, 16, 50, 158, 500, 1581 or 5000 µg/plate +/- S9 activation	Negative.
870.5100	Bacterial Gene Mutation	46904552 (2002) Acceptable/guideline 0, 16, 50, 158, 500, 1581 or 5000 µg/plate +/- S9 activation	Negative.
870.5300	Mammalian Gene Mutation	46904553 (2002) Acceptable/guideline 0, 2.5, 5, 10, 20, 30, 40, 50, 60, 70, or 80 µg/mL (-S9) 0, 20, 40, 60, 80, 92, 100, 108, 116, 120, 124, 132, or 140 µg/mL (+S9)	Negative.
870.5375	In vitro mammalian chromosome aberration	46904554 (2002) Acceptable/guideline 0, 10, 12, 24, 30, 48, or 50 µg/mL (-S9) 0, 20, 40 or 80 µg/mL (+S9)	Weakly clastogenic at cytotoxic concentrations only.
870.5375	In vitro mammalian chromosome aberration	46904555 (2003) Unacceptable/guideline 0, 30, 50, 70, 90 or 110 µg/mL (-S9) 0, 40, 60, 80, 100 or 120 µg/mL (+S9)	N/A
870.5395	*In vivo* erythrocyte micronucleus assay (mouse)	46904556 (2002) Acceptable/guideline 0, 125, 250, or 500 mg/kg bw	Negative.

Table 7. Subchronic, Chronic and Genotoxicity Profile of Spirotetramat.

Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results
870.5385	*In vivo* bone marrow chromosomal aberration assay (mouse)	46904558 (2003) Acceptable/guideline 0, 125, 250 or 500 mg/kg bw	Negative.
870.5550	*In vivo*/*in vitro* UDS assay (rat hepatocytes)	46904557 (2003) Acceptable/guideline 0, 1000, or 2000 mg/kg bw	Negative.
870.6200a	Acute neurotoxicity screening battery	46904560 (2005) Acceptable/guideline 0, 50, 100, 200, 500 or 2000 mg/kg bw	NOAEL = 100 mg/kg/day. LOAEL = 200 mg/kg/day based on clinical signs (males and females) and decreased motor activity (males).
870.7485	Metabolism and pharmacokinetics (rat)	46904504 (2006) Acceptable/guideline 2 or 100 mg/kg bw (single) 2 mg/kg bw (repeat)	Absorption: 89-98% after 48 hrs (no significant differences among low dose, high dose, and repeated dose tests). Distribution: $AUC_{0-\infty}$ (measure of systemic exposure) slightly higher for males than females; <0.2% of administered dose detected in body 48 hrs after sacrifice; highest equivalent concentrations detected in liver and kidney. Metabolism: parent compound undetected in urine and feces of all tests; main metabolic reaction was cleavage of the ester group which resulted in formation of the primary metabolite BYI 08330-enol (53-87% of administered dose); all other identified metabolites could be derived from enol; male rats exhibited much higher rates of demethylation of BYI 08330-enol to BYI 08330-desmethyl-enol (25-37%) vs. females rats (5-10 %). Excretion: 88-95% of administered dose eliminated via urine and 2-11% via feces within 48 hrs.
870.7485	Metabolism and pharmacokinetics (rat)	46904561 (2006) Acceptable/guideline 2 or 1000 mg/kg bw (single)	At 1000 mg/kg bw: Absorption and excretion less than low dose, with 27% of dose excreted in urine after 24 hours (18% in feces); plasma radioactivity slightly higher than in liver and kidney; these results are consistent with saturation of cellular transport mechanisms. Tissue radioactivity decreased from 1 h to 24 h post dose. Metabolism profile qualitatively similar to that of the low dose; BYI 08330-enol was most prominent metabolite; similar to low dose group, BYI 08330-desmethyl-enol levels greater in urine than in plasma and organs.

Table 7. Subchronic, Chronic and Genotoxicity Profile of Spirotetramat.

Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results
870.7600	*In vivo* dermal penetration (rat)	46904563 (2006) Acceptable/guideline 100, 15, or 5 µg ai/cm^2 (OD150 formulation)	Dermal absorption = 10%.
Special study	Male reproductive toxicity	46904569 (2005) Acceptable/non-guideline 1000 mg/kg bw/day (3, 10, 21 or 41 days)	Primary testicular effects on or after day 10 were degeneration of round and elongating spermatids (stage 7-8 and 9-14, respectively), decreased sperm count, and increased numbers of aberrant/abnormal spermatozoa in the epididymis.

Table 8. Subchronic, Chronic, and Other Toxicity of Metabolites.

Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results
Exploratory study	10-day gavage (enol metabolite)	46904601 (2006) Acceptable/non-guideline 800 mg/kg bw/day	Decreased BWG; histopathology not evaluated.
Special study	21-day gavage (enol metabolite)	47070901 (2006) Acceptable/non-guideline 800 mg/kg bw/day	Clinical signs of toxicity, decreased BWG, Testicular/spermatotoxicity.
870.5100	Bacterial Gene Mutation (ketohydroxy metabolite)	46904594 (2005) Acceptable/guideline 0, 16, 50, 158, 500, 1581 or 5000 µg/plate +/- S9 activation	Negative.
870.7485	Metabolism and Pharmacokinetics (rat) (ketohydroxy metabolite)	46904595 (2006) Acceptable/guideline 2 mg/kg bw (single)	Absorption: ≥55% after 48 hrs. Distribution: highest concentrations detected in GI, liver, and kidney; <0.2% of administered dose detected in body 48 hrs post dose. Metabolism: parent compound undetected in urine and trace amounts in feces; main metabolic reaction was oxidative demethylation of cyclohexyl-O-methyl group to form desmethyl-ketohydroxy metabolite (15% of administered dose); all other identified metabolites could be derived from desmethyl-ketohydroxy metabolite. Excretion: 54% of administered dose eliminated via urine and 44% via feces within 48 hrs.

Guideline No.	Study Type	MRID No. (year)/ Classification /Doses	Results
870.5100	Bacterial Gene Mutation (desmethyl-ketohydroxy metabolite)	46904597 (2006) Acceptable/guideline 0, 16, 50, 158, 500, 1581 or 5000 µg/plate +/- S9 activation	Negative.
870.5100	Bacterial Gene Mutation (dihydroxy metabolite)	46904599 (2005) Acceptable/guideline 0, 16, 50, 158, 500, 1581 or 5000 µg/plate +/- S9 activation	Negative.
870.7485	Metabolism and Pharmacokinetics (rat) (enol glucoside metabolite)	46904602 (2006) Acceptable/non-guideline 0.1 mg/kg bw (single; 1 rat)	Absorption: 54% after 48 hrs. Distribution: plasma concentrations peaked 4 hrs post dose; 1% of administered dose detected in body 48 hrs post dose. Metabolism: parent compound detected in feces (21%); main metabolite was enol (64% of administered dose). Excretion: 53% of administered dose eliminated via urine and 44% via feces within 48 hrs.
870.5100	Bacterial Gene Mutation (monohydroxy metabolite)	46904604 (2005) Acceptable/guideline 0, 16, 50, 158, 500, 1581 or 5000 µg/plate +/- S9 activation	Negative.

Food Quality Prtotection Act (FQPA) Decisions

The 10X FQPA safety factor (SF) was reduced to 1X for spirotetramat, based on the following:

- There was no evidence of increased susceptibility of offspring following pre- or post-natal exposure in any study. In the rat developmental toxicity study, toxicity to offspring was observed at the same dose as maternal toxicity, which was also the limit dose. In the developmental toxicity study in the rabbit, only maternal toxicity was observed. In both reproductive toxicity studies, toxicity to offspring (decreased body weight) was observed at the same dose as parental toxicity. Therefore, no evidence of increased susceptibility of offspring was found across four relevant toxicity studies with spirotetramat.
- Spirotetramat does not operate by way of a neurotoxic mechanism of action in target pests.
- Spirotetramat is not considered a neurotoxic chemical in mammals. Clinical signs of toxicity and decreased motor activity were observed in adult rats following a single dose of spirotetramat in the acute neurotoxicity study in the rat; however,

these effects only attained statistical significance at high doses and were not observed at the limit dose in the acute oral toxicity study in the rat.

- There is no concern for neurotoxicity with spirotetramat in the developing animal based on the fact that brain dilation in the one-year dog study is most likely a congenital anomaly that was not observed in any other study in the database, and the fact that the structurally related Bayer compounds spirodiclofen and spiromesifen are not neurotoxic in adults or young.
- The dietary food exposure assessment utilizes tolerance-level residues and 100% crop treated (CT) information for all proposed commodities. By using this screening-level assessment, the acute and chronic exposures/risks will not be underestimated.
- The dietary drinking water assessment (Tier 1 estimates) utilizes values generated by model and associated modeling parameters which are designed to provide conservative, health-protective, high-end estimates of water concentrations.
- There are no registered or proposed uses of spirotetramat which would result in residential exposure.

Toxicological Endpoints:

Toxicological doses and endpoints for spirotetramat for use in dietary and occupational human health risk assessments are summarized in Tables 9 and 10 below:

Table 9. Summary of Toxicological Doses and Endpoints for Spirotetramat for Use in Dietary Human Health Risk Assessments.

Exposure Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Relevant Toxicological Effects
Acute Dietary (General Population, including Infants and Children)	NOAEL = 100 mg/kg/day	UF_A = 10X UF_H = 10X UF_{FQPA} = 1X	aRfD = aPAD = 1.0 mg/kg/day	**Acute neurotoxicity (rat; gavage)** LOAEL = 200 mg/kg based on clinical signs (M&F) and decreased motor activity (M).
Chronic Dietary (All populations)	NOAEL = 5 mg/kg/day	UF_A = 10X UF_H = 10X UF_{FQPA} = 1X	cRfD = cPAD = 0.05 mg/kg/day[1]	**Chronic toxicity (dog; dietary)** LOAEL = 20 mg/kg/day (M) based on thymus involution.
Cancer (oral, dermal, inhalation)	Classification: "Not Likely to be Carcinogenic to Humans" based on lack of evidence of carcinogenicity in two oral rodent carcinogenicity studies.			

