



# Pesticide Fact Sheet

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<b>Name of Chemical:</b>	<b>Fenpropimorph</b>
<b>Reason for Issuance:</b>	<b>New Chemical</b>
	<b>Tolerance Established</b>
<b>Date Issued:</b>	<b>March 2006</b>

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## Description of Chemical

Generic Name:	<i>rel</i> -(2 <i>R</i> ,6 <i>S</i> )-4-[3-[4-(1,1-dimethylethyl)phenyl]-2-methylpropyl]-2,6-dimethylmorpholine
Common Name:	Fenpropimorph
Trade Name:	VOLLEY™ 88OL (foreign)
Chemical Class:	Morpholine Fungicide
EPA Chemical Code:	121402
Chemical Abstracts Service (CAS) Number:	67564-91-4
Registration Status:	Not Registered; Import Tolerance Established
Pesticide Type:	Fungicide
U.S. Producer:	BASF Corporation Agricultural Products Division 26 Davis Drive, P.O. Box 13528 Research Triangle Park, NC 27709

**Tolerance Established**

Tolerances were established for fenpropimorph in the 40 CFR §180.616 for imported bananas at 2.0 ppm.

**Use Pattern and Formulations**

Fenpropimorph is a systemic morpholine fungicide which controls Sigatoka diseases (*Mycosphaerella spp.*) in bananas and plantains imported into the U.S. Fenpropimorph provides protectant and eradicant activity by inhibiting ergosterol biosynthesis. The fungicide, known as VOLLEY™ 880L Fungicide, is proposed for registration in Mexico, Guatemala, Belize, El Salvador, Honduras, Columbia, Nicaragua, Costa Rica, and Panama. There are currently no U.S. tolerances established for residues of fenpropimorph in plant or animal commodities and BASF is not proposing any uses for fenpropimorph on bananas grown in the U.S.

<b>TABLE 1 Summary of Current Foreign Use Directions for Fenpropimorph on Imported Bananas<sup>1</sup>.</b>				
<b>End-Use Product (EUP)</b>	<b>Applications</b>			
	<b>Timing<sup>2</sup> [Application Sequence]</b>	<b>Maximum Single Rate/Seasonal Rate<sup>2</sup> (kg ai/ha)</b>	<b>RTI<sup>3</sup> (Days)</b>	<b>PHI<sup>4</sup> (Days)</b>
VOLLEY™ 880L  Foliar broadcast spray to underside of leaves (ground equipment) or to foliage canopy (aerial equipment)	[1] Raceme formation	single rate = 0.44	NA <sup>5</sup>	0
	[2] Raceme development	maximum seasonal rate = 1.76 applied 4 times per season	12	
	[3] Raceme development		44	
	[4] Mature mats		12	

1. There are no current uses for fenpropimorph in the US.
2. Not specified in the current use directions, but supported by the field trials.
3. RTI = Re-Treatment Interval; not specified in the current use directions, but supported by the field trials.
4. PHI = Pre-Harvest Interval.
5. NA = Not Applicable.

## Science Findings

Available product chemistry and toxicology data supporting the proposed tolerance are summarized below.

Physical/Chemical Structure:

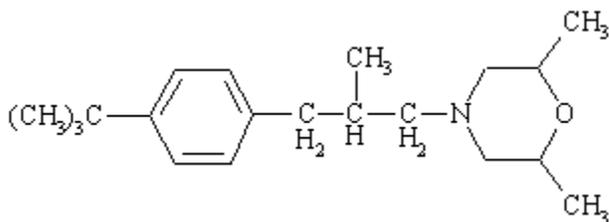


TABLE 2 Physicochemical Properties.*	
Parameter	Value
Melting Point/Range (°C)	Liquid at STP
pH	Not available
Density at 20°C (g/cm <sup>3</sup> )	0.933 [technical material]
Water Solubility at 20°C, pH 7 (mg/L)	4.32
Solvent Solubility at 20°C (g/100 ml)	Acetone 760.35 Ethyl Acetate 777.95 Toluene 764.60 Dichloromethane (DCM) 774.20 n-Heptane 725.35 ACN 772.70 Methanol 789.15 Iso-propanol 816.70 Octanol 770.50
Vapor Pressure at 20°C (Pa)	3.5 x 10 <sup>-3</sup>
Dissociation Constant (pK <sub>a</sub> )	Does not dissociate
Octanol/Water Partition Coefficient at 22°C, pH 7 (Log [K <sub>ow</sub> ])	4.1
UV/Visible Absorption	Not available

\* References: PP#7E4874 administrative materials (MRIDs #44323902, 45857201, 46097501).

