United States
Environmental Protection
Agency

Office of Prevention, Pesticides
and Toxic Substances
(7505C)

Pesticide
Fact Sheet

Name of Chemical: **Spirodiclofen**
Reason for Issuance: **Conditional Registration**
Year Issued: **2005**

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1. DESCRIPTION OF CHEMICAL

Generic Name:	Spirodiclofen
Chemical Name:	3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutanoate
Trade Name:	Spirodiclofen Technical
EPA PC Code:	124871
Chemical Abstracts Service (CAS) Number:	148477-71-8
End-use product:	Envidor 2SC Miticide
Year of Initial Registration:	2005
Pesticide Type:	Insecticide/Miticide
Chemical Class:	Tetronic acid
Mode of Action:	Inhibition of lipid synthesis

Registrant:	Bayer CropScience 2 T.W. Alexander Drive Research Triangle Park, NC 27709

2. USE PATTERNS AND FORMULATIONS

Pests/Application Sites:	Controls mites and San Jose scale in **citrus** (orange [sweet and sour], grapefruit, lemon, lime, calamondin, citrus citron, citrus hybrids [includes chironja, tangelo and tangor], kumquat, mandarin [tangerine], pummelo, satsuma mandarin), **grapes, pome fruit** (apple, crabapple, loquat, mayhaw, pear, Oriental pear, quince), **stone fruit** (apricot, cherry [sweet and tart], nectarine, peach, plum [includes Chickasaw plum, damson plum and Japanese plum], plumcot, prune), **and tree nut crops** (almond, beechnut, Brazil nut, butternut, cashew, chestnut, Chinquapin, filbert, hickory nut, Macadamia nut, pecan, pistachio, walnut [black and English])
Application Methods:	Foliar spray application (ground only)
Application Rates:	0.16 to 0.53 lbs a.i./acre
Frequency/Timing:	1 application/season Application should be timed to coincide with early threshold level in developing mite population
Carrier:	Water
Formulations:	Technical: Spirodiclofen Technical (97.8% a.i.) End use: Envidor 2SC (22.3% a.i., 2 lb a.i./gallon)

3. SCIENCE FINDINGS

The exposure and risk assessment of spirodiclofen is a cooperative effort by Pesticide Management Regulatory Agency, Health Canada and U.S. EPA.

Spirodiclofen is a tetronic acid with acaricidal action. It acts by interfering with mite development, thereby controlling such pests as *Panonychus* spp., *Phyllocoptruta* spp., *Brevipalpus* spp., and *Aculus* and *Tetranychus* species. Spirodiclofen is active by contact to mite eggs, all nymphal stages, and adult females (adult males are not effected). Spirodiclofen is structurally similar to spiromesifen, which is also a tetronic acid insecticide.

Available product chemistry, residue, toxicology, ecological effects and environmental fate data supporting the proposed food uses have been reviewed. The data and estimated risks to human health and the environment from its proposed uses are summarized below.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The physical and chemical characteristics of technical spirodiclofen are shown in Table 1 below:

Table 1. Physicochemical Properties of Spirodiclofen

Parameter	Value	
Color	White	
Physical state	Solid	
Odor	No characteristic odor	
Melting point	94.8 °C	
pH	4.2	
Henry's law constant at 20°C	2×10^{-3} Pa x m^3 x mol^{-1}	
Water solubility at 20˚C and pH 4	50 µg/L (spirodiclofen is rapidly hydrolysed at pH > 4)	
Solvent solubility (g/L at 20˚C)	**Solvents**	**Solubilities**
	n–heptane	20
	xylene	>250
	dichloromethane	>250
	2-propanol	47
	1-octanol	44
	polyethylene glycol	24
	acetone	>250
	ethyl acetate	>250
	acetonitrile	>250
	dimethylsulfoxide	75

Vapor pressure	**Vapor pressure**	**Temp.**
	3×10^{-7} Pa	20˚C
	7×10^{-7} Pa	25˚C
Dissociation constant (pK_a)	Not determinable due to the instability of spirodiclofen in aqueous solutions with pH greater than 4.	
Octanol/water partition coefficient Log(K_{OW}) at 20˚C and pH 4	Log Kow = 5.83	
UV/visible absorption spectrum	λmax = 201 nm; not expected to absorb UV at λ > 350 nm	

METABOLISM ASSESSMENT

The metabolic pathway in the proposed primary crops, ruminant, and rat were similar and involved cleavage of the parent ester linkage with the formation of the free enol metabolite (BAJ 2510) followed by hydroxylation of the cyclohexane ring of BAJ 2510. In the rat and in the proposed crops, metabolism continued with cleavage of the enol ring structure leading to the formation of 2,4-dichloro-mandelic acid-cyclohexylester compounds which are further metabolized to 2,4-dichloro-mandelic acid derivatives.

HAZARD CHARACTERIZATION

Acute Toxicity

Technical spirodiclofen has a low acute toxicity *via* oral, dermal, or inhalation routes. It is not an eye or dermal irritant. However, it is a potential skin sensitizer. (Table 2).

Table 2. Acute Toxicity Profile for Spirodiclofen

Guideline #	Study Type /	MRID #	Toxicity Category
870.1100	Acute oral toxicity - rat	45696616	III
870.1200	Acute dermal toxicity - rat	45696617	III
870.1300	Acute inhalation toxicity - rat	45696717	IV
870.2400	Primary eye irritation - rabbit	45696706	IV
870.2500	Primary dermal irritation - rabbit	45696707	IV
870.2600	Dermal sensitization - guinea pig	45696703	Sensitizer

Subchronic and Chronic Toxixicty

Neurotoxicity

Spirodiclofen did not show any evidence of neurotoxicity in the acute and subchronic neurotoxicity studies. However, in a developmental neurotoxicity study, a decrease in retention was observed in the memory phase of the water maze for PND 60 females at all doses.

Endocrine Effects

Spirodiclofen has been shown to have endocrine disruptive effects resulting in direct and indirect endogenously-mediated toxicological response. Testicular effects were observed in dogs, rats and mice, manifested as Leydig cell vacuolation in dogs, hypertrophy in dogs and mice, and hyperplasia progressing to adenomas in rats following chronic exposure. In female rats, increased incidence of uterine nodules and uterine adenocarcinoma were observed at terminal sacrifice in the chronic study. Cytoplasmic vacuolation in the adrenal cortex, accompanied by increased adrenal weight, was consistently observed in rats, dogs, and mice of both sexes.

Developmental/Reproductive Toxicity

Evidence of developmental toxicity was not observed in the rat and rabbit developmental studies. In the two-generation reproductive toxicity study, effects were observed in males [i.e., delayed sexual maturation, decreased testicular spermatid and epididymal sperm counts (oligospermia); and atrophy of the testes, epididymides, prostate, and seminal vesicles] and females (i.e., increased severity of ovarian luteal cell vacuolation/degeneration).

Mutagenicity

Mutagenicity studies conducted on technical spirodiclofen formulation and its major metabolites did not demonstrate any mutagenic potential.

Carcinogenicity

Chronic toxicity and carcinogenicity studies showed increased incidence of uterine adenocarcinoma in female rats, Leydig cell adenoma in male rats, and liver tumors in mice. The Agency classified spirodiclofen as "likely to be carcinogenic to humans" by the oral route based on evidence of testes Leydig cell adenomas in male rats, uterine adenomas and/or adenocarcinoma in female rats, and liver tumors in mice.

The results of subchronic, chronic, and other toxicity studies conducted on spirodiclofen are summarized in Table 3.

Table 3. Subchronic, Chronic and Other Toxicity Profile for Spirodiclofen

Guideline #	Study Type	MRID Nos.	Results
870.3100	Subchronic Oral - Rat	45696715, 45696716	For males, NOAEL = 32.1 mg/kg/day, LOAEL = 166.9 mg/kg/day based on increased incidence and severity of small cytoplasmic vacuolation in the cortex of adrenal glands, decreased cholesterol (week 5 and 13), and decreased triglycerides (week 5), For females, NOAEL= 8.1 mg/kg/day, LOAEL= 47.1 mg/kg/day based on increased incidence of small cytoplasmic vacuolation in the cortex of adrenal glands.
870.3100	Subchronic Oral - Mouse	45696711, 45696712, 45696713	For males, NOAEL= 15 mg/kg/day, LOAEL= 164 mg/kg/day based on an increased incidence of hypertrophic Leydig cells in the testes. For females, NOAEL = 30 mg/kg/day, LOAEL= 234mg/kg/day based on an increased incidence of cytoplasmic vacuolation of the adrenal cortex.
870.3150	Subchronic Oral - Dog	45696803, 45696804	For males, NOAEL= 7.7 mg/kg/day, LOAEL = 26.6 mg/kg/day based on decreased body weight gains, increased liver and adrenal weights, decreased prostate weights, and histopathology findings in the adrenal glands, testes, epididymis, thymus, and prostates. For females, NOAEL $\leq$8.4 mg/kg/day. LOAEL=8.4 mg/kg/day based on increased adrenal gland weight (two out of four animals) which coincided with histopathology findings (cytoplasmic vacuoles in the Zona fasciculata of the adrenal glands).
870.3200	28-Day dermal toxicity - Rat	45696806	The NOAEL=1000 mg/kg/day (HDT; highest dose tested); however, the histopathology was not appropriately conducted as required by the guideline. The study did not examine all of the tissues, especially the possible target organs (i.e., uterus, prostate, etc).
870.3700a	Prenatal developmental - Rat	45696906	Maternal: NOAEL =1000mg/kg/day (HDT) Developmental:NOAEL= 300 mg/kg/day, LOAEL =1000 mg/kg/day based on an increased incidence of slight dilatation of the renal pelvis.

