United States
Environmental Protection
Agency

Office of Chemical Safety
and Pollution Prevention
(7101M)

Pesticide Fact Sheet

Name of Chemical: Isopyrazam
Reason for Issuance: New Chemical
Tolerances Established
Date Issued: October 5, 2011

Description of Chemical

Generic Name:	SYN520453
Common Name:	Isopyrazam
Trade Name Used: In Foreign Countries:	Reflect 125 EC, SYN 125 EC
Chemical Class:	Carboxamide
EPA Chemical Code:	129222
Chemical Abstracts Service (CAS) Number:	881685-58-1
Registration Status:	Not Registered; New Tolerance on Banana Established
Pesticide Type:	Fungicide
U.S. Producer:	Syngenta Crop Protection, Inc.

Tolerances Established

Import tolerances are established for or residues of the fungicide Isopyrazam, including its metabolites and degradates, in the 40 CFR §180.654 for bananas at 0.05 ppm.

Use Patterns and Formulation

Isopyrazam (SYN520453) is a fungicide developed to control black sigatoka, a leaf spot disease in banana production. Isopyrazam is a pyrazole carboxamide. The mode of action (MOA) of this group of fungicides is understood to be inhibition of succinate dehydrogenase (SDH), which is a functional part of the tricarboxylic acid cycle (TCA) and the mitochondrial electron transport chain. Isopyrazam is used on bananas grown in a number of Central and South American countries. Isopyrazam/SYN520453 is a mixture of 97% syn- (SYN534968) and 3% anti- (SYN534969) isomer. Isopyrazam is not currently registered in the United States. The active ingredient for use on banana is formulated as an emulsifiable concentrate (Reflect 125 EC, 125 g/L). It is applied aerially or by backpack sprayer outside the U.S. The proposed use on bananas is for foliar applications at a rate of 0.6 L/ha (0.067 lb ai/A) with a minimum retreatment interval of 10 days.

Science Findings

Available product chemistry and toxicology data supporting the approved use are summarized below.

Table 1. Nomenclature of Isopyrazam.

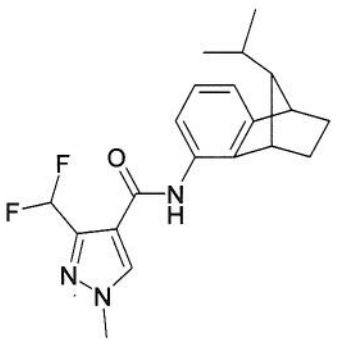
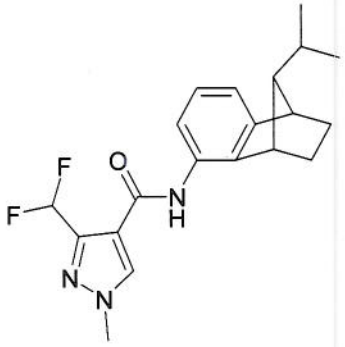
Chemical structure	 *syn*-isomer (SYN 534969)  *anti*-isomer (SYN 534968)
Common name	Isopyrazam
Company experimental name	SYN520453
IUPAC name	3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid (9-isopropyl-1,2,3,4-tetrahydro-1,4-methano-naphthalen-5-yl)-amide
CAS name	1*H*-Pyrazole-4-carboxamide, 3- (difluoromethyl)-1-methyl-*N*-[1,2,3,4-tetrahydro-9-(1-methylethyl)-1,4-methanonaphthalen-5-yl]
CAS number	881685-58-1
PC Code Number	129222

Table 2. Physicochemical Properties	
Parameter	**Value**
Melting point/range	144.5°C for SYN534968;130.2°C for SYN534969
pH	6.1 @22°C (1% aqueous solution)
Density	1.332 g/cm³ (1.332 x 10^3 kg/m³) (typical) at 19.5 °C
Water solubility (pure water)	SYN534968: 0.55 mg/L @25°C
	SYN534969: 1.05 mg/L @25°C
Solvent solubility (g/L)	Acetone: 314; dichloromethane:330; ethyl acetate 179; *n*-hexane 1.17; methanol 119
	n-octanol 44.1; toluene 77.1
Vapor pressure	SYN534968 and SYN534969: 5.7x10^{-8} Pa @25°C
Dissociation constant, pK_a	No pKa observed in the pH range of 1.0 – 12.0 by spectrophotometric titrations of both SYN534968 and SYN534969
Octanol/water partition coefficient	Log Pow = 4.4 for SYN534968 and 4.1 for SYN534969 @25°C
UV/visible absorption spectrum	SYN534969: 17,576 l/mol*cm (neutral solution); 17,439 l/mol*cm (acidic solution); 17,328 l/mol*cm (basic solution)

