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WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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MEMORANDUM

August 6, 2001

SUBJECT: EFED Risk Assessment for Section 3 Registration of Bispyribac-Sodium (Sodium 2,6-bis[(4,6-dimethoxypyrimidin-2-yl)oxy]benzoate)(Regiment™)

TO: Jim Tompkins, Product Manager 25
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THROUGH: Norman Birchfield, Risk Assessment Process Leader
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Attached please find the Environmental Fate and Effects Division's (EFED) environmental risk assessment for bispyribac-sodium 2,6-bis[(4,6-dimethoxypyrimidin-2-yl)oxy]benzoate) (Regiment™) registration as a postemergence contact herbicide on rice. Although bispyribac-sodium is a moderately persistent and mobile compound and will likely move to surface and ground water through runoff and leaching, the herbicide is practically nontoxic to both terrestrial and aquatic animals and is unlikely to pose either an acute or chronic risk to animals at the maximum proposed application rate of 0.0265 lbs a.i./acre (0.05 lbs. ai./acre/season) on rice. Additionally, bispyribac-sodium is not expected to pose a risk to aquatic plants; however, EFED is uncertain regarding the effects of this herbicide to terrestrial and semi-aquatic plants. Terrestrial plant studies (vegetative vigor and seedling emergence) were classified as supplemental, and underscored some uncertainties regarding the observed stimulatory growth effects of bispyribac sodium at very low concentrations. However, based on risk quotients derived from the data in the studies, acute risk levels of concern are exceeded for terrestrial and semi-aquatic plants.

Uncertainties

The environmental fate data base for the parent compound is complete (**Table A1**). However, if it should be determined that any of the metabolites prove to be of toxicological concern, additional studies would be required. While the laboratory studies successfully characterize the degradation of bispyribac-sodium, formation and decline of the metabolites have not been adequately described in either of the two aquatic metabolism studies. Additionally, only two of the six compounds identified as major metabolites in the laboratory studies were monitored in the aquatic field dissipation studies. Bispyribac-sodium, the parent compound, is mobile and moderately persistent in the environment, and will (depending on soil conditions) likely move to surface and groundwater where it may accumulate. The true extent of this compound's ultimate fate can only be gauged through a review of additional environmental fate studies capable of identifying the fate characteristics of the compound's degradates.

Although the ecological effect data base is relatively complete (**Table A2**), several of the studies are classified as supplemental. Aquatic toxicity tests using fish and invertebrates were classified as supplemental since water quality parameters did not adhere to standards recommended by the Environmental Fate and Effects Division. If the registrant can demonstrate that pH, water hardness and the use of dechlorinated tap water do not effect the toxicity of bispyribac-sodium, these studies can be upgraded to core. However, EFED is not requiring that the aquatic toxicity tests be repeated.

Additionally, EFED is uncertain regarding the dose responsiveness of terrestrial plants treated with the compound and the actual, *i.e.* measured concentrations, of bispyribac-sodium applied during the terrestrial plant studies. Both the seedling emergence and vegetative vigor studies were classified as supplemental and as not having fulfilled guideline testing requirements. In both studies, plant dry weight was the most sensitive indicator of treatment effects. Stimulatory growth effects of bispyribac sodium at very low concentrations combined with the already low nominal concentrations used, *i.e.*, 0.00002 lbs active ingredient per acre, suggest that actual application rates may have potentially differed from nominal application rates. However, as an alternative explanation the low-dose stimulatory effect of the compound may be related to the phenomenon of "hormesis" where low doses of some compounds result in enhanced growth whereas larger doses inhibit growth. Based on the uncertainties regarding the terrestrial plant studies, the reviewer has suggested that application rates be confirmed by conducting residue analysis on test plants and spray collectors in the treatment area.

Finally, the aquatic plant study of the freshwater green algae (*Selenastrum capricornutum*) is classified as supplemental since the study exceeds EFED's recommended values for initial cell densities and light intensity. Although the study provided useful information for conducting an aquatic risk assessment, the reviewer was uncertain about the effects these study conditions would have on the test's ability to demonstrate a treatment effect. In spite of these uncertainties, EFED is requesting that the test be repeated.

Data Gap

Because of uncertainties regarding how environmental conditions might effect the outcome of the aquatic plant toxicity study (Guideline 122-2) of green algae (*Selenastrum capricornutum*), EFED is requesting that this study be repeated.. EFED also requests that residue data are provided for both the seedling emergence and vegetative vigor terrestrial plant studies to confirm the low nominal application rates.

Table A1. Status of environmental fate data requirements for Bispyribac-sodium.

Guideline #		Data Requirement	Is Data Requirement Satisfied?	MRID #'s	Study Classification
161-1	835.2120	Hydrolysis	yes	448892-26	acceptable
161-2	835.2240	Photodegradation in Water	yes	448892-27	acceptable
161-3	835.2410	Photodegradation on Soil	yes	448892-28	acceptable
161-4	835.2370	Photodegradation in Air	not required		
162-1	835.4100	Aerobic Soil Metabolism	yes	449299-31	acceptable
162-2	835.4200	Anaerobic Soil Metabolism	not required		
162-3	835.4400	Anaerobic Aquatic Metabolism	yes	448892-29 453593-01	invalid [1] acceptable
162-4	835.4300	Aerobic Aquatic Metabolism	yes	448892-30	acceptable
163-1	835.1240 835.1230	Leaching-Adsorption/Desorption	yes	448892-31	acceptable
163-2	835.1410	Laboratory Volatility	not required	na	na
163-3	835.8100	Field Volatility	not required	na	na
164-1	835.6100	Terrestrial Field Dissipation	not required	na	na
164-2	835.6200	Aquatic Field Dissipation	yes[5]	449299-32 448892-33 453545-01 448892-35 448892-34 453301-01 448892-32	supplemental invalid [2] supplemental supplemental invalid [2] supplemental invalid [3]
164-3	835.6300	Forestry Dissipation	not required	na	na
164-4	835.6400	Combination Products and Tank Mixes Dissipation	not required	na	na
165-4	850.1730	Accumulation in Fish	waived [4]	na	na
165-5	850.1950	Accumulation- aquatic non-target	not required	na	na
166-1	835.7100	Ground Water- small prospective	not required	na	na
201-1	840.1100	Droplet Size Spectrum	reserved	na	na
202-1	840.1200	Drift Field Evaluation	reserved	na	na

[1]-mislabeling of chromatography peaks in MRID #448892-29 was corrected in MRID #453593-01; [2]-abstracts from MRID #'s 448892-33 and 448892-34 had been transposed. MRID #'s 453545-01 and 453301-01 correct the error; [3]-insufficient data was provided to determine if this study was acceptable; [4]-EFED concurs with waver request, see appended memo. [5] Studies fulfill guideline requirement if degradates are nontoxic.

Table A2. Status of ecological effect data requirements for bispyribac-sodium.

Guideline #	Data Requirement	MRID #	Classification	Is data requirement satisfied?
71-1	Avian acute oral LD_{50}	449299-03	Core	yes
71-2	Avian subacute dietary LC_{50} bobwhite quail mallard duck	 449299-05 449299-04	 Core Core	yes
71-4	Avian reproduction bobwhite quail mallard duck	 451973-02 451973-01	 Core Core	yes
72-1	Freshwater fish acute LC_{50} rainbow trout bluegill sunfish	 448891-14 448891-15	 Supplemental [3] Supplemental [3]	yes
72-2	Freshwater invertebrate acute LC_{50} (daphnia)	448891-16	Core	yes
72-3a	Estuarine/marine fish acute LC_{50} (sheepshead minnow)	448891-18	Supplemental[2]	yes
72-3b	Estuarine/marine acute invertebrateEC_{50} (mysid)	448891-19	Supplemental[2]	yes
72-3c	Estuarine/marine acute invertebrate EC_{50} (oyster)	448891-17	Supplemental[2]	yes
72-4c	Freshwater invertebrate life cycle (daphnia)	448891-20	Core	yes
81-1[1]	Acute mammalian oral LD_{50} (rat)	448891-27	Acceptable	yes
83-5[1]	Two-generation mammalian reproduction (rat)	449299-22 449299-23	Acceptable	yes
122-1	Terrestrial plant vegetative vigor	445950-15	Supplemental[3]	no
122-1	Terrestrial plant seedling emergence	445950-14	Supplemental[3]	no
123-2	Aquatic plant acute EC_{50} (*Lemna gibba*)	448892-23	Core	yes
122-2	Aquatic plant (green algae) acute EC_{50} (*Psuedokirchnellia subcapitata*)	448892-17	Core	yes
122-2	Aquatic plant acute EC_{50} freshwater diatom (*Anabaena flos-aquae*)	448892-18	Core	yes
122-2	Aquatic plant acute EC_{50} (*Navicula pelliculosa*)	448892-19	Core	yes
122-2	Aquatic plant (green algae) acute EC_{50} (*Skeletonema costatum*)	448892-20	Supplemental[4]	no
144-1	Acute honeybee contact	448892-24	Core	yes

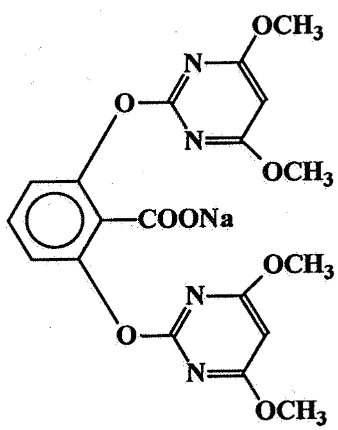
[1]Health Effects Division guidelines[2]Formulated product (Bispyribac-sodium 80S; 79% active ingredient) tested rather than technical grade active ingredient. [3]Study can be upgraded to core if registrant provides data indicating that pH, water hardness, nor the use of dechlorinated tap water affect the toxicity of bispyribac-sodium to aquatic organisms; however, no additional study is required at this time.[3] Terrestrial plant studies can be upgraded to core if chemical residue data are available to confirm nominal application rate. [4] Freshwater green algae study classified as supplemental due to use of too great a light intensity and cell density.

United States
Environmental Protection
Agency

Office of Prevention, Pesticides,
and Toxic Substances

Environmental Fate and Ecological Risk Assessment for the Registration of

Bispyribac-sodium (Sodium 2,6-bis[(4,6-dimethoxypyrimidin-2-yl)oxy]benzoate)



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EXECUTIVE SUMMARY

Bispyribac-sodium is a postemergence herbicide proposed for control of weeds associated with direct-seeded rice. Based on the available data, the compound is moderately persistent and mobile and will likely move into surface and ground water through runoff and leaching. Although bispyribac-sodium is expected to be persistent and mobile, the compound is practically nontoxic to both terrestrial and aquatic animals and it is unlikely that it will represent a threat of either acute or chronic ecological risk to animals at the maximum proposed application rate of 0.053 lbs. a.i./A per year. Although bispyribac-sodium is likely to reach surface water via runoff, based on RQ values, aquatic plants are unlikely to be at risk. As might be expected for a herbicide, acute levels of concern are exceeded for terrestrial and/or semiaquatic plants (RQ range 1.1 - 2.9). EFED is uncertain regarding the potential effects of bispyribac-sodium on terrestrial and semi-aquatic plants. Plant weight was the most sensitive indicator of terrestrial plant effects. Stimulatory growth effects of bispyribac sodium at very low concentrations combined with the already low nominal concentrations used, i.e., 0.00002 lbs active ingredient per acre, suggest that actual application rates may have potentially differed from nominal application rates; however, an alternative explanation is that the increased growth rates observed at very low doses are a result of a phenomenon termed "hormesis" where at low concentrations, herbicides can result in a stimulatory effect and at higher concentrations result in an inhibitory effect on plants.

INTRODUCTION

Bispyribac-sodium (PC Code 078906) is a postemergence contact herbicide belonging to the pyrimidinyl oxybenzoic acid group. Valent Chemical Company is developing bispyribac-sodium (Trade name: Regiment™) for use on rice (direct seeded) in the U.S.

Mode of Action

The chemical's mode of action is through inhibition of acetolactate synthase (ALS) and the biosynthesis of three-branched amino acids: valine, leucine and isoleucine. This inhibition interferes with cell division and causes cessation of plant growth. Plant chlorosis, necrosis and death of sensitive plants follows. Herbicidal selectivity is determined by adsorption and translocation and differential metabolism. In sensitive plants, bispyribac-sodium is adsorbed through the leaf surface and translocated throughout the plant. In rice plants, bispyribac-sodium is rapidly metabolized to nonherbicidal products.

Use Characterization

Bispyribac-sodium will be applied to rice as a post-emergent spray, formulated as 81.6% active ingredient (a.i.) by weight, after the 3-leaf stage of development until the panicle initiation (green ring) stage of development (excluding the rice variety CM 101). The compound is to be applied at a maximum rate of 12 grams a.i./A (0.026 lbs a.i./A) not to exceed 24 grams a.i./A per season (0.053 lbs a.i./A) The recommended application interval is at least 3 weeks using either aircraft or ground application spraying of 10 to 20 gallons of aqueous solution/Acre.

ENVIRONMENTAL FATE AND TRANSPORT ASSESSMENT

Summary

Bispyribac-sodium is a moderately persistent, mobile compound on most soils. **Table 1** summarizes the physico-chemical properties of bispyribac-sodium. The primary degradation pathways are aerobic and anaerobic metabolism, forming six major metabolites (**Appendix A**; DesMe-2023, Bx-180, DesMe-180, 2,6-DBA, MeBa and Me_2Ba). These metabolites break down further, eventually mineralizing to carbon dioxide. Batch adsorption studies, when considered together with model simulation results, indicate a potential for both leaching and runoff. Due to the aquatic nature of rice cultivation, irrigation canals and flood water holding ponds associated with rice paddies are particularly vulnerable to both spray drift and potential runoff due to overflow and/or breeching of levies associated with large rainfall events. Once clay sub-soils associated with the cropped paddies have swelled sufficiently to eliminate any cracks, leaching is unlikely to emanate directly from a rice field which has been specifically designed to maintain a permanent flood. However, until clay soils of newly flooded paddies become fully saturated, leaching can occur. The possibility for leaching also exists when flood waters are released from the paddy; however, the potential for this compound to leach is mitigated by the low application rate (0.053 lbs a.i./Acre/season).