Abbreviations: UF = uncertainty factor, UF_A = extrapolation from animal to human (interspecies), UF_H = potential variation in sensitivity among members of the human population (intraspecies), UF_{FQPA} = FQPA Safety Factor, NOAEL = no-observed adverse-effect level, LOAEL = lowest-observed adverse-effect level, RfD = reference dose (a = acute, c = chronic), PAD = population-adjusted dose, MOE = margin of exposure, LOC = level of concern.

[1] The cRfD has been harmonized across American (USEPA), Canadian (PMRA), and Austrian (AGES) regulatory agencies. However, it is noted that USEPA considered a NOAEL=6 mg/kg/day in males and a NOAEL=19 mg/kg/day in females to more accurately reflect the toxicological data. The difference between 5 mg/kg/day (NOAEL in females for PMRA and AGES) and 6 mg/kg/day was considered negligible for risk assessment.

The aRfD for the general population, including females 13-49 years of age, was established based on the NOAEL (100 mg/kg/day) from the acute neurotoxicity study in rats. The LOAEL of 200 mg/kg/day is based on clinical signs of toxicity in males and females and decreased motor activity in males. This study and endpoint are the most appropriate single-dose effects for the general population, including women of childbearing age. For reasons outlined below, the 10X FQPA SF has been reduced to 1x.

The cRfD was established based on the NOAEL (5 mg/kg/day) from the 1-year toxicity study in the dog. The LOAEL of 20 mg/kg/day is based on thymus involution in males. The NOAEL of 5 mg/kg is the lowest in the database. In addition, the study duration is appropriate for the duration of exposure. For reasons outlined below, the 10X FQPA SF has been reduced to 1x.

Table 10. Summary of Toxicological Doses and Endpoints for Spirotetramat for Use in Occupational Human Health Risk Assessments.

Exposure Scenario	Point of Departure	Uncertainty Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Dermal Short- and Intermediate-Term (1-30 days and 1-6 months)	NOAEL = 10 mg/kg/day Dermal absorption factor = 10%	UF_A = 10X UF_H = 10X	Occupational LOC for MOE <100	**Prenatal developmental toxicity (rabbit)** Maternal LOAEL = 40 mg/kg/day based on late abortion (≥GD 22), clinical signs, impaired food and water consumption and body weight loss.
Dermal Long-Term (>6 months)	NOAEL = 5 mg/kg/day Dermal absorption factor = 10%	UF_A = 10X UF_H = 10X	Occupational LOC for MOE <100	**Chronic toxicity (dog; dietary)** LOAEL = 20 mg/kg/day (M) based on thymus involution.
Inhalation Short- and Intermediate-Term (1-30 days and 1-6 months)	NOAEL = 10 mg/kg/day 100% inhalation assumed	UF_A = 10X UF_H = 10X	Occupational LOC for MOE <100	**Prenatal developmental toxicity (rabbit)** Maternal LOAEL = 40 mg/kg/day based on late abortion (≥GD 22), clinical signs, impaired food and water consumption and body weight loss.
Inhalation Long-Term (>6 months)	NOAEL = 5 mg/kg/day 100% inhalation assumed	UF_A = 10X UF_H = 10X	Occupational LOC for MOE <100	**Chronic toxicity (dog; dietary)** LOAEL = 20 mg/kg/day (M) based on thymus involution.
Cancer (oral, dermal, inhalation)	Classification: Not likely to be carcinogenic to humans based on lack of evidence of carcinogenicity in two oral rodent carcinogenicity studies.			

Abbreviations: UF = uncertainty factor, UF_A = extrapolation from animal to human (interspecies), UF_H = potential variation in sensitivity among members of the human population (intraspecies), UF_{FQPA} = FQPA Safety Factor, NOAEL = no-observed adverse-effect level, LOAEL = lowest-observed adverse-effect level, RfD = reference dose (a = acute, c = chronic), LOC = level of concern.

4. HUMAN HEALTH EXPOSURE AND RISK ASSESSMENT

Residue Profile:

Dietary Exposure and Risk:

Risk assessments were conducted for the following exposure scenarios: The acute and chronic reference doses (aRfD and cRfD) were calculated by dividing the no-observed-adverse-effect-level (NOAEL) by 100 (10X for interspecies extrapolation and 10X for intraspecies variation). Since the FQPA SF has been reduced to 1X, the acute and chronic

population-adjusted doses (aPAD and cPAD) are equal to the aRfD and cRfD, respectively. A 100% oral-equivalent inhalation-absorption factor is assumed. The level of concern (LOC) for occupational dermal and inhalation exposures are for margins of exposure (MOEs) <100 (Table 11).

Table 11. Exposure (aRfD, cRfD, and occupational) Scenarios for Spirotatramat.

Exposure Scenario	Point of Departure	RfD, PAD, LOC for Risk Assessment	Study/Effect
Acute dietary	NOAEL = 100 mg/kg/day	aRfD = aPAD = 1.0 mg/kg/day	Acute neurotoxicity in rats (gavage)/Clinical signs (M&F) and decreased motor activity (M) seen at the lowest-observed-adverse-effect-level (LOAEL) of 200 mg/kg/day.
Chronic dietary	NOAEL = 5 mg/kg/day	cRfD = cPAD = 0.05mg/kg/day	Chronic toxicity study in dogs (dietary)/Thymus involution seen at LOAEL of 20 mg/kg/day (M).
Short- and Intermediate-term dermal	NOAEL = 10 mg/kg/day	LOC for MOE < 100 (occupational)	Prenatal developmental study in rabbits/ Late abortion (≥GD 22), clinical signs, impaired food and water consumption and body weight loss seen at maternal LOAEL of 40 mg/kg/day.
Short- and Intermediate-term inhalation	NOAEL = 10 mg/kg/day	LOC for MOE < 100 (occupational)	Prenatal developmental study in rabbits/ Late abortion (≥GD 22), clinical signs, impaired food and water consumption and body weight loss seen at maternal LOAEL of 40 mg/kg/day.

Residue Chemistry, Analytical Methodology, and Drinking Water Assessment:

The residue chemistry and drinking water databases are adequate to assess potential human exposure to spirotetramat.

The residues of concern in plants (primary crops) for tolerance expression and risk assessment purposes are spirotetramat and its metabolites BYI 08330-enol, BYI 08330-ketohydroxy, BYI08330-enol-Glc, and BYI 08330-mono-hydroxy. The residues of concern for rotational crops are spirotetramat and BYI 08330-ketohydroxy and free and conjugated BYI 08330-desmethyl-ketohydroxy, BYI 08330-desmethyl-di-hydroxy and BYI 08330-ketohydroxy-alcohol. Based on the currently proposed uses, the residues of concern for the tolerance expression for livestock commodities are spirotetramat and its metabolite BYI 08330-enol and the residues of concern for the risk assessment for livestock commodities are spirotetramat and its metabolites BYI 08330-enol and BYI 08330-enol-GA. If future proposed uses result in significant exposure of livestock to the plant metabolites BYI 08330-ketohydroxy, BYI08330-enol-Glc, and BYI 08330-mono-hydroxy, then these metabolites may need to be included as additional residues of concern for livestock commodities. For drinking water, the residues of concern for risk assessment purposes are spirotetramat, BYI 08330-enol, and BYI 08330-ketohydroxy.

Adequate crop field trial data have been submitted for citrus, cucurbit vegetables, fruiting vegetables, grapes, hops, leafy *Brassica* vegetables, leafy non-*Brassica* vegetables, pome fruit, tuberous and corm vegetables, stone fruit, and tree nuts and the European residue for strawberries and onions data are adequate. For all commodities, the data reflect the maximum rates and minimum preharvest intervals (PHIs) requested and have sufficient geographic representation to support tolerances for the proposed uses. All crop field trial studies are supported by adequate storage stability data. Adequate processing data indicate that tolerances should be established for citrus oil, raisins, potato flakes, and almond hulls. Based on the available livestock feeding study, it was determined that tolerances on several

livestock commodities should be established.

The Agency has determined that high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) Methods 00857 and 00966 are suitable enforcement methods for plant and livestock commodities, respectively, since the methods passed a successful petition method validation (PMV) by Agency chemists at ACL/BEAD. The existing confined and field rotational crop data are adequate to support the proposed rotational crop restrictions.

Spirotetramat and its metabolites, BYI 08330-enol, BYI 08330-ketohydroxy and BYI 08330-MA-amide, were highly mobile to moderately mobile, and low levels of binding are expected. It appears that spirotetramat metabolites BYI 08330-enol and BYI 08330-ketohydroxy are of high concern because the parent and BYI 08330 degrade relatively fast in most environments. Tier 1 estimated drinking water concentrations (EDWCs) for surface and ground water were generated using the FQPA Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, respectively.

Dietary (Food and Drinking Water) Exposure Estimates:

Acute and chronic dietary exposure analyses were conducted using the Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FCID™; ver. 2.03) program which incorporates consumption data from the United States Department of Agriculture's (USDA's) Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996/1998. For acute and chronic dietary risk estimates, Agency's level of concern is for estimates that exceed 100% aPAD or cPAD, respectively. Drinking water was incorporated directly in the dietary assessment using the acute or chronic concentrations for surface water generated by the FIRST model.

The acute analysis assumed 100% CT and tolerance-level residues for all foods. Empirical and DEEM™ (ver. 7.81) default processing factors were used for processed commodities. The acute dietary exposure estimates (95th percentile) are below the Agency's level of concern (<100% of the aPAD) for the general U.S. population (4.2% of the aPAD) and all other population subgroups. The most highly exposed population subgroup is children 1-2 years old at 10% of the aPAD.

A conservative chronic dietary assessment assuming average field-trial residues, empirical and DEEM™ (ver. 7.81) default processing factors, and 100% CT was also conducted. The chronic dietary exposure estimates are below the Agency's level of concern (<100% of the cPAD) for the general U.S. population (28% of the cPAD) and all population subgroups. The most highly exposed population subgroup is children 1-2 years old at 77% of the cPAD.

These assumptions result in conservative, health-protective estimates of exposure which are well below the Agency's level of concern (100% of the aPAD and cPAD). The maximum estimate is less than 1% of the cPAD for all population subgroups. These analyses indicate that there are no dietary exposure considerations that would preclude registration of spirotetramat for the requested uses. Table 12 summarizes the dietary (food

and drinking water) exposure/risk for Spirotetramat.

