



Pesticide Fact Sheet

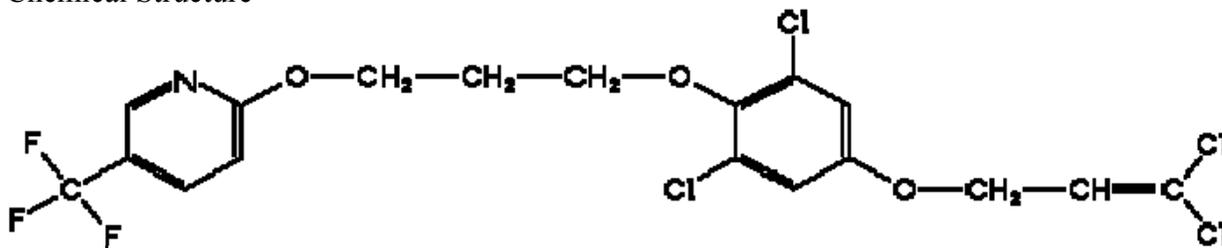
Name of Chemical:
Reason for Issuance:
Date Issued:

Pyridalyl
New Chemical Registration
April 24, 2008

DESCRIPTION OF CHEMICAL

Common Name	Pyridalyl
Company Experimental Name	S-1812
IUPAC Name	2,6-dichloro-4-(3,3-dichloroallyloxy)phenyl 3-[5-(trifluoromethyl)-2-pyridyloxy]propyl ether
CAS Name	2-[3-[2,6-dichloro-4-[(3,3-dichloro-2-propenyl)oxy]phenoxy]propoxy]-5-(trifluoromethyl)pyridine
Chemical Formula	$C_{18}H_{14}Cl_4F_3NO_3$
Chemical Abstracts Service (CAS) Number	179101-81-6
EPA Chemical Code	295149
Pesticide Type	Insecticide
Chemical Class	Unclassified
U. S. Technical Registrant	Valent USA Corporation

Chemical Structure



USE PATTERN AND FORMULATIONS

Pyridalyl is a new insecticide intended for the control of lepidopterous larvae and thrips as part of Insect Resistance Management (IRM) and Integrated Pest Management (IPM) programs. It is registered for use in enclosed greenhouses only.

Pyridalyl is registered as a wettable powder formulation packaged in water soluble packets containing 35% active ingredient. It is registered for use on fruiting vegetable transplants, *Brassica* head and stem vegetable transplants, leafy vegetable transplants, shrubs, ornamentals, ground cover, non-bearing fruit, nut trees, and vines grown in enclosed greenhouses. Outdoor and residential uses are not allowed.

Pyridalyl is to be applied as a foliar spray at 0.19 - 0.38 lb ai/A with a 14-day retreatment interval and a maximum application rate of 1.2 - 2.3 lb ai/A (up to 3 reapplications per crop cycle or no more than 3 times per six months).

SCIENCE FINDINGS

Human Health Risk Assessment

Acute Toxicity

Technical pyridalyl has low acute toxicity (Toxicity Category IV) via the oral, dermal and inhalation routes of exposure. Pyridalyl is not an eye or dermal irritant, but showed sensitization in both the Buehler and Maximization assays. The wettable powder formulation showed low acute toxicity (Toxicity Category IV) via the oral, dermal and inhalation routes of exposure and was a mild eye irritant (Toxicity Category III). The formulation produced slight dermal irritation, but did not produce dermal sensitization.

Subchronic Toxicity

Subchronic oral toxicity was evaluated in the rat, mouse and dog and a 28-day dermal toxicity study in the rat. Decreased body weight and/or body weight gain were observed in the rat, mouse and dog. No treatment-related clinical pathological effects were observed in either the rat or dog. Mice, however, had hematological (decreased HCT, RBC, and HGB) and blood biochemical (increased cholesterol and decreased

triglycerides) effects. Increased liver weights were observed in the rat, mouse and dog studies, while kidney weights were either increased (dog and rat) or decreased (mouse). Female mice also had decreased ovary weight. Histopathological changes in the liver included necrosis and/or hypertrophy in rats, mice and dogs. Other histological findings were observed in the ovaries of rats (vacuolation of interstitial gland cells) and mice (atrophy), the adrenals of both rats and dogs (vacuolation) and mice (pigmentation), and lungs of rats (foamy cell accumulation) and dog (thickening of arterial and arteriole walls). The 28-day dermal toxicity study in rats did not produce any signs of dermal or systemic toxicity at 1000 mg/kg/day (limit dose).

Chronic Toxicity

Pyridalyl has been tested in chronic studies with dogs, rats and mice. Observations in the combined chronic toxicity/oncogenicity study in rats included decreased body weight gain, hematological alterations and histopathological alterations of the spleen. In the 78-week feeding study in mice decreased body weight gain and food consumption/efficiency, and increased liver and kidney weights were observed. In a 12-month oral study with dogs, pyridalyl produced alterations in blood biochemistry and increased liver weights.

Neurotoxicity

There is no concern for neurotoxicity resulting from exposure to pyridalyl. No neurotoxicity studies were submitted, but no evidence of neurotoxicity was seen in either the subchronic and chronic toxicity studies or the developmental and reproductive toxicity studies.

Carcinogenicity

Pyridalyl is classified as “Not Likely to be Carcinogenic to Humans” based on lack of carcinogenicity in mice and rats and overall negative findings in various mutagenicity assays.

Mutagenicity

There is no concern for mutagenicity resulting from exposure to pyridalyl based on negative results from various *in vivo* and *in vitro* mutagenicity assays.

Metabolism

In a series of metabolic studies radiolabeled pyridalyl was administered by gavage to male and female Sprague Dawley rats at concentrations of 5 or 500 mg/kg. Greater than 90% of the amount of radiolabeled material was eliminated in the feces within 72 hours of treatment.

Prenatal Developmental/Reproductive Toxicity

Acceptable developmental toxicity studies in the rat and rabbit, as well as a two-generation reproductive toxicity study in the rat, are available. A potential concern for effects of pyridalyl exposure on the developing immune system was raised due to findings suggestive of delayed thymus development. These concerns were mitigated by the overall weight of the evidence, which suggests that pyridalyl does not directly target the immune system : *i*) there were no effects noted in examination of the spleens of developing rat or rabbit fetuses in the prenatal developmental toxicity studies, or in gross necropsy evaluations and organ weight data for weanling rats in the two-generation reproduction study; *ii*) there were no treatment-related postmortem findings (organ weight, gross pathology, and microscopic pathology) in the immune system organs (spleen, thymus, lymph nodes) of adult animals in the subchronic or chronic studies in any species; and *iii*) hematology data from these studies did not identify any treatment-related findings that could be attributed to immune system dysfunction, and the clinical observations in the animals did not suggest compromised immune function.

Following the weight of evidence evaluation of the database for pyridalyl, the HED HIARC determined that a developmental immunotoxicity study was not required.