<b>Table 3a: Acute Toxicity for Fenpropimorph Technical (91%)</b>				
<b>GDLN</b>	<b>Study Type</b>	<b>MRID No.</b>	<b>Results</b>	<b>Toxicity Category</b>
870.1100	Acute Oral - rat	45857208	LD <sub>50</sub> : M = 2830 mg/kg F = 1670 mg/kg combined = 2230 mg/kg	III
870.1100	Acute Oral - rat	45857209	LD <sub>50</sub> : M = 3650 mg/kg F = 3425 mg/kg combined = 3515 mg/kg	III
870.1200	Acute Dermal - rat	45857210	LD <sub>50</sub> : M = >4000 mg/kg F = > 4000 mg/kg combined = > 4000 mg/kg	III
870.1300	Acute Inhalation - rat	45857211	LC <sub>50</sub> : M = 3.7 mg/L F = >2.2, <2.4 mg/L combined = 2.9 mg/L	IV
870.2400	Acute Eye Irritation - rabbit	45857212	Redness (no observations between 72 hr and day 8)	IIa
870.2500	Acute Dermal Irritation - rabbit	45857213	Severely irritating after 1-hr exposure	I
870.2600	Dermal Sensitization - guinea pig	b	b	N/A

a = no worse than Category II

N/A = not applicable

b = study not provided

<b>Table 3b: Acute Toxicity for End-Use Product (5.4%)</b>				
<b>GDLN</b>	<b>Study Type</b>	<b>MRID</b>	<b>Results</b>	<b>Toxicity Category</b>
870.1100	Acute Oral - rat	45857203	LD <sub>50</sub> : M = >2000 mg/kg F = > 2000 mg/kg combined = > 2000 mg/kg	III
870.1200	Acute Dermal - rat	45857204	LD <sub>50</sub> : M = > 2000 mg/kg F = > 2000 mg/kg combined = > 2000 mg/kg	III
870.1300	Acute Inhalation - rat	45857205	LC <sub>50</sub> : M = 3.62 mg/L F = 1.52 mg/L combined not reported	III
870.2400	Acute Eye Irritation - rabbit	45857206	severely irritating	I

<b>Table 3b: Acute Toxicity for End-Use Product (5.4%)</b>				
<b>GDLN</b>	<b>Study Type</b>	<b>MRID</b>	<b>Results</b>	<b>Toxicity Category</b>
870.2500	Acute Dermal Irritation - rabbit	45857207	severely irritating and irreversible damage	I
870.2600	Dermal Sensitization - guinea pig	a	a	N/A

a = study not provided

N/A = not applicable

<b>Table 4 Acute, Subchronic, Chronic and Other Toxicity Profile</b>		
<b>Guideline No./ Study Type</b>	<b>MRID No. (year)/ Classification/Doses</b>	<b>RESULTS</b>
870.1100 870.6100 Acute oral toxicity and acute delayed neurotoxicity of organophosphorus substances - Hens (gavage) 92.5%	44323909 (1980) Acceptable/guideline  Acute oral study single dose: 250, 500, 1000, 2000, or 4000 mg/kg (with or without pretreatment with atropine sulfate and PAM)  Acute delayed study single dose: 425, 850 or 1700 mg/kg (pretreated with atropine sulfate and PAM)  10 hens treated with fenpropimorph at 1700 mg/kg	<b>ACUTE ORAL STUDY</b> Oral LD <sub>50</sub> : Unprotected = 1,600 mg/kg Protected = 1,700 mg/kg Toxicity Category = III  <b>ACUTE DELAYED STUDY</b> NOAEL = ≥ 1700 mg/kg (HDT) LOAEL = not observed for delayed neurotoxicity
870.3100 90-Day dietary toxicity - Rat 91.1%	44380103 (1979) Acceptable/guideline  ppm=0, 6.25, 12.5 or 25  M= 0, 0.382, 0.768 or 1.54 mg/kg/day F=0, 0.465, 0.915 or 1.80 mg/kg/day	NOAEL= M: 0.768 mg/kg/day F: 0.915 mg/kg/day LOAEL= M: 1.54 mg/kg/day based on increased relative liver weights and increase incidence of liver single cell necrosis  F: 1.80 mg/kg/day based on increased absolute and relative liver weights and increase incidence of liver single cell necrosis