Table 1. Physical-chemical properties of Bispyribac-sodium.

PARAMETER	VALUE
Chemical name	sodium 2,6-bis[(4,6-dimethoxypyrimidin-2-yl)oxy] benzoate
Molecular Weight	452.4
Solubility	73.3 g/L
Vapor Pressure	1×10^{-7}
Hydrolysis half life (pH 5)	88 days
Hydrolysis half life (pH 7)	stable
Hydrolysis half life (pH 9)	stable
Aqueous photolysis half life	stable
Soil photolysis half life	stable
Aerobic soil metabolism half life	18.9 days (first 55 days) and 97 days (day 55 to study termination)
Aerobic aquatic dissipation half life	46 days in silt loam and 82 days in sandy loam soils
Anaerobic aquatic dissipation half life	88 days in silt loam and 109 days in sandy loam soil
Soil-water distribution coefficient (K_d)	0.604 - 2.01 mL/g
Octanol-water partition coefficient (K_{ow})	114 ± 86

Degradation and Metabolism

Hydrolysis

Bispyribac-sodium hydrolized at pH 5 with a half-life of 88 ± 15 days (95 % confidence interval), and is stable to hydrolysis at pH 7 and pH 9 (MRID #448892-26). Dual 2-position pyrimidine labeled [^{14}C]-bispyribac-sodium (1.0 ppm) was hydrolytically stable in buffer solutions at pH 7 (HEPS and TRIS buffers) and at pH 9 held in darkness, at 25°C for the 30-day test period. Sterility was maintained throughout the test period This study is acceptable and satisfies the hydrolysis data requirement.

Aqueous Photolysis

Bispyribac-sodium is stable to aqueous photolysis (MRID #448892-27). Dual 2-position pyrimidine labeled [^{14}C]-bispyribac-sodium (1 mg/mL) is photolytically stable in a sterile, pH 7 aqueous buffer solution irradiated for 30 days with a xenon arc lamp. This study is acceptable and satisfies the aqueous photolysis data requirement.

Soil Photolysis

Bispyribac-sodium is stable to soil photolysis (MRID #448892-28). Dual 2-position pyrimidine labeled [^{14}C]-bispyribac-sodium (2.0 ppm) is photolytically stable on Gridley clay loam soil samples sealed at 75 % of 0.33 bar soil moisture content and incubated at 25°C for 30 days of 12 hour light/dark cycles. Degradation (attributed to hydrolysis) was observed to occur in both the irradiated and the dark control systems, with slightly differing distributions of the concentrations of the various metabolites. After subtracting away the contribution from the dark control system, soil photolysis was shown to be an insignificant route for degradation. This study is acceptable and satisfies the soil photolysis data requirement.

Aerobic Soil Metabolism

Uniformly benzene-labeled bispyribac-sodium and bispyribac-sodium labeled in the 2 position of the pyrimidine ring (nominal application rate of 0.6 mg/g; combined data) degraded through a two-step model, with half-lives of 18.9 days for the first 55 days, and 97 days from day 55 to study termination (MRID #449299-31). Specifically, in a Gridley series (clay loam soil at pH 6.1 adjusted to 75 % of the moisture content at 0.33 bar and incubated in darkness at 25°C for 348 days) a half-life of 18.9 days (18 to 20 days at 95% confidence interval; $r^2 = 0.995$) fits the data well for up to the first 55 days. From 55 days to study termination, a half-life of 97.0 days (83 to 118 days at 95% confidence interval; $r^2 = 0.958$) fits the data well. The bi-phasic degradation curve characterized by two half-lives, fits the data better than a single first-order half-life.

Three of the eight identified metabolites which where were monitored during this study are considered major degradates (**Table 2;** see **Appendix A** for chemical structures of major degradates). Up to 57 % of the applied radiation could be found in evolved CO_2 by study termination. However, without additional data, the complexity of the ostensive degradation pathway for bispyribac-sodium precludes accurate half-life estimations for these aerobic metabolism products. This study is acceptable and satisfies the aerobic soil metabolism data requirement.

Table 2. Major Aerobic Soil Metabolism Residues of bispyribac-sodium degradation products

Metabolite / [^{14}C] Residue	Maximum Values		% of Applied Radiation at Study Termination	
	%	Day	Benzene Label	Pyrimidin Label
Bx-180	11.4 %	55	3.4 %	1.9 %
2,6-DBA	11.8 %	187	9.2 %	--[1]
Me_2Ba	12.1 %	14	--[1]	1.4 %

[1]Not detected.

Aerobic Aquatic Metabolism

Uniformly benzene-labeled bispyribac-sodium and bispyribac-sodium labeled in the 2 position of the pyrimidine ring (0.5 ppm) degraded (**Table 3;** see **Appendix A** for chemical structures of major degradates) with half-lives of 46 days in silt loam soil and 82 days in sandy loam soil (MRID #448892-30). In Louisiana silt loam soil (pH 7.3), bispyribac-sodium (combined data from both labels), flooded with well water and incubated in darkness at 25°C under aerobic conditions for 30 days, degraded with a calculated, first-order half-life of 46 ± 5 days. In Arkansas sandy loam soil (pH 6.1), bispyribac-sodium (combined data from both labels), flooded with well water and incubated in darkness at 25°C under aerobic conditions for 30 days, degraded with a calculated, first-order half-life of 82 ± 26 days. Tabulated data submitted with this study report indicates that greater than 75 % of measured concentrations of parent and metabolites are found in the water phase of the test system, indicating a possible potential for leaching. The aerobic aquatic metobolism half-life used to estimate water numbers, *i.e,* 25.1 days, represents upper 90[th] percentile confidence interval on mean of two calculated values estimated by nonlinear regression of untransformed data

Table 3. Calculated Aerobic Aquatic Metabolism First Order Half-Life (95% confidence interval)

Louisiana Silt Loam			Arkansas Sandy Loam		
Benzene Label	Pyrimidine Label	Combined Data	Benzene Label	Pyrimidine Label	Combined Data
45.4 (39-55) days	46.8 (40-57) days	**46.2 ± 4.9 days (42 - 52 days)**	102 (70-179) days	68.0 (46-130) days	**81.7 ± 26 days (64 - 115 days)**

Should any of the metabolites prove to be of toxicological concern, additional data may be required. While the common moiety method used for the conformational mass spectroscopy is unable to differentiate between the parent and/or any of the proposed metabolites with an identical backbone structure, the tabulated retention times for the analytical standards agreed well enough with the chromatographic peaks from the test systems to enable meeting current needs for identification of metabolites. Additionally, the Biological and Economic Assessment Division (BEAD) Method Validation Report (No. ECM 0183W1) for determination of bispyribac-sodium in water indicates that the analytical method submitted by Valent U. S. A., *i.e.*, gas chromatography with a nitrogen-phosphorus flame-ionization detector, has a limit of detection of 0.5 ppb and a limit of quantitation of 1.0 ppb. This method is believed to be adequate for monitoring of the parent compound at these concentrations, when found in the environment.

Only one metabolite, DesMe-2023, was reported to be present at 13.6 % on day 30 in the pyrimidine labeled Louisiana silt loam soil No other degradates were detected at greater than 5 % of the applied radio-activity in any test system. No evolved $^{14}CO_2$ was detected in any test system. This study is acceptable and satisfies the aerobic aquatic metabolism data requirement.

Anaerobic Aquatic Metabolism

Uniformly benzene-labeled bispyribac-sodium and bispyribac-sodium labeled in the 2 position of the pyrimidine ring (0.5 ppm) degraded (**Table 4**; see **Appendix A** for chemical structures of major degradates) with half-lives of 88 days in silt loam soil and 109 days in sandy loam soil (MRID #453593-01). In Louisiana silt loam soil (pH 7.3), bispyribac-sodium (combined data from both labels), flooded with well water and incubated under anaerobic conditions, in darkness, at 25°C for 367 days, degraded with a calculated, first-order half-life of 88 ± 11 days. In Arkansas sandy loam soil (pH 6.1), bispyribac-sodium (combined data from both labels), flooded with well water and incubated under anaerobic conditions, in darkness, at 25°C for 30 days, degraded with a calculated first-order half-life of 82 ± 26 days. Greater than 80 % of measured concentrations of parent and metabolites is found in the water phase of the test system, confirming the potential for leaching indicated by the reported K_d value.

Table 4. Calculated Anaerobic Aquatic Metabolism First Order Half-Life (95% confidence interval)

Louisiana Silt Loam			Arkansas Sandy Loam		
Benzene Label	Pyrimidine Label	Combined Data	Benzene Label	Pyrimidine Label	Combined Data
97.2 (83-118) days	81.1 (69-98) days	**88.4 ± 11 days (79 - 101 days)**	133 (107-175) days	92.8 (71-136) days	**109 ± 26 days (89 - 141 days)**

Should any of the metabolites prove to be of toxicological concern, additional data may be required. While the common moiety method used for the conformational mass spectroscopy is unable to differentiate between the parent and/or any of the proposed metabolites with an identical backbone structure, the tabulated retention times for the analytical standards agreed well enough with the chromatographic peaks from the test systems to enable meeting current needs for identification of metabolites.

Five major metabolites (DesMe-2023, DesMe-180, 2,6-DBA, MeBa, and Me_2Ba) were monitored during this study (**Table 5**). No half-lives were calculated for these anaerobic metabolism products due to the complexity of the ostensive degradation pathway for bispyribac-sodium. No evolved [^{14}C]organic volatiles were detected in any system. This study is acceptable and satisfies the anaerobic aquatic metabolism data requirement.

Table 5. Reported Anaerobic Aquatic Metabolism residues of bispyribac-sodium degradation products

Metabolite / [^{14}C] Residue	Maximum Values		% Applied Radiation at Study Termination			
			Louisiana Silt Loam		Arkansas Sandy Loam	
	% Applied Radiation	Day	Bz	Py	Bz	Py
DesMe-2023	24.8 %	183	5.72 %	5.69 %	20.3 %	8.31 %
DesMe-180	15.8 %	122	--[1]	<1.6 %	<2.7 %	13.7 %
2,6-DBA	42.3 %	367	42.3 %	--[1]	34.2 %	--[1]
MeBa	44.5 %	275	--[1]	40.9 %	--[1]	18.2 %
Me_2Ba	21.9 %	367	--[1]	1.95 %	--[1]	21.9 %

[1] Not detected.

Adsorption/Desorption

Bispyribac-sodium is not expected to bind extensively to either soil or aquatic sediment. Desorption coefficient (K_d) values ranged from 0.604 to 2.01 mL/g, with an overall organic carbon partition coefficient (K_{oc}) value of 114. Soil characteristics such as organic carbon content, cation exchange capacity and clay content, indicate a good correlation between the partitioning constant and all three physical factors. A regression K_{oc} of 114 ± 86 at the 95% confidence interval was derived for bispyribac-sodium from a plot of the adsorption K_d verses percent organic matter in soil generated from isothermal plots of the adsorption/desorption data (MRID #448892-31). The slope of the resulting line provided the overall K_{oc} for this compound. Individual K_d and K_{oc} values were calculated by applying the Freundlich isotherm model **Table 6**. Although only two soils in the definitive study (clay loam and silt loam sediment) reached the desired 20% to 80% absorption range desired for the Freundlich model, all of the adsorption isotherms displayed a high degree of linearity for plots of ln (Ce) *vs.* ln (x/m), indicating that the Freundlich model adequately describes the data for this compound. As K_{oc} values decrease, leaching potential of bispyribac-sodium increases. The coefficient of determination (r^2) for the relationships $K_{d(ads)}$ *versus* organic matter content, $K_{d(ads)}$ *versus* cation exchange capacity, and $K_{d(ads)}$ *vs.* clay content were 0.925, 0.829 and 0.961 respectively, indicating a good correlation between all three physical factors. These three factors, coupled with the cationic nature of bispyribac-sodium in solution, influence the sorption of bispyribac-sodium in soil. This study is acceptable and satisfies the adsorption/desorption data requirement for parent compound, bispyribac-sodium.

Table 6. Summary of submitted mobility studies for Bispyribac-sodium.

Study	Soil	K_d (mL/g)	n	K_{oc} (mL/g)
Adsorption/Desorption	clay loam	2.01	1.06	143
	silt loam sediment	1.62	1.04	270
	sandy loam	0.929	1.07	186
	silt loam	0.616	1.01	308
	sand	0.604	1.04	604

Aquatic Field Dissipation

Aquatic field dissipation studies, conducted in cropped rice paddies located in Louisiana and Arkansas, were submitted as four separate studies; one for the parent (MRID #'s 449299-32 and 448892-35) and one for two metabolites, DesMe-2023 and Me_2BA, (MRID #'s 453545-01 and 453301-01) at each test site. These studies were determined to be scientifically valid, but provided only supplemental information for use in evaluating the aquatic field dissipation of bispyribac-sodium. No data were provided to indicate if reported water concentrations were normalized to account for either variations in flood water depth, or the "normal agricultural practice" of maintaining a flow of fresh water through the rice paddy. Additionally, no data were provided indicating either the volume of water removed, or the concentration of either parent or metabolites in pore water drained from sample soil cores before capping and freezing. Data from both of the aquatic metabolism studies (MRID #'s 453593-01 and 448892-30), and an overall K_{oc} value of 114 from the adsorption/desorption study (MRID # 448892-31), indicate that the majority of measured bispyribac-sodium and metabolite residues should be found in the aqueous phase of the test system. It is not possible to accurately monitor environmental concentrations, mobility, or other avenues of residue dissipation, of either bispyribac-sodium, or its metabolites, when an unknown sized portion of the one component of the test system most likely to contain these residues, i.e. pore water, has been removed from the core samples before testing.