Guideline #	Study Type	MRID Nos.	Results
870.3700b	Prenatal developmental - Rabbit	45696714	Maternal: NOAEL = 100 mg/kg/day, LOAEL =300 mg/kg/day based on body weight loss and decreased food consumption. Developmental: NOAEL =1000 mg/kg/day (HDT)
870.3800	Reproduction and fertility effects - Rat	45696802, 45696709	**Parental/system:** For males: NOAEL= 5.2-6.4 mg/kg/day, LOAEL =26.2-30.2 mg/kg/day based on decreased body weight in F_0 males; decreased absolute and relative liver weight in F_0 males; decreased cholesterol and triglycerides in F_1 males; and increased severity of adrenal cortical vacuolation in F_1 males. For females, NOAEL= 5.5-7.0 mg/kg/day, LOAEL= 27.6-34.4mg/kg/day based on decreased unesterified fatty acids in F_1 females, and increased severity of adrenal cortical vacuolation in F_0 and F_1 females. **Reproductive**: For males: NOAEL= 26.2-30.2 mg/kg/day, LOAEL=134.8-177.6 mg/kg/day based on delayed sexual maturation; decreased testicular spermatid and epididymal sperm counts (oligospermia); and atrophy of the testes, epididymides, prostate and seminal vesicles. For females: NOAEL= 27.6-34.4 mg/kg/day, LOAEL= 139.2-192.7 mg/kg/day based on increased severity of ovarian luteal cell vacuolation/ degeneration. **Offspring**: NOAEL= 5.2-6.4 (M)/5.5-7.0 (F) mg/kg/day, LOAEL= 26.2-30.2 (M)/ 27.6-34.4(F) mg/kg/day based on decreased body weight and weight gain in F_1 male and female pups.

Guideline #	Study Type	MRID Nos.	Results
870.4300	Chronic toxicity - Rat	45696808, 45696809	For males: NOAEL= 14.7 mg/kg/day, LOAEL= 110.1 mg/kg/day based on decreased body weights, decreased body weight gain, increased APh levels, decreased cholesterol and triglyceride levels, increased vacuolated jejunum enterocytes, and increased incidences of Leydig cell hyperplasia. For females: NOAEL= 19.9 mg/kg/day, LOAEL= 152.9 mg/kg/day based on decreased body weights, decreased body weight gain, increased APh levels, increased TSH, uterus nodules, and increased vacuolated jejunum enterocytes. ↑ **testes Leydig cell adenoma in males, ↑ uterine adenoma and/or adenocarcinoma in females.**
870.4100b	Chronic toxicity-dog	45696810, 45696811	NOAEL= 1.38 (M)/1.52(F) mg/kg/day, LOAEL= 4.33(M)/4.74 (F) mg/kg/day based on increased relative adrenal weights in both sexes, increased relative testis weight in males and histopathology findings in the adrenal gland of both sexes.
870.4200b	Carcinogenicity - mouse	45696724	NOAEL= 4.1(M)/5.1(F) mg/kg/day, LOAEL= 610 (M) mg/kg/day based on increased absolute and relative liver and adrenal weights, decreased absolute and relative kidney weight, enlarged adrenal gland, discolored testis, adrenal gland vacuolization, interstitial cell degeneration of the testes. For females, LOAEL= 722 mg/kg/day based on increased absolute and relative adrenal weight, decreased absolute and relative kidney weight, increased incidences of adrenal gland pigmentation, and adrenal vacuolization. ↑ **Hepatocellular adenoma and carcinoma.**
870.5100	Gene mutation Salmonella typhimurium	45696702	There was no evidence of increased revertant colonies above control in 5 Salmonella strains (TA1535, TA1537, TA1538, TA100, TA98) ± S9 at concentrations up to 5000 µg/plate.

Guideline #	Study Type	MRID Nos.	Results
870.5300	In vitro Mammalian Cell Gene Mutation	45696614	Negative, tested in Chinese Hamster lung fibroblast V79 cells at concentrations up to 300 ug/mL -S9 and +S9. Cytotoxicity was observed at ≥15 ug/mL -S9 and 80 ug/mL +S9.
870.5375	In vitro Mammalian Chromosome Aberration	45696615	Negative, tested in Chinese hamster lung (V79) cells at concentrations 5-80 ug/mL or 0.75-12 ug/mL -S9 or 10-160 ug/mL +S9.
870.5395	In vivo Mouse Bone Morrow Micronucleus	45696701	Negative, tested at a dose 800 mg/kg (MTD). Clinical signs and cytotoxicity were seen at 800 mg/kg.
870.6200	Acute Neurotoxicity - Rat	45696725	NOAEL = 2000 mg/kg/day, no neurotoxicity observed.
870.6200	Subchronic neurotoxicity - Rat	45696726	NOAEL= 70.3(M)/87.3(F) mg/kg/day. LOAEL= 1088.8(M)/ 1306.5(F) mg/kg/day based on decreased body weights, food consumption, and increased urine staining in both sexes and decreased motor and locomotor activity (week 4) in females only.
870.6300	Developmental neurotoxicity	46324901	Maternal NOAEL = 135.9/273.8 mg/kg/day LOAEL = Not established. Offspring NOAEL = Not established LOAEL = 6.5/14.0 mg/kg/day based on effects in memory phase of the water maze test in PND 60 females.

For abbreviations, see Appendix I : Glossary of Terms and Acronyms

Cancer

The Agency has classified spirodiclofen as "likely to be carcinogenic to humans." Quantification of cancer risk used a Q_1^* $(mg/kg/day)^{-1}$ of 1.49×10^{-2} in human equivalents based on male rat testes Leydig cell adenoma.

DOSE RESPONSE ASSESSMENT AND FOOD QUALITY PROTECTION ACT (FQPA) CONSIDERATION

Dose Response Assessment

Based on the submitted data, the Agency determination for the acute and chronic Reference Doses (RfDs), toxicological endpoint selections, and appropriate margins of exposure (MOEs) for use as appropriate in occupational/residential exposure risk assessments, is summarized below:

The critical effect for the overall risk assessment is based on the toxic effects seen in the developmental neurotoxicity (DNT) study in rats. In this study, decreased retention (memory) was seen in females on day PND 60 in the water maze at all doses.

Acute dietary exposure limits for all populations, including infants and children were not performed because an endpoint of concern attributable to a single exposure (dose) was not identified from the oral toxicity studies. In addition, there are no developmental concerns based on rat and/or rabbit developmental toxicity studies.

Based on toxicological considerations, and the assumptions used in the exposure assessments, it was determined that an additional 10X special Food Quality Protection Act (FQPA) safety factor in the form of a database uncertainty factor be retained to account for the use of a LOAEL (instead, of a NOAEL) in calculating the reference dose for chronic risk. The uncertainty factors used in determining the cRfD were 1000 [10x for intraspecies variation, 10x for interspecies extrapolation and an additional 10X for use of a lowest-observed adverse effect level (LOAEL)]. The level of concern for all non-dietary exposure durations (short-intermediate- and long-term) is 1000 since the dose level chosen was based on a LOAEL. The chronic dietary reference dose (cRfD) is 0.0065 mg/kg/day, based on the LOAEL of 6.5 mg/kg/day from the developmental neurotoxicity study, and an uncertainty factor of 1000.

A summary of doses and toxicology endpoint selection for various exposure scenarios is given in Table 4.

Table 4. Summary of Toxicology Endpoint Selection for Spirodiclofen

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary	**Acute RfD** = Not established.	An effect of concern attributable to a single dose was not identified.	

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Chronic Dietary (All populations)	LOAEL= 6.5 mg/kg/day UF = **1000** **Chronic RfD** = 0.0065 mg/kg/day	FQPA SF = 1X **cPAD** = Chronic RfD FQPA SF = 0.0065 mg/kg/day	**Developmental Neurotoxicity Study - Rat** LOAEL of 6.5 mg/kg/day based on decreased retention (memory) in females on day 60 in the water maze at all doses.
Short-Term Incidental Oral (1 - 30 Days)	LOAEL = 6.5 mg/kg/day	**Occupational** LOC for MOE = 1000	**Developmental Neurotoxicity Study - Rat** See above section.
Intermediate-Term Incidental Oral (1 - 6 Months)	LOAEL = 6.5 mg/kg/day	**Occupational** LOC for MOE = 1000	**Developmental Neurotoxicity Study - Rat** See above section.
Short-Term Dermal (1 - 30 days)	Oral LOAEL = 6.5 mg/kg/day (dermal absorption rate= 2%)	**Occupational** LOC for MOE = 1000	**Developmental Neurotoxicity Study - Rat** See above section.
Intermediate-Term Dermal (1 - 6 Months)	Oral LOAEL= 6.5 mg/kg/day (dermal absorption rate = 2%)	**Occupational** LOC for MOE = 1000	**Developmental Neurotoxicity Study - Rat** See above section.
Long-Term Dermal (> 6 Months)	Oral LOAEL= 6.5 mg/kg/day (dermal absorption rate = 2%)	**Occupational** LOC for MOE = 1000	**Developmental Neurotoxicity Study - Rat** See above section.
Short-Term Inhalation (1 - 30 days)	Oral LOAEL = 6.5 mg/kg/day	**Occupational** LOC for MOE = 1000	**Developmental Neurotoxicity Study - Rat** See above section.

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Intermediate-Term Inhalation (1 - 6 Months)	Oral LOAEL= 6.5 mg/kg/day	**Occupational** LOC for MOE = 1000	**Developmental Neurotoxicity Study - Rat** See above section.
Long-Term Inhalation (>6 Months)	Oral LOAEL= 6.5 mg/kg/day	**Occupational** LOC for MOE = 1000	**Developmental Neurotoxicity Study - Rat** See above section.
Cancer (Oral, dermal, inhalation)	Classification: "Likely to be Carcinogenic to Humans" with Q_1* $(mg/kg/day)^{-1} = 1.49 \times 10^{-2}$		

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

FQPA Decisions

The Agency concluded that the toxicology database is adequate for Food Quality Protection Act (FQPA) purposes. Available studies include developmental toxicity studies in rats and rabbits, a two-generation reproductive toxicity study in rats, acute and subchronic neurotoxicity studies in rat, and the developmental neurotoxicity study in rats. There are no neurotoxicity concerns based on acute and subchronic neurotoxicity studies.and there is no evidence of increased susceptibility following *in utero* and/or pre-/post-natal exposure in the developmental toxicity studies in rabbits and two-generation reproduction studies in rats. In the DNT study, toxicity in the offspring (effects in the memory phase of the water maze test at post natal day 60 in females) was observed in the absence of maternal toxicity, indicating increased susceptibility. The 10X FQPA Safety Factor was retained for the use of LOAEL in a critical study in calculating the reference dose for chronic risk.