Table 12. Summary of Dietary (Food and Drinking Water) Exposure Risk for Spirotetramat.

Population Subgroup	Acute Dietary (95th Percentile)		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.042364	4.2	0.013768	28
All Infants (<1 year old)	0.081433	8.1	0.019464	39
Children 1-2 years old	0.102892	**10**	0.038373	**77**
Children 3-5 years old	0.080506	8.1	0.029638	59
Children 6-12 years old	0.050723	5.1	0.018032	36
Youth 13-19 years old	0.035371	3.5	0.011795	24
Adults 20-49 years old	0.033504	3.4	0.011145	22
Adults 50+ years old	0.033253	3.3	0.011139	22
Females 13-49 years old	0.033564	3.4	0.011180	22

*The values for the highest exposed population for each type of risk assessment are bolded.

Residential (Non-Occupational) Exposure/Risk Characterization:

There are currently no registered or proposed residential uses for spirotetremat. Therefore a residential exposure assessment was not conducted.

Aggregate Risk:

Aggregate exposure risk assessments were performed for the following scenarios: acute aggregate exposure (food and drinking water), and chronic aggregate exposure (food and drinking water). Short- and intermediate-term assessments, which are used to evaluate aggregate dietary and residential exposures, were not performed because there are no registered or proposed residential non-food uses.

Acute Risk. The acute aggregate risk assessment takes into account exposure estimates from dietary consumption of spirotetremat (food and drinking water). The acute dietary exposure estimates are not of concern (<100% aPAD) at the 95th exposure percentile for the general U.S. population and all other population subgroups (see Table 12). The dietary exposure assessment was a screening-level assessment, utilizing tolerance-level residues and 100% CT information for all proposed agricultural uses and a Tier 1 acute surface water EDWCs generated by FIRST. Therefore, the acute aggregate risk associated with the proposed uses of spirotetramat is not of concern for the general U.S. population or any population subgroups.

Chronic Risk. The chronic aggregate risk assessment takes into account average exposure estimates from dietary consumption of spirotetramat (food and drinking water). The chronic dietary exposure estimates are not of concern (<100% cPAD) for the general U.S. population and all population subgroups (see Table 12). The dietary exposure assessment was a conservative assessment, utilizing average field-trial residues and 100% CT information for all proposed agricultural uses and a Tier 1 chronic surface water EDWCs generated by FIRST. Therefore, the chronic aggregate risk associated with the proposed uses of spirotetramat is not of concern for the general U.S. population or any population subgroups.

Cancer Risk. Spirotetramat is classified as "Not Likely to be Carcinogenic to Humans;" therefore, cancer aggregate risk assessments were not performed.

Determination of Safety. Based on the risk assessments, we conclude that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to chlorantraniliprole residues.

Occupational Exposure/Risk:

Based on the proposed use patterns, occupational handler and post-application exposure to spirotetramat is expected.

Short-term (1-30 days) dermal and inhalation exposures are expected for commercial and private applicators. However, the short- and intermediate-term toxicological endpoints are the same; therefore, the estimates of risk for short-term duration exposures are protective of those for intermediate-term duration exposures. The most highly exposed occupational workers are expected to be mixer/loaders of liquids for aerial applications, applicators using air blast equipment, and mixer/loader/applicators of liquid concentrates using high-pressure hand wand equipment. No chemical-specific data are available with which to assess potential exposure to pesticide handlers; therefore, estimates of exposure are based on data available in the Pesticide Handler Exposure Database Version 1.1 (PHED Surrogate Exposure Guide, 8/98). Exposure/risks for short-term dermal and inhalation handler mixer/loader exposures were presented at baseline (workers wearing a single layer of work clothing consisting of a long-sleeved shirt, long pants, shoes plus socks and no protective gloves). Provided workers wear protective gloves as recommended on the label, all occupational handler MOEs are >100; and, therefore, are not of concern (*i.e.*, MOE>100). Table 13 presents the exposure/risks for short and intermediate-term dermal and inhalation exposures at baseline and with gloves.

Table 13. Occupational Handler Dermal and Inhalation Exposures and Risks.

Dermal and Inhalation Unit Exposures (mg/lb ai)	Application rate (lb ai/A)[a]	Area Treated Daily (A)[b]	Short- and Intermediate-term Doses (mg/kg/day)[c]	Short- and Intermediate-term MOEs[d]	Combined Short- and Intermediate-term MOEs[i]
Mixer/Loader – Aerial Application					
Dermal Baseline[e]: 2.9 (HC)[h] Single layer w/gloves[g]: 0.023 (HC) Inhalation Baseline[f]: 0.0012 (HC)	0.16	350	Dermal Baseline: 0.27 Single layer w/gloves: 0.0021 Inhalation Baseline: 0.0011	Dermal Baseline: 37 Single layer w/gloves: 4700 Inhalation Baseline: 8,900	Baseline: 37 Single layer w/gloves: 3100
Applicator –Airblast Application					
Dermal Baseline: 0.36 (HC) Single layer w/gloves[g]: 0.24 Inhalation Baseline: 0.0045 (HC)	0.16	40	Dermal Baseline: 0.0038 Single layer w/gloves: 0.0026 Inhalation Baseline: 0.00048	Dermal Baseline: 2,600 Single layer w/gloves: 3900 Inhalation Baseline: 21,000	Baseline: 2,300 Single layer w/gloves: 3,200
Mixer/Loader – High Pressure Handwand					
Dermal Baseline: No Data Single layer w/gloves[g]: 2.5 (LC) Inhalation Baseline: 0.12 (LC)	0.00125 lb ai/gallon	1000 gallons	Dermal Single layer w/gloves: 0.0052 Inhalation Baseline: 0.0025	Dermal Single layer w/gloves: 1,900 Inhalation Baseline: 4,000	Single layer w/gloves: 1300

a. Application rates are the maximum recommended rates provided on the spirotetramat product labels.
b. Area treated per day and amount handled values are HED estimates based on ExpoSAC Policy #9 "Standard Values for Daily Acres Treated in Agriculture," industry sources, and HED estimates.
c. Dose (mg/kg/day) = Unit exposure(mg/lb ai) x App Rate (lb ai/acre or lb ai/gallon) x Area Treated/Amount Handled (acres/day or gallons/day) x %Absorption (10% dermal and 100% inhalation assumed) / Body weight (60 kg).
d. MOE = NOAEL/Dose; where the short- and intermediate-term dermal and inhalation NOAEL = 10 mg/kg/day .
e. Baseline Dermal: Long-sleeve shirt, long pants, and no gloves.
f. Baseline Inhalation: no respirator.
g. Single layer w/gloves: Single layer baseline attire plus chemical-resistant gloves.
h. Data Confidence for PHED unit exposures: LC = Low Confidence, MC = Medium Confidence, HC = High Confidence.
i.. Combined MOE = NOAEL / (dermal + inhalation daily dose).

Short- and intermediate-term (1-30 days and 1-6 months, respectively) dermal exposures are expected for post-application agricultural activities. Post-application inhalation exposure is expected to be negligible due to the low vapor pressure of spirotetramat. There are no chemical-specific data with which to estimate post-application exposure of agricultural workers to dislodgeable residues of spirotetramat. Therefore, post-application worker exposure was estimated using Agency default assumptions for dislodgeable residues, which lists scouting and irrigating as the activities with the highest

(*i.e.*, most conservative) transfer coefficients (TCs) related to the proposed uses. All MOEs are >100; therefore, post-application dermal exposure to agricultural workers is not of concern (*i.e.*, MOE >100). Table 14 presents a summary of occupational post-application risks.

Table 14 Summary of Occupational Post-application Risks for Spirotetramat.

Crop Grouping	Application rate (lb ai/A)	TC (µg/cm^2)	Day after Treatment	Short- and Intermediate-term MOE at Day 0 (Level of Concern = 100)
Vine / trellis	0.125	10,000 (Tying (Cane turning); Turning (Cane turning); Girdling)	0 (12 hours)	270
Tree, "fruit", evergreen	0.16	8,000 (Hand-harvest; Staking; Topping; Training)		260

Based on the acute Toxicity Category classification for spirotetramat, the interim Worker Protection Standard (WPS) REI of 24 hours is adequate to protect agricultural workers from post-application exposures.

5. ENVIRONMENTAL EXPOSURE AND RISK

Environmental Fate Characteristics:

There are two possible stereoisomers of spirotetramat, *cis*- and *trans*-isomers; but only the *cis*-isomer is the active material. The ratio of *cis*- to *trans*-isomers is about 98:2. Spirotetramat's major transformation product, spirotetramat-enol, is the product of the hydrolytic cleavage of the ester bond in the parent, resulting in an alcohol. Spirotetramat-enol is further oxidized at the benzylic carbon to yield spirotetramat-ketohydroxy, another major metabolite. For the structure of spirotetramat and its metabolites, please refer to Table 1 in this document.

Although acute toxicity data with aquatic receptors suggest that the degradates are equivalent to (for duckweed) or lower in toxicity than the parent (all other instances) for the taxonomic groups tested, the data set is incomplete and there is insufficient evidence for drawing the same conclusion for terrestrial organisms. Therefore, this assessment conservatively assumed equivalent toxicity among them and included the two transformation products in exposure modeling and subsequent risk calculations. The potential presence of these major metabolites was accounted for because they may be of concern in soils, sediments, and water due to their high concentrations in the laboratory studies (spirotetramat–enol) and their persistence relative to the parent (spirotetramat–ketohydroxy).

Exposure Characterization

Spirotetramat may degrade/ transform through various routes, which include hydrolysis in alkaline media, photolysis in natural water and biodegradation in aerobic and

anaerobic environments, both in soil and aquatic media (calculated half-dissipation times or DT_{50}'s range <<1-2.8 days). Hydrolysis in neutral and acidic environments (DT_{50}'s 8.6-47.6 days at pH's 4-7 and 20-25°C) and photolysis in sterile buffered solution (DT_{50} = 14.4 Phoenix, AZ days) appear to be routes of transformation of lower importance for spirotetramat. For the soil metabolism studies, the proposed transformation pathway involves the hydrolytic cleavage of the spirotetramat ester moiety into spirotetramat-enol (assumed to be quantitative); subsequently, spirotetramat-enol is oxidized at the benzylic carbon position into spirotetramat-ketohydroxy. Spirotetramat-enol may further yield other minor transformation products. Several of the metabolism studies follow a similar transformation pathway. For the structure and nomenclature of spirotetramat and its major metabolites, please, refer to Table 1.