Parent bispyribac-sodium was applied once, to dry fields, up to three days prior to establishment of the permanent flood, as a wettable powder, at a nominal maximum seasonal application rate of 0.054 lb a.i./acre, in an over-the-top application to a growing rice crop at the five-leaf stage to plots of Norwood silty clay loam soil in Louisiana and Crowley silt loam soil in Arkansas. Agency review of residue data shows dissipation of bispyribac-sodium from the total test systems with half-lives of 9.0 ± 0.8 days (MRID #448892-35) for the Louisiana test site, and 80.9 ± 21days (MRID #449299-32) days for the Arkansas test site. Given the nature of the variability of the test systems, theses results are reasonably consistent with the laboratory data.

Only two of the six major metabolites identified in the laboratory studies, *i.e.* DesMe-2023 and Me_2BA, were monitored in the aquatic field dissipation studies. Residues were occasionally detected in lower soil profiles, but in only one or two of the three replicates. EFED questions if more closely spaced sampling intervals might have detected a downward movement through the test system.

Table 7. Reported Maximum Metabolism Residues of Bispyribac-sodium Degradation Products

Metabolite	Aerobic Soil Metabolism (MRID #449299-31)	Aerobic Aquatic Metabolism (MRID #48892-30)	Anaerobic Aquatic Metabolism (MRID #453593-01)
DesMe-2023	8.7 %	13.6 %	24.8 %
Bx-180	11.4 %	3.70 %	6.74 %
DesMe-180	8.1 %		15.8 %
2,6-DBA	11.8 %	<2.65 %	42.3 %
MeBa	7.6 %	4.93 %	44.5 %
Me_2Ba	12.1 %		21.9 %
2,6-MDB	9.6 %		
Bispyribac Methyl Ester	0.6 %		

From aquatic field dissipation data alone, it is not possible to: (1) follow the formation and decline of all major degradates, (2) determine by what mechanism the parent compound will dissipate from soil/water, or (3) to track possible dissipation through leaching through the soil profile from the submitted aquatic field dissipation data alone. Laboratory studies (hydrolysis, photolysis, metabolism, and mobility studies; **see Table 1**), predicts that bispyribac-sodium is moderately persistent in the environment and fairly mobile in most soils. The data suggest that, in addition to biotic degradation, leaching through the soil profile and/or runoff are major dissipation mechanisms. EFED models use these degradation rates as input values rather than field dissipation rates. These input values are then mathematically manipulated in an attempt to recreate the processes that are expected to act upon the compound(s) of interest in the environment. Measured field dissipation rates, on the other hand, represent a combination of mechanisms encompassing both degradation and transport processes. Scientifically solid field dissipation data can be invaluable in confirming modeled assessments derived from laboratory data sources. Taken together, these four aquatic field dissipation studies are supplemental, and do not fully satisfy the aquatic field dissipation data requirement. However, unless toxicological data indicate that one or more of the metabolites monitored in the laboratory studies are of ecological concern, no additional studies are required at this time.

BIOACCUMULATION

Valent USA Corporation has requested a waver for the bioaccumulation in fish data requirement (Guideline Number 165-4) for bispyribac-sodium, formulated as Regiment™ Herbicide. Based on (1) a low maximum use rate of 0.053 lb active ingredient per acre, (2) an intended use solely on rice crops, and (3) the low K_{oc} partitioning coefficient value of 114 (from MRID #448892-31), Environmental Fate and Effects Division concurred with the registrant's rationale and recommended granting the waiver (**Appendix F**).

WATER RESOURCE ASSESSMENT

The Office of Pesticide Programs currently has no official model for estimating environmental concentrations (EEC's) in surface water for pesticides used in rice culture; therefore, a screening calculation method was developed for rice culture and hence the EEC's are provisional only. The estimates in **Table 8** reflect soils and management practices prevalent in the Southeastern U.S. Gulf Coast for rice culture. Note that these concentrations are in nanograms per liter (ng/L), or parts per trillion. These low concentrations indicate that, in spite of a relatively modest overall K_{oc} value of 114, *i.e.*, low tendency to sorb to organic matter in soil, the potential for bispyribac-sodium to either leach into ground water, or to be transported with runoff, is of minimal environmental concern.

Table 8. Estimated Environmental Concentrations for Bispyribac-sodium Use on Rice.

Surface water - ecological risk assessment	**312 ng L^{-1}**
Surface water - drinking water risk assessment	**272 ng L^{-1}**
Groundwater - drinking water risk assessment	**7.2 ng L^{-1}**

Ground Water

Estimates for ground water concentrations were made using the Screening Concentrations in Ground Water (SCI-GROW) model according to the method described in Barrett, 1997. SCI-GROW is based on a regression approach which relates the concentrations found in ground water in Prospective Ground Water studies to aerobic soil metabolism rate and soil-water partitioning properties of the chemical. Input values and results are presented in **Table 9.**

Table 9. Input Parameters and Results from SCI-GROW for Bispyribac-sodium Applied to Rice.

Parameter	*Value*
Mean Aerobic Soil Metabolism Half-life	20.0 days
Soil Water Partition Coefficient, K_{oc}	114 L kg^{-1}
Total Annual Application Rate	0.0528 lb $acre^{-1}$
Ground Water EEC	**7.2 ng L^{-1}**

Surface Water

A description of the model used for surface water concentrations appear in **Appendix B.** This model is a new tool for screening aquatic EEC's in rice and has not been fully evaluated. It is used on a provisional basis only. Estimates were done for each of the three major rice growing regions in the United States, the Gulf Coast of Louisiana and Texas, the Mississippi Valley including parts of northern Louisiana, Mississippi, Arkansas, and southern Missouri, and California in the Sacramento River Basin. A soil was selected for each region representative of those used for rice production in each area. Because agricultural management practices differ in each region, a brief description of the extent to which these practices have been modeled in this assessment, along with the model input parameters, are tabulated below in **Tables 10** and **11**, respectively.

Table 10. Management Practices, as Simulated for Rice Growing Regions.

Practice	Gulf Coast	Mississippi Valley	California
Seeding Method	Wet	Dry	Wet
Interval to Flood (Dry Seeded)	NA	28 days	NA
Flood Management Method	Pinpoint	Delayed	Continuous
Drain Flood Water Prior to Panicle Initiation	Yes	No	Yes

Table 11. Input Parameters for Modeling Surface Water Concentrations for Bispyribac-sodium Applied to Rice.

Parameter	*Value*
Aerobic Soil Metabolism Half-life	118.1 days[1]
Aerobic Aquatic Metabolism Half-life	25.1 days[2]
Soil Water Partition Coefficient, K_{oc}	114 L kg^{-1}
Number of Applications	2
Application Rate	9.6 g $acre^{-1}$, 14.4 g $acre^{-1}$
Application Interval	21 days

[1] Aerobic soil metabolism half-life (118.1 days) represents upper 90th percentile on longest reported half-life, *i.e.*, 97 days, from data collected Day 55 to study termination.
[2] Aerobic aquatic metobolism half-life (25.1 days) represents upper 90th percentile confidence interval on mean of two reported values estimated by nonlinear regression of untransformed data.

AQUATIC EXPOSURE ASSESSMENT

The estimated environmental and drinking water concentrations presented in **Table 12** are point estimates representing only peak, or acute, concentrations. However, no attempt has been made to determine chronic exposure. The chronic exposure should be less than acute estimates; however, acute exposure values can be used for screening purposes in both acute and chronic risk assessments. The maximum of the estimated environmental concentrations, **312 ng L^{-1}** from the Gulf Coast scenario, is the **recommended EEC for surface water**. Estimated drinking water concentrations (EDWC's) were derived by multiplying the aquatic life (environmental) EEC's by the default Percent Crop Area (PCA) Factor of 0.87. The use of the default PCA is described in Office of Pesticide Programs, 1999.

Table 12. Regional Results from Modeling Surface Water Concentrations for Bispyribac-sodium Applied to Rice.

Regional Scenario	*Aquatic Life*	*Drinking Water*
California	**136 ng L^{-1}**	**118 ng L^{-1}**
Gulf Coast	**312 ng L^{-1}**	**272 ng L^{-1}**
Mississippi Valley	**137 ng L^{-1}**	**119 ng L^{-1}**

TERRESTRIAL EXPOSURE ASSESSMENT

Terrestrial exposure was evaluated using estimated environmental concentrations generated from a spreadsheet-based model that calculates the decay of a chemical applied to foliar surfaces for single or multiple applications. The model uses the same principle as the batch code models FATE and TERREEC for calculation of terrestrial estimated exposure concentrations (TEEC) on plant surfaces following application. Input parameters for the model are presented in **Table 13**; further explanation of the model is presented in **Appendix C**.

Table 13. Environmental Fate Input Parameters for spreadsheet-based terrestrial exposure model for bispyribac-sodium.

Input Parameter	Rice
Application Rate	0.053 lb a.i/acre
Application Frequency	1
Foliar Dissipation Half Life	35 days[1]

[1]Foliar dissipation half life set at 35 days (see text for explanation).

The terrestrial exposure assessment is based on the methods of Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994). Terrestrial estimated environmental concentrations (EECs) for a nongranular formulation (**Table 14**) was derived for rice using proposed application rates of 0.053 lbs. a.i./A applied 1 time per season. Uncertainties in the terrestrial EECs are primarily associated with a lack of data on interception and subsequent dissipation from foliar surfaces. EFED assumes the foliar dissipation rate is based on a number of routes which include photolysis, hydrolysis and volatilization. It could also include uptake in plants as well as wash off if those data were available. When data are absent, as in this case, EFED assumes a 35-day foliar dissipation half life for chemicals that are not volatile and which are stable to photolysis and hydrolysis. This 35-day half-life assumption is based on the work of Willis and McDowell (1987).

Table 14. Estimated environmental concentrations on avian and mammalian food items (ppm) following a single application at 0.053 lb. ai/A (Hoerger and Kenaga, 1972, as modified by Fletcher *et al.*, 1994)

Food Items	Rice Foliar Spray EEC (ppm) Predicted Maximum Residue	Rice Foliar Spray EEC (ppm) Predicted 56-day Mean Residue
Short grass	12.7	7.8
Tall grass	5.8	3.6
Broadleaf plants and small insects	7.2	4.4
Fruits, pods, seeds, and large insects	0.8	0.5

ECOLOGICAL EFFECTS ASSESSMENT

Appendix D summarizes the 19 ecological toxicity studies submitted by the registrant for consideration: 77% were classified as core and as having fulfilled guideline requirements. The remaining studies (23%) were classified as supplemental. Although these studies did not completely fulfill guideline requirements, they do provide information useful in characterizing the ecological effects of bispyribac; EFED is not requiring that any of the studies classified as supplemental be repeated. Based on the ecological effect studies, bispyribac-sodium is practically nontoxic to aquatic (**Table 15**) and terrestrial (**Table 16**) animals on an acute exposure basis. Chronic toxicity testing on both terrestrial and aquatic animals failed to establish a treatment-related effect up to the maximum required dose for testing. **Table 17** summarizes toxicity data on the most sensitive species of terrestrial plants and as expected from a herbicide, bispyribac-sodium exhibits effects at application rates, *i..e.*, 0.0005 lbs a.i./acre, two orders of magnitude less than the current maximum proposed seasonal rate of 0.05 lbs a.i./acre. Additionally, of the aquatic plants tested, duck weed (*Lemna gibba*) was the most sensitive vascular plant (EC_{50} = 0.01 mg/L).

Toxicity testing reported in this section does not represent all species of bird, mammal, or aquatic animals. Only a few surrogate species for both freshwater fish and birds are used to represent all freshwater fish (2000+) and bird (680+) species in the United States. For mammals, acute studies are usually limited to Norway rat or the house mouse. Estuarine/marine testing is usually limited to a crustacean, a mollusk, and a fish. Also, neither reptiles nor amphibians are tested. The assessment of risk or hazard makes the assumption that avian and reptilian toxicities are similar. The same assumption is used for fish and amphibians.

Table 15. Acute and chronic toxicity estimates for aquatic organisms exposed to Bispyribac-sodium.

Species	Acute Toxicty 96-hr LC_{50} (mg/L)	Acute Toxicity (MRID)	Chronic Toxicity NOEC / LOEC (ppm)	Affected Endpoints (MRID)
Rainbow trout ***Oncorhychus mykiss***	>102	practically nontoxic (448891-15)		
Bluegill sunfish ***Lepomis macrochirus***	>102	practically nontoxic (448891-14)	--	--
Waterflea ***Daphnia magna***	>99.2	practically nontoxic (448891-16)	110 / > 110	No adverse effect reported (448891-20)
Sheepshead minnow ***Cyprinodon variegatus***	>120*	practically nontoxic (448891-18)	--	--
Eastern oyster ***Crassostrea virginica***	>110*	practically nontoxic (448891-17)	--	--
Mysid shrimp ***Mysidopsis bahia***	>130*	practically nontoxic (448891-19)	--	--

***Toxicity estimate based on testing of formulated endproduct Bispyribac-sodium 80S (79% active ingredient).**

Table 16. Summary of acute and chronic toxicity data for terrestrial organisms exposed to bispyribac-sodium.

Species	Acute Toxicty				Chronic Toxicity		
	LD_{50} (ppm)	Acute Oral Toxicity (MRID)	5-day LC_{50} (ppm)	Subacute Dietary Toxicity (MRID)	NOEC (ppm) (MRID)	LOEC (ppm)	Affected Endpoints
Northern bobwhite quail *Colinus virginianus*	2,250	practically toxic (449299-03)	> 5,620	practically nontoxic (449299-05)	1,000 (451973-01)	--	no adverse effects noted
Mallard duck *Anas platyrhynchos*	--	--	> 5,620	practically nontoxic (449299-04)	1,000 (451973-02)	--	no adverse effects noted
Honey bee *Apis meliferus*	> 25	practically nontoxic (448892-24)[1]	--	--	--	--	--
Laboratory rat *Rattus norvegicus*	3,565	practically nontoxic (448891-27)	--	--	1,000 (449299-23)	10,000	growth

Table 17. Summary of acute toxicity datt for terrestrial and semiaquatic plants exposed to bispyribac-sodium.