<b>Table 4 Acute, Subchronic, Chronic and Other Toxicity Profile</b>		
<b>Guideline No./ Study Type</b>	<b>MRID No. (year)/ Classification/Doses</b>	<b>RESULTS</b>
870.3100 870.6200 90-Day dietary toxicity and neurotoxicity - Rat 94.3%	44380105 (1997) Acceptable/guideline  ppm=0, 1, 10, 100 or 1000  M=0, 0.1, 0.7, 7.1 or 71.0 mg/kg/day F= 0, 0.1, 0.8, 8.5 or 77.7 mg/kg/day  [FOB & motor activity days -7, 22, 50, 85; 5/sex/group profused neurohistology exams]	<b>SYSTEMIC</b> NOAEL=M: 0.7 mg/kg/day F: 0.8 mg/kg/day  LOAEL=M: 7.1 mg/kg/day based on ↓ BW & BWG, ↑ absolute & relative liver wt F: 8.5 mg/kg/day based on ↓ BW & BWG, ↑ relative liver wt  <b>NEUROTOX</b> NOAEL= M: 7.1 mg/kg/day F: 8.5 mg/kg/day LOAEL= M: 71.0 mg/kg/day based on differences in landing foot splay values F: 77.0 mg/kg/day based on differences in landing foot splay values
870.3150 90-Day dietary toxicity - Dog 91.1%	44380104 (1980) Acceptable/guideline  ppm=0, 50, 100, 200 or 400  M=0, 1.46, 2.96, 6.40 or 11.63 mg/kg/day F=0, 1.77, 3.69, 7.92 or 14.64 mg/kg/day	NOAEL= M: 11.63 mg/kg/day F: 14.64 mg/kg/day LOAEL= M: not established F: not established
870.3200 28-Day dermal toxicity - Rat 96.6%	45868902 (2001) Acceptable/guideline  M= 0, 0.2, 0.6 or 2.0 mg/kg/day F= 0, 0.2, 0.6 or 2.0 mg/kg/day	NOAEL = M: 2.0 mg/kg/day F: 2.0 mg/kg/day LOAEL = M: not established F: not established  <b>NOTE:</b> from a range-finding study, the material was tested at the maximum dose that would not produce severe skin irritation

<b>Table 4 Acute, Subchronic, Chronic and Other Toxicity Profile</b>		
<b>Guideline No./ Study Type</b>	<b>MRID No. (year)/ Classification/Doses</b>	<b>RESULTS</b>
870.3700 Developmental toxicity - Rat (gavage) 92.5%	44380108 (1978) Acceptable/guideline (PRE-GLP)  2000 - Supplemental submission of data concerning test article preparation, solubility & stability (no MRID #)  mg/kg/day=0, 2.5, 10, 40 or 160	<b>MATERNAL</b> NOAEL= 40 mg/kg/day LOAEL= 160 mg/kg/day based on clinical signs of toxicity (vaginal bleeding) and ↓BW & BWG  <b>DEVELOPMENTAL</b> NOAEL= 40 mg/kg/day LOAEL= 160 mg/kg/day based on ↓# live fetuses/dam, ↑ resorptions, ↑% postimplantation loss, ↑incidence of cleft palate 14/274 fetuses (7/24 litters) with 0 in controls
870.3700 Developmental toxicity - Rat (gavage) 92.5%	44323912 (1979) Acceptable/non-guideline (dosing during gestation & lactation; partial developmental neurotox thru PND 21)  2000 - Supplemental submission of data concerning test article preparation, solubility & stability (no MRID #)  mg/kg/day=0, 2.5, 10, 40 or 160	<b>MATERNAL</b> NOAEL=10 mg/kg/day LOAEL=40 mg/kg/day based on ↓BWG  <b>DEVELOPMENTAL</b> NOAEL=10 mg/kg/day LOAEL= 40 mg/kg/day based on ↓# live fetuses/dam, 1% postimplantation loss, ↓ mean litter size & # live pups, ↓ survival indices  <b>NEUROTOXICITY</b> NOAEL=10 mg/kg/day LOAEL= 40 mg/kg/day based on ↓ F grip strength  <b>NOTE:</b> no visceral or skeletal examinations of fetuses/pups
870.3700 Prenatal Developmental - Rabbit (gavage) 95.6%	44323914 (1993) Acceptable/guideline  mg/kg/day=0, 7.5, 15 or 30	<b>MATERNAL</b> NOAEL = 15 mg/kg/day LOAEL = 30mg/kg/day based on clinical signs (9/20 swelling of anus GD 15-29)  <b>DEVELOPMENTAL</b> NOAEL = 15 mg/kg/day LOAEL = 30 mg/kg/day based on cleft palate 4/116 fetuses (2/20 litters), 0 in control; anomalies