4. HUMAN HEALTH EXPOSURE AND RISK ASSESSMENT

Exposure pathways resulting from the use of spirodiclofen are: dietary (food and drinking water) and occupational. There are no residential uses. The residue chemistry, toxicology and exposure data bases are sufficient to assess risk from the proposed uses.

Residue Profile

The apple, orange, lemon, grapefruit, and grape metabolism studies indicated that metabolism of spirodiclofen in these crops was similar and involved the following steps: cleavage of the parent ester linkage with the formation of the free enol metabolite (BAJ 2510); hydroxylation of BAJ 2510 in the 3- or 4- position of the cyclohexyl ring (3-OH-enol, 4-OH-enol); cleavage of the

enol ring structure leading to the formation of 2,4-dichloro-mandelic acid-cyclohexylester compounds; and hydroxylation and/or conjugation of 2,4-dichloro-mandelic acid-cyclohexylester with carbohydrates followed by further degradation to 2,4-dichloro-mandelic acid (free or conjugated).

The goat metabolism study indicated that the metabolism of spirodiclofen in ruminants proceeds via hydrolysis of the parent ester linkage resulting in the formation of BAJ 2510 followed by hydroxylation of the 4-position of the cyclohexyl ring (4-OH-enol). BAJ 2510 accounted for the majority of the radioactivity in all matrices (81-95% TRR in tissue and milk). The 4-OH-enol metabolite was the only other metabolite identified, accounting for $\leq$8.7% in kidney, liver, and milk (not detected in muscle and fat). Spirodiclofen was not detected in any of the matrices; however, it was identified as the major residue in fat samples collected from the ruminant feeding study.

Data were not submitted concerning the residues of concern in poultry. Since there are no poultry feed commodities associated with the proposed crops, these data are unnecessary at this time. Data were also not submitted concerning the residues of concern in rotational crops. Since all of the proposed crops are considered perennials, these data are unnecessary at this time.

Based on the metabolism and environmental fate studies, the Agency made the following conclusion regarding the residues of concern in plants, livestock, rotational crops, and drinking water (the toxicity of all metabolites/degradates indicated below are considered to be identical to parent).

Table 5. Proposed Residues for Tolerance Expression and Risk Assessment

Matrix	Residues included in Risk Assessment	Residues included in Tolerance Expression
Apple, Citrus, and Grape[1]	spirodiclofen	spirodiclofen
Livestock - Ruminants	spirodiclofen, BAJ 2510	spirodiclofen, BAJ 2510
Drinking Water	spirodiclofen, BAJ 2510, BAJ 2740-dihydroxy, BAJ 2740-ketohydroxy	not applicable

[1]This conclusion will be reevaluated upon submission and review of the requested apple and grape processing studies. Prior to the submission of these data, the theoretical processing factors for all fruit juice was assumed.

Dietary Exposure and Risk

Chronic and cancer dietary risk assessments were conducted using the Lifeline™ (ver. 2.0) and DEEM-FCID™, ver. 1.30) models. Both of these models use food consumption data from the USDA's Continuing Survey of Food Intakes by Individuals (CSFII); 1994-1996 and 1998. An acute dietary risk assessment was not conducted because an effect of concern attributable to single exposure was not identified in the database.

The chronic and cancer analyses were refined through the use of average field trial residues, experimentally determined processing factors, and projected average percent crop treated estimates for apple, peach, grape, orange, and grapefruit. These averages were based on the typical average of all insecticides used to control all pests on the specific crop. The projected percent crop treated estimates for peach, apple, and grapefruit were translated to the remaining crops in the stone fruit, pome fruit, and citrus crop groups, respectively.

Since the analysis made use of average residues derived from crop field trial studies (maximum application rate and minimum preharvest interval (PHI)), incorporated maximum theoretical processing factors for juice, and surface drinking water estimates which assumed 87% of the basin cropped and 100% of the cropped area treated at the maximum rate (citrus, pecan, apple, peach, and grape), the Agency concluded that the exposure estimates are unlikely to underestimate actual exposure.

Table 6. Chronic Dietary Exposure and Risk for Spirodiclofen (drinking water included) Using Both DEEM-FCID and LifeLine Software

Population Subgroup	cPAD (mg/kg/day)	Chronic Exposure (mg/kg/day)		Chronic %cPAD	
		DEEM-FCID™	Lifeline™	DEEM-FCID™	Lifeline™
General U.S. Population	0.0065	0.000177	0.000092	3.7	1.4
All Infants (< 1 year old)		0.000517	0.000259	8.0	4.0
Children 1-2 years old		0.000515	0.000397	7.9	6.1
Children 3-5 years old		0.000379	0.000290	5.8	4.5
Children 6-12 years old		0.000209	0.000132	3.2	2.0
Youth 13-19 years old		0.000129	0.000067	2.0	1.0
Adults 20-49 years old		0.000140	0.000068	2.2	1.0
Adults 50+ years old		0.000150	0.000069	2.3	1.1
Females 13-49 years old		0.000144	0.000077	2.2	1.2

The Agency has classified spirodiclofen as "likely to be carcinogenic to humans." Quantification of cancer risk used a Q_1^*(mg/kg/day)$^{-1}$ of 1.49 x 10^{-2} in human equivalents based on male rat testes Leydig cell adenoma**.**

As indicated above, the chronic and cancer analyses incorporated average field trial residues; processing factors from the apple, grape, plum, and orange processing studies (DEEM-FCID™(ver. 7.76) default processing factors assumed for juice commodities, projected average percent crop treated estimates; and the SCI-GROW and/or PRZM-EXAMS drinking water estimates.

DEEM-FCID™ resulted in similar chronic and cancer risk estimates (all included drinking water), but due to differing drinking water assumptions, the result was a higher risk estimate using DEEM-FCID™. Based on a critical commodity analysis conducted in DEEM-FCID™, the major contributors to the cancer risk were water (34% of the total exposure), orange (20% of the total exposure) and apple (16% of the total exposure). A summary of cancer dietary exposure and risk is given in Table 7.

Table 7. Cancer Dietary Exposure and Risk for Spirodiclofen

Population Subgroup	Q_1*	Cancer			
		Exposure (mg/kg/day)		Risk	
		DEEM-FCID™	Lifeline™	DEEM-FCID™	Lifeline™
without drinking water					
General U.S. Population	0.0149	0.000072	0.00007	1.07×10^{-6}	1.03×10^{-6}
with drinking water					
General U.S. Population[1]	0.0149	0.000177	0.00009	1.59×10^{-6}	1.36×10^{-6}

[1]Differences between DEEM-FCID and Lifeline cancer risk estimates due to differences in the water estimates permitted in each program; DEEM-FCID permits only a single point drinking water estimate when conducting a cancer analysis; Lifeline permits incorporation of the entire PRZM-EXAMS distribution and incorporation of the SCI-GROW point estimate

Water Exposure/Risk Pathway

The major routes of degradation for spirodiclofen in the laboratory studies were hydrolysis, photolysis in water, and metabolism. Spirodiclofen is expected to be moderately persistent in the soil (half-life of 10-64 days), but dissipate rapidly from aquatic environments (half-life of <1 hour-4 days). The major residue identified in the aerobic soil and anaerobic/aerobic aquatic degradation studies was BAJ 2510 (52-95% the applied dose at intervals of $\leq$56 days). The aerobic soil degradation study also resulted in significant residues of BAJ 2740-dihydroxy (17% of the applied dose at an interval of 120 days), BAJ 2740-ketohydroxy (44% of the applied dose at an interval of 30 days), and DCB-acid (40% of the applied dose at an interval of 120 days). The aquatic photolysis study resulted in significant residues of BAJ 2740-dioxoketone (26% of the applied dose after an interval of 1 day). Under terrestrial field conditions, the major transformation products of spirodiclofen were BAJ 2510, BAJ 2740-ketohydroxy, BAJ 2740-dihydroxy, and DCB-acid. Spirodiclofen is expected to be immobile in soil (K_{oc} range 31,037 to 238,000) while the identified degradation products are expected to be mobile.

The Agency determined that aquatic photolysis is not expected to be an important degradation route and, therefore, concluded that BAJ 2740-dioxoketone is not of concern in drinking water. In addition, it was concluded that DCB-acid is likely to be significantly less toxic than spirodiclofen and, therefore, this compound was excluded from the risk assessment. Based on the currently available data, the Agency concluded that the residues of concern in drinking water for purposes of risk assessment are spirodiclofen, BAJ 2510, BAJ 2740-dihydroxy, and BAJ 2740-ketohydroxy.

Based on the [PRZM/EXAMS and SCI-GROW models, the EECs of [spirodiclofen (total residue including its three metabolites: spirodiclofen-enol, spirodiclofen-ketohydroxy, and spirodiclofen-dihydroxy] for acute exposures are estimated to be 22.86 parts per billion (ppb) for surface water and 0.44 ppb for ground water. The EECs for chronic (non-cancer) exposures are estimated to be 4.99 ppb for surface water and 0.44 ppb for ground water. The EECs for chronic (cancer) exposures are estimated to be 1.67 ppb for surface water and 0.44 ppb for ground water.

Residential Exposure Estimates

Because there are no residential uses, this pathway was not considered in the risk assessment.

Aggregate Risk

In accordance with the FQPA, EPA must consider and aggregate (add) pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. For spirodiclofen, no residential uses are proposed. Therefore, aggregate risk will consist of exposure from food and drinking water sources. Since an effect of concern attributable to a single dose was not identified in the database, acute aggregate risk was not addressed. Chronic and cancer aggregate risks were calculated and are discussed below.