Food Quality Protection Act (FQPA) Safety Factor

The toxicology database for pyridalyl is complete and adequate for FQPA assessment. The HED HIARC concluded that the FQPA Safety Factor can be reduced to 1X for pyridalyl:

- There is no concern for neurotoxicity resulting from exposure to pyridalyl.
- There is low concern for pre- and/or postnatal toxicity resulting from exposure to pyridalyl. In the developmental toxicity study in rats, developmental effects were seen at a dose higher than the dose that caused maternal toxicity. In the developmental toxicity study in rabbits, abortions/premature delivery were seen at the highest dose tested which can be attributed to maternal toxicity. There was evidence of quantitative susceptibility in the two-generation reproduction study, however, the concern is low since there was a clear NOAEL for the offspring toxicity, and the effects of concern were well defined and used for risk assessment. It was therefore concluded that there is no residual uncertainty for pre and/or postnatal toxicity.

Aggregate Exposure and Risk Characterization

Pyridalyl residues of concern for tolerance expression and risk assessment were determined to be: pyridalyl (all crops, ruminants, and drinking water), 3,5-dichloro-4-[3-(5-trifluoromethyl-2-pyridyloxy)]propoxy phenol (S-1812-DP; cotton gin byproducts and drinking water), 2-hydroxy-5-trifluoromethylpyridine (HTFP; rotational crops and

drinking water), and 3-hydroxy-5-trifluoromethylpyridone (HPDO; rotational crops only). Pyridalyl is the predominant residue in crops and livestock. S-1812-DP is the only major metabolite observed in any of the metabolism studies. Pyridalyl is expected to be persistent in both soil and aquatic environments. However, S-1812-DP and HTFP, the major metabolites in the terrestrial field-dissipation studies, are expected to be more soluble and mobile than the parent compound, and therefore are included in the drinking water assessment. The metabolites, S-1812-DP, HTFP, and HPDO are assumed to be of equivalent toxicity to the parent compound.

The toxicological endpoints relevant to this risk assessment are as follows:

- Chronic dietary NOAEL = 3.4 mg/kg/day
- Chronic RfD and cPAD = 0.034 mg/kg/day
- Oral NOAEL = 2.8 mg/kg/day
- Target MOE = 100 (occupational)

An acute aggregate risk assessment was not performed for pyridalyl since an endpoint of concern attributable to a single exposure was not identified by HIARC from oral toxicity studies, including the developmental toxicity studies in rats and rabbits. Short- and intermediate-term aggregate risk assessments were not performed because there are no proposed residential uses.

A long-term aggregate assessment was performed, based on maximum dietary exposures from food sources. The chronic dietary exposure analysis was performed using tolerance level residues and 100% crop treated information for all commodities. In addition, DEEM (version 7.76) default processing factors were used for all processed commodities. Lifeline™ CARES and DEEM-FCID™ yielded similar results. The most highly exposed population subgroup was children 1-2 years old which accounted for 59% of the cPAD (DEEM-FCID; Lifeline: 52% cPAD).

Drinking Water Assessment

Potential human exposure to pyridalyl and its degradates in drinking water (S-1812-DP and HTFP) were evaluated through modeling since no monitoring data are available. Surface water concentrations were estimated using the Tier II model PRZM version 3.12/EXAMS version 2.98.04. Ground water concentrations were estimated using the Tier I model SCIGROW version 2.2. HED conducted a conservative risk assessment by using the highest residues in drinking water (EDWCs) from the models. For surface water, the EDWC for parent pyridalyl plus its metabolites HTFP and S-1812-DP was used (1.64 ppb), and for ground water the EDWC for the metabolite HTFP was used (3.4 ppb). Chronic drinking water levels of concern (DWLOCs) ranged from 140 to 800 ppb. Surface and ground water model estimates from EFED do not exceed the chronic aggregate DWLOCs. Therefore, based on the proposed uses, the chronic aggregate risk from pyridalyl is not expected to exceed the Agency's level of concern.

Occupational Exposure and Risk Characterization

The estimates of exposure to pesticide handlers are based upon surrogate study data available in the Pesticide Handler's Exposure Database (PHED, v.1.1, 1998). The occupational use scenarios most likely to have the highest exposure were assessed. Handler risks do not exceed the Agency's level of concern when handlers wear the personal protective equipment (PPE) and clothing listed on the proposed labels (long-sleeved shirt, long pants, chemical resistant gloves, and shoes plus socks).

ENVIRONMENTAL FATE AND ECOLOGICAL RISK ASSESSMENT

Summary of Environmental Fate and Transport Properties

The major routes of degradation for pyridalyl in laboratory studies are photodegradation in water and soil and to a lesser degree aerobic microbial degradation. Pyridalyl is expected to be persistent in both soil and aquatic environments. It is stable to hydrolysis but degraded with aqueous photolysis half-lives of 2 to 6 days. However, outside of clear, shallow water bodies that are low in organic matter (oligotrophic systems), aqueous photolysis is not likely to contribute significantly to the degradation of pyridalyl. Pyridalyl degraded in an aerobic soil metabolism study with half-lives of 187.3, 210.0, 346.6, 150.7, 93.7, 115.5, and 177.7 days and had half-lives of 46.2 days to 256 days in several terrestrial field dissipation studies. In an aerobic aquatic metabolism study pyridalyl degraded with a half lives of 133.3, 203.9, 165, and 128.4 days and in an anaerobic aquatic metabolism study, pyridalyl degraded with a half-life of 370 days in the whole system. Pyridalyl is highly immobile with K_d values between 2,473 and 3,848 and corresponding K_{oc} values between 402,000 and 2,060,000, respectively. Finally, pyridalyl is highly insoluble in water with a solubility limit of 0.15 micrograms per liter ($\mu\text{g/L}$) and has a high bioaccumulation potential with a reported log K_{ow} of 8.1 (MRID 45685108) and bioconcentration factor (BCF) of $>16,000$ (estimated steady state BCF = approximately 27,000 L/kg) in whole fish tissues. Given these factors, pyridalyl is expected to be persistent in soil, sediment, and water and may accumulate over time with repeated use, and these properties are expected to control runoff in that movement off-site is expected to be dominated by soil/sediment bound residues.

Exposure Assessment

A new chemical environmental risk assessment was completed for pyridalyl in September, 2004 that resulted in estimates with a high degree of uncertainty. Due to its very low water solubility, high bioaccumulation potential, and high affinity for organic matter, when pyridalyl enters the water, it will not remain in the water column, but will partition to the sediment and biota. Toxicity studies and the standard EECs typically used for aquatic risk assessment are based on water concentrations of the pesticide. Therefore, the 2004 assessment was considered inadequate because for pyridalyl, water exposure may represent only a minor pathway relative to dietary exposures. Modeling estimates suggest that not considering dietary exposures could underestimate the risks by

1,000 fold. Additional data (including bioaccumulation and toxicity in sediment organisms, and bioaccumulation in fish) were submitted to allow for a better characterization of potential risks from the proposed pyridalyl uses. These data were incorporated in an alternative framework for risk assessment that does not necessarily represent standard methodology, but is specific to the chemical and fate properties of pyridalyl.

The additional methodologies used for the revised risk assessment focused on characterization of the potential risks to aquatic animals from exposure via consumption of contaminated food, to sediment organisms after long-term exposures, and to terrestrial animals that consume contaminated aquatic organisms.

Potential exposures were estimated in terms of body burden of the assessed organism. Body burden estimates are based on pyridalyl levels in the exposure media (water, pore water, and sediment) and its bioaccumulation potential. Multiple methods were used to estimate body burdens used as EECs including use of laboratory data, microcosm/mesocosm studies, and modeling.