Species	EC_{25} (lbs a.i./acre)	Response	Study/MRID
Onion (monocot)	0.0013	plant weight	Seedling emergence 448892-22
Radish, cabbage (dicot)	0.0019	plant weight	Seedling emergence 448892-22
Onion	0.0020	plant weight	Vegetative vigor 448892-21
Soybean (dicot)	0.0005	plant weight / height	Vegetative vigor 448892-21

AQUATIC RISK ASSESSMENT

Based on a peak estimated surface water concentration (EEC) of 312 ng/L (ppt: see Aquatic Exposure Assessment) and aquatic toxicity estimates showing that bispyribac-sodium is practically nontoxic to both fish (LC_{50} > 102 mg/L) and invertebrates (EC_{50} > 99.2 mg/L), neither freshwater nor marine risk quotients (RQ), *i.e.*, ratio of exposure (EEC) to toxicity, exceed acute levels of concern (RQ < 0.1) (**Appendix E**). Chronic risk quotients, although typically based on a 21-day estimated surface water concentration compared to the chronic toxicity endpoint, *i.e.*, daphnid NOEC = 100 mg/L, were calculated using an estimated peak exposure value (312 ng/L); however, the chronic level of concern was not exceeded (**Appendix E**). Therefore, based on RQ values derived using Tier I screening level exposure estimates, the proposed use of bispyribac-sodium represents neither an acute nor chronic risk to either freshwater or marine animals. Additionally, risk quotients for aquatic plants were below levels of concern (RQ < 1.0).

TERRESTRIAL RISK ASSESSMENT

On the basis of risk quotients (**Appendix E**), exposure to bispyribac-sodium at the proposed application rate for rice is unlikely to result in either acute or chronic risk to avian, mammalian, or insect species. Using peak estimated foliar residues (see Terrestrial Exposure Assessment) on terrestrial forage items and avian (LD_{50} = 2,250 mg/Kg) and mammalian (LD_{50} = 3,565 mg/Kg), no terrestrial acute risk quotients exceed levels of concern (RQ < 0.1). However, risk quotients for terrestrial and semi-aquatic plants ranged from 1.1 to 2.9 based on a single application of 0.0265 lbs. a.i./acre. Since the label allows for two applications per season it is therefore likely that risk quotients will be even greater than those calculated.

ECOLOGICAL RISK CHARACTERIZATION

Bispyribac-sodium is a post-emergence herbicide proposed for control on weeds associated with direct-seeded rice. Based on the available data, the compound is moderately persistent and mobile and will likely move into surface and ground water through runoff and leaching. The primary routes of degradation are through both aerobic and anaerobic metabolism. Although bispyribac-sodium is expected to be persistent and mobile, the compound is practically nontoxic to both terrestrial and aquatic animals and it is unlikely that it will represent a threat of either acute or chronic ecological risk to animals at the maximum proposed application rate of 0.05 lbs. a.i./A per year. Although bispyribac-sodium is likely to reach surface water via runoff, based on RQ values, aquatic plants are unlikely to be at risk.

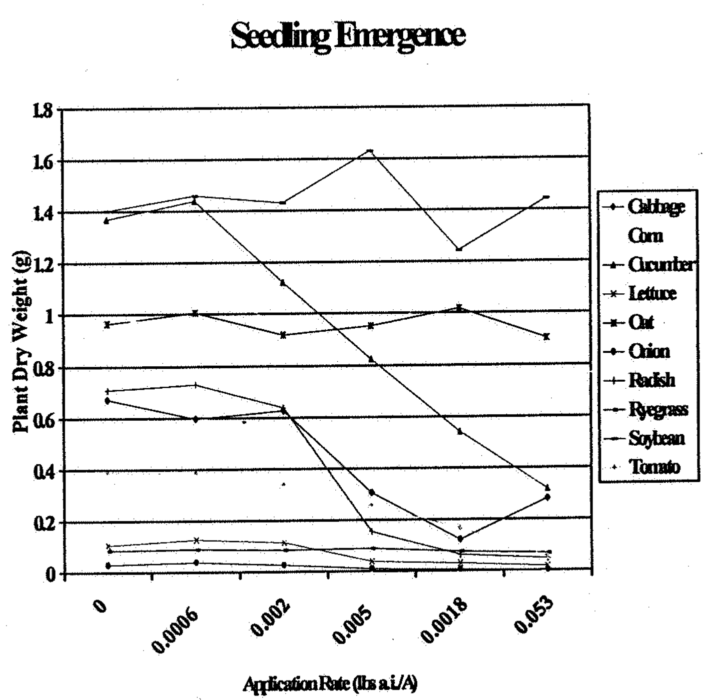

Figure 1. Plant dry weight (g) with increasing concentrations (equivalent application rate in lbs a.i./acre) of bispyribac sodium for various plants in terrestrial plant seedling emergence study.

As might be expected for a herbicide, acute levels of concern are exceeded for terrestrial and/or semiaquatic plants (RQ range 1.1 - 2.9). EFED is uncertain regarding the potential effects of bispyribac-sodium on terrestrial and semi-aquatic plants. Plant weight was the most sensitive indicator of terrestrial plant effects. Larger treatment effects at lower doses combined with the already low nominal concentrations used, *i.e.*, 0.00002 lbs active ingredient per acre, suggest that actual application rates may have potentially differed from nominal application rates. In both the seedling emergence (**Figure 1**) and vegetative vigor (**Figure 2**) studies a similar effect was noted in that at lower doses there appeared to be an enhanced effect on growth-related endpoints (plant dry weight in grams) and these irregular dose responses were attributed by the reviewer to be the possible

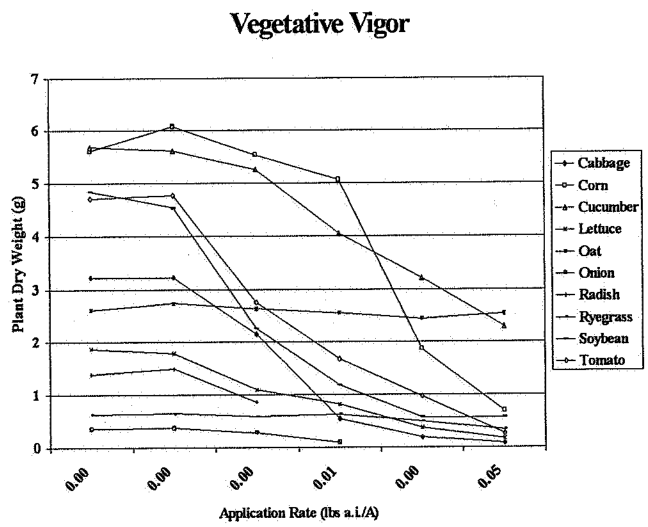

Figure 2. Plant dry weight (g) with increasing concentration (equivalent application rate in lbs. a.i./acre) of bispyrbac sodium for various plants in terrestrial plant vegetative vigor study.

discrepancies in exposure. It is possible however, that the u-shaped dose response observed in the terrestrial plant studies is reflective of a phenomenon termed "hormesis" where low doses elicit a stimulatory response. These low-dose stimulatory effects in toxicity studies have been associated with growth responses and have been observed at levels 4- to 5- fold below the NOEL for particular responses (Calabrese and Baldwin 2001; Calabrese et al. 1999; Calabrese and Baldwin 1998).

Endangered Species

The proposed use of bispyribac sodium under this Section 3 registration may harm threatened and endangered species of terrestrial and semi-aquatic plants. The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered/threatened species and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register notice. The Agency is not imposing label modifications at this time through this IR-4 petition. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program. Currently available county specific information, maps and a downloadable version of the Endangered Species data base can be found on the Internet at the Agency's web site, http://www.epa.gov/ESPP.

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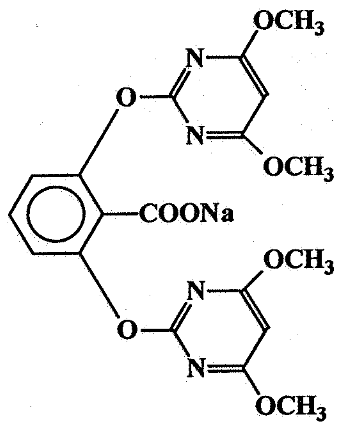
APPENDIX A. CHEMICAL STRUCTURES OF PARENT Bispyribac-sodium AND ITS AEROBIC SOIL, AEROBIC AQUATIC AND ANAEROBIC AQUATIC DEGRADATES.

Parent Compound

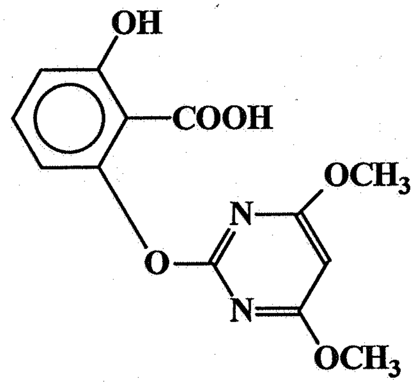


Bispyribac-Sodium

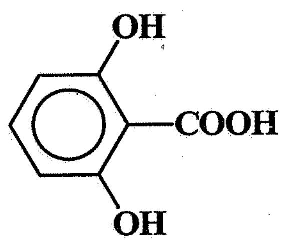
sodium 2,6-bis[(4,6-dimethoxypyrimidin-2-yl)oxy] benzoate

26

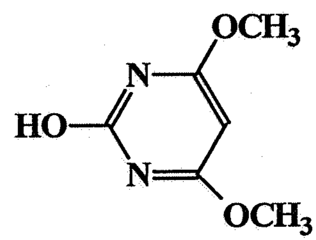
Major Aerobic Soil Metabolites



Bx-180
2-[(4,6-dimethoxypyrimidin-2-yl)oxy]-6-hydroxybenzoate

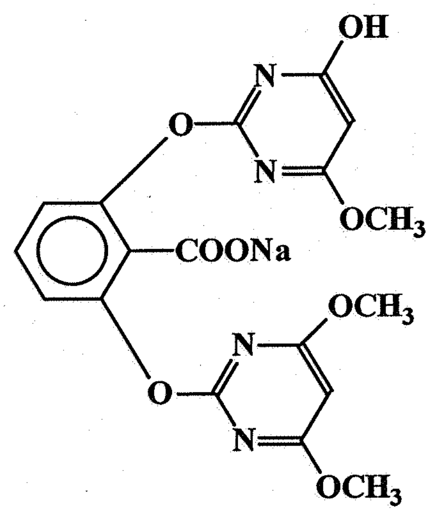


2,6-DBA
2,6-dihydroxybenzoic acid



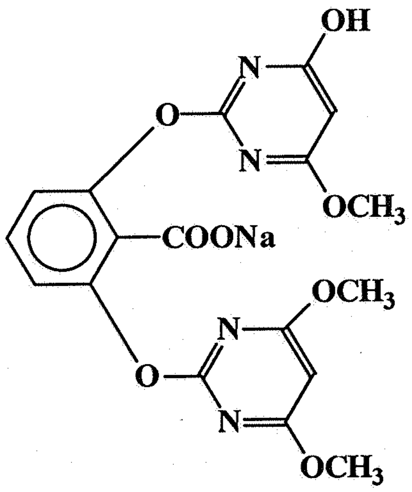
Me2BA
4,6-dimethoxy-2-hydroxypyrimidine

Major Aerobic Aquatic Metabolite

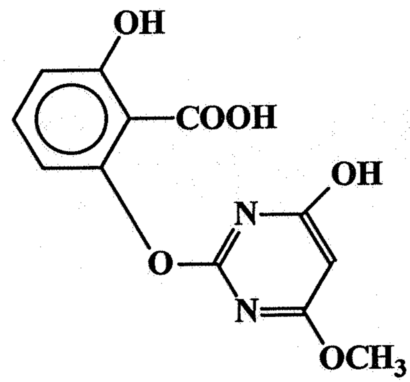


DesMe-2023
sodium 2-(4,6-dimethoxypyrimidin-2-yl)oxy-6-(4-hydroxy-6-methoxypyrimidin-2-yl) benzoate

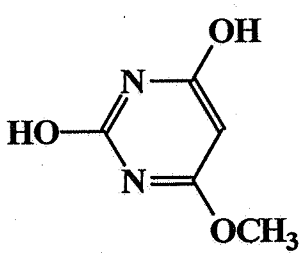
Major Anaerobic Aquatic Metabolites



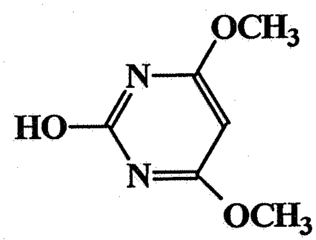
DesMe-2023
sodium 2-(4,6-dimethoxypyrimidin-2-yl)oxy-6-(4-hydroxy-6-methoxypyrimidin-2-yl) benzoate



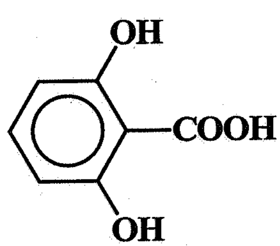
DesMe-180
2-hydroxy-6-[(4-hydroxy-6-methoxypyrimidin-2-yl)oxy] benzoic acid



MeBA
4,6-dihydroxy-2-methoxypyrimidine



Me_2BA
4,6-dimethoxy-2-hydroxypyrimidine



2,6-DBA
2,6-dihydroxybenzoic acid

APPENDIX B. AQUATIC EXPOSURE ASSESSMENT (H. E. D. WATER MEMO)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

August 7, 2001

SUBJECT: Tier 1 Estimated Environmental Concentration for Bispyribac-sodium in Water Resources
PC Code: 078906

TO: Jim Tompkins,
Product Manager 25
Herbicide Branch
Registration Division

FROM: R. David Jones, Ph.D., Agronomist
Environmental Risk Branch

THROUGH: Betsy Behl, Chief
Environmental Risk Branch IV

This memo describes Tier 1 estimated environmental concentrations (EEC's) in water from rice culture for bispyribac-sodium. EEC's were calculated for ecological and drinking water risk from surface water and groundwater (See Table 1). The groundwater EEC's were estimated with SCIGROW. The Office of Pesticide Programs currently has no official model for estimating EEC's in surface water due to for rice culture, and a screening calculation method was developed hence these EEC's are provisional only. The estimates in Table 1 reflect soils and management practices prevalent in the Gulf Coast for rice culture. Note that these concentrations are in ng L^{-1} or parts per trillion.