Chronic Aggregate Risk Assessment (Food and Drinking Water)

To assess aggregate chronic risk, drinking water estimates were incorporated directly into the dietary analysis. To better evaluate aggregate risk associated with exposure through food and drinking water, the Agency is no longer comparing Estimated Drinking Water Concentration (EDWCs) generated by water quality models with Drinking Water Levels of Comparison (DWLOC) . Instead, EPA is now directly incorporating the actual water quality model output concentrations into the risk assessment. This method of incorporating water concentrations into our aggregate assessments relies on actual CSFII-reported drinking water consumptions and more appropriately reflects the full distribution of drinking water concentrations. Using the exposure assumptions described in the unit for chronic dietary exposure above, the Lifeline™ chronic risk estimates (including drinking water) were less than the Agency's level of concern (≤6.1% cPAD; children 1-2 years old were the most highly exposed population). The DEEM-FCID™ chronic risk estimates (including drinking water) were also less than the Agency's level of concern (≤8.0% cPAD; infants <1 year old were the most highly exposed population) The chronic dietary risks to various population subgroups are summarized in Table 8 below.

Since the analysis made use of average residues derived from crop field trial studies (maximum application rate and minimum preharvest interval), incorporated maximum theoretical processing factors for juice, and surface drinking water estimates which assumed 87% crop treated (citrus, pecan, apple, peach, and grape). it was concluded that the exposure estimates are unlikely to underestimate actual exposure.

Table 8. Chronic Aggregate (including drinking water) Risk for Spirodiclofen

Population Subgroup	cPAD (mg/kg/day)	Chronic			
		Exposure (mg/kg/day)		%cPAD	
		DEEM-FCID™	Lifeline™	DEEM-FCID™	Lifeline™
General U.S. Population	0.0065	0.000177	0.000092	3.7	1.4
All Infants (< 1 year old)		0.000517	0.000259	8.0	4.0
Children 1-2 years old		0.000515	0.000397	7.9	6.1
Children 3-5 years old		0.000379	0.000290	5.8	4.5

Population Subgroup	cPAD (mg/kg/day)	Chronic Exposure (mg/kg/day)		%cPAD	
		DEEM-FCID™	Lifeline™	DEEM-FCID™	Lifeline™
Children 6-12 years old		0.000209	0.000132	3.2	2.0
Youth 13-19 years old		0.000129	0.000067	2.0	1.0
Adults 20-49 years old		0.000140	0.000068	2.2	1.0
Adults 50+ years old		0.000150	0.000069	2.3	1.1
Females 13-49 years old		0.000144	0.000077	2.2	1.2

Cancer Aggregate Risk Assessment

To assess aggregate cancer risk, drinking water estimates were incorporated directly into the dietary analysis. Cancer aggregate risk was calculated for the U.S. population only. The Lifeline™ cancer risk estimates with drinking water estimates included was $1.36 \times 10^{-6.}$ Using DEEM-FCID™, the cancer risk estimate with drinking water was $1.59 \times 10^{-6.}$ DEEM-FCID™ resulted in in a higher cancer risk estimate due to differing drinking water assumptions. Lifeline™ permits incorporation of the entire PRZM-EXAMS distribution when conducting a cancer analysis while DEEM-FCID™ permits only a point estimate.

EPA has consistently interpreted negligible cancer risks to be risks within the range of an increased cancer risk of 1 in 1 million. For risk management purposes, the Agency has treated cancer risks up to 3 in 1 million as within the range of 1 in 1 million. The estimated cancer risk of 1.59 in 1 million is within the negligible risk range. Also, the cancer risk estimates were generated using average residues derived from crop field trial studies (maximum application rate and minimum preharvest interval), incorporated maximum theoretical processing factors for juice, and incorporated surface drinking water estimates which assumed 87% of the basin was cropped and 100% of the cropped area was treated at the maximum rate. EPA concludes that the estimated cancer risk is within the range of a risk of 1 in 1 million and therefore is negligible. A summary of aggregate cancer risk is given in Table 9 below.

Table 9. Cancer Aggregate Risk (including drinking water) for Spirodiclofen

Population Subgroup	Q_1*	Cancer Exposure (mg/kg/day)		Cancer risk	
		DEEM-FCID	Lifeline™	DEEM-FCID	Lifeline™
with drinking water					
General U.S. Population[1]	0.0149	0.000177	0.00009	1.59×10^{-6}	1.36×10^{-6}

[1] differences between DEEM-FCID and Lifeline™ cancer risk estimates due to differences in the water estimates permitted in each program; DEEM-FCID permits only a single point drinking water estimate when conducting a cancer analysis; Lifeline™ permits incorporation of the entire PRZM-EXAMS distribution and incorporation of the SCI-GROW point estimate

Occupational Exposure

Spirodiclofen is proposed to be applied one time per crop season by airblast equipment. It may not be applied aerially or through any type of irrigation equipment or in any type of enclosed structures such as green houses or plant houses. The rates of application in concentrate sprays range from 0.16 lb ai/acre (citrus) to 0.28 lb ai/acre high rate (for tree nuts and grapes). For occupational exposure and risk assessment, handlers and workers exposed to post-application residues were assessed. Cancer risks were calculated for both handlers and postapplication workers. The LOAEL of 6.5 mg/kg/day from the DNT was used for estimating risk from occupational exposure to spirodiclofen for short- and intermediate-term durations. Cancer risk was calculated using the Q_1* of 1.49×10^{-2} based on male rat testes Leydig cell adenoma. A MOE of 1,000 is adequate to protect occupational pesticide handlers.

Short and Intermediate-term Occupational Handler Risk

The most highly exposed occupational pesticide handlers (i.e., mixers, loaders, applicators) would be mixer/loaders using liquid, open-pour technique and applicators using open-cab, air-blast equipment. Short-term (1-30 days), intermediate-term (1-6 months) and cancer risks were assessed for handlers. Estimates of exposure to pesticide handlers are based upon the Pesticide Handler's Exposure Database (PHED) (v. 1.1, 1998).

For handlers, all margins of exposure (MOEs) exceed 1000 except for a mixer/loader that is **not** using gloves. However, the label directs mixers, loaders and other handlers to wear protective gloves; therefore, short-, intermediate-term risks for handlers following the label for the proposed use pattern do not exceed the Agency's level of concern. For cancer risk to handlers, the highest risk estimate was for mixer/loaders with a cancer risk of 4.3×10^{-6}. Therefore, all occupational handler risk estimates, including cancer risk, do not exceed Agency's level of concern.

Short/Intermediate/Long-Term Postapplication Risk

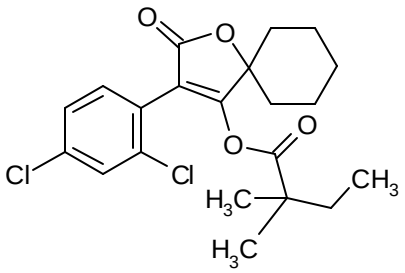
Chemical-specific data were available to estimate postapplication exposure in citrus and apple (but not for grapes). Standard default values were used to estimate exposure and risk for grapes.

For postapplication risk, estimated MOEs are greater than 1,000 for all post-application activities assessed, except for grapes. The estimated MOE for post-application activities in wine grapes is 800 and the MOE for post-harvest activities in table and raisin grapes is 400. Since both grape risk estimates result in MOEs below 1000, re-entry into treated vineyards exceeds Agency's level of concern on day zero. Since the estimated risk includes an additional 10X data gap safety factor, in this case EPA considers an MOE of 800 to be adequate to protect agricultural workers. However, an MOE of 400 (that results from vine girdling, cane turning and cane tying of raisin and table grapes) is not adequate. Therefore, a 6-day REI for vine girdling, cane turning and cane tying of raisin and table grapes is required to mitigate risk to postapplication workers. For all other uses, a REI of 12 hours is appropriate. The label lists a 14 day preharvest interval for grapes thus it would appear that a 6 day REI for some activities would not pose an undue burden to growers.

5. ENVIRONMENTAL EXPOSURE AND RISK

The physical and chemical properties of spirodiclofen are characterized by its low water solubility, hydrophobicity, and tendency to bind to soil and sediment and to bioconcentrate in aquatic organisms. Spirodiclofen is not highly persistent in the environment and its low vapor pressure and Henry's law constant limit its volatility. The chemical and physical properties of spirodiclofen are shown in Table 9.

Table 9. Physical and Chemical Properties of Spirodiclofen

Property	Value	Reference
Chemical Structure		
Molecular Weight	414.4	Registrant provided
SMILES Notation	ClC1=CC=C(C2=C(OC(C(CC)(C)C)=O)C3(CCCCC3)OC2=O)C(Cl)=C1	
CAS number	148477-71-8	Registrant provided
Water solubility	50 µg/L (pH 4 and 20°C)	MRID 45697217
Melting point	NA	
Boiling point	NA	
Vapor pressure	5.25×10^{-7} torr (25°C)	MRID 45697217
log K_{ow}	5.8 (pH 4 and 20°C)	Tomlin 2003
Henry's law constant	5.7×10^{-6} atm-m^3/mol	VP/WSOL
Hydrolysis half-life pH 4 pH 7 pH 9	 63 days 31 days 5 days	MRID 45697217
Aqueous photolysis half-life	13.7 days (artificial light) 43.8 days (Phoenix, AZ - estimated) 61.6 days (Edmonton , Canada - estimated)	MRID 45697218
Soil photolysis half-life	Stable	MRID 45697230

Aerobic soil metabolism half-life (All studies conducted at 20 degrees Celsius)	63.9 days (Hesperia fine sandy loam from California) 16.8 days (Winder fine sand from Florida) 23.8 days (Loamy sand from Germany) 10.0 days (Silt from Germany) 24.4 days (Sandy loam from California)	MRID 45697204; 45697206; 45697228;
Aerobic aquatic half-life	1-7 days	MRID 45697205
Anaerobic aquatic half-life	40.4 days	MRID 45697212
Adsorption coefficient K_{oc}	75,019 German Sandy loam 51,097 German silt loam 61,338 California loam 101,366 Texas clay loam	MRID 45697219
Bioconcentration factor (BCF)	699 (whole fish) 1,439 (non-edible tissue) 166 (edible tissues)	MRID 45697002
NA: not available		

Environmental Fate Characteristics

Transport and Mobility

The environmental fate and transport properties of spirodiclofen are well characterized. Its low vapor pressure, low Henry's law constant, and its high affinity for soils and sediment make volatilization from soils and water surfaces unlikely. Spirodiclofen is expected to be immobile in soil surfaces based on K_{oc} values in the range of 51,000 to 101,000 measured in 4 soils with thin layer chromatography (MRID 45697219). The degradation products BAJ2740-enol, BAJ2740-dihydroxy, and 2,4-dichlorobenzoic acid were all shown to have much greater mobility than the parent compound. In adsorption/desorption studies using sandy loam, clay loam, sand, and silt soils, the transformation product BAJ2470-enol was very highly mobile (K_{Foc} ranging from 11.2 to 28.59), BAJ2740-dihydroxy was highly to very highly mobile (K_{Foc} ranging from 8.9 to 131.2), and 2,4-dichlorobenzoic acid was very highly mobile (K_{Foc} ranging from 4.7 to 21.8). Additionally, estimations of adsorption coefficients in soil using HPLC determined that spirodiclofen could be classified as immobile, BAJ2740-ketohydroxy as having low to slight mobility (K_{oc} ranging from 612 to 2722 , BAJ2740-dihydroxy as having moderate mobility, BAJ2740-dioxoketone as having slight mobility with a K_{oc} of 3,720, and BAJ2740-enol and 2,4-dichlorobenzoic acid as having very high mobility. Based on its vapor pressure and Henry's law constant, volatilization from water and soil surfaces is not expected to be an important environmental fate process for spirodiclofen.