The environmental risk assessment specifically addresses potential risks from exposure to pyridalyl. Potential risks to degradates were not quantified because the available data suggest that the major degradates (including S-1812 DP, S-1812 PYP, and S-1812 HTFP) are orders of magnitude less toxic than pyridalyl to daphnids. It is noted, however, that the toxicity of degradates has not been tested in other species.

Risk Assessment - Summary of Key findings

Key findings of the environmental risk assessment are as follows:

- Characteristics of pyridalyl are consistent with characteristics of persistent, bioaccumulative, and toxic chemicals.
 - Pyridalyl is highly immobile with K_d values between 2,473 and 3,848 and corresponding K_{oc} values between 402,000 and 2,060,000, respectively. Given the high sorption potential of this compound it is likely that pyridalyl will accumulate in soil and sediment.
 - Pyridalyl is highly insoluble in sterile water with a solubility limit of 0.15 micrograms per liter ($\mu\text{g/L}$).
 - Pyridalyl has high potential for bioaccumulation with a log K_{ow} of 8.1 and bioconcentration factors (BCF) as high as 7152, 28671, and 16323 for the edible, non-edible and whole fish tissues, respectively. This suggests that pyridalyl is lipophilic and has the potential to bioaccumulate in aquatic organisms.

The available data do not suggest that pyridalyl will accumulate in higher trophic level organisms to an extent that is expected to result in potential direct effects at levels of concern to such organisms under the proposed use conditions. However, several additional studies are needed to evaluate the assumptions used for the risk assessment.

- RQs used to estimate potential risks to aquatic and benthic invertebrates exceeded LOCs. RQs ranged from approximately 2 to 150 depending on surrogate organism and use pattern. A single application could result in EECs that have been shown to affect sensitive species.
 - Given the high persistence of pyridalyl in sediment, potential effects could occur for an extended period of time for sensitive organisms if levels reach a toxic threshold.
 - It is uncertain if potential risks to benthic invertebrates result from exposure to contaminated water or from exposure to contaminated sediment.
 - RQs were not exceeded for the greenhouses that discharge to publicly owned treatment works (POTW). However, effects to sensitive benthic invertebrates could occur for facilities that discharge waste water directly to aquatic ecosystems.

- RQs used to estimate potential risks to fish did not exceed concern levels for any proposed use; however, toxicity studies that associate body burden with toxicity in fish are needed to evaluate the validity of these conclusions.
- RQs used to estimate potential risk to terrestrial animals that consume aquatic organisms were lower than concern levels.
- There is an exceedance of the endangered species LOC for pyridalyl use on outdoor ornamentals for birds feeding on short grass and broadleaf plants and for the vegetable uses for birds feeding on short grass. The chronic LOC was also exceeded for birds; however, the available data are insufficient to allow for a definitive assessment of chronic risk to birds.
- There is an exceedance of the chronic LOC for pyridalyl use on outdoor ornamentals (0.4 lb ai/acre) for mammals feeding on short grass.
- Modest reductions in the maximum labeled application rates would result in no LOC exceedance for birds and mammals.

Risk Characterization

Fish: Fish RQs were as high as 0.04. Multiple lines of evidence were used to estimate potential body burdens and risks to fish. RQs based on estimates from Arnot and Gobas (2004) methodology would not result in LOC exceedance (RQ = 0.01). RQs based on residue estimates using methodology from the Great Lakes Initiative (U.S. EPA, 1995) would result in endangered species LOC exceedance (RQ = 0.06 to 0.09). The estimates based on the submitted laboratory data and the Arnot and Gobas (2004) methodology are considered more reliable because the methods incorporate accumulation data specific for pyridalyl whereas the methodology from the Great Lakes Initiative uses a generic food chain multiplier that is estimated based on the Kow of the chemical.

It is noted that there is considerable uncertainty in the estimate of toxicity used in the assessment. The estimate of toxicity assumes that 100% of pyridalyl was bioavailable. However, a solvent was used to facilitate dissolution in the studies, which may have

resulted in some proportion of pyridalyl being sequestered in the solvent, thereby decreasing the bioavailable fraction and the apparent toxicity. Any alternative assumption of bioavailability would increase RQs proportional to the amount of bioavailable fraction assumed to be in the test solutions. In addition, the critical body burden (CBB) was estimated based on data from a study in bluegill sunfish; however, the most sensitive toxicity endpoint was from an acute toxicity study in rainbow trout. It is uncertain if accumulation potential is equivalent for these two species. An acute study that associates measured pyridalyl levels in fish with toxicity would address this uncertainty.

| Benthic Invertebrates: The RQs ranged from 2 to 150 and exceeded LOCs for all proposed outdoor uses. Aquatic invertebrate LOCs were exceeded for several surrogate invertebrate species; however, there appears to be a wide range of sensitivity within benthic invertebrate species to pyridalyl.

The most sensitive benthic invertebrate species tested was *Asellus aquaticus* which is an isopod. Reduced abundance in *Asellus aquaticus* was observed in a microcosm study that applied 4 applications of pyridalyl to overlying water at 0.05 µg/L and higher, which is considerably lower than the drift only EECs. Therefore, a single application of pyridalyl could impact *Asellus* and other species that are as sensitive as *Asellus*. Effects (reduced emergence, reduced abundance) have also been observed in chironomids in several studies.

| Aquatic Invertebrates (Water Column): Potential risks to invertebrates in the water column remain uncertain, but are apparently greater than concern levels. Based on water concentrations, potential risks to aquatic invertebrates that are located in the water column exceed acute LOCs for up to several days after application. Also, even if water concentrations of pyridalyl are reduced to its water solubility limit of 0.15 µg/L, accumulated residue levels within invertebrates could exceed body burdens associated with levels of concern several days to several weeks after exposure. Drift exposure is expected to result in higher body burdens in aquatic invertebrates located in the water column compared with pyridalyl that enters the water bound to soil. The assessment suggests that a single drift event or runoff event could result in body burdens in zooplankton that approach critical body burdens in daphnids and exceed LOCs.

| Birds and Mammals: No LOCs were exceeded for birds or mammals that consume sediment invertebrates with accumulation potential similar to those observed in oligochaetes. Fish tissue levels were estimated to be lower than tissue levels in benthic invertebrates; therefore, risk would also presumably be lower than LOCs for fish-eating wildlife because estimated pyridalyl levels in fish were lower than estimated levels in invertebrates. The highest acute and chronic RQ in terrestrial animals was 0.02 and 0.6, respectively based on estimated oligochaete body burdens. Available data in fish and limited data in cows do not suggest that pyridalyl accumulates in these organisms after oral exposure. No data are available in birds.

| Plants: No toxicity data on plants are available. Therefore, risk quotients were not calculated, and risk could not be characterized.

Non-Target Insects: Pyridalyl is practically non-toxic to honeybees. Although this suggests low potential for risk to honeybees, some risk to non-target insects would presumably be possible because pyridalyl is an insecticide and its specificity has not been comprehensively evaluated. Greatest risk would presumably be to lepidopteran species.