Table 1. Estimated environmental concentrations for bispyribac-sodium use on rice.	
Surface water - ecological risk assessment	312 ng L^{-1}
Surface water - drinking water risk assessment	272 ng L^{-1}
Groundwater - drinking water risk assessment	7.2 ng L^{-1}

This memorandum first describes the ground water estimate made by SCIGROW. It then describes the scenarios used for the surface water estimates, followed by the chemistry used for the surface water estimates. A description of the model used for surface water follows as this model has not been previously used or documented elsewhere.

SCIGROW

SCI-GROW estimates were made according to the method described in Barrett, 1997. SCIGROW is a screening model for ground water. It is based on a regression approach which relates the concentrations found in ground water in Prospective Ground Water studies to aerobic soil metabolism rate and soil-water partitioning properties of the chemical. The input values are in Table 2.

Table 2. Input parameters and results from SCIGROW for bispyribac-sodium applied to rice.

Parameter	Value
Mean Aerobic Soil Metabolism Half-life	20.0 d
K_{oc}	114 L kg^{-1}
Total Annual Application Rate	0.0528 lb $acre^{-1}$
Ground Water EEC	7.2 ng L^{-1}

Surface Water Estimates

Estimates were done for each of the three major rice growing regions in the United States, the Gulf Coast of Louisiana and Texas, the Mississippi Valley including parts of northern Louisiana, Mississippi, Arkansas, and southern Missouri, and California in the Sacramento River Basin. A soil was selected for each region representative of those used for growing rice in each area. Agricultural management practices differ in each region and descriptions are below to the extent they have been modeled in this assessment. The general management approaches to rice culture in each region are summarized in Table 3.

Gulf Coast. Rice in this region is generally wet seeded with pre-sprouted seed (LSU Agricultural Center, 1999). After seeding, the paddy is drained until the rice has rooted in the soil and then a regular flood is applied. This flood is maintained primarily to control red rice. This is called pinpoint flooding. The flood is often released around panicle initiation to avoid straighthead, a disease caused by arsenic toxicity. The field is then re-flooded around 5 to 7 days later. The last flood is then held until just prior to harvest. Because of the high rainfall in this area, releases of paddy water can occur due to a large rainfall event overflowing the paddy.

Table 3. Management Practices for Rice Growing Regions Simulated			
	Gulf Coast	**Mississippi Valley**	**California**
Seeding Method	Wet	Dry	Wet
Interval to Flood (Dry Seeded)	NA	28 days	NA
Flood Management Method	Pnpoint	Dlayed	Continuous
Drain for Straighthead Control	Yes	No	Yes

The sequence of events for modeling the Gulf Coast region are in Table 4. Pre-sprouted seed is applied on day 0 to a wet field and the field is drained the next day. After the rice is firmly rooted, the field is re-flooded on day 7. The first application is on day 12 at the three leaf stage of the rice. The second application occurs on day 33 just prior to panicle initiation which is when the window for bispyribac application closes. The flood is released 3 days later for straighthead control. This concentration in this release is used for the EEC. While the paddy is re-flooded after field has dried, further modeling of bispyribac is not done after the release on day 36.

Table 4. Sequence of events for rice culture in each regional scenario for surface water EEC's			
Day	**California**	**Gulf Coast**	**Mississippi Valley**
-7			Seeding
0	Seeding	Seeding	Emergence
1		Drain Flood	
7		Flood	
12	1st application	1st application	1st application
28			Flood
33	2nd application	2nd application	2nd application
36		Drain Flood	
43			Overflow release
90	Release Flood	Release Flood	Release Flood

Mississippi Delta. Rice is most often dry seeded in this region (LSU Agricultural Center, 1999). A flood is applied around 28 days after seedling emergence. While red rice is of less concern in this area, adequate weed control is maintained with herbicides until the flood is applied. This flood will be maintained until harvest. As with the Gulf Coast, this area receives a great deal of rainfall and is somewhat prone to paddy overflow during large rainfall events. The release used for the EEC is generated from a levee overflow from precipitation which is assumed to occur 10 days after application.

The sequence of events (Table 4) for this have seeding on day -7 and emergence on day 0. The first application is made on day 12 to a dry field. The paddy is flooded on day 28 and the second application is made on day 33. The paddy is assumed to overflow from rain fall on day 43.

California. Wet seeding is also used in California. However, a continuous flood rather than a pin-point flood is more commonly used here. There is little rainfall during the growing season, so paddy overflow is relatively uncommon. There are regulations in place by the state that require minimum holding times for paddy water in order to reduce the amount herbicide in the drainage as the water impacts drinking water facilities down stream.

The sequence of events for each scenario is represented in Table 4. In all 3 locations, the 1st application was applied at the day 12 which corresponds roughly with the 3 leaf stage for rice. This application is made to a flooded field in California and on the Gulf Coast and to a dry field in the Mississippi Valley. The second application was made 21 days later. In all three cases this is made to a flooded field. The release date of the flood differed with each scenario. The release for California was at the final release of the flood prior to harvest. On the Gulf Coast, the release was was made after 3 days and this release was for straighthead control. In the Mississippi Valley, the release was made 10 days after the second application and reflects an levee overflow due to rainfall.

Table 5. Chemical Property and Application Practice Parameters Used to Estimate Environmental Concentrations from Rice

Parameter	Value
Aerobic Soil Metabolism Half-life	118.1 d
Aerobic Aquatic Metabolism Half-life	25.1 d
Soil Water Partition Coefficient (K_{oc})	114 L kg^{-1}
Number of Applications	2
Application Rate	9.6 g acre^{-1} , 14.4 g acre^{-1}
Application Interval	21 days

Chemistry and Application Parameters for Surface Water Modeling. All chemistry input parameters were calculated according to current guidance. The two metabolism half-lives represent the upper 90% confidence bound on the mean of two half-life estimates done on a single soil, the Gridley clay loam. The soil water partition coefficient (K_{oc}) represents the slope of the regression line for K_d as a function of organic carbon content.

The application amounts and timing are taken from the Regiment label. Application is limited to a total of 24 g of active ingredient per acre per season with at least 21 days between applications. Applications were to be made between the three leaf stage and panicle initiation, a period of about three weeks for many varieties of rice grown in the United States. The second application was made at the highest recommended for the control of any weed, late watergrass, while still leaving sufficient room in the total for control of other weeds.

Surface Water Model for Rice. Soils were chosen to represent those which are typical of rice culture in each area. These soils are listed in Table 6. Properties for these soils were taken from the STATSGO database (USDA, 1995). Soil classification information was taken from the Soil Series description on the Internet (National Resource Conservation Service, 2001).

Table 6. Soil and site properties for rice growing regions simulated.

	Gulf Coast	Mississippi Valley	California
Soil	Evadale	Sharkey	Gridley
Soil Classification	Fine, smectitic, thermic Typic Glossaqualf	Very-fine, smectitic, thermic Chromic Epiaquert	Fine, smectitic, thermic Typic Argixeroll
Bulk Density	1.35 kg L^{-1}	1.35 kg L^{-1}	1.425 kg L^{-1}
Organic Carbon Content	0.725%	1.30%	1.16%
Depth of Active Flooded Soil	1 cm	1 cm	1 cm
Paddy Depth	13 cm	13 cm	13 cm

The primary way that rice culture causes contamination of surface water with pesticides is through release of the flood water on the paddy. This can occur because precipitation causes overflow of the levee or through the intentional release of the paddy water as part of the agricultural management of the paddy. The calculation described here attempts to estimate the concentration in the paddy water at the time of release as affected by soil and aquatic metabolism, and through binding to the paddy soil. The calculation consists of three steps 1) degradation of pesticide on the soil prior to flooding by aerobic soil metabolism; 2) partitioning of the pesticide between the active sediment layer and the paddy water; and 3) degradation of the pesticide by both aerobic and anaerobic aquatic metabolism. Step two and three are repeated for the second application. Step one is only used for the Mississippi Valley scenario, where the paddy is dry for the first 28 days. The chemical is applied at day 12 and degrades by a first order rate law:

$$C_{soil} = C_{0,soil} e^{-k_1 t} \quad (1$$

where C_{soil} is the concentration in the soil, $C_{0,soil}$ is the initial concentration in the soil k_1 is the rate constant for aerobic soil metabolism and t is the during which the chemical is degrading by this route, In this case the chemical degrades until the second application is made after 21 days (See Table 4).

Step 2 partitions the chemical that is remaining after degradation on the soil in the Mississippi Valley scenario, or applied to the flood water in the California scenarios, and partitions it between sediment and the water. For the purposes of this calculation, the active sediment layer which is in full contact with the paddy water is assumed to be 1 cm deep and the depth of water in the paddy is assumed to be 13 cm deep. It is also assumed that 1/3 of the sediment volume is water. The mass of the sediment present was dependent on the bulk density of the soil. For the purposes of this calculation, the mass of suspended sediment was assumed to be negligible. The mass of chemical bound to the sediment was calculated assuming equilibrium partitioning between the sediment and the water. The partition coefficient K_d for each site was estimated from the K_{oc} (see Table 5) for the chemical and the organic carbon content of the soil, and thus varies from scenario to scenario. The equation used to calculate the mass in the sediment was:

$$M_{sed} = \frac{M_T m_{sed} K_d}{V_T + m_{sed} K_d} \quad (2$$

where M_{sed} is the concentration of the chemical on the sediment, M_T is the total mass of pesticide, m_{sed} is the mass of sediment to a depth one centimeter, V_T is the total volume of water present including the water column and the sediment water, and K_d is the soil water partition coefficient. The mass in the water was then calculated as the difference between the total mass of chemical and the chemical bound to the sediment.

In step 3, the chemical is degraded in the flooded paddy. The chemical in the water column is degraded by first order degradation at the aerobic aquatic metabolism rate.

$$C_{wc} = C_{0,wc} e^{-k2t} \quad (3$$

where C_{wc} is the concentration in the water column, $C_{0,wc}$ is the initial concentration in the water column, and k_2 is the aerobic aquatic metabolism rate constant. The chemical in the sediment, including that in the sediment water, was degraded at the anaerobic aquatic metabolism rate:

$$C_{sed} = C_{0,sed} e^{-k_3 t} \quad (4$$

where C_{sed} is the concentration in the water column, $C_{0,sed}$ is the initial concentration in the water column, and k_3 is the anaerobic aquatic metabolism rate constant.

For the second application, the total remaining mass from the previous application plus the new application is run through steps two and three again. The degradation following the second application varies with the scenario as shown in Table 4. At this point the paddy water is released and the concentration in the paddy water is used as the EEC. The EEC's for the three regional scenarios are in Table 7.

Table 7. Surface water EEC's for 3 regional rice scenarios		
Scenario	**Aquatic (Environmental) Life**	**Drinking Water**
California	136 ng L^{-1}	118 ng L^{-1}
Gulf Coast	312 ng L^{-1}	272 ng L^{-1}
Mississippi Valley	137 ng L^{-1}	119 ng L^{-1}

These EEC's are point estimates representing only peak or acute concentrations. However, as no attempt has been made to determine chronic exposure, and the chronic exposure should be less than in this acute estimate, they can be used for both acute and chronic risk assessments. The maximum estimate of the three, from the Gulf Coast, is the recommended EEC for surface water from this assessment. Drinking water EEC's were estimated by multiplying the aquatic life EEC by the default Percent Crop Area Factor of 0.87.

While there is a reasonable expectation based on comparisons of similar methods (Hetrick, 2000) to monitoring data that these results are not wholly inaccurate, it is not certain that the scenarios used do in fact represent scenarios which are more vulnerable than most for rice culture.

Literature Citations

Barrett, Michael. 1997. *Proposal for Method to Determine Screening Concentration Estimates for Drinking Water Derived from Ground Water Sources*. Internal EPA Memorandum to Joe Merenda dated June 30, 1997.

Hetrick, James, 2000. Fipronil Water Assessment Memo.

Louisiana State Agricultural Center. 1999. *Louisiana Rice Production Handbook*. Louisiana State University.

Natural Resource Conservation Service. 2001. *Official Soil Series Descriptions*. http://www.statlab.iastate.edu/cgi-bin/osd/osdname.cgi.

United States Department of Agriculture, Natural Resource Conservation Service, National Soil Survey Center. 1995. *State Soil Geographic (STATSGO) Data Base*. Miscellaneous Publication Number 492. http://www.ftw.nrcs.usda.gov/pdf/statsgo_db.pdf

APPENDIX C. SPREADSHEET-BASED TERRESTRIAL EXPOSURE VALUES

A first order decay assumption is used to determine the concentration at each day after initial application based on the concentration resulting from the initial and additional applications. The decay is calculated from the first order rate equation:

$$C_T = C_i e^{-kT}$$

or in integrated form:

$$\ln (C_T/C_i) = -kT$$

Where:

C_T = concentration at time T on day zero

C_i = concentration in parts per million (ppm) present initially (on day zero) on the surfaces. C_i is calculated based on Kanega and Fletcher by multiplying the application rate, in pounds active ingredient per acre, by 240 for short grass, 110 for tall grass, and 135 for broad-leaf plants/insects and 15 for seeds. Additional applications are converted from pounds active ingredient per acre to PPM on the plant surface and the addition mass added to the mass of the chemical still present on the surfaces on the day of application.

k= degradation rate constant determined from studies of hydrolysis, photolysis, microbial degradation, etc. Since degradation rate is generally reported in terms of half-life, the rate constant is calculated from the input half-life ($k = \ln 2/T1/2$) instead of being input directly. Choosing which process controls the degradation rate and which half-life to use in terrestrial exposure calculations is open for debate and should be done by a qualified scientist.