<b>Table 4 Acute, Subchronic, Chronic and Other Toxicity Profile</b>		
<b>Guideline No./ Study Type</b>	<b>MRID No. (year)/ Classification/Doses</b>	<b>RESULTS</b>
870.3700 Prenatal Developmental - Rabbit (gavage) 92.5%	44323913 (1980) Acceptable/guideline  mg/kg/day=0, 2.4, 12 or 60 (mortality at 60)  supplementary: mg/kg/day=0 or 36	<b>MATERNAL</b> NOAEL = 12 mg/kg/day LOAEL = 36 mg/kg/day based on mortality, abortions and clinical signs of toxicity  <b>DEVELOPMENTAL</b> NOAEL = 12 mg/kg/day LOAEL = 36 mg/kg/day based on increased incidence of resorptions, external anomalies and skeletal variations/retardations.
870.3800 2-Generation reproduction study - Rat, diet 92.5%	44323915 (1982) Acceptable/non-guideline  ppm=0, 6.25, 12.5 or 25 M=0, 0.51, 1.03 or 2.04 mg/kg/day F=0, 0.71, 1.46 or 2.79 mg/kg/day	<b>PARENTAL</b> NOAEL=M: 2.04 mg/kg/day F: 2.79 mg/kg/day LOAEL=M: not attained F: not attained  <b>REPRODUCTION</b> NOAEL=M:2.04 mg/kg/day F: 2.79 mg/kg/day LOAEL=M: not attained F: not attained  <b>OFFSPRING</b> NOAEL=M: 2.04 mg/kg/day F: 2.79 mg/kg/day LOAEL=M: not attained F: not attained  <b>NOTE:</b> animals not dosed high enough; 25 ppm based on 1 relative liver wts in 3-month rat study
870.4300 114-Week chronic/carcino- genicity dietary study -Rat 92.5%	44380106 (1982) Acceptable/guideline  ppm=0, 5, 10, 50 or 250  M=0, 0.2, 0.3, 1.7 or 8.8 mg/kg/day F=0, 0.2, 0.4, 2.1 or 11.2 mg/kg/day	NOAEL =M: 1.7 mg/kg/day F: 2.1 mg/kg/day LOAEL =M: 8.8 mg/kg/day based on histopathological liver findings F: 11.2 mg/kg/day based on histopathological liver findings  NO EVIDENCE OF CARCINOGENICITY

<b>Table 4 Acute, Subchronic, Chronic and Other Toxicity Profile</b>		
<b>Guideline No./ Study Type</b>	<b>MRID No. (year)/ Classification/Doses</b>	<b>RESULTS</b>
870.4100 12-Month dietary toxicity - Dog, diet ≥94.7%	44323911 (1990) Acceptable/guideline  ppm=0, 25, 100 or 400  M= 0, 0.8, 3.2 or 12.3 mg/kg/day F=0, 0.8, 3.2 or 13.2 mg/kg/day	NOAEL=M: 3.2 mg/kg/day F: 3.2 mg/kg/day LOAEL=M: 12.3 mg/kg/day based on ↑ blood enzyme activity ≥200% (ALT, liver) F: 13.2 mg/kg/day based on ↑ blood enzyme activity ≥200% (ALT, liver)
870.4200 Carcinogenicity study - Mouse, diet 92.5%	44380107 (1982) Acceptable/guideline  ppm=0, 5, 30, 150 or 1000  M=0, 0.5, 3.0, 16 or 106 mg/kg/day F=0, 0.5, 3.5, 17 or 118 mg/kg/day  treatment=95 wks; 10/sex/group terminated wk 52 & wk 95; survivors untreated until wk 103/104	NOAEL=M: 16 mg/kg/day F: 118 mg/kg/day LOAEL=M: 106 mg/kg/day based on ↓ BWG F: not attained  NO EVIDENCE OF CARCINOGENICITY
870.5100 Reverse Gene Mutation Assay ( <i>Salmonella</i> <i>typhimurium</i> ) 95.6%	44323917 (1994) Acceptable/guideline	No evidence of induced mutant colonies over background.
870.5375 <i>In vitro</i> Chinese hamster lung cells 95.6%	44323919 (1995) Acceptable/guideline	There were no treatment-related increases in total aberration frequency at any dose level with or without metabolic activation.
870.5395 <i>In vivo</i> mammalian cytogenetics - micronucleus assay in mice 95.6%	44323918 (1994) Acceptable/guideline	No significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow at any dose at any sampling time.

<b>Table 4 Acute, Subchronic, Chronic and Other Toxicity Profile</b>		
<b>Guideline No./ Study Type</b>	<b>MRID No. (year)/ Classification/Doses</b>	<b>RESULTS</b>
870.5550 Unscheduled DNA synthesis in primary rat hepatocytes 94.7%	44323916 (1988) Acceptable/guideline	There was no evidence that unscheduled DNA synthesis, as determined by radioactive tracer procedures, was induced.
870.6200 Acute neurotoxicity screening battery - rat 94.3%	44323910 (1997) Acceptable/guideline  M=0, 100, 500 or 1500 mg/kg (single gavage dose)	NOAEL=M: 500 mg/kg F: 500 mg/kg  LOAEL=M: 1500 mg/kg based on piloerection observations during the clinical examinations and FOB and neuropathy (one had slight dilation of ventricles in the frontal lobe, parietal lobe and the midbrain) F: 1500 mg/kg based on piloerection observations during the clinical examinations and FOB and decreased overall motor activity
870.6200 Subchronic toxicity and neurotoxicity - Rat, diet [See 870.3100]	44380105 (1997) Acceptable/guideline  <b>NOTE:</b> for doses, see 870.3100	<b>NOTE:</b> for results, see 870.3100