Earthworms: Pyridalyl is of low toxicity to earthworms (LC50 >2000 mg/kg-soil). Therefore, low risk to earthworms was presumed.

| Endangered Species Concerns: Potential risks that exceeded the endangered species LOC were identified for aquatic invertebrates and species that rely on aquatic invertebrates for survival or reproduction. In addition, potential risks that exceeded the endangered species LOC were identified for herbivorous and insectivorous birds and mammals. Based on pyridalyl proposed use as an insecticide, there is presumably risk to terrestrial invertebrates that also exceed the endangered species LOCs. There is also potential for pyridalyl to cause indirect effects to organisms that depend on other organisms for which LOCs were exceeded.

| Endocrine Disruption: Effects observed in the reproduction toxicity studies, particularly in birds, indicate that pyridalyl could potentially cause endocrine disruption. When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, pyridalyl may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Enclosed Greenhouse Uses

Pyridalyl has been proposed for use on shade houses, lath houses, and greenhouses. Only enclosed greenhouse uses are being registered at this time, since shade houses and lath houses are considered outdoor uses for risk assessment purposes. Use within enclosed green houses would be expected to significantly reduce (10x decrease) environmental exposures compared with outdoor uses.

If wastewater is not released to the outside of greenhouses, exposure and risk to aquatic organisms would not be expected. However, use of pyridalyl in any greenhouse where the discharge of excess water is uncontrolled and/or leads directly to surface water (or groundwater) should be considered a risk to non-target aquatic organisms. Greenhouse drainage may be directed either to surface waters or to a POTW. Verifiable information on the number or identity of greenhouses that discharge excess irrigation water to surface water drains versus those that discharge to a POTW is not available. However, greenhouses that direct the excess irrigation water to sanitary sewer systems that eventually reach a POTW will present different ecological risks than greenhouses that do not discharge to POTWs.

Estimation of Pyridalyl in Surface Water and Sediment from Proposed Use in Greenhouses:

The EPA model Exposure and Fate Assessment Screening Tool (E-Fast) version 2.0 was used to estimate concentrations of pyridalyl in water. The E-Fast allows the user to estimate concentrations in water derived from discharges from point sources. The analysis assumed 0% removal efficiency (non-POTW scenario) and 94% removal efficiency (POTW scenario). Water concentrations are predicted to range between 0.5 parts per trillion (ppt) to 20 ppt for non-treated water (non-POTW scenario) and between 0.03 ppt and 1.1 ppt for treated water (POTW scenario). The analysis also indicates that in greenhouse settings for discharges going directly to surface water bodies, sediment concentrations are predicted to approach 1 part per million (ppm) after only one year of use (at the 90th percentile). For those greenhouses under the assumption of 94% removal efficiency from POTW's lower sediment concentrations are predicted but they approach approximately 0.05 ppm (50 parts per billion (ppb)) after one year of use at the lowest assumed total usage (730 kg/year).

Fish: For greenhouses that discharge directly to water without treatment the Fish RQs for the proposed greenhouse use was calculated as 0.004, approximately 10-fold lower than those estimated for outdoor uses. RQs would be reduced by an additional 10-fold for greenhouses that discharge to a treatment facility prior to environmental release.

Benthic Invertebrates: The estimated exposure levels in benthic animals resulting from pyridalyl use in greenhouses are expected to be lower than estimated levels for the proposed outdoor uses. However, effects to sensitive benthic invertebrates could occur for some greenhouse facilities.

Estimated body burden EECs were below all critical body burdens for greenhouses that discharge waste water to treatment facilities prior to environmental release. For facilities that discharge wastewater to a treatment facility, EECs are approximately 50 times lower than water levels associated with effects to the most sensitive benthic invertebrate tested (*Asellus*, 4 applications of 0.05 ug/L), whereas water EECs for facilities that do not discharge to a treatment facility are approximately 2.5 times lower.

Because toxicity thresholds for *Asellus* have not been established (effects occurred at all levels tested in the only available study), it is uncertain if the water concentration or body burden that approach levels associated with effects (water concentration of 0.02 ug/L or body burden of 120 ug/kg) is expected to affect species that are as sensitive as *Asellus*. However, risk to benthic invertebrates that are as sensitive as oligochaetes or chironomids are lower than levels that are of concern for the greenhouse use.

SUMMARY OF REGISTRATION DECISION

Available data provide adequate information to support the conditional registration of pyridalyl for enclosed greenhouse uses and establishment of the associated tolerances for residues. In order to address the uncertainties associated with the risk assessments, registration is limited to use in enclosed greenhouses with permeable floors or that discharge waste water to a treatment facility prior to environmental release

Required Label Statements

The following label statements are required as a condition of registration:

- For use in enclosed greenhouses only.
- Do not use in greenhouses that discharge irrigation runoff to surface water drains.
- Do not allow pesticide spray solution to runoff outside of the application area.
- If applied in an area with a non-permeable floor and a floor drainage system, excess application spray or irrigation runoff must be collected and subjected to secondary wastewater treatment.

Data Requirements

The following data are required as a condition of registration:

- Acute and life-cycle toxicity studies that associate body burden with toxicity in fish
- Acute and life-cycle toxicity studies that associate body burden with toxicity in daphnids
- Life-cycle study that associates body burden with toxicity endpoint in chironomids
- Study that evaluates accumulation potential in birds.

Public Interest Finding

The Agency believes that registering pyridalyl is in the public interest based on the designation of pyridalyl as an organophosphate alternative chemical.

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

APPENDIX I - Summary of Physical and Chemical Properties

Physicochemical Properties of Technical Grade Pyridalyl.				
Parameter	Value			
Boiling point	227 °C (degradation)			
pH	5.5 at 25 °C (1% aqueous suspension)			
Density	1.442 g/cm ³ at 20 °C			
Water solubility	0.15 ppb at 20 °C			
Solvent solubility	>1000 g/L in acetone, acetonitrile, chloroform, dimethylformamide, ethyl acetate, hexanes, 1-octanol, and xylenes >500 g/L in methanol (temperature unspecified)			
Vapor pressure	6.2 x 10 ⁻⁸ Pa at 20 °C (extrapolated)			
Dissociation constant, pK _a	None provided; is practically insoluble in water and does not ionize under acidic or basic conditions			
Octanol/water partition coefficient, Log(K _{ow})	8.1 at 20 °C			
UV/visible absorption spectrum	pH	λ _{max} (nm)	A	log ε
	1.1	208	1.339	4.65
		274	0.146	3.69
	7.4	208	1.447	4.64
274		0.159	3.68	
13.1	222	0.719	4.38	
	274	0.146	3.69	