T= time, in days, since the start of the simulation. The initial application is on day 0. The simulation is set to run for 365 days.

The program calculates concentration on each type of surface on a daily interval for one year. The maximum concentration during the year and the average concentration during the first 56 days are calculated.

Terrestrial Exposure Model Output

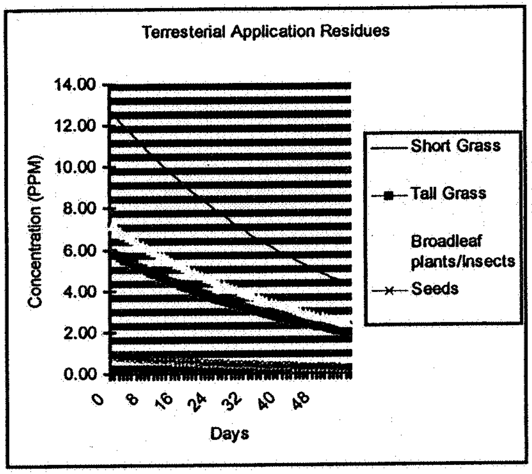
Chemical Name: [redacted]
Use
Formulation

Inputs

Application Rate	[redacted]	lbs a.i./acre
Half-life		days
Frequency of Application		days
Maximum # Apps./Year		

Outputs

	Maximum Concentration (PPM)	56 Day Average Concentration (PPM)	
Short Grass	12.72	7.76	
Tall Grass	5.83	3.56	# days
Broadleaf plants/Insects	7.16	4.37	Exceeded
Seeds	0.80	0.49	on short grass (in first 56)



Avian

Acute LC50 (ppm)	[redacted]	0
Chronic NOAEC (ppm)		0

	Acute RQ	Chronic RQ (Max. res. mult. apps.)	
Short Grass	0.00	0.01	
Tall Grass	0.00	0.01	# days
Broadleaf plants/Insects	0.00	0.01	Exceeded
Seeds	0.00	0.00	on short grass (in first 56)

Max Single Application which does NOT exceed

Avian Acute	23.417	
Avian Chronic	4.167	(lb a.i.)
Mammalian Acute	99.03	
Mammalian Chronic	4.17	

Mammalian

Acute LD50 (mg/kg)	[redacted]	0
Chronic NOAEL (mg/kg)		0

Rat Calculated LC50 (ppm) 71300

	15 g mammal Acute RQ (mult. apps)	35 g mammal Acute RQ (mult. apps)	1000 g mammal Acute RQ (mult. apps)	Rat Acute Dietary RQ	Rat Chronic Dietary RQ
Short Grass	0.00	0.00	0.00	0.00	0.01
Broadleaf plants/ Insects	0.00	0.00	0.00	0.00	0.01
Large Insects	0.00	0.00	0.00	0.00	0.01
Seeds (granivore)	0.00	0.00	0.00	0.00	0.00

Length of Simulation 1 year
Level of Concern [redacted] (ppm)

APPENDIX D. ECOLOGICAL TOXICITY DATA

Toxicity to Terrestrial Animals

Acute and Subacute Toxicity to Birds

Acute oral toxicity data for bobwhite quail, a preferred species, indicated that the LD_{50} was greater than 2,250 mg/kg, the maximum tested dose (MRID 449299-03). Birds exhibited no treatment-related mortality, sublethal signs of toxicity, or adverse changes in body weight and food consumption. Because the LD_{50} was shown to exceed 2,000 mg/kg, bispyribac-sodium is classified as practically nontoxic to avian species on an acute oral toxicity basis **(Table 1)**. Guideline 72-1 is fulfilled.

Table 1. Summary of avian acute toxicity test on bobwhite quail (*Colinus virginianus*) exposed to bispyribac-sodium.

Species	% Active Ingredient	LD_{50} mg/L	Test Type Y	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirements
Bobwhite quail	99.9	>2,250	Acute oral	44929903 Campbell *et al.* 1993	practically nontoxic	Core

Two subacute dietary studies were conducted using preferred avian species to evaluate the toxicity of bispyribac-sodium to birds. Studies with bobwhite quail (MRID 449299-05) and mallard duck (MRID 44929904) both determined the LC_{50} to be greater than the highest concentration tested, 5,620 mg/kg. Birds from both studies showed no signs of treatment-related mortality, clinical toxicity, or adverse effects on body weight and food consumption. In both studies, the LC_{50} was shown to be greater than 5,000 mg/kg; therefore, bispyribac-sodium was categorized as practically nontoxic to avian species on a subacute dietary toxicity basis **(Table 2)**. Guideline 71-2 is fulfilled.

Table 2. Summary of avian subacute toxicity tests on bobwhite quail (*Colinus virginianus*) and mallard duck (*Anas platyrhynchos*) exposed to bispyribac-sodium.

Species	% Active Ingredient	LC_{50} mg/L	Test Type Y	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirements
Bobwhite quail	99.9	>5,620	Subacute dietary	44929905 Campbell and Beavers 1993	practically nontoxic	Core
Mallard duck	99.9	>5,620	Subacute dietary	44929904 Campbell and Beavers 1993	practically nontoxic	Core

Chronic Toxicity to Birds

Avian reproduction tests were conducted with mallard ducks (MRID 45197301) and Northern bobwhite quail (MRID 45197302). There were no significant adverse effects of treatment with bispyribac-sodium on body weight, feed consumption, survival, or reproduction in either study. The NOEC for both studies was 1,000 ppm, the highest concentration tested **(Table 3).** The chronic/reproductive quotient in both studies was determined to be <1; therefore, bispyribac-sodium has minimal risk to bird species. Guideline 71-4 is fulfilled.

Table 3. Summary of avian reproduction studies on mallard ducks (*Anas platyrhynchus*) and bobwhite quail (*Colinus virginianus*) exposed to bispyribac-sodium.

Species	% Active Ingredient	NOEC ppm	MRID No. Author/Year	Chronic/Reproductive Quotient	Fulfills Guideline Requirements
Mallard duck	99.9	1000	45197301 Frey *et al.* 2000	<1, minimal chronic risk	Core
Bobwhite quail	99.9	1000	45197302 Frey *et al.* 2000	<1, minimal chronic risk	Core

Acute and Chronic Toxicity to Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. Since the LC_{50} exceeded 2,000 mg/kg **(Table 4)**, bispyribac-sodium is classified as practically nontoxic on an acute exposure basis. Guideline 81-1 is fulfilled (MRID 448891-27).

Chronic toxicity data derived from a 2-generation reproduction study of rats revealed decreased body weights, decreased body weight gain, decreased liver weights and histopathological changes in the liver, *i.e.*, hyperplasia of the common bile duct (LOAEL = 10,000 ppm); however, the LOAEL for reproductive performance was not observed.. Guideline 83-5 is fulfilled (MRID 449299-23).

Table 4. Summary of acute and chronic mammalian toxicity data based on acute oral toxicity study with rats, *Ratus norvegicus*, and a 2-generation reproduction study in rats using bispyribac-sodium.

Species/ Study Duration	% ai	Test Type	Toxicity Value	Affected Endpoints	MRID No.
laboratory rat (*Rattus norvegicus*)	95.2%	Acute oral LD_{50}	3,565 mg/kg	mortality	448891-27
laboratory rat	98.2%	2-generation rat reproduction study	NOAEL = 1,000 ppm LOAEL = 10,000 ppm	decreased body weight; decreased body weight gain; decreased liver weights	449299-23

Toxicity to Insects

An acute contact study was conducted with honeybees using the TGAI, because honeybees may be exposed to bispyribac-sodium during field applications. The acute contact LD_{50} of bispyribac-sodium was determined to be greater than 25 µg a.i./bee, the highest concentration tested. Since the LD_{50} was greater than 11 µg a.i./bee, bispyribac-sodium is categorized as practically nontoxic to bees on an acute contact basis **(Table 4)**. Guideline 141-1 is fulfilled.

Table 4. Summary of acute contact 48-hr toxicity test on honeybees (*Apis mellifera*) exposed to bispyribac-sodium.

Species	% Active Ingredient	LC_{50} µg/bee	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirements
Honeybee	99.9	>25	448892-24 Collins 1999	practically nontoxic	Core

Other terrestrial toxicity studies

Data were submitted from a subchronic toxicity test using earthworms (MRID 448892-25). Currently there are no data requirements involving earthworms under Subdivision E guidelines; therefore, the study is classified as supplemental. The reviewer evaluated the study using EPA Ecological Effects Test Guidelines, OPPTS 850.6200, Earthworm Subchronic Toxicity Test, and although there were numerous deviations from the 850 guideline protocol, the study was judged to be scientifically sound. There was, however, no treatment-related mortality or effect of bispyribac-sodium on body weight. The LC_{50} was determined to be greater than 1,000 ppm, the highest concentration tested **(Table 5)**.

Table 5. Summary of subchronic toxicity test on earthworms (*Eisenia foetida*) exposed to bispyribac-sodium.

Species	% Active Ingredient	LC_{50} ppm	MRID No. Author/Year
Earthworm	95.7	>1,000	448892-25 Johnson 1994

Toxicity to Freshwater Aquatic Animals

Acute Toxicity to Freshwater Fish

Acute toxicity studies were conducted to determine the effects of bispyribac-sodium (TGAI) on two preferred species of freshwater fish. There were no signs of treatment-related mortality or toxicity for bluegill sunfish (*Lepomis macrochirus*), a warmwater species, exposed to bispyribac-sodium (MRID 448891-15). This study was classified as supplemental due to use of significantly lower initial fish weights (64%) than the lowest initial weights recommended by guidelines and for water quality parameters (pH, water hardness, and the use of dechlorinated tap water) which deviated significantly from guideline recommendations. The LC_{50} for this study was shown to exceed 102 mg a.i./L, so bispyribac-sodium was categorized as practically nontoxic to juvenile bluegill sunfish under test conditions **(Table 6)**. Rainbow trout (*Oncorhynchus mykiss*), a coldwater species, also showed no signs of treatment-related mortality or toxicity when exposed to bispyribac-sodium (MRID 448891-14). This study was also classified as supplemental for having water quality parameters markedly different from recommended; however, the study demonstrated that under the conditions tested, the LC_{50} exceeds 102 mg a.i./L and bispyribac-sodium is practically nontoxic to rainbow trout **(Table 6)**. Although both freshwater fish studies were classified as supplemental, EFED is not requiring that the studies be repeated.

Table 6. Summary of acute 96-hr toxicity tests on bluegill sunfish (*Lepomis macrochirus*) and rainbow trout (*Oncorhynchus mykiss*) exposed to bispyribac-sodium.

Species	% Active Ingredient	LC_{50} mg/L	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirements
Bluegill Sunfish	95.2	>102	44889115 Douglas *et al.* 1998	practically nontoxic	Supplemental
Rainbow Trout	95.2	>102	44889114 Douglas *et al.* 1998	practically nontoxic	Supplemental

The registrant has requested a waiver of the fish full life-cycle toxicity test (Guideline 72-5) based on the low acute toxicity of bispyribac-sodium to fish, the low chronic toxicity to aquatic invertebrates (see below), and the low potential for exposure. Registrant-calculated acute and chronic risk quotients (< 0.01) for aquatic organisms are below acute and chronic levels of concern. Thus, EFED concurs with the waiver request.

Acute Toxicity to Freshwater Invertebrates

A freshwater aquatic invertebrate toxicity test exposed technical grade bispyribac-sodium to to the water flea *(Daphnia magna)* (MRID 448891-16). The study was classified as supplemental since pH, water hardness, and the use of dechlorniated tap water were significant deviations from recommended water quality guidelines. The EC_{50} exceeded 99.2 mg/L (mean measured) and bispyribac-sodium was categorized as practically nontoxic to aquatic invertebrates on an acute basis **(Table 7)**. Although the study was classified as supplemental, EFED is not requiring that the study be repeated.

Table 7. Summary of 48-hr toxicity test on water fleas (*Daphnia magna*) exposed to bispyribac-sodium.

Species	% Active Ingredient	EC_{50} mg/L	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirements
Daphnia magna	95.2	>99.2	448891-16 Douglas *et al.* 1998	practically nontoxic	Core

Chronic Toxicity to Freshwater Invertebrates

A freshwater aquatic invertebrate life-cycle test using technical grade bispyribac-sodium was conducted with the water flea, *Daphnia magna* (MRID 448891-20). There were no observed treatment-related effects on parental survival, reproduction, weight, or length. The NOEC was 110 mg a.i./L, the mean-measured limit concentration **(Table 8)**. The reviewer, however, noted a trend toward a significant difference between the treatment and the control weight endpoints ($p=0.06$), suggesting that the LOEC was close to the NOEC. Guideline 72-4(b) is fulfilled.

Table 8. Summary of aquatic invertebrate life-cycle test of *Daphnia magna* exposed to bispyribac-sodium.

Species	% Active Ingredient	NOEC LOEC mg/L	MRID No. Author/Year	Fulfills Guideline Requirements
Daphnia magna	99.9	110 >110	448891-20 Putt 1999	Core

Toxicity Estuarine and Marine Animals

Acute Toxicity to Estuarine and Marine Fish

An acute toxicity test was conducted to determine the effects of formulated bispyribac-sodium (80S) on sheepshead minnow (MRID 448891-18). Fish exhibited no treatment-related signs of mortality or toxicity. The LC_{50} exceeded 120 mg a.i./L, so bispyribac-sodium was categorized as practically nontoxic to marine/estuarine fish **(Table 9)**. Since the study was conducted on formulated product (79% active ingredient) rather than technical grade active ingredient, the study is classified as supplemental; however, EFED is not requiring that the study be repeated with technical grade active ingredient.