## **Toxicological Endpoints**

<b>Table 5 Fenpropimorph - Summary of Toxicological Doses and Endpoints for Chemical for Use in Human Health Risk Assessments</b>			
<b>Exposure Scenario</b>	<b>Dose Used in Risk Assessment, UF</b>	<b>Special FQPA SF and Level of Concern for Risk Assessment</b>	<b>Study and Toxicological Effects</b>
Acute Dietary (females 13-49)	NOAEL = 15 mg/kg/day  Total UF = 100X  Acute RfD = 0.15 mg/kg/day	FQPA SF = 1X  aPAD = $\frac{\text{Acute RfD}}{\text{FQPA SF}}$  aPAD = 0.15 mg/kg/day	Rabbit Developmental Study  Developmental LOAEL = 30 mg/kg/day based on cleft palates
Acute Dietary (general population)	No toxicological endpoint attributable to a single exposure was identified in the available toxicity studies		

Chronic Dietary (all populations)	NOAEL = 3.2 mg/kg/day  Total UF = 100 X  Chronic RfD = 0.032 mg/kg/day	FQPA SF = 1X  cPAD = $\frac{\text{Chronic RfD}}{\text{FQPA SF}}$  cPAD = 0.032 mg/kg/day	One-Year Dog and Chronic/Carcinogenicity Rat Studies [Co-critical studies for endpoint selection].  LOAEL of 9-11 mg/kg/day, based on liver histopathology
Cancer (oral, dermal, inhalation)	<b>Classification: “Not likely to be carcinogenic to humans.”</b> No increased incidences in tumors in a chronic/carcinogenicity rat study or a carcinogenicity mouse study.		

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

### **Food Quality Protection Act Considerations:**

#### *FQPA Safety Factor:*

There is a complete toxicity database and the Special FQPA Safety Factor was removed, reduced to 1X, because: 1) there is a low degree of concern for the qualitative susceptibility in developmental rat and rabbit studies, because the fetal effects were observed only in the presence of maternal toxicity; and 2) there is no concern for pre/post natal toxicity since no off-spring toxicity was seen in the 2-generation reproduction study; 3) the endpoints of concern are addressed in this risk assessment; and 4) the dietary exposure assessment assumed tolerance level residues and 100% crop treated.

### **Exposure Assessment:**

Fenpropimorph is proposed for use only on imported bananas. Since there are no registered (neither agricultural, occupational nor residential) uses associated with fenpropimorph in the U.S., the only route of exposure is dietary (food only). Dietary exposure will be limited to residues from imported bananas. With no proposed U.S. registrations, there is no expectation that fenpropimorph residues would occur via water consumption or residential use. Therefore, neither a residential, water or aggregate exposure is expected.

Acute: An acute dietary dose and an endpoint attributable to a single dose were identified for only one subpopulation, females ages 13 through 49. The acute exposure estimate of approximately 0.004 mg/kg/day corresponds to 2.6 % of the aPAD. An appropriate endpoint attributable to a single exposure was not identified for the general population nor any of the other population subgroups.

Chronic: The chronic exposure estimate for the most highly exposed population subgroup (children 1-2 years old) was approximately 0.004 mg/kg/day, or 11 % of the cPAD. Risks for the general U.S. population and all other population subgroups were lower. Based on

the dietary exposure analyses conducted, there are no dietary risk concerns for fenpropimorph.

Cancer: Fenpropimorph has been classified as not likely to be carcinogenic to humans, and therefore it is not expected to pose a cancer risk.

### **DATA GAP**

- Requested additional acceptable method validation recovery data using either BASF Method 456/0, the Dutch or the German Multiresidue Method.

### **Contact person at USEPA**

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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:

