



Pesticide Fact Sheet

Name of Chemical: Fluopicolide
Reason for Issuance: New Chemical
Date Issued: December 19, 2007

Description of Chemical

Generic Name: 2,6-dichloro-*N*-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl] benzamide

Common Name: Fluopicolide

EPA Chemical Code: 027412

Chemical Class: benzamide
Pyridine

Chemical Abstracts
Service (CAS) Number: 239110-15-7

Registration Status: New Chemical Registration

Pesticide Type: Fungicide

U.S. Producer: Valent U.S. Corporation

Use Pattern and Formulations

Fluopicolide is a new fungicide approved for foliar use on grape; grape, raisin; vegetable, cucurbit, group 9; vegetable fruiting, group 8; vegetable, leafy, except Brassica, group 4; and vegetable, tuberous and corm (except potato), subgroup 1D. Non-food uses for turf and ornamentals are also approved.

Fluocopicolide belongs to the benzamide class and the pyridine class. The mode of action of fluopicolide has not been determined; however, it is a mode of action unlike the known modes of action of other registered fungicides. Fluopicolide is a mesosystemic fungicide; it translocates toward the stem tips via the xylem but it does not translocate toward the roots. Fluopicolide is effective at low application rates against a wide range of Oomycete (Phycomycete) diseases including downy mildews (*Plasmopara*, *Pseudoperonospora*, *Peronospora*, *Bremia*), late blight (*Phytophthora*), and some *Pythium* species.

Fluopicolide is formulated as a suspension concentrate. There are four end use products and one technical proposed for registration in the U.S. Fluocopicolide Technical is for formulating use only. Two of these products: V-10161 VPP for turfgrass and ornamental use, and V-10161 4 SC for cucurbit vegetables, fruiting vegetables, grapes, leafy vegetables, and sweet potatoes are both formulated as 39.5% fluocopicolide. While the other two products: V-10162 Premix for cucurbit vegetables, fruiting vegetables, Lettuce (head and leaf), and V-10162 VPP for turf, and ornamental are both formulated as 5.54% Fluocopicolide and 55.40% Propamocarb Hydrochloride.

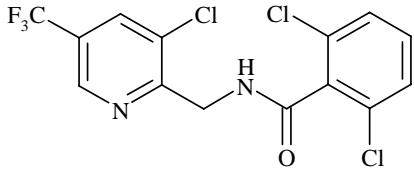
There is a previously existing tolerance for residues of fluopicolide on imported grapes. Three foliar applications are to be made to grapes in Europe at the maximum seasonal application rate of 0.36 lb ai/A. Minimum retreatment intervals of 10 days and a preharvest interval of 21 days are to be observed.

2,6-Dichlorobenzamide (BAM) is a metabolite and/or environmental degradate of both fluopicolide and dichlobenil. For use on imported grapes BAM was not included in the risk assessment however, both parent fluopicolide and BAM were included in risk assessments for uses of fluopicolide on domestic crops since more exposure to BAM is expected with domestic uses.

No Codex, Canadian, or Mexican MRLs have been established for fluopicolide.

SCIENCE FINDINGS

Structure and Nomenclature

Table 1 Fluopicolide Nomenclature.	
Chemical structure	
Empirical Formula	C ₁₄ H ₈ Cl ₃ F ₃ N ₂ O
Common name	Fluopicolide
Company experimental name	AE C638206
IUPAC name	2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide
CAS name	2,6-dichloro-N-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide
CAS Registry Number	239110-15-7
End-use products (EPs)	1. V-10161 VPP 2. V-10161 4 SC 3. V-10162 Premix 4. V-10162 VPP 5. Fluopicolide Technical
Chemical Class	Fungicide
Known Impurities of Concern	None

Physical and Chemical Properties

The physical/chemical properties of fluopicolide as they affect inhalation or dermal exposure are not relevant for an imported crop.