APPENDIX II – Chemical Name of Pyridalyl and its Transformation Products

Company Name	Chemical Name
Pyridalyl; S-1812	2-[3-[2,6-dichloro-4-[(3,3-dichloro-2-propenyl)oxy]phenoxy]propoxy]-5-(trifluoromethyl)pyridine
S-1812-DP	3,5-dichloro-4-[3-(5-trifluoromethyl-2-pyridyloxy)propoxy]phenol
S-1812-Ph-CH ₂ COOH	2-{3,5-dichloro-4-[3-(5-trifluoromethyl-2-pyridyloxy)propoxy]phenoxy} acetic acid
TPPA	3-(5-trifluoromethyl-2-pyridyloxy)propionic acid
S-1812-PYP	3-(5-trifluoromethyl-2-pyridyloxy)propanol
HFTP	2-hydroxy-5-trifluoromethylpyridine
HPDO	3-hydroxy-5-trifluoromethyl-2-pyridone
S-1812-DP glucose-6-sulfate conjugate	sulfuric acid mono-(6-{3,5-dichloro-4-[3-(5-trifluoromethyl-pyridin-2-yloxy)-propoxy]-phenoxy}-3,4,5-trihydroxy-tetrahydro-pyran-2-ylmethyl) ester
S-1812-PYP glucose-6-sulfate conjugate	sulfuric acid mono-{3,4,5-trihydroxy-6-[3-(5-trifluoromethyl-pyridin-2-yloxy)-propoxy]-tetrahydro-pyran-2-ylmethyl} ester
TPPA aspartic acid conjugate	2-[3-(5-trifluoromethyl-pyridin-2-yloxy)-propionylamino]-succinic acid
DCHM	3-[2,6-dichloro-4-(3,3-dichloro-2-propenyl)oxy]phenol
S-1812-DP-Py-OH	4-[3-[3-hydroxy-5-(trifluoromethyl)pyridin-2-yl]oxy]propoxy-3,5-dichlorophenol
N-Methyl-HFTP	N-methyl-5-trifluoromethyl-2-pyridone
N-Methyl-HPDO	N-methyl-3-hydroxy-5-trifluoromethyl-2-pyridone
O-Malonyl glucoside of HFTP	Malonic acid mono-[3,4,5-trihydroxy-6-(5-trifluoromethyl-pyridin-2-yloxy)-tetrahydropyran-2-ylmethyl] ester
O-Malonyl glucoside of HPDO	Malonic acid mono-[3,4,5-trihydroxy-6-(2-oxo-5-trifluoromethyl-1,2-dihydro-pyridin-3-yloxy)-tetrahydro-pyran-2-ylmethyl] ester
O-Malonyl glucoside of N-methyl HPDO	Malonic acid mono-[3,4,5-trihydroxy-6-(1-methyl-2-oxo-5-trifluoromethyl-1,2-dihydro-pyridin-3-yloxy)-tetrahydro-pyran-2-ylmethyl] ester

APPENDIX III - Toxicity Data

Acute Toxicity of Pyridalyl Technical (93.7%)

Study Type	Results	Toxicity Category
Acute Oral (Rat)	LD ₅₀ => 5000 mg/kg (males & females)	IV
Acute Dermal (Rat)	LD ₅₀ => 5000 mg/kg (males and females)	IV
Acute Inhalation (Rat)	LC ₅₀ => 2.01 mg/L (males and females)	IV
Primary Eye Irritation (Rabbit)	Non-irritating	IV
Dermal Sensitization	Sensitizer	--

Subchronic, Chronic, and Other Toxicity

Guideline	Study Type	Results
870.3100	90-Day Oral Toxicity-Rat	NOAEL = 5.56 (M), 6.45 (F)mg/kg/day LOAEL = 56.0 (M), 64.0 (F) mg/kg/day , based on decreased body weight gain, decreased food consumption, and lung histopathology (alveolar foamy cells) in both sexes and microscopic changes in the ovary (vacuolation of interstitial gland cells) in females.
870.3100	90-Day oral toxicity-Mouse	NOAEL 81.7 mg/kg/day (M), 86.78 (F) mg/kg/day LOAEL = 378.5 (M), 415.0 (F) mg/kg/day based on decreased body weight and body weight gain in males and females, and pigmentation in the adrenal gland in males, and ovarian atrophy in females.
870.3100	90-Day oral (capsule) toxicity-Dog	NOAEL= 100 (M) and 10 (F) (mg/kg/day LOAEL = 300 (M) and 100 (F) mg/kg/day, based on histopathology findings in the adrenal glands (vacuolation of cortical cells).
870.3200	21/28-Day dermal toxicity-Rat	Systemic and dermal NOAEL = 1000 mg/kg/day Systemic and dermal LOAEL = not determined
870.3700	Developmental Toxicity Study - Rat	Maternal toxicity (mg/kg/day.) NOAEL =10 LOAEL= 50 based on reduced body weight gain Developmental toxicity (mg/kg/day) NOAEL = 50 LOAEL = 250 based on decreased incidence of thymic remnants in the neck.
870.3700	Developmental Toxicity - Rabbit	Maternal toxicity NOAEL = 50 mg/kg/day.

Guideline	Study Type	Results
		<p>LOAEL = 150 mg/kg/day based on death, abortion/premature delivery, and decreased body weight gain and food consumption.</p> <p>Developmental toxicity NOAEL = 50 mg/kg/day LOAEL = 150 mg/kg/day based on abortion/premature delivery and decreased fetal body weight.</p>
870.3800	2-Generation Reproductive Toxicity - Rat	<p>Parental systemic toxicity (mg/kg/day) NOAEL = 13.8-17.0 (M) and 15.7-18.3 (F) LOAEL = 68.7-83.7 (M) and 79.1-91.4 (F), based on decreased body weight, body weight gain and food consumption in males and decreased body weight, body weight gain and lesions in the thyroid (an increase in small-sized follicles) in females.</p> <p>Reproductive toxicity (mg/kg/day) NOAEL ≥ 68.7-83.7 (M) and 15.7-18.3 (F). LOAEL = Not identified (M) and 79.1-91.4 (F) based on increased ovarian weight, microscopic lesions in the ovary of F0 and F1 adults and delayed vaginal opening in F1 and F2 offspring.</p> <p>Offspring toxicity (mg/kg/day) NOAEL = 2.8-3.4 (M) and 3.11-3.62 (F). LOAEL = 13.8-17.0 (M) and 15.7-18.3 (F) based on decreased thymus weights.</p>
870.4100	12-Month Feeding Study - Dog	<p>NOAEL = 80 mg/kg/day (M,F) LOAEL was not identified</p>
870.4200	Oncogenicity Study - Mouse	<p>NOAEL = 5.04 (M) and 4.78 (F) mg/kg/day</p> <p>LOAEL = 103 (M) and 99 (F) mg/kg/day, based on decreased body weight (females only) and body weight gain and decreased food efficiency.</p> <p>No evidence of carcinogenicity was observed.</p>
870.4300	24- Month Chronic Toxicity/ Carcinogenicity Study - Rat	<p>NOAEL= 3.4 (M) and 4.1 (F) mg/kg/day LOAEL = 17.1 (M) and 21.1 (F) mg/kg/day based on decreased body weights, weight gain, and food efficiency.</p> <p>No evidence of carcinogenicity was observed</p>
870.5100	Bacterial reverse gene mutation assay	<p>TA98, TA100, TA1535 and TA1537 of S. typhimurium and strain WP2(uvrA) of E. coli were exposed to Pyridalyl (Lot No. PS-98041G, 93.7% a.i.) in DMSO at concentrations of 9.77, 19.5, 39.1, 78.1, 156 or 313 µg/plate without added metabolic activation (S9-mix) and at concentrations of 39.1,</p>