Toxicology Profile

Table 3. Acute Toxicity Profile				
Guideline No.	**Study Type**	**MRID(s)**	**Results**	**Toxicity Category**
870.1100	Acute oral, rat	47746821 47746822 47746823 47746824 47746825	LD_{50} > 2000 mg/kg in female rat LD_{50} > 2000 mg/kg in female rat LD_{50} > 2000 mg/kg in female rat (syn) LD_{50} > 2000 mg/kg in female rat LD_{50} > 2000 mg/kg in female rat	III
870.1200	Acute dermal, rat	N/A and not required for import tolerance		
870.1300	Acute inhalation, rat	N/A and not required for import tolerance.		
870.2400	Acute eye irritation, rabbit	N/A and not required for import tolerance.		
870.2500	Acute dermal irritation, rabbit	N/A and not required for import tolerance.		
870.2600	Skin sensitization, guinea pig	N/A and not required for import tolerance.		

Table 4. Subchronic, Chronic, and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification/ Doses**	**Results**
870.3100	Subchronic (Oral) Toxicity (Rat)	47746832 (2008) Acceptable/guideline 0, 500, 2500, or 7000 ppm M: 0, 76.5, 390.8, or 1382.8 mg/kg/day F: 0, 87.2, 448.9, or 1759.6 mg/kg/day	NOAEL was not observed LOAEL = 76.5/87.2 mg/kg/day (M/F), based on decreased food utilization in males.
	Subchronic (Oral) Toxicity - (Rat)	47746833 (2008) Acceptable/guideline 0, 100, 250, or 2000 ppm SYN520453 (89.5% Syn:6.9% Anti) M: 0, 8.30, 20.29, or 158.67 mg/kg/day F: 0, 8.24, 20.75, or 163.26 mg/kg/day SYN520453 (63.3% Syn:27.5% Anti) M: 0, 9.87, 24.14, or 192.92 mg/kg/day F: 0, 9.49, 24.15, or 197.02 mg/kg/day	NOAEL = 20.29/20.75 mg/kg/day (M/F; 89.5% Syn:6.9% Anti) and 24.14/24.15 mg/kg/day (M/F; 63.3% Syn:27.5% Anti) LOAEL = 158.67/163.26 mg/kg/day (M/F; 89.5% Syn:6.9% Anti) and 192.92/197.02 mg/kg/day (M/F; 63.3% Syn:27.5% Anti), based on the following findings with each test material: decreased body weight, body weight gain, and food utilization in females; decreased plasma alkaline phosphatase in both sexes; and increased incidences of centrilobular hepatocyte hypertrophy, midzonal vacuolation in liver, and increased liver weight in both sexes.
	Subchronic (Oral) Toxicity - (Rat)	47746834 (2007) Acceptable/guideline 0, 300, 1500, or 6000 ppm M: 0, 21.3, 106.3, or 463.0 mg/kg/day F: 0, 23.8, 117.8, or 484.4 mg/kg/day	NOAEL = Not identified LOAEL = 21.3/23/8 mg/kg/day (M/F), based on decreased body weight in females, and increased centrilobular hepatocyte hypertrophy and increased liver weight of 14%
870.3150	Subchronic (Oral) Toxicity - Non-Rodent (Dog)	47746835 (2008) Acceptable/guideline 0, 10, 30, or 250 mg/kg/day	NOAEL = 30 mg/kg/day LOAEL = 250 mg/kg/day, based on increased incidence of salivation, and transient decreases in food consumption and body weight in