Table 2. Physicochemical Properties of Fluopicolide.		
Parameter	Value	Reference
Molecular Weight	383.59	
Melting point/range	149 °C	MRID 46474015
pH	6.5 at 22.0 °C	MRID 46474013
Density	1.65 g/cc	MRID 46474016
Water solubility (20 °C)	2.86 mg/L at pH 4 2.80 mg/L at pH 7 2.80 mg/L at pH 9	MRID 46474021
Solvent solubility (g/L at 20 °C)	n-Hexane: 0.20 Ethanol: 19.2 Toluene: 20.5 Ethyl acetate: 37.7 Acetone: 74.7 Dichloromethane: 126 Dimethyl sulfoxide: 183	MRID 46474022
Vapor pressure at 25 °C	8.03 x 10 ⁻⁷ Pa	MRID 46474023

Table 2. Physicochemical Properties of Fluopicolide.		
Parameter	Value	Reference
Dissociation constant (pKa)	No evidence of ionization in the pH range of 1.9 to 9.8	MRID 46474017
Octanol/water partition coefficient Log(K _{ow})	Log P _{ow} = 3.26 at pH 7.8 and 22 ± 1 °C	MRID 46474018
	Log P _{ow} = 2.9 at pH 4.0, 7.3 and 9.1 and 40 °C	MRID 46474019
UV/visible absorption spectrum	Absorption maxima wavelengths (nm): In methanol: 203 and 271 In methanol/HCl: 202 and 270 In methanol/NaOH: 219 and 271	MRID 46474014

Hazard Characterizations

The toxicology database for fluopicolide (AC 638206) is complete and deemed adequate for hazard assessment and for FQPA evaluation.

Fluopicolide is a fungicide that is effective in controlling plant disease caused by *Oomycetes*. The biological activity is mesosystemic in that it controls pathogens on contact through translocation toward the stem tips and not the roots. The exact mode of action of disease control has not been fully determined. The test substance is mostly used on grapes and raisins.

The toxicity database is complete for fluopicolide and is adequate for risk assessment evaluations and determination of FQPA. All studies evaluated were deemed acceptable and met guideline criteria except for one reverse gene mutation study. This study was unacceptable because purity of the test material was not provided; however, there were enough adequate studies for gene mutation that this does not constitute a data gap.

The studies that are available and were considered (animal, human, general literature) for Fluopicolide (AC638206) are as follows:

Acute- oral, dermal, inhalation, eye irritation, skin irritation, dermal sensitization
Subchronic- oral 90-day rat, oral 90-day mouse (2 studies), oral 90-day dog
Chronic- oral rat (combined chronic/carcinogenicity) and oral dog
Reproductive/developmental- oral developmental rat and rabbit, rat reproduction/fertility
Other- acute and subchronic rat neurotoxicity, oral mouse carcinogenicity, mutagenicity studies (*in vitro* and *in vivo*), metabolism/pharmacokinetics studies and phenobarbital 28-day hepatotoxicity mouse studies (2 studies)

Toxicology

Acute Toxicity: Fluopicolide has moderate toxicity with no deaths noted in male or female rats at doses of > 2000 mg/kg when given orally, and > 4000 mg/kg dermally. Following inhalation exposure, an LC₅₀ of >1.789 to < 5.16 mg/L was calculated. Toxicity was observed primarily in the inhalation studies and included a decrease in body weight, decrease in mean body temperature and signs of irritation (piloerection, hunched

posture, reddened nostrils). Moderate eye irritation occurred in the form of chemosis and corneal opacities, but all effects were gone by 72 hours. Slight dermal irritation occurred, but the test substance was not a skin sensitizer.

Subchronic Toxicity: The most common effect observed in the 90 day studies was a decrease in body weight gain. Weight gain was markedly decreased in male and female rats in a subchronic study at doses that exceeded the limit dose (1668-1673 mg/kg/day), and male and female rats in a subchronic neurotoxicity study had reduced body weight gain at doses of 780.6 and 125.2 mg/kg/day, respectively. There was no effect on weight gain in dogs or mice in subchronic studies. Besides effects on body weight and body weight gain, no definitive cross-species target organ was identified in subchronic studies with fluopicolide. No organ lesions were found in dogs administered up to 1000 mg/kg/day for 90 days. Male rats had hypertrophy of the zona glomerulosa in the adrenal gland, trabecular hyperostosis of the bone joint, and decreased bone marrow cellularity after exposure to 1668 mg/kg/day for 90 days. Similar lesions in the adrenal gland and bone marrow were found in female rats administered 119 mg/kg/day for 90 days. In mice, females administered 965 mg/kg/day showed an increased incidence of hepatic oval cell proliferation.