### GLOSSARY OF TERMS AND ABBREVIATIONS

<b>ADNT</b>	<b>Acute delayed neurotoxicity</b>
<b>a.i.</b>	<b>Active Ingredient</b>
<b>aPAD</b>	<b>Acute Population Adjusted Dose</b>
<b>ARI</b>	<b>Aggregate Risk Index</b>
<b>BCF</b>	<b>Bioconcentration Factor</b>
<b>BW</b>	<b>Body Weight</b>
<b>BWG</b>	<b>Body Weight Gain</b>
<b>CAS</b>	<b>Chemical Abstracts Service</b>
<b>ChE</b>	<b>Cholinesterase</b>
<b>ChEI</b>	<b>Cholinesterase inhibition</b>
<b>cPAD</b>	<b>Chronic Population Adjusted Dose</b>
<b>%CT</b>	<b>Percent crop treated</b>
<b>DAT</b>	<b>Days after treatment</b>
<b>DEEM-FCID</b>	<b>Dietary Exposure Evaluation Model - Food Consumption Intake Database</b>
<b>DNA</b>	<b>Deoxyribonucleic acid</b>
<b>DNT</b>	<b>Developmental neurotoxicity</b>
<b>DIT</b>	<b>Developmental immunotoxicity</b>
<b>DWLOC</b>	<b>Drinking Water Level of Comparison.</b>
<b>EC</b>	<b>Emulsifiable Concentrate Formulation</b>
<b>EEC</b>	<b>Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.</b>
<b>EPA</b>	<b>U.S. Environmental Protection Agency</b>
<b>FOB</b>	<b>Functional Observation Battery</b>
<b>FQPA</b>	<b>Food Quality Protection Act</b>
<b>GLC</b>	<b>Gas Liquid Chromatography</b>
<b>GLN</b>	<b>Guideline Number</b>
<b>HDT</b>	<b>Highest Dose Tested</b>
<b>LC<sub>50</sub></b>	<b>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.</b>
<b>LD<sub>50</sub></b>	<b>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.</b>
<b>LOAEL</b>	<b>Lowest Observed Adverse Effect Level</b>
<b>LOAEC</b>	<b>Lowest Observed Adverse Effect Concentration</b>
<b>LOC</b>	<b>Level of Concern</b>
<b>LOD</b>	<b>Limit of Detection</b>
<b>LOQ</b>	<b>Limit of quantitation</b>
<b>mg/kg/day</b>	<b>Milligram Per Kilogram Per Day</b>
<b>mg/L</b>	<b>Milligrams Per Liter</b>
<b>MOE</b>	<b>Margin of Exposure</b>

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

## Appendix II

### Citations Considered to be Part of the Data Base Supporting the Registration of Fenpropimorph

MRID	Citation
44323900	BASF Corp. (1997) Submission of Product Chemistry, Toxicology, Nature of Residue in Plants and Animals, and Residue in Plants Data in Support of the Import Tolerance Petition for Fenpropimorph in/on Bananas. Transmittal of 32 Studies.
44323901	Tobia, A. (1997) FQPA Informative Summary: Fenpropimorph Import Tolerance for Bananas: Lab Project Number: 97/5276. Unpublished study prepared by BASF Corp. 12 p.
44323902	Ohnsorge, U. (1997) Product Identity and Composition of Fenpropimorph TGAI: Lab Project Number: 97/10567. Unpublished study prepared by BASF Aktiengesellschaft. 40 p. {OPPTS 830.1600, 830.1620, 830.1670}
44323903	Bross, M. (1993) Preliminary Analysis: Composition of Five Batches of Fenpropimorph...Technical: Lab Project Number: 93/10078: PCP02250. Unpublished study prepared by BASF Aktiengesellschaft. 41 p. {OPPTS 830.1700}
44323904	Kastel, R. (1994) Physical and Chemical Properties Report for Fenpropimorph...TGAI: Lab Project Number: 94/10392: PCF 01296. Unpublished study prepared by BASF Aktiengesellschaft. 9 p. {OPPTS 830.6313, 830.7300, 830.7000, 830.7220, 830.6315, 830.7100, 830.6302, 830.6303, 830.6304}
44323905	Ohnsorge, U. (1997) Storage Stability Data for Fenpropimorph TC: Lab Project Number: 97/10577. Unpublished study prepared by BASF Aktiengesellschaft. 4 p. {OPPTS 830.6317}
44323906	Bross, M. (1992) Determination of Fenpropimorph in Technical Fenpropimorph by Capillary GC: Analytical Method CP No. 149/1: Lab Project Number: 92/11989. Unpublished study prepared by BASF Aktiengesellschaft. 9 p. {OPPTS 830.1800}
44323907	Bross, M. (1992) Determination of Impurities in Technical Fenpropimorph by Capillary GC: Analytical Method CP No. 179: Lab Project Number: 92/11988. Unpublished study prepared by BASF Aktiengesellschaft. 32 p. {OPPTS 830.1800}
44323908	Bross, M. (1993) Validation of GC-Methods CP 149/1 and CP 179: Determination of Active Ingredient and Impurities in Fenpropimorph Technical: Lab Project Number: 93/10190: PCP02195. Unpublished study prepared by BASF Aktiengesellschaft. 44 p.
44323909	Robert, N.; Fairley, C.; Prentice, D.; et al. (1980) The Acute Oral Toxicity (LD50) and Neurotoxic Effects of Fenpropimorph...to the Domestic Hen: Lab Project Number: 80/0204: BSF 336/80382: BSF/336. 40 p.
44323910	Mellert, W.; Kaufmann, W.; Hildebrand, B. (1997) Acute Oral Neurotoxicity of Fenpropimorph...in Wistar Rats: Lab Project Number: 97/10592: 20C0047/93061. Unpublished study prepared by BASF Aktiengesellschaft. 420 p.