Table 4. Subchronic, Chronic, and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification/ Doses**	**Results**
			both sexes; and increased abnormal behavior and decreased activity in males.
		47746836 (2007) Acceptable/guideline 0, 30, 100, or 300 mg/kg/day	NOAEL = 30 mg/kg/day LOAEL = 100 mg/kg/day, based decreased body weight gains, clinical signs of toxicity (side-to-side head wobble in one male), increased alkaline phosphatase and decreased plasma albumin in both sexes; and increased adjusted for bw/liver weights in males
870.3700a	Prenatal Developmental Toxicity (Han Wistar Rat)	47746843 (2008) Acceptable/guideline 0, 20, 75, or 200 mg/kg/day	**Maternal** NOAEL = 20 mg/kg/day. LOAEL = 75 mg/kg/day, based on decreased food consumption, body weights and BW gains. **Fetal** NOAEL = 20 mg/kg/day. LOAEL = 75 mg/kg/day, based on decreased body weight and non- or incomplete ossification
		47746845 (2008) Acceptable/guideline 0, 20, 75, or 250 mg/kg/day	**Maternal** NOAEL = 75 mg/kg/day. LOAEL = 250 mg/kg/day, based on decreased body weight gain and food consumption; and increased mortality in dams and early intra-uterine death. **Fetal** NOAEL = 75 mg/kg/day. LOAEL = 250 mg/kg/day, based on decreased fetal body weight and delayed ossification.
870.3700b	Prenatal Developmental Toxicity – Non-Rodent (New Zealand White Rabbit)	47746840 (2008) Acceptable/guideline 0, 30, 150, or 500 mg/kg/day	**Maternal** NOAEL = 150 mg/kg/day. LOAEL = 500 mg/kg/day, based on based on mortality, decreased food consumption, decreased defecation, increased liver weights, and microscopic findings in the liver. **Fetal** NOAEL = 500 mg/kg/day. LOAEL = was not observed.
870.3800	Reproduction and Fertility Effects (Rat)	47746847 (2008) Acceptable/guideline 0, 100, 500, or 3000 ppm	**Parental** NOAEL = 8.9/9.8 (M/F) mg/kg/day. LOAEL = 44.5/48.4 (M/F) mg/kg/day, based on decreased body weight and food consumption

Table 4. Subchronic, Chronic, and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification/ Doses**	**Results**
		M: 0, 8.9, 44.5, or 269.3 mg/kg/day [a] F: 0, 9.8, 48.4, or 289.0 mg/kg/day [a]	in females; and increased hepatocellular hypertrophy and liver weights in both sexes. **Reproductive** NOAEL = 269.3/289.0 (M/F) mg/kg/day. LOAEL was not observed. **Offspring** NOAEL = 44.5/48.4 (M/F) mg/kg/day LOAEL = 269.3/289.0 (M/F) mg/kg/day, based on increased liver weights in both sexes.
870.4100b	Chronic (Oral) Toxicity - Non-Rodent (Dog)	47746848 (2008) Acceptable/guideline 0, 25, 100, or 250 mg/kg/day	NOAEL = 25 mg/kg/day LOAEL = 100 mg/kg/day, based on decreased body weight gains, increased liver weights, decreased albumin and bilirubin in males, and increased plasma alkaline phosphatase in both sexes. No increased incidence of neoplasia was noted.
870.4200b	Carcinogenicity (Mouse)	47746849 (2008) Acceptable/guideline 0, 70, 500, or 3500 ppm M: 0, 7.8, 56.2, or 432.6 mg/kg/day F: 0, 9.9, 74.9, or 553.6 mg/kg/day	NOAEL = 56.2/74.9 (M/F) mg/kg/day LOAEL = 432.6/553.6 (M/F) mg/kg/day, based on decreased body weights and food utilization in both sexes; and increased liver weight and incidence of hepatocellular hypertrophy in both sexes. No increased incidence of neoplasia was noted.
870.4300	Combined Chronic Toxicity/ Carcinogenicity (Rat)	47746851 (2008) Acceptable/guideline 0,100, 500, or 3000 ppm M: 0, 5.5, 27.6, or 173.5 mg/kg/day F: 0, 6.9, 34.9, or 232.8 mg/kg/day	NOAEL = 5.5/6.9 (M/F) mg/kg/day LOAEL = 27.6/34.9 (M/F) mg/kg/day, based on decreased body weight and body weight gain in females; increased incidences of hepatocellular hypertrophy, pigment in centrilobular hepatocytes, eosinophilic foci of altered hepatocytes, vacuolation of