Spirotetramat-enol is also generally short lived in aerobic soil environments (DT_{50} <1 day), but could be more persistent to hydrolysis or in aquatic or anaerobic media (stable to hydrolysis; DT_{50} = 37.9-59.0 days to aerobic aquatic metabolism; stable to anaerobic soil and aquatic metabolism). Spirotetramat-ketohydroxy showed DT_{50}'s ranging from 1.5 to 16.7 days in aerobic soils [maximum of 24.0% of the applied radioactivity (AR)]. These results are generally supported by an aerobic outdoors study in which spirotetramat degraded quickly (DT_{50}'s of 1.1-2.9 days in two soils).

The likely route of exposure to spirotetramat to aquatic environments will be from spray drift and the contamination of surface waters from runoff events occurring shortly after application to a few days after application. There is also the chance that the chemical would be deposited off-target by spray drift. Spirotetramat is not generally expected to be an important leacher (despite its moderately mobile classification), for its low persistence. Similar routes of exposure will be observed for spirotetramat-enol, since it is the product of the rapid breakdown of the parent.

It appears that parent spirotetramat and its major metabolites spirotetramat-enol and spirotetramat-ketohydroxy may be of concern in soils and water due to their high concentrations in the laboratory studies (for the parent and spirotetramat–enol) or to their relative persistence (for spirotetramat–ketohydroxy). The soils may also be repositories of toxic residues since high levels of non-extracted residues were observed in metabolism studies (up to 60% of AR). The total residues of spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy and non-extracted residues are much more persistent than the parent or spirotetramat-enol alone. Half-lives ($t_{½}$'s) of 161-204 days were estimated from the aerobic soil metabolism studies for spirotetramat-enol + spirotetramat-ketohydroxy + non-extracted residues; while half-lives ($t_{½}$'s) of 141-693 days were estimated from the aerobic aquatic metabolism studies for spirotetramat + spirotetramat-enol + spirotetramat-ketohydroxy + non-extracted residues. The registrant indicated that the non-extracted residues were immobile and not accessible; however, no data to support this contention were provided. A conservative approach was taken and for the half-life calculation, it was assumed that the non-extracted residues were persistent compounds.

Due to their higher persistence, moderate to high solubility, and relatively low levels of binding, spirotetramat residues of concern (*i.e.* spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy and non-extracted residues) have a potential to contaminate

adjacent bodies of water for periods of weeks to several months posttreatment due to runoff events (both via dissolution or erosion). In addition, there is some potential to move subsurface and contaminate groundwater. It appears that spirotetramat and/ or its residues may be incorporated/ translocated into the targeted crop/ canopy/ foliage (leaves and shoots) or young root systems with the aid of an adjuvant added to the application mixture. While the total residues are available, the chewing insects will take them. These chemicals could be released via plant wash-off to soils environments during large rain events.

The photolysis studies followed different patterns of transformation/ degradation. Under aqueous photolysis condition, in sterile natural water at a pH 7.9, spirotetramat degraded with a dark controled corrected half-dissipation time of 0.74 Phoenix, AZ days. Two major phototransformation products were formed besides the hydrolysis product spirotetramat-enol: methoxy-cyclohexylamino-carboxylic acid and methoxy-cyclohexanone (11.3-17.5% of AR). In contrast, under aqueous photolysis condition, in sterile buffered solution at a pH of 5, spirotetramat degraded with a half-life of 14.4 Phoenix, AZ days. In buffered solution, spirotetramat is transformed to the major photo-rearrangement products spirotetramat-photo-cyclopentyl, spirotetramat-photo-hydroxymethyl, spirotetramat-photo-formyl and spirotetramat-photomethyl carbonate (11.5-42.9% AR). On the other hand, the soil photodegradation study was found to have certain deficiencies that one could not draw definite conclusions on the rate of soil photodegradation. Information on the identity of the degradates in the study indicated that spirotetramat-enol, spirotetramat-ketohydroxy, methoxycyclohexanone (10% AR) and dimethylbenzoic acid (21.8% of AR) were observed in the samples. Methoxy-cyclohexanone and dimethylbenzoic acid were observed only in the irradiated samples.

For spirotetramat (mean K_d = 4.39 mL/g; mean K_{OC} = 289 mL/g_{OC}), spirotetramat-enol (mean K_{OC} = 55 mL/g_{OC}) and spirotetramat-ketohydroxy's (mean K_d = 1.067 mL/g; mean K_{OC} = 65.3 mL/g_{OC}), mobility was classified as moderately mobile, mobile and mobile to highly mobile, respectively (according to the FAO mobility classification). Given the low vapor pressure of spirotetramat ($4.2x10^{-11}$ mmHg) and its low Henry's Law Constant ($6.90x10^{-13}$ Atm-m^3/mol), the chemical and its residues are not expected to volatilize readily or substantially from wet surfaces.

Terrestrial field dissipation studies, with a pH range of 7.0 – 8.1 (in water, equivalent to ~5.5 – 7.3 in $CaCl_2$), conducted in NY, FL, CA and WA, also confirm the laboratory findings of rapid degradation/ dissipation of spirotetramat (DT_{50}'s of 0.3-1.0 days, in the 0-45 cm soil layer). The major transformation products found in the field are likely to be spirotetramat-enol and spirotetramat-ketohydroxy. They were not present at significant amounts below the 0-15-cm soil layer. Half-dissipation times for the combined residues of spirotetramat-enol and spirotetramat-ketohydroxy ranged from 4.6-31.6 days, in the 0-45 cm soil depth. Spirotetramat-MA-amide was also monitored in the field, with very limited detections.

Spirotetramat, spirotetramat-enol and spirotetramat-ketohydroxy are not likely to bioaccumulate/ bioconcentrate because their K_{OW}'s are low: 324, 2.1 and 20, respectively (or <<1000). Table 15 summarizes physical/ chemical and environmental fate/ transport properties of spirotetramat (and transformation products).

Table 15. Summary of physical/ chemical and environmental fate and transport properties of spirotetramat and its major transformation products.

<table>
<tr><th>PARAMETER</th><th>VALUE(S) (units)</th><th>COMMENT</th></tr>
<tr><td>Solubility (20 °C)</td><td colspan="2">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</td></tr>
<tr><td>Solubility of Spirotetramat in Organic Solvents (20 °C)</td><td colspan="2">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</td></tr>
<tr><td>Vapor Pressure (20 °C)/
Henry's Law constant</td><td>$5.6x10^{-9}$ Pa = $4.2x10^{-11}$ mm Hg
$6.99x10^{-8}$ Pa-m^3/mol = $6.90x10^{-13}$ Atm-m^3/mol</td><td>HLC at 20°C and pH 7, estimated from VP and S</td></tr>
<tr><td>pKa Spirotetramat</td><td>10.7</td><td>Loss of the H attached to the nitrogen in spirotetramat</td></tr>
<tr><td>Octanol-Water Partition Coefficient Spirotetramat (K_{OW}, at 20 °C)</td><td>324</td><td>–</td></tr>
<tr><td>Spirotetramat-enol
Solubility; K_{OW} and log K_{OW}; pKa</td><td colspan="2">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 pH9 = 0.06 and -1.3, respectively; pKa = 5.2</td></tr>
<tr><td>Spirotetramat-ketohydroxy
Solubility; K_{OW} and log K_{OW}; pKa</td><td colspan="2">Solubility =0.228 g/L; K_{OW} and log K_{OW} = 20 and 1.3, respectively at pH 7; pKa = 11.0</td></tr>
<tr><td>Hydrolysis Half-life Spirotetramat
[pH 4, 7, 9; (20 and 25 °C)]</td><td>SFO; 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</td><td>SFO=single first order kinetics.
Major metabolite – spirotetramat-enol.</td></tr>
<tr><td>Hydrolysis Half-life of spirotetramat-enol (pH 4, 7, 9; 50 °C)</td><td>Stable
The study was conducted for 5 days at 50 °C.</td><td>.</td></tr>
<tr><td>Aqueous Photolysis Half-life</td><td>$t_{1/2}$ = 14.4 Phoenix, AZ days (pH 5.0) vs.
[$t_{1/2}$ = 0.74 Phoenix, AZ days in natural water at pH 7.9]</td><td>SFO=single first order kinetics. All values are corrected for dark control. Different metabolites were observed in buffered solution and natural water.</td></tr>
<tr><td>Soil Photolysis Half-life</td><td>A fine SL and a L; Dimethyl benzoic acid & methoxycyclo-hexanone observed in irradiated samples only:</td><td>Supplemental study, the dark control degraded faster than the irradiated samples.</td></tr>
<tr><td>Aerobic Soil Metabolism Half-life of parent spirotetramat</td><td>Half-lives for spirotetramat (DFOP-best fit)
For FL SL, SL, SiL and Si; $t_{1/2}$'s = 0.30, 0.24, 0.26 and 0.09 days, respectively
Upperbound 90th percentile = 0.298 days</td><td>DT_{90} (for DFOP kinetics) = 1.26, 0.89, 0.97 and 0.34, respectively.
DFOP=double first order kinetics.</td></tr>
<tr><td>Aerobic Soil Metabolism Half-life study conducted with spirotetramat-enol</td><td>
<table>
<tr><th colspan="4">DT_{50}'s derived from the study (days)</th></tr>
<tr><th>Chemical:</th><th>enol</th><th>ketohydroxy</th><th>MA-amide</th></tr>
<tr><th>Kinetics:</th><th>SFORB</th><th>SFO</th><th>SFO</th></tr>
<tr><td>FL SL</td><td>0.05</td><td>16.7</td><td>5.4</td></tr>
<tr><td>SL</td><td>0.02</td><td>4.2</td><td>1.1</td></tr>
<tr><td>SiL</td><td>0.16</td><td>5.1</td><td>1.8</td></tr>
<tr><td>Si</td><td>0.02</td><td>1.5</td><td>0.3</td></tr>
<tr><td>Upperbound 90th perc.</td><td>0.117</td><td>12.38</td><td>3.99</td></tr>
</table>
</td><td>For FL SL, SL, SiL and Si,
DT_{90} for enol = 0.17, 0.07, 0.53 and 0.06 days, respectively.
Respective DT_{90} for ketohydroxy= 55.6, 13.9, 16.9 and 5.1 days.
Respective DT_{90} for MA-amide= 18.1, 3.6, 6.3 and 1 days.
SFORB=single first order reverse binding kinetics. SFO=single first order kinetics.</td></tr>
<tr><td>Aerobic Soil Metabolism Half-life of 4-methoxycyclohexanone</td><td>Half-lives for 4-methoxycyclohexanone (SFO)
<1day (obs.), <1day (obs.) and 0.6 days, for SiL, L and FL LS, respectively</td><td>DT_{90} = 1.8 days for LS; DT_{90} could not be calculated for SiL and L. SFO=single first order kinetics.</td></tr>
<tr><td>Anaerobic Soil Metabolism
Half-life</td><td>SL; $t_{1/2}$ = 0.06 days (FOMC)
The spirotetramat-enol reached a maximum amount at the last test interval; spirotetramat-ketohydroxy was a maximum at 1 day interval.</td><td>DT_{90} = 1.33 days.
FOMC=first order multi-compartment</td></tr>
<tr><td>Anaerobic Aquatic Metabolism
Half-life</td><td>KS CL sediment; $t_{1/2}$ = 2.8 days (SFO)</td><td>DT_{90} = 9.3 days.
SFO=single first order kinetics.</td></tr>
</table>