44323911	Hellwig (1990) Report on the Study of Fenpropimorph...in Beagle Dogs--Administration via the Diet over 12 Months: Lab Project Number: 90/0172: 33D0133/87021. Unpublished study prepared by BASF Aktiengesellschaft. 842 p.
44323912	Hoffmann, T.; Merkle, J. (1979) Study of the Perinatal and Postnatal Toxicity of Fenpropimorph...in Rats: Lab Project Number: 79/10164: T282R. Unpublished study prepared by BASF Aktiengesellschaft. 344 p.
44323913	Zeller, H.; Merkle, J. (1980) Study to Determine the Prenatal Toxicity of Fenpropimorph...in Rabbits: Lab Project Number: 80/0109: T316K. Unpublished study prepared by BASF Aktiengesellschaft. 258 p.
44323914	Marty, J. (1993) CGA 101 03 1 (Fenpropimorph) Technical: Rabbit Oral Teratogenicity: (Final Report): Lab Project Number: 93/11016: 923154. Unpublished study prepared by Ciba-Geigy Ltd. 263 p.
44323915	Merkle, J. (1982) Report on a Reproduction Study with Fenpropimorph...in Rats After Oral Administration (Feeding): 2-Generation Study: Lab Project Number: 82/079. Unpublished study prepared by BASF Aktiengesellschaft. 1152 p.
44323916	Cifone, M. (1988) Report on the Mutagenicity Test on Fenpropimorph in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay: (Revised Final Report): (Includes Phase 3 Summary): Lab Project Number: 88/0210: 10001-0-447: 61M0133/879008. Unpublished study prepared by Hazleton Labs America, Inc. 37 p.
44323917	Engelhardt, G. (1994) Report on the Study of Fenpropimorph in the Ames Test (Salmonella/Mammalian-Microsome Mutagenicity Test--Standard Plate Test and Preincubation Test): Lab Project Number: 94/10180: 40M0047/934047: 934047. Unpublished study prepared by BASF Aktiengesellschaft. 40 p.
44323918	Engelhardt, G. (1994) Cytogenetic Study in vivo of Fenpropimorph in Mice Micronucleus Test: Single Intraperitoneal Administration: (Includes Phase 3 Summary): Lab Project Number: 94/10966: 26M0047/934049. Unpublished study prepared by BASF Aktiengesellschaft. 72 p.
44323919	Engelhardt, G. (1995) In vitro Chromosome Aberration Assay (with Fenpropimorph in V79 Cells): Lab Project Number: 95/10325: 32M0047/934078. Unpublished study prepared by BASF Aktiengesellschaft. 93 p.
44323920	van Dijk, A. (1989) (Carbon 14)-RO 14/3169: Absorption, Distribution, Excretion, and Metabolism after Single Oral Intravenous, Single Oral, and Repeated Oral Administration to the Rat: Lab Project Number: 89/0315: 063641. Unpublished study prepared by RCC Umweltchemie AG. 413 p.
44323921	Hawkins, D.; Down, W.; Ballard, S.; et al. (1981) The Effect of Fenpropimorph (BAS 108 406) on Hepatic Drug-Metabolizing Enzyme Activity in the Rat: (Final Report): Lab Project Number: 81/0367: BSF 368/81203. Unpublished study prepared by Huntingdon Research Centre. 72 p.
44323922	Hamm, R. (1995) Plant Uptake with (carbon 14)-Fenpropimorph (Phenyl-U-(carbon 14)) in Banana: Lab Project Number: P94/16867: 95/10710. Unpublished study prepared by BASF