Table 4. Subchronic, Chronic, and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification/ Doses**	**Results**
			centrilobular hepatocytes, bile duct hyperplasia, and bile duct fibrosis in both sexes; and brown pigment in the kidney in females. There were increased incidences of uterine endometrial adenocarcinoma and liver hepatocellular adenoma in females at 3000 ppm.
870.6200a	Neurotoxicity Screening Battery - Acute - (Rat)	47746866 (2009) Upgradable/ guideline Requires positive control data 0, 30, 250 or 2000 mg/kg/day	NOAEL = 2000 mg/kg/day. LOAEL was not observed. Only transient decreases in activity, slight rearing in both sexes and body weight gain in females were noted.
870.6200b	Neurotoxicity Screening Battery - Subchronic (Rat)	47746865 (2009) Upgradable/ guideline Requires positive control data 0, 300, 1500, or 6000 ppm M: 0, 20, 98, or 382 mg/kg/day F: 0, 25, 114, or 468 mg/kg/day	NOAEL = 98/114 (M/F) mg/kg/day. LOAEL = 382/468 (M/F) mg/kg/day, based on decreased body weight gain and food consumption in both sexes. No indications of neurotoxicity were observed.
870.3050	28-Day Oral (Dietary) Toxicity Study (Rat)	47746827 (2008) Unacceptable/upgradable/guideline Requires dietary formulation analyses data 0, 2000, 6000, or 12,000 ppm M: 0, 175, 497, or 1018 mg/kg/day F: 0, 176, 525, or 1107 mg/kg/day	NOAEL = 1018/1107 (M/F) mg/kg/day. LOAEL was not observed. This study examined a metabolite of the test compound.
		47746828 (2009)	NOAEL = 927/906 (M/F)

Table 4. Subchronic, Chronic, and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification/ Doses**	**Results**
		Acceptable/guideline 0, 300, 4000, or 10,000 ppm M: 0, 27, 370, or 927 mg/kg/day F: 0, 29, 388, or 906 mg/kg/day	mg/kg/day. LOAEL was not observed. At 4000 ppm, increased incidences of hepatocellular hypertrophy, thyroid follicular cell hypertrophy; increased liver weight and cytochrome P450 levels considered adaptive and/or secondary effects. Metabolite of test compound was examined
870.5100	Bacterial Reverse Mutation Test *SYN 520453 (parent)	47746852 (2008) Acceptable/guideline 33, 100, 333, 1000, 2500, or 5000 µg/plate (with and without activation)	There was no evidence of induced reverse mutations with or without activation. [Negative]
		*47746853 (2008) Acceptable/guideline 33, 100, 333, 1000, 2500, or 5000 µg/plate (with and without activation)	There was no evidence of induced reverse mutations with or without activation. [Negative]
		*47746854 (2008) Acceptable/guideline 10, 33, 100, 333, 1000, 2500, or 5000 µg/mL (with and without activation)	There was no evidence of induced reverse mutations with or without activation. [Negative]
		47746855 (2008) Acceptable/guideline 100, 200, 500, 1000, 2500, or 5000 µg/plate (with and without activation)	There was no evidence of induced reverse mutations with or without activation. [Negative]
870.5300	In vitro mammalian cell gene mutation test	47746857 (2008) Acceptable/guideline 25, 50,100, 200, 300, 400, 800 µg/mL (with and without activation)	There was no evidence of induced forward mutations with or without activation. [Negative]
		47746858 (2006)	There was no evidence of induced