Field Dissipation

Spirodiclofen applied at a target application rate of 0.543 kg a.i./ha to fields located in California, Florida, Washington, and Canada dissipated rapidly with a calculated half-life in the range of 3-5 days for each study (MRIDs 45697207, 45697208, 45697209, 45697210). Major transformation products (>10% of the applied amount) identified were BAJ2740-enol (all test sites), BAJ2740-ketohydroxy (Florida, Washington, and Ontario test sites), 2,4-dichlorobenzoic acid (California, Washington, and Ontario test sites), and BAJ2740-dihydroxy (Florida test site). Spirodiclofen and its transformation products were not detected below the 0-15 cm depth,

Aquatic Exposure and Dissipation

Although spirodiclofen acculumlates moderately in fish (BCF for total recovered radioactive residues were 699 for the whole fish, 1,439 for non-edible tissue, and 166 for edible tissues), it dissipates rapidly at the depuration phase. After 1 day of depuration, total residues in whole fish tissues had decreased by 70%. After 13 days of depuration, total residues had decreased by 98%.

Surface water estimated environmental concentrations (EECs) of spirodiclofen were generated using the Tier 2 environmental fate program PRZM/EXAMS for six different crop scenarios. Employing maximum application rates, it was observed that the EECs were low for this compound with concentrations ranging from less than 1 ppb to about 4 ppb.

In aquatic systems, spirodiclofen dissipated with half-lives of about 1-7 days in natural water/sediment mesocosms under aerobic conditions (MRID 45697205) and approximately 40 days in mesocosms when maintained under anaerobic conditions (MRID 45697212). In each case, the major degradation product was BAJ2740-enol.

Ecological Effects and Risk

For the assessment of spirodiclofen risks, the risk quotient (RQ) method was used to compare exposure and measured toxicity values (see Appendix F). Estimated environmental concentrations (EECs) are divided by acute and chronic toxicity values. The RQs are then compared to the Agency's levels of concern (LOCs). These LOCs are the Agency's interpretive policy used to analyze potential risk to non-target organisms and the need to consider regulatory action. For non-target aquatic animals (*i.e.*, fish, invertebrates) and plants (*i.e.*, macrophytes, algae), surface water EECs were obtained from the Tier 2 model PRZM/EXAMS. For non-target terrestrial animals (*i.e.*, birds and mammals), EECs were obtained from ELL-FATE. Exposure of terrestrial plants was estimated using the Tier 1 model TERRPLANT. Details of all RQs are provided in tables below.

Terrestrial

Spirodiclofen is practically nontoxic to terrestrial animals on an acute exposure basis, and the likelihood of acute risk from exposure to spirodiclofen and its -enol degradate appears to be low. Although this compound does not appear to cause reproductive effects in avian species, there is the potential for chronic risk to mammals that can be reflected in reduced reproductive success and growth. Chronic risk LOCs are exceeded for mammals based on impaired growth in the F_0 and F_1 generations. In addition, chronic exposure may cause

endocrine effects that are reflected in reduced cholesterol levels (cholesterol is a precursor for several reproduction hormones like estradiol and testosterone). However, risk to small mammals was refined by using the RQ values from T-REX terrestrial model; and by using the dislodgeable foliar residues in place of the 35 day default value. EPA has begun using the new method T-REX using an oral dose which adjusts for the size of the animal and its diet in the wild. The traditional method uses dietary exposure to calculate RQs. Both assessment methods indicated that that RQ values slightly exceed the LOC for mammals. Based on this screening level assessment, these estimated risks to mammals are not a concern. These RQs were calculated at the highest rate being 0.53 lb a.i./A for grapes. This rate has been reduced to 0.28 lb a.i./A. Additionally, the dietary exposure RQs can be compared to RQ values calculated for older pesticides and for the structurally similar pesticide spiromesifen to put the ecological risk from spirodiclofen in perspective.

Table 10. Acute RQs for mammals exposed to spirodiclofen (parent compound only) based on maximum residues as calculated by ELL-FATE and an acute LD_{50} >2000 mg/kg body wt.

Application Rate (lb a.i./A)	Crop Use	Body Weight (g)	Mammalian Acute Risk Quotients (all RQs are < the reported value) [a, b]				
			Short Grass	Tall Grass	Broadleaf Plants/ Small Insects	Fruits/ Pods/Large Insects	Seeds
0.28	Pome and stone fruit	15	0.032	0.015	0.018	0.0020	0.00044
		35	0.022	0.01	0.012	0.0014	0.00032
		1000	0.005	0	0.0028	0.00032	0.000063
0.31	citrus	15	0.035	0.016	0.020	0.0022	0.00049
		35	0.025	0.011	0.014	0.0015	0.00035
		1000	0.006	0	0.0031	0.00035	0.000070
0.53	grapes and nuts	15	0.06	0.028	0.034	0.0038	0.00084
		35	0.042	0.019	0.024	0.0026	0.00060
		1000	0.01	0	0.0054	0.00060	0.00012

[a] RQs are calculated using ELL-FATE. Details are provided in Appendix C.

[b] RQs are below the LOC for acute risk (LOC 0.5), acute restricted use (LOC 0.2), and acute endangered species (LOC 0.1).

Table 11. Chronic RQs for mammals exposed to spirodiclofen (parent compound only) based on maximum residues as calculated by ELL-FATE and a chronic NOAEC = 70 ppm a.i.

Application Rate (lb a.i./A)	Crop Use	Mammalian Chronic Risk Quotients [a]			
		Short Grass	Tall Grass	Broadleaf Plants/ Small Insects	Fruits/Pods/Large Insects
0.28	Pome and stone fruit	0.96	0.44	0.54	0.060
0.31	citrus	1.1 [b]	0.49	0.60	0.066
0.53	grapes and nuts	1.8 [b]	0.83	1.0 [b]	0.11

[a] RQs are calculated using ELL-FATE. Details are provided in Appendix C.

[b] RQ meets or exceeds the LOC for chronic risk (LOC 1)

Table 12. Chronic RQs for mammals exposed to spirodiclofen (parent compound only) based on mean residues as calculated by ELL-FATE and a chronic NOAEC = 70 ppm a.i.

Application Rate (lb a.i./A)	Crop Use	Mammalian Chronic Risk Quotients [a,b]			
		Short Grass	Tall Grass	Broadleaf Plants/ Small Insects	Fruits/Pods/Large Insects
0.28	Stone and pome fruit	0.34	0.14	0.18	0.028
0.31	citrus	0.38	0.16	0.20	0.031
0.53	grapes and nuts	0.64	0.27	0.34	0.053

[a] RQs are calculated using ELL-FATE. Details are provided in Appendix C.

[b] RQs are below the LOC for chronic risk (LOC 1)

Table 13. Mammalian chronic RQ values using the maximum Kenaga residues for Spirodiclofen. RQ were generated with T-REX terrestrial model for application to grapes and nuts at 0.53 lbs ai/A with one application per year.

EEC Equivalent Dose (mg/kg-bw)	15 g mammals	35 g mammals	1000 g mammals
Short Grass	8.59	7.38	3.88
Tall Grass	3.94	3.38	1.78
Broadleaf Plant/Sm. Insects	4.83	4.15	2.18
Fruit/Lg. Insects	0.54	0.46	0.24
Seeds	0.12	0.1	0.05

Table 14. Mammalian chronic RQ values using the mean Kenaga residues for Spirodiclofen. RQ were generated with T-REX terrestrial model for application to grapes and nuts at 0.53 lbs ai/A with one application per year.

EEC Equivalent Dose (mg/kg-bw)	15 g mammals	35 g mammals	1000 g mammals
Short Grass	3.04	2.61	1.37
Tall Grass	1.29	1.11	0.58
Broadleaf Plant/Sm. Insects	1.61	1.38	0.73
Fruit/Lg. Insects	0.25	0.22	0.11
Seeds	0.06	0.05	0.02

Birds

Results of acute toxicity studies in birds indicate that spirodiclofen is practically non-toxic, with the acute LC_{50} for spirodiclofen >5,000 mg a.i./kg diet and all acute RQ values for birds were below the LOCs for acute risk (LOC 0.5), acute restricted use (LOC 0.2), and acute endangered species (LOC 0.1) (Table 19). Similarly, chronic RQs based on the NOAEC of >720 ppm a.i. were below the chronic LOC of 1 (Table 20).

Application Rate (lb a.i./A)	Crop Use	Short Grass	Tall Grass	Broadleaf Plants/ Small Insects	
0.28	Stone and pome fruit	0.013	0.0062	0.0076	0.00084
0.31	citrus	0.015	0.0068	0.0084	0.00093
0.53	grapes and nuts	0.025	0.012	0.014	0.0016

[a] RQs are calculated using ELL-FATE. Details are provided in Appendix C.