Guideline	Study Type	Results
		<p>78.1, 156, 313, 625 or 1250 µg/plate with S9-mix.</p> <p>The solvent and positive controls induced the appropriate responses in the corresponding strains. There was no evidence of induced mutant colonies over background.</p>
870.5100	Bacterial reverse gene mutation assay	<p>TA98, TA100, TA1535 and TA1537 of <i>S. typhimurium</i> and strain WP2 (uvrA) of <i>E. coli</i> were exposed to Pyridalyl (Lot No. PS-98041G, 93.7% a.i.) in DMSO at concentrations of 9.77, 19.5, 39.1, 78.1, 156 or 313 µg/plate without added metabolic activation (S9-mix) and at concentrations of 39.1, 78.1, 156, 313, 625 or 1250 µg/plate with S9-mix.</p> <p>The solvent and positive controls induced the appropriate responses in the corresponding strains. There was no evidence of induced mutant colonies over background.</p>
870.5100	Bacterial reverse gene mutation assay	<p>In a reverse gene mutation assay in bacteria (MRID 45685313), strains TA98, TA100, TA1535 and TA1537 of <i>S. typhimurium</i> and strain WP2(uvrA) of <i>E. coli</i> were exposed to dehydrochlorinated derivative of Pyridalyl (Lot No. Y-4298, 99.4% a.i.) in DMSO at concentrations of 0, 156, 313, 625, 1250, 2500 or 5000 µg/plate with and without added metabolic activation (S9-mix).</p> <p>The solvent and positive controls induced the appropriate responses in the corresponding strains. There was no evidence of a biologically significant induction of mutant colonies over background with or without metabolic activation.</p>
870.5100	Bacterial reverse gene mutation assay	<p>In a reverse gene mutation assay in bacteria strains TA98, TA100 and TA1537 of <i>S. typhimurium</i> were exposed to HTFP in DMSO at concentrations of 0, 15, 50.0, 150, 500, 1500 or 5000 µg/plate with and without metabolic activation (S9-mix) and strains TA1535 of <i>S. typhimurium</i> and strain WP2(uvrA) of <i>E. coli</i> were exposed to HTFP at concentrations of 0, 156, 313, 625, 1250, 2500 or 5000 µg/plate with and without S9-mix.</p> <p>Results were negative in the second assay with TA100 in the presence of S9-mix. The solvent and positive controls induced the appropriate responses in the corresponding strains. There was evidence of induced mutant colonies over background.</p>
870.5300	Chinese Hamster Ovary/HGPRT Forward Gene Mutation Assay	<p>In a mammalian cell gene mutation assay at the HGPRT locus Chinese hamster ovary CHO-K1-BH4 cells cultured in vitro were exposed to Pyridalyl in DMSO in two independent assays at concentrations of 0, 9.40, 18.8, 37.5, 75.0, 150.0 or</p>

Guideline	Study Type	Results
870.5300	<i>In vitro</i> mutagenicity (mammalian forward gene mutation)	<p>300 µg/mL for four hours in the absence of mammalian metabolic activation (S9-mix) and to concentrations of 0, 2.00, 4.00, 5.00, 6.00, 7.00, 8.00 or 10 µg/mL for four hours with S9-mix.</p> <p>No dose-dependency was seen and the actual mutant frequencies were well below the testing laboratory's criterion of 15×10^{-6} for a biologically significant response. The solvent and positive controls induced the appropriate responses. There was no evidence of induced mutant colonies over background.</p> <p>Chinese hamster V79 cells cultured in vitro were exposed for four hours to HPDO (100% a.i., Lot No. YO001221) in DMSO at concentrations of 0, 110, 230, 450, 900 or 1800 µg/mL with and without metabolic activation (S9-mix).</p> <p>The solvent and positive controls (ethyl methanesulfonate) without S9-mix and N-nitrosodimethylamine with S9-mix) induced the appropriate responses. There was no evidence of induction of mutant colonies over background.</p>
870.5300	<i>In vitro</i> mutagenicity (mammalian forward gene mutation)	<p>Chinese hamster lung V79 cells cultured in vitro were exposed to HTFP, (98.5% a.i., Lot No. 00209017) in DMSO in two independent assays at concentrations of 0, 100, 200, 400, 800 or 1600 µg/mL for four hours in the presence and absence of mammalian metabolic activation (S9-mix).</p> <p>In the confirmatory assay at the same five concentrations, the mutant frequency remained below a tripling of the respective solvent control value at all concentrations, with and without S9-mix. The solvent and positive controls induced the appropriate responses. There was no evidence of induced mutant colonies over background.</p>
870.5300	Mouse lymphoma L5178Y TK± cells gene mutation assay at the TK locus	<p>In a mammalian cell gene mutation assay at the TK locus mouse lymphoma L5178Y TK± cells cultured in vitro were exposed for four hours to Pyridalyl at concentrations of 0, 3.13, 6.25, 12.5, 25.0, 50.0 or 100 µg/mL without metabolic activation (S9-mix) and at concentrations of 0, 2.50, 5.00, 7.50, 10.0, 12.5 or 15.0 µg/mL with S9-mix.</p> <p>The RTG at these three experimental points was below 10%, thus the increases in mutant frequency were not considered biologically significant. The solvent and positive controls (ethyl methanesulfonate without S9-mix and 20-methylcholanthrene with S9-mix) induced the appropriate responses. There was no evidence of</p>

Guideline	Study Type	Results
870.5300	<i>In Vitro</i> Mammalian Cells in Culture Gene Mutation assay in V79 Chinese hamster lung fibroblasts	<p>biologically significant induction of mutant colonies over background.</p> <p>Chinese hamster V79 cells cultured in vitro were exposed for four hours to HPDO in DMSO at concentrations of 0, 110, 230, 450, 900 or 1800 µg/mL with and without metabolic activation (S9-mix).</p> <p>The solvent and positive controls (ethyl methanesulfonate without S9-mix and N-nitrosodimethylamine with S9-mix) induced the appropriate responses. There was no evidence of induction of mutant colonies over background.</p>
870.5375	<i>In vitro</i> mammalian cytogenetics (CHL cells)	<p>Chinese hamster CHL/IU cell cultures were exposed to HPDO in DMSO at concentrations of 0, 110, 230, 450, 900 or 1800 µg/mL for six hours with and without metabolic activation (S9-mix).</p> <p>The solvent and positive control values in both assays were appropriate and within the testing laboratory's historical control ranges. There was evidence of chromosome aberrations induced over background.</p>
870.5375	<i>In vitro</i> mammalian cytogenetics (CHL cells)	<p>Chinese hamster CHL/IU cell cultures were exposed to HTFP in DMSO at concentrations of 0, 100, 200, 400, 800 or 1600 µg/mL for six hours with and without metabolic activation (S9-mix).</p> <p>The solvent and positive control values in both assays were appropriate and within the testing laboratory's historical control ranges. There was no evidence of biologically significant induction of chromosome aberrations over background.</p>
870.5375	<i>In vitro</i> mammalian cytogenetics (CHL cells)	<p>Chinese hamster CHL/IU cell cultures were exposed to HTFP (98.5% a.i., Lot # 00209017) in DMSO at concentrations of 0, 100, 200, 400, 800 or 1600 µg/mL for six hours with and without metabolic activation (S9-mix).</p> <p>The solvent and positive control values in both assays were appropriate and within the testing laboratory's historical control ranges. There was no evidence of biologically significant induction of chromosome aberrations over background.</p>
870.5375	<i>In vitro</i> mammalian cytogenetics (CHL cells)	<p>Chinese hamster CHL/IU cell cultures were exposed to Pyridalyl in DMSO in three independent experiments. Cells were exposed at concentrations of 0, 20, 40 or 80 µg/mL (six-hour exposure, 18-hour recovery) without metabolic activation (S9-mix) in experiment 1 and at concentrations of 0, 15, 20 or 25 µg/mL</p>