<table>
<tr><th>PARAMETER</th><th>VALUE(S) (units)</th><th>COMMENT</th></tr>
<tr><td>Aerobic Aquatic Metabolism
Half-life</td><td><u>Spirotetramat* SFO, total system</u>:
For L and LS sediment; $t_{1/2}$ =1.06 and 1.05 days, respectively.
90th percentile = 1.070 days
<u>Rates for spirotetramat-enol**, SFO</u>:
For L and LS sediment; $t_{1/2}$ = 59.0 and 37.9 days, respectively 90th 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</td><td>*Respective spirotetramat DT_{90}‘s = 3.52 and 3.50 days.
**Respective spirotetramat–enol DT_{90}‘s = 196 and 126 days.
SFO=single first order kinetics.four compartment model</td></tr>
<tr><td>Organic Carbon Partition Coefficient (K_{OC})and (K_d) – parent spirotetramat
Organic Carbon Partition Coefficient (K_{FOC}) – parent spirotetramat (mg/kg)/(mg/L)$^{1/n}$; (K_F) – parent spirotetramat (mg/kg$_{OC}$)/(mg/L)$^{1/n}$</td><td><table><tr><th>soil</th><th>K_{OC}</th><th>K_d</th><th>K_{FOC}</th><th>K_F</th></tr><tr><td>LS</td><td>184</td><td>4.38</td><td>201</td><td>4.79</td></tr><tr><td>SL</td><td>437</td><td>3.80</td><td>435</td><td>3.78</td></tr><tr><td>SiL</td><td>201</td><td>4.69</td><td>176</td><td>4.10</td></tr><tr><td>Mol SL</td><td>385</td><td>3.58</td><td>435</td><td>4.05</td></tr><tr><td>L</td><td>237</td><td>5.52</td><td>159</td><td>3.70</td></tr><tr><td>mean</td><td>289</td><td>4.39</td><td>na</td><td>na</td></tr></table></td><td>Mol = Molino</td></tr>
<tr><td>Soil Partition Coefficient (K_d)
Organic Carbon Partition Coefficient (K_{OC}) – spirotetramat-enol</td><td>Range 0.52-0.86 mL/g
27, 65, 29 and 99; mean K_{OC} = 55 mL/g$_{OC}$
(mobile)</td><td>SL, L, SiL and SL, respectively.
Estimated values from the soil column leaching study:</td></tr>
<tr><td>Soil Partition Coefficient (K_d)
Organic Carbon Partition Coefficient (K_{OC}) for spirotetramat-ketohydroxy</td><td>0.560, 0.529, 1.10, 0.867, 2.28 mL/g
Mean = 1.067 mL/g
43.1, 48.1, 42.0, 99.7, 93.7 mL/g$_{OC}$
Mean = 65.3 mL/g$_{OC}$
(mobile)</td><td>SL, SiL, SiL, SL and CL, respectively</td></tr>
<tr><td>Soil Partition Coefficient (K_d)
Organic Carbon Partition Coefficient (K_{OC}) for spirotetramat-MA-amide</td><td>0.071, 0.064, 0.116, 0.119, 0.126 mL/g; mean = 0.099 mL/g
4.2, 7.0, 5.0, 25.6, 5.6 mL/g$_{OC}$
(mobile to highly mobile)</td><td>SL, SiL, SiL, LS and L, respectively</td></tr>
<tr><td>Organic Carbon Partition Coefficient (K_{OC}), obtained using HPLC method, for spirotetramat-enol dimer 1 and spirotetramat-enol dimer 2</td><td>dimer 1, at pHs 6.0 and 1.7, 1771 and 1477 mL/g$_{OC}$, respectively; a mean of 1624 mL/g$_{OC}$ (slightly mobile)

dimer 2, at pHs 6.0 and 1.7, 3115 and 3301 mL/g$_{OC}$, respectively; a mean of 3208 mL/g$_{OC}$ (slightly mobile)</td><td>–</td></tr>
<tr><td>Terrestrial Field Dissipation
Half-life for parent spirotetramat
Half-life for total residues of spirotetramat-enol + spirotetramat-ketohydroxy and for total residues of spirotetramat + spirotetramat-enol + spirotetramat-ketohydroxy</td><td><table><tr><th colspan="4">DT_{50}’s (days), Upper 0-45 cm Soil Depth, SFO</th></tr><tr><th>Chemical</th><th>parent</th><th>enol + ketohydroxy</th><th>All residues</th></tr><tr><td>NY LS, bg</td><td>0.5</td><td>31.6</td><td>23.4</td></tr><tr><td>FL S, bg</td><td>0.9</td><td>6.6</td><td>7.6</td></tr><tr><td>FL S, cr</td><td>1.0</td><td>4.8</td><td>5.7</td></tr><tr><td>CA SL, bg</td><td>1.0</td><td>7.6</td><td>8.4</td></tr><tr><td>CA SL, cr</td><td>1.0</td><td>8.7</td><td>10.2</td></tr><tr><td>WA SL, bg</td><td>0.4</td><td>5.2</td><td>6.3</td></tr><tr><td>WA SL, cr</td><td>0.3</td><td>4.6</td><td>5.0</td></tr></table></td><td>FL S; Cropped; bush beans ‘Blue Lake’; CA SL; Cropped; tomatoes ‘Germain’s Seed’; WA LS; Cropped; yellow sweet Spanish onions.
SFO=single first order kinetics.or SFO in series.
bg = bareground; cr = cropped.</td></tr>
</table>

Ecological Effects and Risk:

Spirotetramat can be classified as practically non-toxic to birds and mammals on an acute basis. Although there currently is no toxicity classification scheme for earthworms, spirotetramat appears to be of relatively low toxicity to earthworms as there were no observed toxic effects up to the highest concentration tested in the sub-chronic 14-day study. Only

a 14-day study with 4-methoxy-cyclohexanone and an 8-week study with spirotetramat-enol demonstrated any toxic effects to earthworms.

Although spirotetramat can be classified as practically non-toxic to honey bees based on acute oral and contact studies, results of brood feeding studies and tunnel tests suggest the potential for effects to broods following spirotetramat applications at rates lower than the maximum proposed label rates; significant brood effects including increased mortality in adults and pupae, massive perturbation of brood development, early brood termination, and decreased larval abundance were detected. Spirotetramat also had a wide range in magnitude of acute effects on other various non-target terrestrial arthropods.

For plants inhabiting dry and semi-aquatic areas, there were no detrimental effects for any measured parameter in dicots or monocots at or above 25% as compared to the controls in the Tier I seedling emergence study. However, there were some significant adverse effects observed on a number of monocots (corn, oats, ryegrass, and shattercane) in the available vegetative vigor studies, including: reduced shoot dry weight, reduced length, and fresh weight. The only dicot affected was canola (reduced fresh weight).

Spirotetramat can be classified as moderately toxic to freshwater and estuarine/marine fish, slightly to highly toxic to freshwater invertebrates, and moderately to highly toxic to estuarine/marine invertebrates on an acute basis. Although there is no toxicity classification scheme for aquatic vascular and non-vascular plants, toxic effects were demonstrated in the available studies with duckweed (yield and growth) and algae (biomass and growth rate).

There is the also the potential for chronic and/or reproductive effects resulting from spirotetramat use as demonstrated in studies with birds (e.g., decreased ↓mean hatchling bodyweight, decreased number of 14-day survivors, decreased number of viable 14-day embryos, decreased number of live embryos, and decreased number of eggs hatched), mammals (e.g., decreased body weight and body weight gain in parental and offspring generations, increased abnormal sperm cells and decreased reproductive performance in parental males), fish (e.g., decreased fry survival), midges (decreased emergence and developmental rate), and water fleas (decreased reproduction, decreased parental growth, and increased mortality in adults).

The risk quotient (RQ) method is used to compare exposure and measured toxicity values to generate RQs that are then compared to the Agency's levels of concern (LOCs) to determine the need to consider regulatory action. The RQs for various non-target species for the proposed uses of Spirotetramat are given in tables 16 to 25 below:

Table 16. Comparison of acute RQs for freshwater and estuarine/marine fish and invertebrates based on the crop/use scenario that resulted in the highest peak EECs of all modeled scenarios and the most sensitive acute toxicity values for each taxonomic group. [a, b]

		Acute Aquatic Animal RQs [d]			
Residues [c]	**Peak EEC (µg a.i./L)**	**Freshwater Invertebrates**	**Freshwater Fish**	**Estuarine/Marine Invertebrates**	**Estuarine/Marine Fish**
Parent only	0.573	0.0009	0.0004	0.0007	0.0003
Total	11.4	0.0173	0.0081	0.0134	0.0058

[a] NC apple aerial application scenario, based on 3 applications at a rate of 0.4 lb a.i./A/season and a 7-day interval, generated the highest peak EECs.
[b] Toxicity values are based on studies with midges (*Chironomus riparius*) for freshwater invertebrates (EC_{50} = 660 µg a.i./L), bluegill sunfish (*Lepomis macrochirus*) for freshwater fish (LC_{50} = 1410 µg a.i./L), eastern oysters (*Crassostrea virginica*) for estuarine/marine invertebrates (EC_{50} = 850 µg a.i./L), and sheepshead minnow (*Cyprinodon variegatus*) for estuarine/marine fish (LC_{50} = 1960 µg a.i./L).
[c] 24-hour peak EEC values generated from PRZM/EXAMS are reported for the parent spirotetramat only as well as for total residues (i.e., residues for the parent plus degradates of concern).
[d] All RQs are below the acute risk (0.5), acute restricted use (0.1), and acute endangered species (0.05) LOCs.