[b] RQs are below the LOC for acute risk (LOC 0.5), acute restricted use (LOC 0.2), and acute endangered species (LOC 0.1).

Table 16. Chronic RQs for birds exposed to spirodiclofen (parent compound only) based on maximum residues as calculated by ELL-FATE and a chronic NOAEC = 720 ppm a.i.

Application Rate (lb a.i./A)	Crop Use	Avian Acute Risk Quotients (all RQs are < the reported value) [a, b]			
		Short Grass	Tall Grass	Broadleaf Plants/ Small Insects	Fruits/Pods/Large Insects
0.28	Stone and pome fruit	0.093	0.043	0.053	0.006
0.31	citrus	0.1	0.047	0.058	0.065
0.53	grapes and nuts	0.18	0.081	0.099	0.011

[a] RQs are calculated using ELL-FATE. Details are provided in Appendix C.

[b] RQs are below the LOC for chronic risk (LOC 1)

Beneficial Insects

In assessing the risk to beneficial insects, the Agency does not calculate RQ values, but does present a qualitative assessment. In the case of spirodiclofen, evaluation of acute studies suggests that exposure of this compound should not present an acute risk to beneficial insects such as honey bees or parasitic wasps. However, longer-term laboratory and field studies conducted using the formulated product show that populations of honey bees and the predaceous mite *Typhlodromus pyri* are adversely affected (i.e., brood development, pupal and larval abundance, colony strength) at application rates ranging from 0.011 to 0.128 lb a.i./A. Since lipid stores are important for early life stage development in honey bees and other beneficial insects, chronic exposure to a compound that affects lipid biosynthesis could compromise the ability of organisms to successfully compete in the environment (i.e., ability to find food, ability to avoid predators, ability to reproduce). Based on this information, beneficial insect populations appear to be at risk from exposure to spirodiclofen at the proposed application rates. Label use restrictions are required for mitigating risk to honey bees.

Aquatic

Assessment of acute risks to aquatic organisms (fish and invertebrates) is substantially limited because definitive toxicity endpoints (*i.e.*, LC_{50} values) and dose responses were not developed due to solubility issues encountered during testing. Since the acute toxicity values for aquatic organisms could not be established, the estimated risk quotients are less than the highest level of exposure; however, since no mortality or sublethal effects were noted at the highest test concentration and since the highest test concentration is relatively close to the solubility limit of spirodiclofen in freshwater (50 ug/L, pH 4), it can be assumed that the solubility of this compound would limit its acute toxicity to aquatic invertebrates and fish. Although this compound has the potential for causing chronic effects in aquatic invertebrates (e.g., number of young/day) and fish (e.g., growth effects in young) the usage pattern described in this report shows that the expected exposure level in the environmental should be below Agency's level of concern by one to two orders of magnitude. This screening level assessment shows that this compound should not present chronic risk to aquatic organisms.

An additional uncertainty includes the toxicity of the degradates, especially BAJ2740-ketohydroxy and the 2,4-dichlorobenzoic acid. Although BAJ2740-enol appears to be less toxic than the parent compound, potential toxicity of the other degradates is unknown. However, since the degradates break-down from the -enol and change very little in structure from the -enol, it can be assumed that their toxicity profile is similar to the -enol.

Application Rate	Use	Organism	LC_{50} (µg a.i./L)	EEC Peak [a] (µg a.i./L)	
0.28 lb a.i./A	Oregon apple	rainbow trout	>35.1	0.155	<0.0044
	Pennsylvania apple	rainbow trout	>35.1	2.06	<0.059
	Georgia peach	rainbow trout	>35.1	1.45	<0.041
0.31 lb a.i./A	Florida citrus	rainbow trout	>35.1	2.7	<0.077
0.53 lb a.i./A	Georgia pecan	rainbow trout	>35.1	4.12	<0.12
	California grape	rainbow trout	>35.1	0.295	<0.008

[a] EEC values (µg/L) are 24-hour peak concentrations in surface water generated from PRZM/EXAMS.

[b] RQs are based on the rainbow trout (*Oncorhynchus mykiss*) 96-hr LC_{50} >35.1 µg/L.

Table 18. Chronic RQs for freshwater fish exposed to spirodiclofen.

Application Rate	Crop Use	Organism	NOAEC (µg a.i./L)	90-Day EEC [a] (µg a.i./L)	Chronic RQ (EEC/NOAEC)
0.28 lb a.i./A	Oregon apple	rainbow trout	1.95	0.0178	0.0091
	Pennsylvania apple	rainbow trout	1.95	0.19	0.097
	Georgia peach	rainbow trout	1.95	0.0735	0.038
0.31 lb a.i./A	Florida citrus	rainbow trout	1.95	0.172	0.088
0.53 lb a.i./A	Georgia pecan	rainbow trout	1.95	0.261	0.13
	California grape	rainbow trout	1.95	0.0187	0.0096

[a] EEC values (µg/L) are 90-day average concentrations in surface water generated from PRZM/EXAMS.

[b] RQs are based on the rainbow trout (*Oncorhynchus mykiss*) 97-day NOAEC 1.95 µg/L.

[c] RQs exceed LOC for chronic risk (LOC 1)

Application Rate	Crop Use	Organism	LC_{50} (µg a.i./L)	EEC Peak [a] (µg a.i./L)	
0.28 lb a.i./A	Oregon apple	*Daphnia magna*	>45.5	0.155	<0.0034
	Pennsylvania apple	*Daphnia magna*	>45.5	2.06	<0.045
	Georgia peach	*Daphnia magna*	>45.5	1.45	<0.032
0.31 lb a.i./A	Florida citrus	*Daphnia magna*	>45.5	2.7	<0.059
0.53 lb a.i./A	Georgia pecan	*Daphnia magna*	>45.5	4.12	<0.091
	California grape	*Daphnia magna*	>45.5	0.295	<0.0065

[a] EEC values (µg/L) are 24-hour peak concentrations in surface water generated from PRZM/EXAMS.

[b] RQs are based on the *Daphnia magna* 48-hr LC_{50} >45.5 µg/L.

Table 20. Chronic RQs for freshwater invertebrates exposed to spirodiclofen.

Application Rate	Crop Use	Organism	NOAEC (µg a.i./L)	21-Day EEC [a] (µg a.i./L)	Chronic RQ (EEC/NOAEC) [c]
0.28 lb a.i./A	Oregon apple	*Daphnia magna*	11.1	0.0676	0.0061
	Pennsylvania apple	*Daphnia magna*	11.1	0.584	0.05
	Georgia peach	*Daphnia magna*	11.1	0.295	0.03
0.31 lb a.i./A	Florida citrus	*Daphnia magna*	11.1	0.561	0.05
0.53 lb a.i./A	Georgia pecan	*Daphnia magna*	11.1	0.932	0.08
	California grape	*Daphnia magna*	11.1	0.0774	0.0070

[a] EEC values (µg/L) are 24-hour peak concentrations in surface water generated from PRZM/EXAMS.

[b] RQs are based on the *Daphnia magna* 21-day NOAEC = 11.1 µg/L.

[c] RQ equals the LOC for chronic risk (LOC 1)

Table 21. Acute RQs for estuarine/marine fish exposed to spirodiclofen.

Application Rate	Crop Use	Organism	LC_{50} (µg a.i./L)	EEC Peak [a] (µg a.i./L)	Acute RQ (EEC/LC_{50})
0.28 lb a.i./A	Oregon apple	sheepshead minnow	>35.2	0.155	<0.0044
	Pennsylvania apple	sheepshead minnow	>35.2	2.06	<0.058
	Georgia peach	sheepshead minnow	>35.2	1.45	<0.041
0.31 lb a.i./A	Florida citrus	sheepshead minnow	>35.2	2.7	<0.077

Table 21. Acute RQs for estuarine/marine fish exposed to spirodiclofen.					
Application Rate	Crop Use	Organism	LC_{50} (µg a.i./L)	EEC Peak [a] (µg a.i./L)	Acute RQ (EEC/LC_{50})
0.53 lb a.i./A	Georgia pecan	sheepshead minnow	>35.2	4.12	<0.12
	California grape	sheepshead minnow	>35.2	0.295	<0.0084

[a] EEC values (µg/L) are 24-hour peak concentrations in surface water generated from PRZM/EXAMS.

[b] RQs are based on the sheepshead minnow 96-hour LC_{50} >35.2 µg a.i./L

Table 22. Acute RQs for estuarine/marine invertebrates exposed to spirodiclofen.					
Application Rate	Crop Use	Organism	LC_{50} (µg a.i./L)	EEC Peak [a] (µg a.i./L)	Acute RQ (EEC/LC_{50})
0.28 lb a.i./A	Oregon apple	mysid shrimp	>37	0.155	<0.0042
	Pennsylvania apple	mysid shrimp	>37	2.06	<0.056
	Georgia peach	mysid shrimp	>37	1.45	<0.039
0.31 lb a.i./A	Florida citrus	mysid shrimp	>37	2.7	<0.073
0.53 lb a.i./A	Georgia pecan	mysid shrimp	>37	4.12	<0.11
	California grape	mysid shrimp	>37	0.295	<0.0080

[a] EEC values (µg/L) are 24-hour peak concentrations in surface water generated from PRZM/EXAMS.

[b] RQs are based on the mysid shrimp 96-hour LC_{50} >37 µg a.i./L

Aquatic and Terrestrial Plants

Since spirodiclofen has structural similarity to a group of chemicals that were developed as herbicides (i.e., the bicyclic tetramic acids), the conceptual model of ecological exposure of spirodiclofen included concerns for potential adverse effects to plants. However, after evaluating the data for aquatic and terrestrial plants, the low RQ values that were calculated suggest little or no risk to plants.

Endangered Species Concerns

Based on the screening level analyses conducted, the Agency's acute levels of concern for endangered species is exceeded for freshwater and estuarine/marine fish and freshwater invertebrates. The LOC for endangered species were also exceeded for amphibians, mammals, and insects. Further refinements of the ecological risk assessment are needed to provide a species-specific understanding of potential risks to the listed species.