Guideline	Study Type	Results
870.5395	Mouse Micronucleus assay	<p>The solvent and positive control values were appropriate. There was evidence of chromosome aberrations induced over background in the presence of S9-mix.</p> <p>In a CD-1 mouse bone marrow micronucleus assay, five male mice/dose were treated once orally with HPDO in 0.5% aqueous methylcellulose at doses of 0, 500, 1000 or 2000 mg/kg body weight.</p> <p>The solvent and positive control induced the appropriate responses. There was no statistically significant increase in the frequency of micronucleated polychromatic erythrocytes in mouse bone marrow at any dose or harvest time.</p>
870.5395	Mouse Micronucleus assay	<p>In a CD-1 mouse bone marrow micronucleus assay, five male mice/dose were treated once orally with Pyridalyl at doses of 0, 500, 1000 or 2000 mg/kg. There was no statistically significant increase in the frequency of micronucleated polychromatic erythrocytes in mouse bone marrow at any dose or harvest time.</p>
870.5395	Mouse Micronucleus assay	<p>In a CD-1 mouse bone marrow micronucleus assay five male mice/dose were treated once orally with HPDO at doses of 0, 500, 1000 or 2000 mg/kg body weight.</p> <p>There was no statistically significant increase in the frequency of micronucleated polychromatic erythrocytes in mouse bone marrow at any dose or harvest time.</p>
870.5550	Unscheduled DNA Synthesis	<p>In an <i>in vivo/in vitro</i> unscheduled DNA synthesis (UDS) assay in rat hepatocytes, pyridalyl at doses of 0, 500, 1000 or 2000 mg/kg body weight, was administered once each to four CrI:CD (SD) IGS BR male rats per test group by gavage.</p> <p>The solvent and positive control (Dimethylnitrosamine) values were appropriate. There was no evidence that Pyridalyl technical increased the incidence of UDS over the solvent control values in this study.</p>
870.7485	Metabolism Study- Rat	<p>In a series of metabolic studies (MRIDs 45685322, 45765701, 45685324, 45685325 and 45685326) S-1812 (pyridalyl, labeled in the propenyl, phenyl, and pyridyl positions) was administered by gavage to male and female Sprague Dawley rats at concentrations of 5 or 500 mg/kg. Absorption was ~15% for male rats and ~21% for female rats following a single 5 mg/kg oral dose of [phenyl-</p>

Guideline	Study Type	Results
		<p>¹⁴C]S-1812. Greater than 72% of the radiolabel was recovered in the feces or gastrointestinal tract of male and female rats representing unabsorbed test material. In the 14-day repeat dose study, absorption of the radiolabeled test material was ~8% for male rats and 5% for female rats.</p> <p>Greater than 90% of the amount of radiolabel eliminated in the feces for all groups occurred within 72 hours of treatment.</p> <p>The predominant radiolabels recovered in the feces of rats treated with S-1812 labeled in the phenyl or pyridyl position were the parent compound or S-1812-DP. The primary metabolites S-1812-DP, S-1812-Py-OH, and HPHM are the result of cleavage of the propenyl side chain; hydroxylation of the pyridyl ring; and cleavage of the either bond between the pyridine and trimethylene chain, respectively.</p>
870.7600	<i>In Vivo</i> Dermal Penetration Study - Rat	<p>In a dermal absorption study phenyl-¹⁴C] Pyridalyl and non-labeled were applied to the dorsal skin of Sprague Dawley rats (four rats per group). An additional group of four rats was exposed for 10 hours at each dose after which the test material was washed off and the animals maintained to 168 hours. Excreta, cage washes, skin washes and swabs, and appliances were analyzed for radioactivity and absorption/excretion assessed. Most absorbed radioactivity was excreted in the feces. Fecal excretion for the rats maintained to 168 hours occurred primarily within 72 hours for the low dose group and within 96 hours for the mid- and high-dose groups. Most of the urinary excretion of radioactivity in these groups occurred within 48-72 hours.</p>
Non Guideline	<i>In vitro</i> cell culture studies	<p>In a series of <i>in vitro</i> cell culture studies with isolated Leydig or ovarian cells from Crj:CD(SD) male and female rats, no treatment-related effects were found on the production of progesterone, estradiol, 17α-OH-progesterone or testosterone and no cytotoxicity was observed. In addition, there was no effect on aromatase activity in cultured ovarian cells. These results suggest that 17β-HSD inhibition is not the mechanism for the increased androstenedione production in Leydig cells.</p>
Non Guideline	Subacute Steroid Hormone Study - Rat	<p>No treatment-related effects were found on testosterone, estradiol or progesterone concentrations, uterine weight, or the estrus cycle. No histopathological effects were found in the adrenal gland and no effects on serum corticosterone concentration were found.</p>

APPENDIX IV - Summary Of Available Accumulation And Sediment Organism Toxicity Data Used To Evaluate Potential Risks To Aquatic Organisms And Terrestrial Organisms That Consume Aquatic Organisms Based The Refined Conceptual Model For Pyridalyl

MRID	Study Type	Organism	Summary
45685203	Water exposure 49-Day BCF study	Fish – Bluegill sunfish	Whole fish BCF was >16,000 (estimated steady state BCF was approximately 27,000). Uptake constant: 515/day to 600/day Depuration constant: 0.022/day to 0.023/day Depuration half-life was 30 days Study used to estimate body burden EECs to fish from water exposure.
46192103	Water exposure. 21-Day outdoor microcosm study; <i>single application</i> to overlying water or sediment.	Fish – Bluegill Sunfish	A single addition of 1.5 ppb a.i. directly to the water or 6.5 ppb pyridalyl added to overlying water as contaminated soil resulted in initial (2 days after dosing) fish tissue residues of approximately 470 ppb or 90 ppb, respectively. Fish were caged (closed bottoms) and fed uncontaminated food throughout the study. Depuration half life of 22 days was reported for fish exposed to overlying water; depuration was insufficient to allow for calculation of a half-life for fish exposed to contaminated soil in the water. Study was not used to calculate RQs, but was used to compare accumulation in various organisms given equivalent exposure scenarios and to characterize relative body burdens after exposure to pyridalyl from drift and runoff simulations.
47271101	Dietary exposure. 56-Day exposure and 56-day depuration.	Fish – Rainbow Trout	Trout were fed oligochaetes that contained 0.92 mg/kg pyridalyl. Mean measured tissue levels in the trout were 0.1 mg/kg. Apparent steady state was reached within the first 7 days of exposure. Study used to estimate body burden in fish from dietary exposures.
46192106	Spiked Sediment Study with 28-Day Accumulation Period	Oligochaetes	BSAF: approximately 5.7 Uptake constant: 0.00453/day Depuration constant: 0.0142/day (however, it is uncertain if depuration occurred in the study because pyridalyl levels at the last exposure day were equivalent to pyridalyl levels at the last day of depuration; see Figure 3.4). Study used to estimate body burden in oligochaetes for use in risk estimation because it provided the most conservative value.
47179701	Spiked sediment study with 56-day accumulation period	Oligochaetes	BSAF: 1.1 Uptake half-life: Not calculated; apparent steady state reached by the first body burden measurement Depuration half-life: 50 days (kd: 0.0138/day; depuration was primarily due to growth dilution). Study not used to quantify body burdens in benthic organisms because MRID 46192106 provided more conservative BSAF; however, this study was used to characterize accumulation potential in equilibrated systems.
47172502	42-Day toxicity study	Oligochaetes	Study considered invalid by the study authors and EFED reviewers