Table 17. Comparison of chronic RQs for freshwater fish and invertebrates based on the crop/use scenario that resulted in the highest 21- and 60-day EECs of all modeled scenarios and the most sensitive chronic toxicity values for each taxonomic group. [a, b]

			Chronic Aquatic Animal RQs [d]	
Residues [c]	**21-day EEC µg a.i./L**	**60-day EEC µg a.i./L**	**Freshwater Invertebrates**	**Freshwater Fish**
Parent only	0.154	0.0563	0.0001	0.0001
Total	11.1	10.8	0.0056	0.0202

[a] NC apple aerial application scenario, based on 3 applications at a rate of 0.4 lb a.i./A/season and a 7-day interval, generated the highest 21-day and 60-day EECs.
[b] Chronic toxicity values are based on studies with water fleas (*Daphnia magna*) for freshwater invertebrates (NOAEC = 2000 µg a.i./L) and fathead minnows (*Pimephales promelas*) for freshwater fish (NOAEC = 534 µg a.i./L).
[c] 21-day and 60-day EEC values generated from PRZM/EXAMS are reported for the parent spirotetramat only as well as for total residues (i.e., residues for the parent plus degradates of concern).
[d] All RQs are below the chronic risk LOC (1).

Table 18. Dose- and dietary-based acute RQs for birds exposed to spirotetramat based on upper-bound total residues on short grass as calculated by T-REX for the maximum exposure scenario. [a]

Type of Analysis	**Size Class (g)**	**LC_{50} or Adjusted Acute LD_{50}** [b]	**Food Item Short Grass**	
			EEC [b]	**Acute RQ** [c, d]
Dose-based	20	>1441 mg/kg-bw	59.72 mg/kg-bw	<0.04
	100	>1834 mg/kg-bw	34.05 mg/kg-bw	<0.02
	1000	>2591 mg/kg-bw	15.25 mg/kg-bw	<0.01
Dietary-based	N/A	>5000 mg/kg-diet	52.44 mg/kg-diet	<0.01

[a] The maximum exposure scenario was the pome fruit scenario, with a maximum single application rate of 0.14 lb a.i./A, a 7-day application interval, and a maximum of 3 applications.
[b] EECs and toxicity values for the dose-based analysis are adjusted based on food intake and body weight differences so that they are comparable for a given weight class of animal.
[c] The most sensitive LD_{50} and LC_{50} values for birds were non-definitive as they were determined to be greater than the highest tested levels in the available toxicity studies. Therefore, because all acute RQs are based on non-definitive toxicity values, they represent

conservative estimates of risk and are expressed with a '<' sign .
[d]All acute RQs are below the acute LOCs for non listed species (0.5), restricted use (0.2), and listed species (0.1).

Table 19. Dietary-based chronic RQs for birds exposed to spirotetramat based on upper-bound residues (total and parent-only) on short grass as calculated by T-REX for the all exposure scenarios. [a]

Use	Max. Single App. Rate lbs a.i./A	Min. Interval Days	Max. No. Apps. Per Year	Short Grass		Tall Grass		Broadleaf Plants /Small Insects		Fruits/Pods/ Seeds/Large Insects	
				EEC mg/kg-diet	RQ	EEC mg/kg-diet	RQ	EEC mg/kg-diet	RQ	EEC mg/kg-diet	RQ
Parent-Only Residues											
Pome fruit	0.14	7	3	43.10	**>1.50[b]**	19.75	>0.69	24.24	>0.84	2.69	>0.09
Xmas trees	0.16	14	2	40.43	**>1.40[b]**	18.53	>0.64	22.74	>0.79	2.53	>0.09
Citrus fruit	0.16	21	2	38.87	**>1.35[b]**	17.81	>0.62	21.86	>0.76	2.43	>0.08
Tree nuts	0.14	14	3	35.47	**>1.23[b]**	16.26	>0.56	19.95	>0.69	2.22	>0.08
Stone fruit	0.14	14	2	35.38	**>1.23[b]**	16.21	>0.56	19.90	>0.69	2.21	>0.08
Grape	0.125	30	2	30.06	**>1.04[b]**	13.78	>0.48	16.91	>0.59	1.88	>0.07
Climbing	0.12	30	2	28.85	**>1.00[b]**	13.22	>0.46	16.23	>0.56	1.80	>0.06
Hops	0.1	14	2	25.27	>0.88	11.58	>0.40	14.21	>0.49	1.58	>0.05
Cucurbit	0.08	7	2	23.61	>0.82	10.82	>0.38	13.28	>0.46	1.48	>0.05
Total Residues											
Pome fruit	0.14	7	3	52.44	**>1.82[b]**	24.03	>0.83	29.50	**>1.02[b]**	3.28	>0.11
Xmas trees	0.16	14	2	44.55	**>1.55[b]**	20.42	>0.71	25.06	>0.87	2.78	>0.10
Citrus fruit	0.16	21	2	40.86	**>1.42[b]**	18.73	>0.65	22.99	>0.80	2.55	>0.09
Tree nuts	0.14	14	3	39.85	**>1.38[b]**	18.26	>0.63	22.41	>0.78	2.49	>0.09
Stone fruit	0.14	14	2	38.98	**>1.35[b]**	17.87	>0.62	21.93	>0.76	2.44	>0.08
Grape	0.125	30	2	30.59	**>1.06[b]**	14.02	>0.49	17.21	>0.60	1.91	>0.07
Climbing	0.12	30	2	29.37	**>1.02[b]**	13.46	>0.47	16.52	>0.57	1.84	>0.06
Hops	0.1	14	2	27.85	>0.97	12.76	>0.44	15.66	>0.54	1.74	>0.06
Cucurbit	0.08	7	2	26.89	>0.93	12.32	>0.43	15.12	>0.53	1.68	>0.06

[a] Chronic risk estimates for birds are based upon a non-definitive NOAEC of <28.8 mg/kg-diet (effects were seen at all tested concentrations) and all RQs are greater than the reported values. Until a discrete NOAEC is established for chronic/reproductive effects to birds, it is impossible to preclude chronic risk to birds feeding on any forage item under any exposure scenario. However, the RQs currently exceeding the chronic LOC (in bold) have been identified separately from those that are not currently exceeding but have the potential to until a definitive NOAEC is established.
[b] The chronic RQ meets or exceeds the chronic risk LOC (1) even based on the non-definitive NOAEC of <28.8 mg a.i./kg diet.

Table 20. Dose- and dietary-based acute and chronic RQs for mammals exposed to spirotetramat based on upper-bound total residues on short grass as calculated by T-REX for the maximum exposure scenario.[a]

Type of Analysis	Size Class (g)	Acute LC_{50} or Adjusted Acute LD_{50} [b]	Chronic NOAEC or Adjusted Chronic NOAEL [b]	Food Item Short Grass		
				EEC [b]	Acute RQ [d, e]	Chronic RQ [f]
Dose-based	15	>4396 mg/kg-bw	155 mg/kg-bw	49.99 mg/kg-bw	<0.01	0.32
	35	>3557 mg/kg-bw	126 mg/kg-bw	34.55 mg/kg-bw	<0.01	0.27
	1000	>1538 mg/kg-bw	54 mg/kg-bw	8.01 mg/kg-bw	<0.01	0.15
Dietary-based	N/A	>2000 mg/kg-diet [c]	1000 mg/kg-diet	52.44 mg/kg-diet	<0.03	0.05

[a] The maximum exposure scenario was the pome fruit scenario, with a maximum single application rate of 0.14 lb a.i./A, a 7-day application interval, and a maximum of 3 applications.
[b] EECs and toxicity values for the dose-based analysis are adjusted based on food intake and body weight differences so that they are comparable for a given weight class of animal.
[c] A conservative estimate of dietary acute toxicity was generated using the existing rat oral LD_{50} and assuming a conservative ingestion rate of 100 percent of the body weight. The resulting estimated dietary acute toxicity endpoint is >2000 mg/kg-diet [(>2000 mg/kg-bw)(1 kg-bw/1kg-diet) = >2000 mg/kg-diet].
[d] The most sensitive LD_{50} and LC_{50} values for mammals were non-definitive as they were determined to be greater than the highest tested levels in the available toxicity studies. Therefore, because all acute RQs are based on non-definitive toxicity values, they represent conservative estimates of risk and are expressed with a '<' sign .
[e] All acute RQs are below the acute LOCs for non listed species (0.5), restricted use (0.2), and listed species (0.1).
[f] All chronic RQs are below the chronic risk LOC (1).

Table 21. Comparison of acute RQs for freshwater and estuarine/marine fish and invertebrates based on the crop/use scenario that resulted in the highest peak EECs of all modeled scenarios and the most sensitive acute toxicity values for each taxonomic group. [a, b]

		Acute Aquatic Animal RQs [d]			
Residues [c]	Peak EEC (µg a.i./L)	Freshwater Invertebrates	Freshwater Fish	Estuarine/Marine Invertebrates	Estuarine/Marine Fish
Parent only	0.573	0.0009	0.0004	0.0007	0.0003
Total	11.4	0.0173	0.0081	0.0134	0.0058

[a] NC apple aerial application scenario, based on 3 applications at a rate of 0.4 lb a.i./A/season and a 7-day interval, generated the highest peak EECs.
[b] Toxicity values are based on studies with midges (*Chironomus riparius*) for freshwater invertebrates (EC_{50} = 660 µg a.i./L), bluegill sunfish (*Lepomis macrochirus*) for freshwater fish (LC_{50} = 1410 µg a.i./L), eastern oysters (*Crassostrea virginica*) for estuarine/marine invertebrates (EC_{50} = 850 µg a.i./L), and sheepshead minnow (*Cyprinodon variegatus*) for estuarine/marine fish (LC_{50} = 1960 µg a.i./L).
[c] 24-hour peak EEC values generated from PRZM/EXAMS are reported for the parent spirotetramat only as well as for total residues (i.e., residues for the parent plus degradates of concern).
[d] All RQs are below the acute risk (0.5), acute restricted use (0.1), and acute endangered species (0.05) LOCs.