Chronic Toxicity: As in the subchronic studies, the main effect in the chronic studies was a decrease in body weight gain with no definitive cross-species target organ identified. Male dogs had reduced weight gain after exposure to 1000 mg/kg/day for one year; body weight of females was not affected. Mice had severely decreased body weight and body weight gain with administration of 551.0 and 772.3 mg/kg/day to males and females, respectively, for 18 months. Male and female rats had decreased weight gain after exposure to 109.4 and 142.2 mg/kg/day for 2 years, respectively. No organ lesions were found in dogs administered up to 1000 mg/kg/day for 52 weeks. Thyroid cystic follicular hyperplasia was seen in male rats after 109.4 mg/kg/day for two years. In mice, altered liver cell foci were seen in males and females given 551.0 or 772.3 mg/kg/day, respectively, for 18 months.

Carcinogenicity: No evidence for carcinogenicity was seen in rats administered fluopicolide in food for 24 months. Treatment of rats did not result in an increase in overall tumor incidence or an increase in the incidence of any specific type of tumor. In contrast, mice had an increased incidence of hepatocellular adenoma following administration of 3200 ppm in the diet for 18 months (551.0 and 772.3 mg/kg/day for males and females, respectively).

Neurotoxicity: No evidence of neurotoxicity was seen in acute or subchronic oral rat neurotoxicity studies with fluopicolide. A transient decrease in body temperature was the only finding in male and female rats given a single dose of 2000 mg/kg. Brain weight, brain morphometry, and neuropathology were not affected by treatment.

Developmental Toxicity: In developmental toxicity studies, maternal toxicity was clearly evident only in rabbits as increased mortality, abortion, and decreased body weight gain at 60 mg/kg/day, the highest dose tested. Minimal maternal toxicity was observed in rats dosed with 700 mg/kg/day; slightly reduced body weight gain did not result in lower

absolute body weight. At the same dose affecting the dam, 700 mg/kg in rats and 60 mg/kg in rabbits, fetal growth was affected in both species and observed as decreases in body weight and crown-rump length. Also, at 700 mg/kg, delays in fetal ossification and increased incidence of skeletal malformations were observed in rat fetuses, with neither of these effects seen in rabbit fetuses. No external or visceral abnormalities were observed in either species. In rats the adverse effect was judged to be greater in the fetus than in the dam, suggesting a greater susceptibility in the fetus compared to that of the dam.

Reproductive Toxicity: Reproductive performance was not affected in a two-generation reproduction toxicity study in which fluopicolide was administered to male and female rats at nominal dietary concentrations of 0, 100, 500, or 2000 ppm (0, 7.4-8.8, 36.4-43.7, 144.6-179.9 mg/kg/day, respectively, for males and 0, 8.1-9.4, 41.0-46.9, 159.7-193.9 mg/kg/day, respectively, for females). Evidence of parental toxicity in the high-dose groups included decreased body weight gain in F₀ females and kidney toxicity in F₀ and F₁ males and females. Kidney lesions consisted of cortical tubular basophilia or dilation, medullary granular casts, cortical scarring, interstitial inflammation, and/or corticomedullary mineralization. Body weight of the high-dose F₁ and F₂ pups was significantly less than that of the controls beginning on lactation day 14. The high-dose pups had decreased weight gain throughout the 28-day lactation interval. Overall weight gain during lactation was decreased by 8-9% of the control level in the high-dose F₁ male and female pups and by 11-14% in the high-dose F₂ male and female pups. No other effects on offspring growth or survival were noted in either generation.

Dermal toxicity: Acute dermal toxicity studies showed that fluopicolide was only a slight dermal irritant (Tox. Category IV). A dermal subchronic toxicity study showed no systemic or local effects at the limit dose.