Table 9. Summary of acute toxicity test on sheepshead minnow (*Cyprinodon variegatus*) exposed to bispyribac-sodium.

Species	% Active Ingredient	LC_{50} mg/L	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirements
Sheepshead Minnow	79.0	>120	44889118 Sousa 1998	practically nontoxic	Supplemental

Acute Toxicity to Estuarine and Marine Invertebrates

Acute toxicity tests were conducted using formulated end-product (79% active ingredient) with estuarine/marine invertebrates. These tests included a 96-hr oyster shell deposition study (MRID 448891-17) and a 96-hr marine shrimp toxicity test (MRID 448891-19). Eastern oysters exhibited no significant treatment-related reductions in shell deposition. The EC_{50} exceeded 110 mg a.i./L, the highest mean-measured concentration **(Table 10)**. As a result, bispyribac-sodium 80S was categorized as practically nontoxic to Eastern oysters. Saltwater mysid shrimp also exhibited no signs of treatment-related mortality or toxicity. The LC_{50} in the mysid study exceeded 130 mg a.i./L, the highest mean-measured concentration **(Table 10)**. Therefore, bispyribac-sodium was categorized as practically nontoxic to juvenile mysid shrimp. Since both estuarine/marine invertebrate study were conducted using formulated endproduct rather than technical grade active ingredient, the studies are classified as supplemental; however, EFED is not requiring that the studies be repeated using technical grade active ingredient.

Table 10. Summary of acute marine/estuarine toxicity tests on the Eastern oyster (*Crassostrea virginica*) and saltwater mysid shrimp (*Mysidopsis bahia*) exposed to bispyribac-sodium.

Species	% Active Ingredient	EC_{50}/LC_{50} mg/L	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirements
Eastern oyster	79.0	>110	448891-17 Dionne 1998	practically nontoxic	Supplemental
Saltwater mysid	79.0	>130	448891-19 Putt 1998	practically nontoxic	Supplemental

Toxicity to Plants

Toxicity to Terrestrial Plants

Seedling emergence (MRID 44889222) and vegetative vigor (MRID 44889221) studies were conducted to determine the toxicity of bispyribac-sodium to terrestrial plant species. For both Tier II studies, recommended plant species (six dicotyledonous and four monocotyledonous species) were exposed to five levels of bispyribac-sodium, up to the maximum application rate (0.053 lb a.i./A).

Results of the seedling emergence study **(Table 11)** indicated that plant dry weight was the most sensitive endpoint for the most sensitive monocot, onion (EC_{25} = 0.0013 lb a.i./A) and for the most sensitive dicot, radish (EC_{25}= 0.0019 lb a.i./A). However, this study is classified as supplemental and as not having fulfilled the data requirements for Guideline 123-1(a) because of significant uncertainty in plant weight and height values for a number of test species. The reviewer noted that statistical analysis indicated problems fitting dose-response curves. In this study the test concentrations were geometrically spaced by a factor of three (nominal concentration range: 0.00065 - .0053 lbs. a.i./A). In many of the plants tested, the lowest test concentration (0.00065 lbs. a..i./A) demonstrated greater effects on plants than next higher concentration (0.0020 lbs. a.i./A). Since this test material affects plants at such low levels (EC_{05} = 0.0004 lbs ai/acre), the accuracy of mixing and applying the test material to the study plots has been cited may be uncertain (MRID 448892-22). The reviewer recommended that the seedling emergence study be repeated with test concentrations spaced with a factor higher than three and that the amount of test material applied be confirmed by chemical residue analysis of plant tissues (for the lowest and highest test concentration, and for the control plots) directly after application or by placing spray collectors in study plots.

Table 11. **Summary of nontarget terrestrial plant seedling emergence toxicity (Tier II) to monocotyledon and dicotyledon plant species exposed to bispyribac-sodium.**

Species	% Active Ingredient	EC_{25} Dose (lb a.i./A)	% Response and Endpoint Affected	MRID No. Author/Year	Fulfills Guideline Requirements
Monocot - corn	80.0	0.0063	-14 plant weight	44889222 Chetram 1998	Supplemental
Monocot - oat	"	>0.053	-5 to -6 all endpoints	"	"
Monocot - ryegrass	"	>0.053	-15 plant height	"	"
Monocot - onion	"	0.0013	-90 plant weight	"	"
Dicot - cabbage	"	0.0019*	-7 plant weight	"	"
Dicot - radish	"	0.0019	-7 plant weight	"	"
Dicot - cucumber	"	0.0026	-18 plant weight	"	"
Dicot - lettuce	"	0.0042	-63 plant weight	"	"
Dicot - soybean	"	0.0280	-10 plant height	"	"
Dicot - tomato	"	0.0047	-34 plant weight	"	"

* Reviewer cautions that the value is questionable, due to poor fit of data to the dose-response curve model. However, the reviewer noted that data analysis using different regression models produced the same results.

The vegetative vigor study **(Table 12)** indicated that plant weight was the most sensitive endpoint for the most sensitive monocot, onion (EC_{25} = 0.0020 lb a.i./A) and plant weight was the most sensitive endpoint for the most sensitive dicot, soybean (EC_{25} = 0.00046 lb a.i./A). However, this study is classified as supplemental and as not having fulfilled data requirements for Guideline 123-1(b) because there is significant uncertainty in plant weight and height values for a number of plant species tested. Statistical analysis indicated that there are problems fitting the dose-response curves using standard statistical methods. In this study the test concentrations were geometrically spaced by a factor of three (nominal concentration range: 0.00065 - .0053 lbs. a.i./A). In many of the plants tested, the lowest test concentration (0.00065 lbs. a..i./A) demonstrated greater effects on plants than next higher concentration (0.0020 lbs. a.i./A). Since this test material affects plants at such low levels (EC_{05} = 0.000024 lbs ai/acre), the accuracy of mixing and applying the test material to the study plots has been cited as an uncertain (MRID 448892-21). The reviewer recommended that the vegetative vigor study be repeated with test concentrations spaced with a factor higher than three and that the amount of test material applied be confirmed by chemical residue analysis of plant tissues (for the lowest and highest test concentration, and for the control plots) directly after application or by placing spray collectors in study plots.

In both the vegetative vigor and seedling emergence studies a similar effect was noted in that at lower doses there appeared to be an enhanced effect on growth-related endpoints and these irregular dose responses were attributed by the reviewer to be the possible result of discrepancies in exposure. It is possible however, that the u-shaped dose response observed in the vegetative vigor studies is reflective of a phenomena termed "hormesis" where low doses elicit a stimulatory response. These stimulatory effects have been associated with growth responses and have been observed at levels 4- to 5- fold below the NOEL for particular responses (Calabrese and Baldwin 2001; Calabrese et al. 1999; Calabrese and Baldwin 1998).

Table 12. Summary of nontarget terrestrial plant vegetative vigor toxicity (Tier II) to monocotyledon and dicotyledon plant species exposed to bispyribac-sodium.

Species	% Active Ingredient	EC_{25} Dose (lb a.i./A)	% Response and Endpoint Affected	MRID No. Author/Year	Fulfills Guideline Requirements
Monocot - corn	80.0	0.0063	-10 plant weight	44889221 Chetram 1998	Supplemental
Monocot - oat	"	>0.053	-3 to -8 all endpoints	"	"
Monocot - ryegrass	"	0.0024	-6 plant weight	"	"
Monocot - onion	"	0.0020	-21 plant weight	"	"
Dicot - cabbage	"	0.0010	-33 plant weight	"	"
Dicot - radish	"	0.0012	-60 plant height	"	"
Dicot - cucumber	"	0.0053	-29 plant weight	"	"

Species	% Active Ingredient	EC_{25} Dose (lb a.i./A)	% Response and Endpoint Affected	MRID No. Author/Year	Fulfills Guideline Requirements
Dicot - lettuce	"	0.0040	-29 plant height	"	"
Dicot - soybean	"	0.00046*	-4 plant weight weightheight	"	"
Dicot - tomato	"	0.0011	-13 plant weight	"	"

* Reviewer cautions that the value is questionable due to a poor fit of data to the dose response curve model.

Toxicity to Aquatic Plants

Acute toxicity studies (Tier I) were conducted to determine the toxicity of formulated bispyribac-sodium (80S) to nontarget aquatic plant species. Studies conducted with *Anabaena flos-aquae* (freshwater blue-green algae; MRID 448892-18), *Navicula pelliculosa* (freshwater diatom; MRID 448892-19), and *Skeletonema costatum* (marine diatom; MRID 448892-20) showed no statistically significant reductions in cell density at the limit concentration (25X the maximum application rate 0.053lbs a.i./A equivalent of 0.039 mg a.i./L in a 15-cm water column. EC_{50} was determined to exceed 1.0 mg a.i./L in all three studies **(Table 13).** Each of the Tier 1 aquatic plant toxicity studies are classified as core and as having fulfilled Guideline 122-2 testing requirements.

Tier II acute toxicity studies were also conducted to determine aquatic plant toxicity to the formulated end product bispyribac-sodium 80S. A study (MRID 448892-17) involving freshwater green algae (*Selenastrum capricornutum*) was classified as supplemental because the initial number of cells was almost 10 times the maximum initial cell count specified by the guidelines and because insufficient detail was provided on the density of algal cells. Additionally, light intensity was greater than 15% of the acceptable deviation specified within the guidelines. After 5 days, EC_{50} for green algae was determined to be 8.7 mg/L for growth rate and 5.62 mg/L for biomass (area under the curve; **Table 13**). A core study was conducted with *Lemna gibba* (MRID 448892-23). The NOEC in this study was less than the lowest dose tested, *i.e.*, 0.0066 mg a.i./L, based on frond appearance; the EC_{50} was 0.010 mg a.i./L for frond density and 0.0102 mg a.i./L for biomass **(Table 12).** As a result, duckweed was shown to be the most sensitive aquatic plant species tested. Although the algistatic study involving green algae is classified as supplemental, EFED is not requiring that the study be repeated..

Table 13. Summary of aquatic plant acute toxicity tests using algae (*Anabaena flos-aquae* and *Selenastrum capricornutum*), diatoms (*Navicula pelliculosa* and *Skeletonema costatum*), and duckweed (*Lemna gibba*).

Species	% Active Ingredient	EC_{50} mg/L	MRID No. Author/Year	Test Type	Fulfills Guideline Requirements
Anabaena flos-aquae	79.0	>1.0	448892-18 Hoberg 1998	Tier I	Core
Navicula pelliculosa	79.0	>1.0	448892-19 Hoberg 1998	Tier I	Core
Skeletonema costatum	79.0	>1.1	448892-20 Hoberg 1998	Tier I	Core
Selenastrum capricornutum	95.2	Growth rate: 2.2 Area under the curve: 3.4	448892-17 Douglas *et al.* 1991	Tier II	Supplemental
Lemna gibba	79.0	Frond density: 0.010 Biomass: 0.0102	448892-23 Hoberg 1998	Tier II	Core

APPENDIX E. EXPOSURE AND RISK TO NONTARGET ANIMALS

Risk Assessment

A means of integrating the results of exposure and ecotoxicity data is called the quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic.

$$RQ = \text{EXPOSURE/TOXICITY}$$

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories: (1) **acute high** - potential for acute risk is high, regulatory action may be warranted in addition to restricted use classification (2) **acute restricted use** - the potential for acute risk is high, but this may be mitigated through restricted use classification (3) **acute endangered species** - the potential for acute risk to endangered species is high, regulatory action may be warranted, and (4) **chronic risk** - the potential for chronic risk is high, regulatory action may be warranted. Currently, EFED does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to mammalian or avian species.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from the results of required studies. Examples of ecotoxicity values derived from the results of short-term laboratory studies that assess acute effects are: (1) LC50 (fish and birds) (2) LD50 (birds and mammals) (3) EC50 (aquatic plants and aquatic invertebrates) and (4) EC25 (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOEC (birds, fish, and aquatic invertebrates) (2) NOEC (birds, fish and aquatic invertebrates) and (3) MATC (fish and aquatic invertebrates). For birds, mammals, and all aquatic organisms, the NOEC is the ecotoxicity test value used in assessing chronic risk. Other values may be used when justified. Risk presumptions, along with the corresponding RQs and LOCs are summarized in **Tables 1** through **3**.