Table 22. Comparison of chronic RQs for freshwater fish and invertebrates based on the crop/use scenario that resulted in the highest 21- and 60-day EECs of all modeled scenarios and the most sensitive chronic toxicity values for each taxonomic group. [a, b]

			Chronic Aquatic Animal RQs [d]	
Residues [c]	21-day EEC µg a.i./L	60-day EEC µg a.i./L	Freshwater Invertebrates	Freshwater Fish
Parent only	0.154	0.0563	0.0001	0.0001

Total	11.1	10.8	0.0056	0.0202

[a] NC apple aerial application scenario, based on 3 applications at a rate of 0.4 lb a.i./A/season and a 7-day interval, generated the highest 21-day and 60-day EECs.
[b] Chronic toxicity values are based on studies with water fleas (*Daphnia magna*) for freshwater invertebrates (NOAEC = 2000 µg a.i./L) and fathead minnows (*Pimephales promelas*) for freshwater fish (NOAEC = 534 µg a.i./L).
[c] 21-day and 60-day EEC values generated from PRZM/EXAMS are reported for the parent spirotetramat only as well as for total residues (i.e., residues for the parent plus degradates of concern).
[d] All RQs are below the chronic risk LOC (1).

Table 23. Dose- and dietary-based acute RQs for birds exposed to spirotetramat based on upper-bound total residues on short grass as calculated by T-REX for the maximum exposure scenario. [a]

Type of Analysis	Size Class (g)	LC_{50} or Adjusted Acute LD_{50} [b]	Food Item Short Grass	
			EEC [b]	Acute RQ [c, d]
Dose-based	20	>1441 mg/kg-bw	59.72 mg/kg-bw	<0.04
	100	>1834 mg/kg-bw	34.05 mg/kg-bw	<0.02
	1000	>2591 mg/kg-bw	15.25 mg/kg-bw	<0.01
Dietary-based	N/A	>5000 mg/kg-diet	52.44 mg/kg-diet	<0.01

[a] The maximum exposure scenario was the pome fruit scenario, with a maximum single application rate of 0.14 lb a.i./A, a 7-day application interval, and a maximum of 3 applications.
[b] EECs and toxicity values for the dose-based analysis are adjusted based on food intake and body weight differences so that they are comparable for a given weight class of animal.
[c] The most sensitive LD_{50} and LC_{50} values for birds were non-definitive as they were determined to be greater than the highest tested levels in the available toxicity studies. Therefore, because all acute RQs are based on non-definitive toxicity values, they represent conservative estimates of risk and are expressed with a '<' sign .
[d] All acute RQs are below the acute LOCs for non listed species (0.5), restricted use (0.2), and listed species (0.1).

Table 24. Dietary-based chronic RQs for birds exposed to spirotetramat based on upper-bound residues (total and parent-only) on short grass as calculated by T-REX for the all exposure scenarios. [a]

Use	Max. Single App. Rate lbs a.i./A	Min. Interval Days	Max. No. Apps. Per Year	Short Grass		Tall Grass		Broadleaf Plants /Small Insects		Fruits/Pods/ Seeds/Large Insects	
				EEC mg/kg-diet	RQ	EEC mg/kg-diet	RQ	EEC mg/kg-diet	RQ	EEC mg/kg-diet	RQ
Parent-Only Residues											
Pome fruit	0.14	7	3	43.10	**>1.50**[b]	19.75	>0.69	24.24	>0.84	2.69	>0.09
Xmas trees	0.16	14	2	40.43	**>1.40**[b]	18.53	>0.64	22.74	>0.79	2.53	>0.09
Citrus fruit	0.16	21	2	38.87	**>1.35**[b]	17.81	>0.62	21.86	>0.76	2.43	>0.08
Tree nuts	0.14	14	3	35.47	**>1.23**[b]	16.26	>0.56	19.95	>0.69	2.22	>0.08
Stone fruit	0.14	14	2	35.38	**>1.23**[b]	16.21	>0.56	19.90	>0.69	2.21	>0.08
Grape	0.125	30	2	30.06	**>1.04**[b]	13.78	>0.48	16.91	>0.59	1.88	>0.07

Climbing	0.12	30	2	28.85	**>1.00**[b]	13.22	>0.46	16.23	>0.56	1.80	>0.06
Hops	0.1	14	2	25.27	>0.88	11.58	>0.40	14.21	>0.49	1.58	>0.05
Cucurbit	0.08	7	2	23.61	>0.82	10.82	>0.38	13.28	>0.46	1.48	>0.05
Total Residues											
Pome fruit	0.14	7	3	52.44	**>1.82**[b]	24.03	>0.83	29.50	**>1.02**[b]	3.28	>0.11
Xmas trees	0.16	14	2	44.55	**>1.55**[b]	20.42	>0.71	25.06	>0.87	2.78	>0.10
Citrus fruit	0.16	21	2	40.86	**>1.42**[b]	18.73	>0.65	22.99	>0.80	2.55	>0.09
Tree nuts	0.14	14	3	39.85	**>1.38**[b]	18.26	>0.63	22.41	>0.78	2.49	>0.09
Stone fruit	0.14	14	2	38.98	**>1.35**[b]	17.87	>0.62	21.93	>0.76	2.44	>0.08
Grape	0.125	30	2	30.59	**>1.06**[b]	14.02	>0.49	17.21	>0.60	1.91	>0.07
Climbing	0.12	30	2	29.37	**>1.02**[b]	13.46	>0.47	16.52	>0.57	1.84	>0.06
Hops	0.1	14	2	27.85	>0.97	12.76	>0.44	15.66	>0.54	1.74	>0.06
Cucurbit	0.08	7	2	26.89	>0.93	12.32	>0.43	15.12	>0.53	1.68	>0.06

[a] Chronic risk estimates for birds are based upon a non-definitive NOAEC of <28.8 mg/kg-diet (effects were seen at all tested concentrations) and all RQs are greater than the reported values. Until a discrete NOAEC is established for chronic/reproductive effects to birds, it is impossible to preclude chronic risk to birds feeding on any forage item under any exposure scenario. However, the RQs currently exceeding the chronic LOC (in bold) have been identified separately from those that are not currently exceeding but have the potential to until a definitive NOAEC is established.
[b] The chronic RQ meets or exceeds the chronic risk LOC (1) even based on the non-definitive NOAEC of <28.8 mg a.i./kg diet.

Table 25. Dose- and dietary-based acute and chronic RQs for mammals exposed to spirotetramat based on upper-bound total residues on short grass as calculated by T-REX for the maximum exposure scenario.[a]

Type of Analysis	Size Class (g)	Acute LC_{50} or Adjusted Acute LD_{50} [b]	Chronic NOAEC or Adjusted Chronic NOAEL [b]	Food Item Short Grass		
				EEC [b]	Acute RQ [d, e]	Chronic RQ [f]
Dose-based	15	>4396 mg/kg-bw	155 mg/kg-bw	49.99 mg/kg-bw	<0.01	0.32
	35	>3557 mg/kg-bw	126 mg/kg-bw	34.55 mg/kg-bw	<0.01	0.27
	1000	>1538 mg/kg-bw	54 mg/kg-bw	8.01 mg/kg-bw	<0.01	0.15
Dietary-based	N/A	>2000 mg/kg-diet [c]	1000 mg/kg-diet	52.44 mg/kg-diet	<0.03	0.05

[a] The maximum exposure scenario was the pome fruit scenario, with a maximum single application rate of 0.14 lb a.i./A, a 7-day application interval, and a maximum of 3 applications.
[b] EECs and toxicity values for the dose-based analysis are adjusted based on food intake and body weight differences so that they are comparable for a given weight class of animal.
[c] A conservative estimate of dietary acute toxicity was generated using the existing rat oral LD_{50} and assuming a conservative ingestion rate of 100 percent of the body weight. The resulting estimated dietary acute toxicity endpoint is >2000 mg/kg-diet [(>2000 mg/kg-bw)(1 kg-bw/1kg-diet) = >2000 mg/kg-diet].
[d] The most sensitive LD_{50} and LC_{50} values for mammals were non-definitive as they were determined to be greater than the highest tested levels in the available toxicity studies. Therefore, because all acute RQs are based on non-definitive toxicity values, they represent conservative estimates of risk and are expressed with a '<' sign .
[e] All acute RQs are below the acute LOCs for non listed species (0.5), restricted use (0.2), and listed species (0.1).
[f] All chronic RQs are below the chronic risk LOC (1).

Risk to Endangered Species

The following table summarizes the conclusions of potential concerns for direct and indirect effects to federally-listed threatened and endangered species (listed species).

Table 26. Potential Direct and Indirect Effects to Listed Species

Listed Taxonomic Group	Is there Potential for Direct Effects?	Basis for Direct Effects Potential	Is there Potential for Indirect Effects Based on Direct Effects LOCs?	Taxonomic Groups Potentially Directly Affected that Could Result in Indirect Effects
Terrestrial and semi-aquatic plants – monocots and dicots	No	No LOCs were exceeded	Yes	Terrestrial invertebrates, birds
Terrestrial invertebrates	Yes	Toxic effects observed in available studies at less than the proposed maximum application rate	Yes	Birds, terrestrial amphibians, and reptiles
Birds, terrestrial amphibians, and reptiles[1]	Yes	Chronic LOCs were exceeded	Yes	Terrestrial invertebrates
Mammals	No	No LOCs were exceeded	Yes	Terrestrial invertebrates
Aquatic plants (vascular and non-vascular)	No	No LOCs were exceeded	Yes	Terrestrial invertebrates
Fish, aquatic amphibians[2]	No	No LOCs were exceeded	Yes	Terrestrial invertebrates, birds, terrestrial amphibians, and reptiles
Aquatic Invertebrates	No	No LOCs were exceeded	Yes	Birds, terrestrial amphibians, and reptiles

[1] Birds are used as surrogate species for terrestrial-phase amphibians and reptiles; therefore, potential direct and indirect effects to endangered avian, reptilian, and amphibian species are considered equivalent.
[2] Fish are used as a surrogate for aquatic phase amphibians; therefore, potential direct and indirect effects to endangered fish and amphibian species are considered equivalent.