MRID	Study Type	Organism	Summary
			and was, therefore, not used in this assessment.
46487601	28-Day spiked water study	Chironomid	NOAEC: 5 µg/L overlying water 3.5 µg/L pore water 18 µg/kg sediment Study used to estimate potential risks to chironomids.
47172501	60-Day range finding toxicity study	Chironomids	Study was supplemental as a range finding study, but was unacceptable as a definitive study. Clear treatment related effects were not observed in this study. However, it was considered to be unreliable for definitive NOAEC determination.
46830801	Outdoor microcosm study	Sediment and sediment organisms	Addition of 0.65 ppb a.i. to overlying water (4 applications, 7-day intervals) resulted in oligochaete and chironomid body burden levels of up to approximately 10,000 ppb. Residue levels in other biota were somewhat lower. Effects to isopods (<i>Asellus aquaticus</i>) occurred at all levels tested (4x 0.05 ppb and higher); effects to chironomids and to overall taxonomic richness of benthic organisms were observed at the 4x 6.5 ppb (NOAEC was 4x 0.65 µg/L). Total organic carbon (TOC) was typically between 5 and 10 mg/L during the study. Study was used to estimate body burden associated with toxicity in benthic organisms. In addition, this study was used to estimate body burden occurring in benthic invertebrates from water (drift) exposure.
46192103	Outdoor microcosm study	Sediment organisms	Total residue levels varied across species, but were approximately 1000 ppb in sediment organisms 21 days after addition of a single application of 1.5 ug a.i./L to overlying water or 6.5 ug a.i. / L added as contaminated soil.

APPENDIX V - Glossary Of Terms And Abbreviations

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

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

APPENDIX VI – Data Base Supporting the Registration of Pyridalyl

MRID	Citation
45685100	Valent U.S.A. Corporation (2002) Submission of Product Chemistry and Toxicity Data in Support of the Applications for Registration of Pyridalyl Technical, S-1812 35 WP Insecticide and S-1812 PPG Insecticide and the Petition for Tolerance of Pyridalyl on Cotton, Fruiting Vegetables (Crop Group 8) and Secondary Residues in Livestock. Transmittal of 28 of 139 Studies.
45685101	Bujor, D. (2002) Supplemental Information: Statutory Findings and Information Summaries to Comply with the Food Quality Act of 1996 in Support of Registration and Tolerances on Cotton and Fruiting Vegetables: Lab Project Number: PYRIDALYL-FQPA-1. Unpublished study prepared by Valent U.S.A. Corporation. 165 p.
45685102	Tucker, K. (2002) Chronic and Acute Dietary (Food and Drinking Water) Analyses for Pyridalyl (S-1812) on Cotton and Fruiting Vegetables: Lab Project Number: PYRIDALYL 02-01: 200200219: Unpublished study prepared by Novigen Sciences, Inc. 86 p.
45685103	Iwamoto, K.; Matsuo, S. (2002) Product Identity and Composition: Description of Materials Used to Produce the Product: Description of Production Process, Discussion on Formation of Impurities: (Pyridalyl Technical): Lab Project Number: SUP-0011: 200200167: SUP-0012. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 165 p. {OPPTS 830.1550, 830.1600, 830.1620, 830.1670}
45685104	Asada, Y. (2002) Preliminary Analysis of S-1812 Technical Grade: Lab Project Number: 3697: 200200103: 3509. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 64 p. {OPPTS 830.1700}
45685105	Asada, Y. (2001) Enforcement Analytical Methods of S-1812 Technical Grade: Lab Project Number: 3538: 200200042. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 96 p.
45685106	Asada, Y. (2002) Certified Limits of S-1812 Technical Grade: Lab Project Number: SUP-0007: 200200168. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 17 p. {OPPTS 830.1750}
45685107	Reitz, G. (2002) Physical and Chemical Properties of Pyridalyl Technical: Lab Project Number: V-01-24264: 200200078: VA-035-00. Unpublished study prepared by Valent U.S.A. Corporation. 67 p. {OPPTS 830.6302, 830.6303, 830.6304, 830.6314, 830.6315, 830.7000, 830.7100, 830.7300, 830.7840}
45685108	Lorence, P. (2000) S-1812/V-1812--Water Solubility, Vapor Pressure and Octanol/Water Partition Coefficient: Lab Project Number: 4067-98-0068-AS-001: 200100287: S-1812/V-1812. Unpublished study prepared by Valent U.S.A. Corporation. 89 p. {OPPTS 830.7570, 830.7840, 830.7950}
45685109	Reitz, G. (1999) UV/VIS Absorption of V-1812 Revised Final Report: Lab Project Number: V-11985A: 9900197: V-98-11985A. Unpublished study prepared by Valent U.S.A. Corporation. 48 p. {OPPTS 830.7050}
45685110	Sweetapple, G. (2002) VP-24352--Boiling Point of S-1812 PAI: Lab Project Number: VP-24352: 200200055: 013989-1. Unpublished study prepared by Ricerca, LLC. 14 p. {OPPTS 830.7220}
45685111	Asada, Y. (2001) Stability of S-1812 Technical Grade to Normal and Elevated Temperatures, Metal and Metal Ions: Lab Project Number: 3615: 200200053. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 14 p. {OPPTS 830.6313}
45685112	Sweetapple, G. (2001) VP-24361--Explosibility of S-1812 T.G: Lab Project Number: VP-24361:

	013916-1. Unpublished study prepared by Ricerca, LLC. 12 p. {OPPTS 830.6316}
45685113	Asada, Y. (2001) Storage Stability of S-1812 Technical Grade: Lab Project Number: 3509: 200200046. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 28 p. {OPPTS 830.6317}
45685114	Asada, Y. (2001) Corrosion Characteristics of S-1812 Technical Grade: Lab Project Number: 3510: 200200047. Unpublished study prepared by Sumitomo Chemical Co., Ltd. 11 p. {OPPTS 830.6320}
45685115	Ha, S.; Taylor, E. (2002) U.S. EPA Product Properties Test Guidelines--Group A and Group B of S-1812 35 WP Herbicide: Lab Project Number: V-24328A: 200200138: 2002-1812-001. Unpublished study prepared by Valent U.S.A. Corporation. 192 p. {OPPTS 830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800, 830.1900, 830.6303, 830.6314, 830.7000, 830.7300}
45685116	Ha, S. (2002) Physical and Chemical Properties of S-1812 35WP: Lab Project Number: V-01-24328A: 200200065: VA-034-00. Unpublished study prepared by Valent U.S.A. Corporation. 51 p. {OPPTS 830.6303, 830.6314, 830.7000, 830.7300}
45685117	Gallagher, S.; Grimes, J.; Beavers, J. (1999) S-1812: An Acute Oral Toxicity Study with the Northern Bobwhite: Lab Project Number: 166-161: 200200087. Unpublished study prepared by Wildlife International, Ltd. 42 p. {OPPTS 850.2100}
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