Table 1. Risk presumptions for terrestrial animals

Risk Presumption	RQ	LOC
Birds		
Acute High Risk	EEC[1]/LC_{50} or LD_{50}/ft^2 or LD_{50}/day[3]	0.5
Acute Restricted Use	EEC/LC_{50} or LD_{50}/ft^2 or LD_{50}/day (or LD_{50} < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD_{50}/ft^2 or LD_{50}/day	0.1
Chronic Risk	EEC/NOEC	1
Wild Mammals		
Acute High Risk	EEC/LC_{50} or LD_{50}/ft^2 or LD_{50}/day	0.5
Acute Restricted Use	EEC/LC_{50} or LD_{50}/ft^2 or LD_{50}/day (or LD_{50} < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD_{50}/ft^2 or LD_{50}/day	0.1
Chronic Risk	EEC/NOEC	1

[1] abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

[2] $\frac{\text{mg/ft}^2}{\text{LD50 * wt. of bird}}$ [3] $\frac{\text{mg of toxicant consumed/day}}{\text{LD50 * wt. of bird}}$

Table 2. Risk presumptions for aquatic animals

Risk Presumption	RQ	LOC
Acute High Risk	EEC[1]/LC_{50} or EC_{50}	0.5
Acute Restricted Use	EEC/LC_{50} or EC_{50}	0.1
Acute Endangered Species	EEC/LC_{50} or EC_{50}	0.05
Chronic Risk	EEC/NOEC	1

[1] EEC = (ppm or ppb) in water

Table 3. Risk presumptions for plants

Risk Presumption	RQ	LOC
Terrestrial and Semi-Aquatic Plants		
Acute High Risk	EEC[1]/EC_{25}	1
Acute Endangered Species	EEC/EC_{05} or NOEC	1
	Aquatic Plants	
Acute High Risk	EEC[2]/EC_{50}	1
Acute Endangered Species	EEC/EC_{05} or NOEC	1

[1] EEC = lbs ai/A

[2] EEC = (ppb/ppm) in water

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Exposure and Risk to Nontarget Terrestrial Animals

For pesticides applied as a nongranular product (e.g., liquid, dust), the estimated environmental concentrations (EECs) on food items following product application are compared to LC_{50} values to assess risk. The predicted 0-day maximum and mean residues of a pesticide that may be expected to occur on selected avian or mammalian food items immediately following a direct single application at 0.053 lbs. a.i./A are presented in **Table 4.**

Table 4. Estimated environmental concentrations on avian and mammalian food items (ppm) following a single application at 0.053 lb ai/A

Food Items	EEC (ppm) Predicted Maximum Residue[1]	EEC (ppm) Predicted 56-day Mean Residue[1]
Short grass	12.72	7.76
Tall grass	5.83	3.49
Broadleaf/forage plants, and small insects	7.16	4.20
Fruits, pods, seeds, and large insects	0.80	0.46

[1] Predicted maximum and mean residues are are based on Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994).

Birds

The acute and chronic risk quotients for single broadcast applications of nongranular products indicate that no avian acute or chronic level of concern is exceeded using the maximum EEC on food items (**Table 5**).

Table 5. Avian acute and chronic risk quotients for single application of nongranular products (broadcast) based on a bobwhite quail LC_{50} of 5,620 ppm.

Site/App. Method	App. Rate (lbs ai/A)	Food Items	Maximum EEC (ppm)	LC_{50} (ppm)	NOEC (ppm)	Acute RQ (EEC/ LC_{50})	Chronic RQ (EEC/ NOEC)
Rice	0.053	Short grass	12.72	5620	1500	<0.01	<0.01
		Tall grass	5.83	5620	1500	<0.01	<0.01
		Broadleaf plants/Insects	7.16	5620	1500	<0.01	<0.01
		Seeds	0.80	5620	1500	<0.01	<0.01

Chronic risk quotients can be calculated based on the average residues on food items. Avian chronic risk quotients based on average residues for single broadcast applications of non-granular products indicate that the avian chronic level of concern is still not exceeded at the registered application rate using the average predicted EEC on food items (**Table 6**).

Table 6. Avian chronic risk quotients for single application of nongranular product (broadcast) based on a bobwhite quail NOEC of 1,000 ppm and average 56-day residues.

Site/Application Method	Application Rate in lbs ai/A	Food Items	Mean 56-day EEC (ppm)	NOEC (ppm)	Chronic RQ (EEC/NOEC)
Rice	0.053	Short grass	7.76	1,000	<0.01
		Tall grass	3.49	1,000	<0.01
		Broadleaf plants/Insects	4.20	1,000	<0.01
		Seeds	0.46	1,000	<0.01

Mammals

Estimating the potential for adverse effects to wild mammals is based upon EEB's draft 1995 SOP of mammalian risk assessments and methods used by Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994). The concentration of bispyribac-sodium in the diet that is expected to be acutely lethal to 50% of the test population (LC_{50}) is determined by dividing the LD_{50} value (rat LD_{50} = 3,565 mg/Kg) by the % (decimal of) body weight consumed. A risk quotient is then determined by dividing the EEC by the derived LC_{50} value. Risk quotients are calculated for three separate weight classes of mammals (15, 35, and 1000 g), each presumed to consume four different kinds of food (grass, forage, insects, and seeds). The results indicate that for a single application of nongranular products, no mammalian acute level of concern is exceeded at the registered application rate for mammals feeding on insects or grasses (**Table 7**) or grains (**Table 8**).

Table 7. Mammalian (herbivore/insectivore) acute risk quotients for single application of nongranular products (broadcast) based on a rat LD_{50} of 3,565 mg/kg.

Site/ Application Method/ Rate in lbs ai/A	Body Weight (g)	% Body Weight Consumed (decimal)	Rat LD_{50} (mg/kg)	EEC (ppm) Short Grass	EEC (ppm) Tall Grass	EEC (ppm) Forage and Small Insects	Acute RQ[1] Short Grass	Acute RQ Tall Grass	Acute RQ Forage and Small Insects
Rice									
0.053	15	0.95	3,565	12.7	5.8	7.2	<0.01	<0.01	<0.01
0.053	35	0.66	3,565	12.7	5.8	7.2	<0.01	<0.01	<0.01
0.053	1000	0.15	3,565	12.7	5.8	7.2	<0.01	<0.01	<0.01

[1] $RQ = \frac{\text{EEC (ppm)}}{LD_{50}\text{ (mg/kg)}/\text{ \% Body Weight Consumed (\% in decimal)}}$

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Table 8. Mammalian (granivore) acute risk quotients for single application of nongranular products (broadcast) based on a (rat) LD_{50} of 3,565 mg/kg.

Site/ Application Method/Rate in lbs ai/A	Body Weight (g)	% Body Weight Consumed (in decimal)	Rat LD_{50} (mg/kg)	EEC (ppm) Seeds	Acute RQ[1] Seeds
Orange (mistblower)					
0.013	15	0.21	3,565	0.5	<0.01
0.013	35	0.15	3,565	0.5	<0.01
0.013	1000	0.03	3,565	0.5	<0.01

[1] RQ = EEC (ppm) / LD50 (mg/kg)/ % Body Weight Consumed (% in decimal)

The chronic risk quotients for broadcast applications of nongranular products are presented in **Table 9**. The results indicate that for single applications of nongranular products, no mammalian chronic level of concern is exceeded at the registered application rate.

Table 9. Mammalian chronic risk quotients for nongranular products (broadcast) based on a Rat NOAEL 75.7 mg/kg/day (or 1,000 ppm [2])

Site/Application Method	Application Rate in lbs ai/A	Food Items	Maximum EEC[1] (ppm)	NOEC (ppm)	Chronic RQ (EEC/NOEC)
Rice	0.03	Short grass	12.7	1,000	<0.01
		Tall grass	5.8	1,000	<0.01
		Broadleaf plants/Insects	7.2	1,000	<0.01
		Seeds	0.8	1,000	<0.01

1. Based on Fletcher without degradation
2. Assuming 1 mg/kg/day equals 20 ppm in diet

Freshwater Fish

Based on a bluegill sunfish acute LC_{50} value of 102 mg/L, no aquatic acute level of concern is exceeded for freshwater fish at the proposed maximum application rate for bispyribac-sodium (**Table 10**).

Table 10. Acute risk quotients for freshwater fish based on a bluegill sunfish LC_{50} of 102 mg/L.

Site/ Application Method	Rate in lbs as/A	LC_{50} (ppm)	EEC Initial/ Peak (ppm)	Acute RQ (EEC/LC_{50})
Rice	0.053	102	0.003	<0.01

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Freshwater Invertebrates

Based on an acute EC_{50} value of 99.2mg/L and a chronic NOEC of 110 mg/L for *Daphnia magna*, no acute or chronic level of concern is exceeded for freshwater invertebrates at the proposed maximum application rate for bispyribac-sodium **(Table 11).**

Table 11. Risk quotients for freshwater invertebrates based on a daphnid EC_{50} of 99.2 mg/L and a chronic NOEC of 110 mg/L.

Site/ Application Method	Rate in lbs as/A	LC_{50} (ppm)	EEC Initial/ Peak (ppm)	Acute RQ (EEC/LC_{50})	Chronic RQ (EEC/NOEC or MATC)
Rice	0.053	99.2	0.003	<0.01	<0.01

Estuarine and Marine Animals

Estuarine/marine Fish

Based on an acute LC_{50} value of 120 mg/L for sheepshead minnow, no acute level of concern is exceeded for estuarine/marine fish at the proposed maximum application rate **(Table 12).**

Table 12. Risk quotients for estuarine/marine fish based on a sheepshead minnow LC_{50} of 120 mg/L.

Site/Application Method	Rate in lbs ai/A	LC_{50} (ppm)	EEC Initial/Peak (ppm)	Acute RQ (EEC/LC_{50})
Rice	0.053	120	0.003	<0.01

Estuarine/marine Invertebrates

Based on an acute LC_{50} value of 110 mg/L for Eastern oysters, no acute levels of concern is exceeded for estuarine/marine invertebrates at the registered application rate **(Table 13).**

Table 13. Risk quotients for estuarine/marine aquatic invertebrates based on a mysid shrimp LC_{50} of 20 ppm.

Site/ Application Method	Rate in lbs ai/A	LC_{50} (ppm)	EEC Initial/ Peak (ppm)	Acute RQ (EEC/LC_{50}
Rice	0.053	110	0.003	<0.01

Exposure and Risk to Nontarget Plants

Terrestrial and Semi-aquatic

Terrestrial and semi-aquatic plants may be exposed to pesticides from runoff, spray drift or volatilization. Semi-aquatic plants are those that inhabit low-lying wet areas that may be dry at certain times of the year. EFED's rice scenario assumes is 5% drift (from aerial application) into adjacent areas and a 1 to 1 dilution factor (50%) of treated water from rice fields draining into adjacent areas. Formulae for calculating EECs for terrestrial plants inhabiting areas adjacent to treatment sites and EECs for semi-aquatic plants inhabiting wet, low-lying areas are in an addendum. Estimated Environmental Concentrations (EECs) for terrestrial and semi-aquatic plants are presented in **Table 15.**

Table 15. Estimated environmental concentrations for terrestrial and semi-aquatic plants for a single application of 0.0265 lbs ai/acre of bispyribac-sodium (assuming no degradations).

Site/Application rate/method/ number of applications	Dilution factor (%) following drainage of water from rice fields into adjacent areas	Drainage into adjacent areas (lbs ia/acre)	Percent Drift	Drift (lbs ai/acre)	Total loading to adjacent areas (Drift + Drainage) (lbs ai/acre)
Rice/ 0.0265 aerial/ 2	50.0	0.013	5.0	0.0013	0.0143

The EC_{25} value of the most sensitive species in the seedling emergence study is compared to runoff and drift exposure to determine the risk quotient (EEC/toxicity value). The EC_{25} value of the most sensitive species in the vegetative vigor study is compared to the drift exposure to determine the acute risk quotient. Based on seedling emergence tests, the most sensitive species was onions (EC_{25} = 0.0013 lbs a.i./acre. Results of the vegetative vigor study indicated that the most sensitive species is soybean (EC_{25} = 0.00046 lb a.i./acre).

Acute risk quotients are provided in **Table 16**. Acute level of concern (LOCs) are exceeded for terrestrial or semi-aquatic plants using the estimated environmental concentrations of 0.0143 lbs ai/acre for seedling emergence and 0.0013 lbs ai/acre for vegetative vigor. These EECs were calculated for a single application of 0.0265 lbs ai/acre. However, bispyribac-sodium may be applied twice per year. If two applications are used in EEC calculations, it is likely that risk quotients will be higher.

Table 16. Acute risk quotients for terrestrial and semi-aquatic plants

Site, Method and Rate of Application (lbs ai/A)	Seedling Emergence EC_{25} (lbs ai/A)	Vegetative Vigor EC_{25} (lbs ai/A)	Drift (lbs ai/A)	Total Loading to Adjacent Areas (Drift + Drainage) (lbs ai/acre)	Seedling Emergence RQ Terrestrial and Semi-Aquatic Plants	Vegetative Vigor RQ Terrestrial and Semi-Aquatic Plants
Rice Aerial, 0.0265	0.013	0.00046	0.0013	0.0143	2.9	1.1

Aquatic Plants

Exposure to nontarget aquatic plants may occur through runoff or spray drift from adjacent treated sites or directly from use on rice. The risk quotient is determined by dividing the pesticide's initial or peak concentration in water by the most sensitive plant, *i.e.*, green algae (nonvascular) and duckweed (vascular) EC_{50} value of 2.2 mg/L and 0.01 mg/L, respectively. The results indicate (**Table 17**) that no aquatic plant acute level of concern is exceeded for either vascular or non-vascular aquatic plants at the maximum proposed rate.

Table 17. Acute risk quotients for aquatic plants based on the vascular plant duckweed (*Lemna gibba*) EC_{50} of 116 mg/L and the nonvascular diatom (*Skeletonema costatum*) EC_{50} of 0.119 mg/L.

Site/ Application Method	Test Species	EC_{50} Initial/Peak (mg/L)	EEC (mg/L)	RQ (EEC/ EC_{50})
Rice aerial	duckweed	116	0.003	0.03
Rice aerial	green algae	0.119	0.003	0.00

APPENDIX F. RESPONSE MEMO FOR REGISTRANT WAIVER REQUEST ON FISH BIOACCUMULATION STUDY.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

August 7, 2001

SUBJECT: Bioaccumulation in Fish Waver Request for Bispyribac-sodium

TO: Jim Tompkins,
Product Manager,
Registration Division

FROM: Lucy Shanaman, Chemist,
EFED, ERB IV

THROUGH: Elizabeth Behl,
Branch Chief,
EFED, ERB IV

This memo describes the Environmental Fate and Effects Division recommendations concerning the waver request submitted by Valent USA Corporation for the bioaccumulation of bispyribac-sodium in fish.

Valent USA Corporation has requested a waver for the bioaccumulation in fish data requirement (Guideline Number 165-4) for bispyribac-sodium, formulated as Regiment™ Herbicide. Based on (1) a low maximum use rate of 0.053 lb active ingredient per acre, (2) an intended use solely on rice crops, and (3) the low K_{oc} partitioning coefficient value of 114 (from MRID #448892-31), Environmental Fate and Effects Division recommends granting the waver.