6. REGULATORY POSITION AND RATIONALE

Available data provide adequate information to support the conditional registration of spirotetramat technical and end-use products on crops and in nursery/greenhouse.

Uncertainties and Data Gaps

1. Human Health

There are no data gaps.

2. Environmental Fate and Effects

a) Environmental Fate

Data Gaps: The environmental fate data base is essentially complete. However, the following confirmatory data requirements have been identified.

OPPTS Guideline 835.2410; Photodegradation on soil:
The available soil photodegradation study, provides only limited supplemental information and is uncertain because the parent in the dark control samples degraded faster than in the light exposed samples. However, from the study, the degradates dimethyl-benzoic acid (21.8% of the applied radioactivity or AR at 7 days, also observed in the aerobic outdoors study at 3.3% of the AR) and methoxycyclohexanone (10.0% of AR at 2 days, also observed in the aqueous photolysis study conducted with sterile natural water at 17.5% of AR) were identified only in the light exposed samples, in addition to other transformation products identified in other biodegradation studies (*e.g.*, spirotetramat-enol and spirotetramat-ketohydroxy). The amount of such degradates and the rate of soil photodegradation on soil are uncertain. In order to obtain an adequate description of the role of soil photodegradation on the environmental fate of spirotetramat, and the presence and quantities of degradation/ transformation products, **a new photodegradation on soil study, conducted on a sterile soil is required.**

OPPTS Guideline 835.1230 & 1240; Leaching-Adsorption/Desorption:
There is uncertainty with one of the five soils used in the batch equilibrium study performed in the parent spirotetramat for which the taxonomic classification is unknown. The registrant provided "Orthic dark brown" as the soil taxonomic classification for the soil (not a soil taxonomic classification). Due to the sampling location, it is believed to be of the suborder Mollisols. This part of the study is considered supplemental. **To upgrade the mobility study for EPA's purposes, the soil taxonomy for the Saskatoon loam soil from Sasketchwan, Canada is required.**

b) Ecological Effects

Data Gaps: The ecological effects database is essentially complete. However, a few additional data needs have been identified as described below.

OPPTS Guideline 850.2300; Avian Reproduction Study with the Mallard Duck (*Anas platyrhynchos*):
A definitive NOAEC based on the available avian reproduction studies has not been established for spirotetramat; adverse reproductive effects were

observed at the lowest tested concentration in the available avian reproduction study with mallards. The most sensitive NOAEC value of <28.8 mg/kg-diet with which chronic avian RQs were calculated, was based on a statistically significant ~6.58% reduction in mean hatchling bodyweight. Although no additional statistically significant effects were observed at this test level, large reductions in other frank effects that were observed at 28.8 mg/kg-diet included reductions in # of 14-day survivors (↓22%), # of viable 14-day embryos (↓18%), # of live embryos (↓18%), and # of eggs hatched (↓22%). Due to the degree of these reductions, it is hard to indicate that these effects are not biologically significant and are considered meaningful. Thus, because of the extent of these observed effects, it is reasonable to assume they are significant biologically. Therefore, the ability of this study to statistically detect what could be considered to be biologically relevant endpoints appears to be limited, and an additional study is needed to reduce uncertainty by establishing a definitive NOAEC capable of capturing biologically relevant reductions in endpoints.

OPPTS Guideline 850.3040; Field Testing for Pollinators

Despite that the intrinsic hazard potential to bees based on the acute oral and contact studies with honey bees appears to be low, brood feeding tests with bees and acute toxicity contact studies with other non-target insects (e.g. parasitoid wasps and predatory mites) conducted at less than the maximum application rate suggest there is potential for mortality in adults and pupae, massive perturbation of brood development, and early brood termination as a result of spirotetramat use. This information, coupled with the fact that two other chemicals representing the ketoenole class of compounds (spiromesifen and spirodiclofen) have also demonstrated the potential for chronic effects on bee broods and development while displaying low acute toxicity, suggests that the mode of action of these compounds (i.e., inhibition of lipid biosynthesis) may adversely affect bee broods and development. Although a study has been submitted for spirotetramat under guideline 850.3040, it was conducted at application rates approximately half of the label-recommended rates and it was not designed in such a manner that adverse effects resulting from treatment could be statistically determined. Therefore, it is recommended that a study design be developed in collaboration with the Environmental Fate and Effects Division's chemical teams for spirotetramat, spiromesifen, and spirodiclofen, as well as with the USDA Agricultural Research Service Bee Research Lab.

OPPTS Guideline 850.1075; Freshwater Fish Toxicity with Fathead Minnows (*Pimephales promelas*): Under part 158 of Title 40 in the U.S. Code of Federal Regulations for the registration of conventional pesticide products, it is stated that if the species used in a single fish early-life stage toxicity test is different from the two species used for the freshwater fish acute toxicity tests, an additional 96–hour LC_{50} on the species tested in the early-life stage study must be submitted. These conditions apply to spirotetramat and an additional study is requested to fill this data gap. These

data would help to reduce the uncertainty associated with chronic risk estimates for freshwater fish.

OPPTS Guideline 850.2100; Avian Oral Toxicity Study with a Passerine Species:
Under part 158 of Title 40 in the U.S. Code of Federal Regulations for the registration of conventional pesticide products, it is stated that data are required on one passerine species in addition to either one waterfowl species or one upland game bird species for terrestrial, aquatic, forestry, and residential outdoor uses. Currently there are no acute oral toxicity studies with passerine species available for spirotetramat. These data would be helpful for characterizing interspecies sensitivity, and testing of a passerine addresses concerns that broad, untested avian taxa may be more sensitive than previously required mallards and bobwhites.

Labeling Restrictions

Manufacturing Use Product:
This pesticide is toxic to aquatic invertebrates and oysters. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

This chemical has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

End-Use Products:
This product is toxic to bees. Direct exposure to treatment or residues on blooming crops or weeds can lead to effects on colonies. Do not apply this product or allow it to drift if bees are visiting the treatment area.

This pesticide is toxic to aquatic invertebrates and oysters. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. This product may contaminate water through drift of spray in wind. Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwaters or rinsate.

This product has a high potential for runoff for several weeks after application. Poorly draining soils and soils with shallow water tables are more prone to produce

runoff that contains this product. A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.

Observe all cautions and limitations on labeling of all products used in mixtures.

7. REDUCED RISK CLASSIFICATION

On February 22, 2007, the Reduced Risk Committee categorized spirotetramat as a "reduced risk" pesticide when used on citrus, cucurbits, fruiting vegetables, grapes, leafy vegetables, hops, pome fruit, stone fruit, tree nuts, and tuberous and corm vegetables. Since a reduced risk classification was granted, additional public interest finding was not conducted.

Spirotetramat is expected to be a major alternative to carbamates and organophosphates for citrus, cucurbits, fruiting vegetables, grapes, leafy vegetables, hops, pome fruit, stone fruit, tree nuts, and tuberous and corm vegetables..

8. CONTACT PERSON AT EPA

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DISCLAIMER: The information presented in this Pesticide Fact Sheet is for informational purposes only may not be used to fulfill data requirements for pesticide registration and reregistration. The information is believed to be accurate as of the date on the document.

APPENDIX I

GLOSSARY OF TERMS AND ABBREVIATIONS

ACL	Analytical Chemistry Laboratory
ADNT	Acute delayed neurotoxicity
a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
aRfD	Acute reference dose
ARI	Aggregate Risk Index
BCF	Bioconcentration Factor
BEAD	Biological and Economic Analysis Division
CAS	Chemical Abstracts Service
ChE	Cholinesterase
ChEI	Cholinesterase inhibition
cPAD	Chronic Population Adjusted Dose
cRfD	Chronic reference dose
%CT	Percent crop treated
DAT	Days after treatment
DEEM-FCID	Dietary Exposure Evaluation Model - Food Consumption Intake Database
DNA	Deoxyribonucleic acid
DNT	Developmental neurotoxicity
DIT	Developmental immunotoxicity
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EPA	U.S. Environmental Protection Agency
FQPA	Food Quality Protection Act
GLC	Gas Liquid Chromatography
GLN	Guideline Number
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEL	Lowest Observed Adverse Effect Level
LOAEC	Lowest Observed Adverse Effect Concentration
LOC	Level of Concern
LOD	Limit of Detection
LOQ	Limit of Quantitation
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter

MOE	Margin of Exposure
MRID	Master Record Identification (number), EPA's system of recording and tracking studies submitted
MTD	Maximum tolerated dose
NA	Not Applicable
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NOAEC	No Observed Adverse Effect Concentration
NPDES	National Pollutant Discharge Elimination System
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
TGAI	Technical Grade Active Ingredient
UF	Uncertainty Factor
µg	micrograms
µg/L	Micrograms Per Liter
µL/g	Microliter per gram
USDA	United States Department of Agriculture
WPS	Worker Protection Standard

APPENDIX II

Citations Considered to be Part of the Data Base Supporting the Registration of Spirotetramat

46904401 Fontaine, L. D.; Product chemistry of Spirotetramat technical; Bayer CropScience, Kansas City, MO, USA; Report No.: BR2533; Document No.: M-277395-01-1; 08-SEP-06; Pages: 293

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46904403 Frank, J. T.; Product chemistry of Movento 150 OD insecticide; Bayer CropScience, Kansas City, MO, USA; Report No.: BR2531; Document No.: M-277301-01-1; 25-AUG-06; Pages: 176

46904404 Frank, J. T.; Product chemistry of Movento 240 SC insecticide; Bayer CropScience, Kansas City, MO, USA; Report No.: BR2530; Document No.: M-277327-01-1; 25-AUG-06; Pages: 230

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