	Aktiengesellschaft. 21 p. {OPPTS 860.1300}
44323923	Hamm, R. (1995) Plant Uptake with (carbon 14)-Fenpropimorph (Morpholine-2,6-(carbon 14)) in Banana: Lab Project Number: P94/16866: 95/10709. Unpublished study prepared by BASF Aktiengesellschaft. 28 p. {OPPTS 860.1300}
44323924	Tilting, N. (1993) Gaschromatographic Determination of Fenpropimorph in Banana Fruit, Peel, and Pulp: Lab Project Number: 93/11464: 241/1. Unpublished study prepared by BASF Aktiengesellschaft. 69 p. {OPPTS 860.1340}
44323925	Shaffer, S. (1997) Specificity Test for BASF Analytical Method No. 241/1, "Gas Chromatographic Determination of Fenpropimorph in Banana Fruit, Peel, and Pulp": Lab Project Number: 97/5003: 96122: 10170. Unpublished study prepared by Horizon Labs, Inc. 48 p. {OPPTS 860.1340}
44323926	Artz, S.; Malinsky, S. (1997) Independent Method Validation of BASF Analytical Method No. 241/1, "Gas Chromatographic Determination of Fenpropimorph in Banana Fruit, Peel, and Pulp" at BASF: Lab Project Number: 97/5077: 96139: 241/1. Unpublished study prepared by BASF Corp. 35 p. {OPPTS 860.1340}
44323927	Zehr, R. (1997) Document Detailing Additional Comments and Procedures Used for the Conduct of the Independent Laboratory Validation...of BASF Method 241/1: Lab Project Number: 97/5290: 93/11464: 97/5077. Unpublished study prepared by BASF Corp. 4 p. {OPPTS 860.1340}
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44323929	Shaffer, S. (1997) Determination of the Freezer Storage Stability of BAS 421 F in Bananas: Lab Project Number: 97/5093: 10171: 96123. Unpublished study prepared by Horizon Labs, Inc. 51 p. {OPPTS 860.1380}
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44323931	Sotack, G. (1997) BAS 421 13 F: Tank Mix Stability/Homogeneity Study of Corbel Fungicide in Oil: Lab Project Number: 97/5165: 97088: FR9729. Unpublished study prepared by BASF Corp. 16 p.
44323932	Burkey, J. (1997) Fenpropimorph Use on Bananas: Residue Chemistry Overview: Lab Project Number: 97/5288. Unpublished study prepared by BASF Corp. 19 p.
44380100	BASF Corp. (1997) Submission of Product Chemistry, Toxicology and Residues Data in Support of Tolerance Petition for Fenpropimorph in/on Banana. Transmittal of 10 Studies.
44380101	Petersen-Thiery, M. (1997) Certification of Limits for Fenpropimorph: Lab Project Number: 97/10429. Unpublished study prepared by BASF Aktiengesellschaft. 12 p. {OPPTS 830.1750}
44380102	Geiger-Jackson, D. (1997) Fenpropimorph: Manufacturing Materials Safety and

	Specifications: Lab Project Number: 97/5275: 97/10581. Unpublished study prepared by BASF Corp. 97 p.
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44380104	Kirsch, P. (1980) Study of the Toxicity of Fenpropimorph (Reg. No. 108 406) in Beagle Dogs in a 3-Month Feeding Study: Lab Project Number: 80/0171. Unpublished study prepared by BASF Aktiengesellschaft. 487 p.
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44380107	Hunter, B.; Heywood, R.; Hayman, R. et al. (1982) Fenpropimorph (Reg. No. 108 406): Assessment of Potential Tumorigenic Effects in Prolonged Dietary Administration to Mice: Lab Project Number: BAF/320/81746: 82/142: BSF/320. Unpublished study prepared by Huntingdon Research Centre. 1201 p.
44380108	Hofmann, H. (1978) Investigation to Determine the Prenatal Toxicity of Fenpropimorph (Reg. No. 108 406) in Rats: Lab Project Number: 78/043. Unpublished study prepared by BASF Aktiengesellschaft. 141 p.
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44380110	Hamm, R. (1997) Metabolism of (carbon 14)-Fenpropimorph (BAS 421 F) in Banana: Lab Project Number: 97/10536: 16868. Unpublished study prepared by BASF Aktiengesellschaft. 150 p.
44835200	BASF Corporation (1999) Submission of Product Chemistry Data in Support of the Petition for Tolerance of Fenpropimorph in/on Bananas. Transmittal of 1 Study.
44835201	Cannan, T. (1998) BAS 421..F: Stability to Normal and Elevated Temperatures, Metals, and Metal Ions: Lab Project Number: 98118: FR9864: 98/5182. Unpublished study prepared by BASF Corporation. 13 p. {OPPTS 830.1630}
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46431601	Hastings, C. (2004) Fenpropimorph: Response to Agency Questions on Analytical Results For Test Material in Feed for 3-Month Rat Study MRID 44380103. Project Number: 2004/7009670. Unpublished study prepared by BASF Corporation. 5 p.

46431602	Hastings, C. (2004) Fenpropimorph: Response to Agency Questions on Analytical Results for Test Material in Feed for 3-Month Dog Study MRID 44380104. Project Number: 2004/7009671. Unpublished study prepared by BASF Corporation. 5 p.
46431603	Hastings, C. (2004) Fenpropimorph: Response to Agency Questions on Analytical Results For Test Material in Feed and Historical Control Data in the Mouse Oncogenicity Study MRID 44380107. Project Number: 2004/7009672. Unpublished study prepared by BASF Corporation. 8 p.
46431604	Hastings, C. (2004) Fenpropimorph: Response to Agency Questions on Analytical Results for Test Material in Feed for 2-Generation Rat Reproduction Study MRID 44323915. Project Number: 2004/7009673. Unpublished study prepared by BASF Corporation. 5 p.