Toxicological Endpoints

Exposure/ Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (All Populations)	None	None	None	An endpoint attributable to a single dose was not identified from the available data.
Chronic Dietary (All Populations)	Maternal NOAEL=20 mg/kg/day	UF _A =10x UF _H =10x FQPA SF = 1X	Chronic RfD = 0.2 mg/kg/day cPAD = 0.2 mg/kg/day	Developmental Toxicity Study in Rabbits LOAEL = 60 mg/kg/day based on death, abortions/premature deliveries, decreased food

				consumption, decreased body weight gain.
Incidental Oral Intermediate-Term (1 - 6 months)	maternal NOAEL = 20 mg/kg/day	UF _A =10x UF _H =10x FQPA SF = 1X	MOE = 100 (occupational) MOE = 100 (residential)	Developmental Toxicity Study in Rabbits LOAEL = 60 mg/kg/day based on death, abortions/ premature deliveries, decreased food consumption, decreased body weight gain.
Dermal Short- Intermediate- and Long-Term (1-30 days and 1-6 months)	maternal NOAEL = 20 mg/kg/day	UF _A =10x UF _H =10x FQPA SF = 1X	MOE = 100 (occupational) MOE = 100 (residential)	Developmental Toxicity Study in Rabbits LOAEL = 60 mg/kg/day based on death, abortions/ premature deliveries, decreased food consumption, decreased body weight gain.
Inhalation Short- Intermediate- and Long-term (1-30 days and 1-6 months)	maternal NOAEL = 20 mg/kg/day	UF _A =10x UF _H =10x FQPA SF = 1X	MOE = 100 (occupational) MOE = 100 (residential)	Developmental Toxicity Study in Rabbits LOAEL = 60 mg/kg/day based on death, abortions/ premature deliveries, decreased food consumption, decreased body weight gain.
Cancer (oral, dermal, inhalation)	Classification: “Not Likely to be Carcinogenic to Humans” .			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key data (i.e., lack of a critical study). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

Food Quality Protection Act Considerations

FQPA Safety Factor

The Agency has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X for fluopicolide. That decision is based on the following findings: (1) The toxicity database for fluopicolide is complete. (2) There is no indication that fluopicolide is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. (3). Although there is qualitative evidence of increased susceptibility in the prenatal developmental studies in rats, the risk assessment team did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of fluopicolide. The degree of concern for pre-and/or postnatal toxicity is low. (4) There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated and tolerance-level residues. Conservative ground and surface water modeling estimates were used. Similarly conservative Residential SOPs were used to assess post-application exposure to children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluopicolide.

EPA is retaining the 10X FQPA SF for BAM for those exposure scenarios that do not rely on dichlobenil toxicity data. These scenarios are acute dietary for the general population including infants and children, females 13-49 years of age, chronic dietary, and incidental oral non-dietary. This is due to the incompleteness of the data base with regard to the systemic neurotoxic potential of BAM, including olfactory toxicity via the oral route of exposure.

For the dermal and inhalation routes of exposure, for which the Agency is relying on dichlobenil toxicity data, the Agency has reduced the FQPA SF for BAM toxicity to 1X. The reasons for this are that, based on a comparison of toxicity via the intraperitoneal route of exposure, higher doses of BAM are needed to induce levels of olfactory toxicity that are similar to those caused by dichlobenil, and olfactory toxicity was the endpoint chosen for these exposure scenarios.

Dietary Exposure and Risk

Dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model DEEM-FCID™, Version 2.03, which uses food consumption data from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. A dietary exposure assessment was conducted for residues of fluopicolide in food and drinking water. A second assessment was conducted for combined residues of BAM in food and drinking water from uses of both fluopicolide and dichlobenil.

Acute: An acute dietary assessment was not conducted because an endpoint attributable to a single dose was not identified from the available data for fluopicolide.

Chronic: The chronic dietary (food and drinking water) exposure to fluopicolide is below the Agency's level of concern for the general U.S. population and all population subgroups. The chronic dietary exposure estimates are 6% cPAD for the general U.S. population and 9% cPAD for children 1-2 years old, the most highly exposed subgroup. A conservative chronic dietary exposure assessment for the metabolite of fluopicolide, BAM was conducted using maximum residues from field trials and 100% crop treated. The chronic dietary exposure estimates for BAM are 29% of the chronic cPAD for the general U.S. population and 93% cPAD for all infants (< year old), the most highly exposed group which is not of concern to the Agency.

Cancer: Fluopicolide has been classified as "not likely to be carcinogenic to humans", and is thus not expected to pose a cancer risk.

Residential Handler, Postapplication and Occupational Exposures

Total MOEs for residential handlers are well above the LOC of 100, and are not of concern. Residential postapplication exposure via the dermal route is likely for adults and children entering treated lawns. The short-/intermediate-term MOEs for each scenario are above the LOC of 100, and are not of concern. The results of the handler and postapplication occupational exposure indicate that risks are not of concern. The total MOEs range from 100 to 19,000.