6. REGULATORY POSITION AND RATIONALE

Available data provide adequate information to support the conditional registration of spirodiclofen technical and end-use products for use on agricultural crops.

Labeling Restrictions

A. Manufacturing Use Products

1. Precautionary Statements/Environmental Hazards

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless it is 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.

B. End-Use Products

1. Surface Water Advisory and Runoff Management

This product may contaminate water through runoff or through drift of spray in wind. 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.

2. Environmental Hazards

This pesticide is toxic to fish and aquatic invertebrates. Avoid contamination of surface water through runoff or spray drift. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water cleaning equipment or disposing of equipment washwater.

This product is toxic to honey bees. Do not apply this product during crop blooming period or if hives are present within the orchard or grove when application is planned.

3. Endangered Species

The use of any pesticide in a manner that may kill or otherwise harm endangered species or adversely modify their habitat is a violation of Federal law.

4. Use Restrictions for Grapes

In the Agricultural Use Requirements box, state the following: "Do not allow workers to enter treated areas during the restricted entry interval (REI) of 12 hours following application. An REI of 6 days is required for certain post-application activities in grapes. Refer to this use site for details."

In the Direction for Use, Notes for grapes, state the following: "Do not allow workers to perform the following activities for 6 days after application: vine girdling, cane turning, and cane tying of raisin and table grapes."

5. Mixing Instructions

Mix pesticides in areas not prone to runoff such as concrete mixing/loading pads, disked soil in flat terrain or graveled mix pads, or use a suitable method to contain spills and/or rinsate. Properly empty and triple-rinse pesticide containers at time of use.

6. Resistance Management

Revise according to PR Notice 2001-5.

7. DATA GAPS

Product Chemistry

1. Provide details of the commercial scale production process for the TGAI/MUP for the facility located in Germany.

2. Provide the 5-batch analysis for TGAI/MUP batches produced on a commercial scale. Submit a revised basic formulation based on the 5-batches produced on a commercial scale.

Residue Chemistry

Apple (juice) and grape (juice) processing studies which monitor for residue of spirodiclofen, BAJ 2510, 3-OH-enol, and 4-OH-enol.

Toxicology

1. In the developmental neurotoxicity study, additional morphometric analyses of the caudate putamen, parietal cortex, hippocampal gyrus, and dentate gyrus at the mid and low doses are required for both sexes.

2. A 28-day inhalation toxicity study is required as a condition of registration. However, based on the low volatility and low inhalation toxicity (Category IV) of spirodiclofen and inhalation MOEs of at least 1000 for the proposed uses, spirodiclofen qualifies for a waiver of the 28-day inhalation toxicity study for the proposed uses. The requirement for the 28-day inhalation toxicity study is waived for this action only. If in the future, requests for new uses or formulations are submitted that may result in a significant change in either the toxicity profile or exposure scenarios, EPA will reconsider this data requirement.

Environmental Fate and Effects

Although the risk appears low, EPA still needs certain data points in order to be consistent in our requirements. All registrants are expected to submit toxicity tests, preferable with a dose response. However, if there is a problem with solubility, the registrant must use different solvents and then if the insolubility continues, they are expected to contact the Agency for guidance. In the case of spirodiclofen the registrant only tried one solvent and assumed that the limit of solubility would suffice for risk assessment and DER requirements. As mentioned previously, there is considerable uncertainty regarding whether spirodiclofen's solubility or sorption to glass affected the extent to which the pesticide could be recovered in aquatic systems. The following studies must be repeated to establish a dose response, and to enable refinement of the risk.:

Freshwater Fish Acute Toxicity Study using Bluegill Sunfish (Guideline §72-1a)

Freshwater Fish Acute Toxicity Study using Rainbow trout (Guideline §72-1a)

Freshwater Invertebrate Toxicity Study using Daphnia magna (Guideline 72-2a)

Estuarine/Marine Acute Toxicity using Sheepshead Minnow(Guideline 72-3a)

Estuarine/Marine Acute Toxicity using Mysid Shrimp (Guideline 72-3b)

The new tests should attempt to use a teflon-lined test apparatus or better equilibrate the exposure system such that there are fewer sorption sites available for spirodiclofen. Additionally, greater effort should be expended to examine alternative co-solvents.

8. CONTACT PERSON AT EPA

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Appendix I

GLOSSARY OF TERMS AND ABBREVIATIONS

ADNT	Acute delayed neurotoxicity
a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
ARI	Aggregate Risk Index
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
ChE	Cholinesterase
ChEI	Cholinesterase inhibition
cPAD	Chronic Population Adjusted Dose
CSFII	Continuing Survey of Food Intake by Individuals
%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

GLOSSARY OF TERMS AND ABBREVIATIONS (Continued)

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
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
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 SPIRDICLOFEN

MRID	Citation
45696500	Bayer Corp. (2002) Submission of Residue, Fate and Product Chemistry Data in Support of the Applications for Registration of Spirodiclofen Technical and Envidor 2SC Miticide and the Petition for Tolerance of Spirodiclofen on Grapes, Citrus, Pome Fruits, Stone Fruits, and Tree Nuts. Transmittal of 21 of 225 Studies.
45696501	Fontaine, L. (2002) Product Chemistry of Envidor 2SC Miticide: Lab Project Number: BR 2086: 200125: FDT-1020. Unpublished study prepared by Bayer Corp. 167 p.
45696502	Fontaine, L. (2002) Product Chemistry of Spirodiclofen Technical: Lab Project Number: BR 2101: 15-920-2102: 2005-0010101-99 E. Unpublished study prepared by Bayer Corp. 270 p. {OPPTS 830.1550, 830.1620, 830.1670, 830.1700, 830.1750, 830.1800}
45696503	Fontaine, L. (2002) Product Chemistry of Spirodiclofen Technical: Lab Project Number: BR 2102: 15-600-2116: 2005-003002-99E. Unpublished study prepared by Bayer Corp. 157 p.
45696504	Babczinski, P. (1999) Metabolism of BAJ 2740 in Citrus (Oranges) After Early Application: Lab Project Number: M 1730821-2: 109589: MR-226/98. Unpublished study prepared by Bayer AG. 71 p. {OPPTS 860.1300}
45696505	Babczinski, P. (1999) Translocation of BAJ 2740 in Citrus (Grapefruits): Lab Project Number: M 1720824-4: 109590: MR228/98. Unpublished study prepared by Bayer AG. 39 p. {OPPTS 860.1300}
45696506	Babczinski, P.; Bornatsch, W. (1999) Metabolism of BAJ 2740 in Grapes After Early and After Late Application: Lab Project Number: M 1730853-7: 109591: MR 227/98. Unpublished study prepared by Bayer AG. 127 p. {OPPTS 860.1300}
45696507	Babczinski, P.; Bornatsch, W. (1999) Metabolism of BAJ 2740 in Citrus (Lemons) After Late Application: Lab Project Number: 109593: M 1730822-3: 13507.1096.6116.761. Unpublished study prepared by Bayer AG. 97 p. {OPPTS 860.1300}
45696508	Jalali, K.; Hiler, R.; Gibson, N. (1999) The Metabolism of (Carbon 14) BAJ 2740 in the Lactating Goat: Lab Project Number: 1154E726W: 109727. Unpublished study prepared by Bayer AG. 129 p. {OPPTS 860.1300}

45696509 Koester, J. (2000) Dihydrofuranone-3-(Carbon 14) BAJ 2740: Distribution of the Total Radioactivity in the Rat Determined by Quantitative Whole Body Autoradiography: Lab Project Number: 109854: M 9990832-0: MR 227/00. Unpublished study prepared by Bayer AG. 57 p. {OPPTS 870.7485}

45696510 Koster, J.; Bornatsch, W.; Haas, M. (1999) Metabolism of (Dihydrofuranone-3-(Carbon 14)) BAJ 2740 by Plant Cell Cultures: Lab Project Number: 110642: M 1710823-2. Unpublished study prepared by Bayer AG. 55 p. {OPPTS 860.1300}

45696511 Andersch, I.; Koester, J. (2000) (Dihydrofuraone-3-(Carbon 14)) BAJ 2740: Investigation of Biokinetic Behaviour and the Metabolism in the Rat: Lab Project Number: 110646: M 51819060: M 1820831-3. Unpublished study prepared by Bayer AG. 224 p. {OPPTS 870.7485}

45696512 Koster, J.; Andersch, I. (2000) (Dihydrofuranone-3-(Carbon 14)) BAJ 2740: Investigation of Biokinetic Behaviour and the Metabolism in the Rat Following Subchronic Feeding: Lab Project Number: M 01819074: 110647: MR-610/99. Unpublished study prepared by Bayer AG. 108 p. {OPPTS 870.7485}

45696513 Koster, J. (1999) Metabolism of BAJ 2740 in Apples: Lab Project Number: 110857: M 1730852-6: MR 137/99. Unpublished study prepared by Bayer AG. 90 p. {OPPTS 860.1300}

45696514 Moore, S.; Bretch, F.; Murphy, I.; et al. (2002) An Analytical Method for the Determination of BAJ 2740 Residue in Various Plant Matrices by LC-MS/MS: Lab Project Number: BJ111601: 109351: 109726. Unpublished study prepared by Bayer Corp. 173 p. {OPPTS 860.1340}

45696515 Mattern, G.; Woodard, D. (2001) Analytical Method for the Determination of BAJ 2740 Residue and its Enol Metabolite (BAJ 2510) in Animal Tissues and Milk: Lab Project Number: 109720: BJ120201. Unpublished study prepared by Bayer Corp. 78 p. {OPPTS 860.1340}

45696516 Krolski, M. (2000) BAJ 2740 240 SC--Magnitude of the Residue in Orange Processed Commodities: Lab Project Number: BJ19OR02: 109726: BJ111601. Unpublished study prepared by Bayer Corp. 222 p. {OPPTS 860.1520}