Aggregate Risk

The Agency does not expect that fluopicolide will pose an aggregate acute risk because an endpoint attributable to a single dose was not identified from the available data for fluopicolide. The acute dietary exposure estimates for BAM at the 99.9th percentile of the exposure distribution are 11% of the acute aPAD for the general U.S. population and 28% aPAD for all infants <1 year old, the most highly exposed group.

The chronic dietary exposure estimates for fluopicolide are 6% cPAD for the general U.S. population and 9% cPAD for children 1-2 years old, the most highly exposed subgroup. The chronic dietary exposure estimates for BAM are 29% of the chronic cPAD for the general U.S. population and 93% cPAD for all infants (< year old), the most highly exposed group which is not of concern to the Agency. Based on the use pattern, chronic residential exposure to residues of fluopicolide is not expected.

Fluopicolide is proposed for registration of uses that could result in short-term residential exposure. The Agency has concluded that food, water and residential exposures result in aggregate MOEs greater than the LOC of 100 for all population groups, and the aggregate short-term estimates for fluopicolide are below the Agency's level of concern. Also, short-term exposures for fluopicolide's metabolite BAM, may occur as a result of activities on treated turf. Incidental oral exposures related to turf activities have been combined with chronic dietary exposure estimates to assess short-term aggregate exposure for BAM. Since aggregate MOEs for BAM are greater than the

LOC, they represent risk estimates that are below the Agency's level of concern.

The intermediate-term aggregate risk for fluopicolide and BAM is the same as calculated for the short-term aggregate risk. In examining long-term aggregate risk, the Agency has assumed that the only pathway of exposure relevant to that time frame is dietary exposure. Therefore, the long-term aggregate risk is composed of exposures to fluopicolide residues in food and drinking water and is equivalent to the chronic dietary risk. The chronic risk estimates are below the Agency's level of concern for all population subgroups.

Cumulative Risk

Fluopicolide and the herbicide dichlobenil can form the common metabolite, BAM. To support existing tolerances and to establish new tolerances for fluopicolide, EPA conducted a human health risk assessment for exposure to BAM resulting from the use of all current and pending uses of fluopicolide and dichlobenil. This risk assessment is conservative in terms of potential dietary and non-dietary exposures. The assessment includes evaluations of risks for various subgroups, including those composed of infants and children. For this assessment the Agency retained the additional tenfold (10X) FQPA safety factor (SF) for the protection of infants and children.

ENVIRONMENTAL RISK ASSESSMENT

Fate Characterization

Fluopicolide will not volatilize from soil or aqueous solution. Neither photolysis nor hydrolysis is expected to be a significant degradation pathway for the dissipation of fluopicolide. Photolysis does, however, enhance the degradation of fluopicolide soil degradates. The primary pathway for dissipation of fluopicolide is by microbial or mineral-catalyzed degradation in soil. Fluopicolide is unlikely to leach in soil but its moderate water solubility suggests the potential for runoff in storm or irrigation water. The range of BCFs for edible tissue, nonedible tissue, and whole fish indicate a low potential for bioconcentration in fish and living organisms. The 2,6-Dichlorobenzamide (BAM) is the major potential toxic degradation product from aerobic soil metabolism, aquatic photolysis and soil photolysis studies. Guideline fate studies for BAM were not available, therefore, literature data were used to assess its fate properties.

Risk Assessment

A screening-level (Level I) risk assessment, based on proposed uses was completed. The calculated RQs for most groups are well below 1.0. The highest RQs (eg., 3.95) were determined from the small mammal ornamentals/short grass consumption scenarios. For the food and turf uses, there are no acute or chronic LOCs exceeded for any of the aquatic organisms. Acute LOCs are not exceeded for aquatic organisms exposed to the degradate, BAM (2,6-dichlorobenzamide) based on the scenario with the highest EEC, Florida nursery. There were no chronic LOCs exceeded

for the turf or food uses. There are no avian acute LOCs exceeded for the food uses. There were no acute or chronic dietary-based mammalian LOCs exceeded for BAM for any of the proposed uses.

DATA NEEDS AND LABEL REQUIREMENTS

Label Requirements

- Sufficient rotational crop data is not available to support the proposed rotational crop restrictions. The label must be modified to state that rotation is limited only to those crops on the current label.