45696517 Perez, R.; Perez, S.; Jacquart, B. (2001) Evaluation of BAJ2740 and its Enol Metabolite (BSJ2510) By FDA Multiresidue Method (MRM) Testing: Lab Project Number: 109749: BJ162301: ADPEN-982-2K-0805. Unpublished study prepared by ADPEN Laboratories, Inc. 134 p. {OPPTS 860.1340 and 860.1360}

45696518 De Haan, R. (2000) BAJ 2740 340SC--Magnitude of the Residue in Grape Processed Commodities: Lab Project Number: 109750: BJ19GR02: 109351. Unpublished study prepared by Bayer Corp. 153 p. {OPPTS 860.1520}

45696519 Woodard, D.; Mattern, G. (2000) Extraction Efficiency of the Analytical Residue Method for the Determination of BAJ 2740 Residues in Animal Tissues and Milk:

Lab Project Number: BJ220201: 2000B167: 109867. Unpublished study prepared by Bayer Corp. 36 p. {OPPTS 860.1340}

45696520 De Haan, R. (2000) BAJ 2740 240SC--Magnitiude of the Residue in Plum Processed Commodities: Lab Project Number: BJ19PM02: 109871: 109351. Unpublished study prepared by Bayer Corp. 113 p. {OPPTS 860.1520}

45696521 Beedle, E. (2001) BAJ 2740 240SC and BAJ 2740 40 WG--Magnitiude of the Residue in Almonds and Pecans (Crop Group 14--Tree Nuts): Lab Project Number: BJ19AM01: BJ19PA01: 109872. Unpublished study prepared by Bayer Corp. 213 p. {OPPTS 860.1500}

45696600 Bayer Corp. (2002) Submission of Residue, Exposure, Risk and Toxicity Data in Support of the Applications for Registration of Spirodiclofen and Envidor 2SC and the Petitions for Tolerance of Spirodiclofen on Citrus, Stone Fruits, Pome Fruits and Tree Nuts and the Import Tolerance on Grapes. Transmittal of 17 of 225 Studies.

45696601 Krolski, M. (2001) BAJ 2740--A 29-Day Dairy Cattle Feeding Study: Lab Project Number: BJ060401: 109898: 200-0445B. Unpublished study prepared by Bayer Corp. and Southwest BioLabs, Inc. 161 p. {OPPTS 860.1480}

45696602 Harbin, A. (2002) BAJ 2740 240 SC--Magnitude of the Residue in Apple Processed Commodities: Lab Project Number: 110025: BJ19AP02: 109351. Unpublished study prepared by Bayer Corp. and ACDS Research, Inc. 148 p. {OPPTS 860.1520}

45696603 Nelson, S.; Hoshowski, J. (2001) Independent Laboratory Validation of the "Analytical Method for the Determination of BAJ 2740 and its Enol Metabolite (BAJ 2510) in Animal Tissues and Milk": Lab Project Number: 00ILV02BAY: BJ110201: 110477. Unpublished study prepared by Enviro-Test Laboratories. 94 p. {OPPTS 860.1340}

45696604 Wehrman, J. (2001) Independent Laboratory Validation of "An Analytical Method for the Determination of BAJ 2740 Residue in Various Plant Matrices": Lab Project Number: BJ111602: 110760: 109351. Unpublished study prepared by ABC Laboratories. 115 p. {OPPTS 860.1340}

45696605 De Haan, R. (2002) BAJ 2740 240 SC and 40 WG--Magnitude of the Residue in Cherries, Peaches, and Plums (Crop Group 12--Stone Fruits): Lab Project Number: 110761: BJ19CH01: BJ19PC01. Unpublished study prepared by Bayer Corp. 302 p. {OPPTS 860.1500}

45696606 De Haan, R. (2002) BAJ 2740 240 SC and 40 WG--Magnitude of the Residue in Apples and Pears (Crop Group 11--Pome Fruit): Lab Project Number: 110762: BJ19AP01: BJ19PR01. Unpublished study prepared by Bayer Corp. 274 p. {OPPTS 860.1500}

45696607 Spiegel, K.; NuBlein, F. (2000) Determination of Residues of BAJ 2740 240 SC (A.S. BAJ 2740) on Grape in the Field of France and the Federal Republic of Germany: Lab Project Number: 111026: RA-2026/98: 811397. Unpublished study prepared by Bayer AG. 50 p. {OPPTS 860.1500}

45696608 Spiegel, K.; NuBlein, F. (2000) Determination of Residues of BAJ 2740 240 SC (A.S. BAJ 2740) on Grape in the Field of Portugal, France, Italy, Greece and Spain: Lab Project Number: 111027: 811389: 912706. Unpublished study prepared by Bayer AG. 68 p. {OPPTS 860.1500}

45696609 Nusslein, F. (2000) Determination of Residues of BAJ 2740 240 SC (A.S. BAJ 2740) Following Spray Application on Tablegrape in the Field in Greece: Lab Project Number: R 1999 0277/8: 111028: RA-2092/99. Unpublished study prepared by Bayer AG. 41 p. {OPPTS 860.1500}

45696610 Nusslein, F.; Andersch, I. (2000) Determination of Residues of BAJ 2740 on Grapes and Vine Leaves After Spray Application of BAJ 2740 240 SC in the Field in Germany and France: Lab Project Number: 111029: R 1999 00880: R 1999 02719. Unpublished study prepared by Bayer AG. 70 p. {OPPTS 860.1500}

45696611 Haas, M. (2000) Extraction Efficiency Testing of the Residue and Confirmatory Method for the Determination of BAJ 2740 Residues in Whole Apples and in Citrus (Peel) Using Aged Radioactive Residues: Lab Project Number: M 9991004-2: 110874: MR 429/99. Unpublished study prepared by Bayer AG. 52 p. {OPPTS 860.1340}

45696612 Krolski, M. (2002) BAJ 2740 240 SC--Magnitude of the Residue and Citrus (Crop Group 10): Lab Project Number: 111030: BJ19OR03: BJ19LM02. Unpublished study prepared by Bayer Corp. 277 p. {OPPTS 860.1500}

45696613 Lenz, C. (2002) Evaluation of Acute and Chronic Dietary Exposure to BAJ 2740 and Assessment of Potential Risk: Lab Project Number: 111021. Unpublished study prepared by Bayer Corp. 55 p.

45696614 Brendler-Schwaab, S. (1997) BAJ 2740 Mutagenicity Study for the Detection of Induced Forward Mutations in the V79-HPRT Assay In Vitro: Lab Project Number: 25974: T 8053749: 107784. Unpublished study prepared by Bayer AG. 36 p. {OPPTS 870.5300}

45696615 Herbold, B. (1996) BAJ 2740 In Vitro Mammalian Chromosome Aberration Test with Chinese Hamster V79 Cells: Lab Project Number: 107785: PH-25716: T 7053748. Unpublished study prepared by Bayer AG. 38 p. {OPPTS 870.5375}

45696616 Kroetlinger, F. (1996) BAJ 2740 Study for Acute Oral Toxicity in Rats: Lab Project Number: 25255: T6060794: 107786. Unpublished study prepared by Bayer AG. 29 p. {OPPTS 870.1100}

45696617 Kroetlinger, F. (1996) BAJ 2740 Study for Acute Dermal Toxicity in Rats: Lab Project Number: 25254: T7060795: 107787. Unpublished study prepared by Bayer AG. 29 p. {OPPTS 870.1200}

45696700 Bayer Corporation (2002) Submission of Toxicity and Product Chemistry Data in Support of the Applications for Registration of Spirodiclofen Technical and Envidor 2SC Miticide and the Petitions for Tolerance of Spirodiclofen on Citrus, Pome Fruits, Stone Fruits and Tree Nuts and the Import Tolerance for Spirodiclofen on Grapes. Transmittal of 29 of 225 Studies.

45696701 Herbold, B. (1996) BAJ 2740 Micronucleus Test on the Mouse: Lab Project Number: PH-25358: T 7060236: 107788. Unpublished study prepared by Bayer Ag. 49 p. {OPPTS 870.5395}

45696702 Herbold, B. (1996) BAJ 2740 Salmonella/Microsome Test Plate Incorporation and Preincubation Method: Lab Project Number: 25325: T 3053744: 107789. Unpublished study prepared by Bayer Ag. 55 p. {OPPTS 870.5100}

45696703 Stropp, G. (1996) BAJ 2740 Study for the Skin Sensitization Effect in Guinea Pigs (Guinea Pig Maximization Test According to Magnusson and Kligman): Lab Project Number: 107796: 25463: T 0060824. Unpublished study prepared by Bayer Ag. 29 p. {OPPTS 870.2600}

45696704 Moore, K.; Brenneke, C. (1997) A Liquid Chromatographic Method for the Determination of BAJ 2740 in Rodent Ration: Lab Project Number: 108004: 96-899-KE. Unpublished study prepared by Bayer Corporation. 20 p.

45696705 Moore, K. (1997) A Liquid Chromatographic Method for the Determination of BAJ 2740 in Rodent Ration: Lab Project Number: 96-899-KE: 108004-1: 108004. Unpublished study prepared by Bayer Corporation. 9 p.

45696706 Leuschner, P. (1997) Acute Eye Irritation Study of BAJ 2740 by Instillation into the Conjunctival Sac of Rabbits: Lab Project Number: 108024: T3060160: R 6954. Unpublished study prepared by LPT Laboratory of Pharmacology and Toxicology. 24 p. {OPPTS 870.2400}

45696707 Leuschner, P. (1997) Acute Skin Irritation Study (Patch Test) of BAJ 2740 in Rabbits: Lab Project Number: 108025: R 6953: T3060160. Unpublished study prepared by LPT Laboratory of Pharmacology and Toxicology. 21 p. {OPPTS 870.2500}

45696708 Moore, K; Brenneke, C. (1998) The Homogeneity and Stability of BAJ 2740 in Rodent Ration: Lab Project Number: 96-872-KK: 108164. Unpublished study prepared by Bayer Corporation. 15 p.

45696709 Eiben, R. (1997) BAJ 2740: One-Generation Study in Wistar Rats: Lab Project Number: PH-26960: T5061530: 108545. Unpublished study prepared by Bayer AG. 165 p.

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