Data Requirements

- Additional storage stability data are needed for celery and spinach reflecting a storage interval of 38 months. One study should be conducted on any representative leafy vegetable.

Government Performance Results Act

Registration of fluopicolide will meet objectives of 6 PRA title 3.1.1 by assuring new pesticides enter the market are safe for humans and the environment.

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DISCLAIMER: The information presented in this Pesticide Fact Sheet is for informational purposes only and may not be used to fulfill data requirements for pesticide registration and reregistration.

APPENDIX I:

GLOSSARY OF TERMS AND ABBREVIATIONS

ADNT	Acute delayed neurotoxicity
a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
ARI	Aggregate Risk Index
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
ChE	Cholinesterase
ChEI	Cholinesterase inhibition
cPAD	Chronic Population Adjusted Dose
%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
LC₅₀	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.

LD₅₀	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

**APPENDIX II:
Citations Considered to be Part of the Data Base Supporting the Registration of
Fluopicolide**

**Study Information For Ingredient
027412 / 239110-15-7 / Fluopicolide**

<u>MRID</u>	<u>Citation</u>	<u>Receipt Date</u>
46474000	Bayer CropScience LP (2005) Submission of Product Chemistry and Residue Data in Support of the Petition for Tolerance of Fluopicolide. Transmittal of 45 Studies.	07-Feb-2005
46474001	Smith, C. (2004) Fluopicolide (AE C638206) Technical: Product Chemistry Data Summary to Support a Tolerance in/on Imported Commodities. Unpublished study prepared by Bayer Ag, Institute of Product Info. 7 p.	07-Feb-2005
46474002	Smith, C. (2004) Fluopicolide (AE C638206) Technical: Product Identity and Composition, Description of Materials Used to Produce the Product, Description of the Production Process, Discussion of Formation of Impurities, and Certified Limits. Unpublished study prepared by Bayer Ag, Institute of Product Info. 108 p.	07-Feb-2005
46474003	Bowen, T. (2004) Material Accountability of AE C638206 Technical: Analytical Profile of Five Representative Batches and the Batch Used in the Long Term Toxicological Testing. Project Number: PA/04/001, C040168. Unpublished study prepared by Bayer CropScience GmbH. 37 p.	07-Feb-2005
46474004	Smith, C. (2004) Analytical Method: Determination of AEC638206 in AE CC638206 Technical Materials by HPLC; Validation of the Analytical Method AM000103FP1 for the Determination of AEC638206 in AE CC638206 Technical Materials; Analytical Method: Determination of Group 1 Impurities in AE CC638206 Technical Materials by HPLC; Validation of the Analytical Method AM000203FP1 for the Determination of Group 1 Impurities in AE CC638206 Technical Materials; Analytical	07-Feb-2005

	Method: Determination of Group 2 Impurities in AE CC638206 Technical Materials by HPLC; Validation of the Analytical Method AM000303FP1 for the Determination of Group 2 Impurities in AE CC638206 Technical Materials. Project Number: C033933, C033934, C033936. Unpublished study prepared by Bayer Ag, Institute of Product Info. 14 p.	
46474005	Bowen, T. (2003) Analytical Method: Determination of AE C638206 in AE C638206 Technical Materials by HPLC. Project Number: AM000103FP1, C033933. Unpublished study prepared by Bayer Cropscience Gmbh. 10 p.	07-Feb-2005
46474006	Bowen, T. (2003) Validation of the Analytical Method AM000103FP1 for the Determination of AE C638206 in AE C638206 Technical Materials. Project Number: AF03/005, C033934, AM000103FP1. Unpublished study prepared by Bayer Cropscience Gmbh. 39 p.	07-Feb-2005
46474007	Bowen, T. (2003) Analytical Method: Determination of Group 1 Impurities in AE C638206 Technical Materials by HPLC. Project Number: AM000203FP1, C033936. Unpublished study prepared by Bayer Cropscience Gmbh. 16 p.	07-Feb-2005
46474008	Bowen, T. (2003) Validation of the Analytical Method AM000203FP1 for the Determination of Group 1 Impurities in AE C638206 Technical Materials. Project Number: AF03/007, C033937, AM000203FP1. Unpublished study prepared by Bayer Cropscience Gmbh. 39 p.	07-Feb-2005
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