Table 4. Subchronic, Chronic, and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification/ Doses**	**Results**
870.5375	In vitro mammalian chromosome aberration test (human lymphocyte)	Acceptable/guideline 0.63, 1.25, 2.5, 5, 10, 20, or 30 µg/mL (without activation) 2.5, 5, 10, 20, 30, 40, or 50 µg/mL (with activation)	forward gene mutations with or without activation. [Negative]
		47746859 (2008) Acceptable/guideline 0.7, 1.4, 2.8, 5.5, 11.0, 22.0, 33.0, or 44.0 µg/mL (without activation) 5.5, 11.0, 22.0, 44.0, 66.0, or 88.0 µg/mL (with activation)	There was no evidence of induced forward gene mutations with or without activation. [Negative]
		47746860 (2008) Acceptable/guideline 574.7, 1005.7, or 1760.0 µg/mL (without activation) 328.4, 574.7, 1005.7, or 1760.0 µg/mL (with activation)	There was no evidence of chromosomal aberrations with or without activation. [Negative]
870.5395	Mammalian erythrocyte micronucleus test	47746861 (2008) Acceptable/guideline 31.8, 55.7, 298.5, or 522.4 µg/mL (without activation) 170.6, 298.5, or 522.4 µg/mL (with activation)	There was no evidence of chromosomal aberrations with or without activation. [Negative]
		*47746862 (2006) Acceptable/guideline 10, 15, 20, 30, or 40 µg/mL (without activation) 20, 30, or 50 µg/mL (with activation)	There was no evidence of chromosomal aberrations with or without activation. [Negative]
	Micronucleus rat	47746863 (2008)	There was no evidence of

Table 4. Subchronic, Chronic, and Other Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification/ Doses**	**Results**
	bone marrow	Acceptable/guideline 3.0, 5.2, 9.1, 16.0, 16.9, 29.6, or 51.7 µg/mL (without activation) 25.0, 29.6, 50.0, 51.7, 75.0, or 90.5 µg/mL (with activation)	chromosomal aberrations with or without activation. [Negative]
		*47746864 (2008) Acceptable/guideline 0 or 2000 µg/mL	There was no significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow of rat. [Negative]
870.7485	Metabolism and pharmacokinetics	47746867 (2008) Pharmacokinetics Acceptable/guideline	Following oral administration of [^{14}C]-SYN520453 at 1 and 75 mg/kg, the time at which maximum plasma concentrations (C_{max}) were attained (T_{max}) was 3-6 hours post dose. Pharmacokinetic parameters of radioactivity in blood were not appreciably different to those in plasma. Systemic exposure in female rats tended to be greater than that in male rats. Systemic exposure to radioactivity was approximately dose proportional in the range 1-75 mg/kg.

Toxicological Endpoints

Table 5. Summary of Toxicological Doses and Endpoints for Isopyrazam for Dietary Human Health Risk Assessments				
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)	NOAEL= 30 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF= 1x	Acute RfD = 0.30 mg/kg/day aPAD = 0.30 m/k/d	Subchronic Toxicity – Dog LOAEL = 100 mg/kg/day based on clinical signs (side-to-side head wobble) in male dogs.
Chronic Dietary (All Populations)	NOAEL= 5.5 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF= 1x	Chronic RfD = 0.055 mg/kg/day cPAD = 0.055 mg/kg/day	Chronic Toxicity/Carcinogenicity - Rats LOAEL = 27.6 mg/kg/day based on decreased body weight and body weight gain in females; increased incidences of hepatocellular hypertrophy, pigment in centrilobular hepatocytes, eosinophilic foci of altered hepatocytes, vacuolation of centrilobular hepatocytes, bile duct hyperplasia, and bile duct fibrosis in both sexes; and brown pigment in the kidney in females.
Cancer (All routes)	Classification: CARC classified isopyrazam as "Likely to be Carcinogenic to Humans" based on increased liver and uterine endometrial epithelial tumors in female rats and increased thyroid follicular cell tumors in male rats. A cancer slope factor of 0.00629 $(mg/kg/day)^{-1}$ was calculated based on an increase in increase in liver tumors in female rats.			

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). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. .

Food Quality Protection Act Considerations:

The FQPA factor for increased susceptibility to infant and children is reduced to 1X based on the following considerations:

- The toxicology data base for Isopyrazam is complete and adequate for assessing increased susceptibility under FQPA;
- There is no indication of increased susceptibility of fetuses to in utero and/or postnatal exposure in the developmental and reproductive toxicity studies in rats;

- There is some evidence for increased susceptibility following pre- and or post-natal exposures based on effects seen in range finding developmental toxicity studies in rabbits. However, these effects occurred at doses 10-fold higher than the chosen POD.
- There are no residual uncertainties in the exposure databases.
- The dietary risk assessment is based on parent plus metabolite residues in/on banana, and will not underestimate dietary exposure to Isopyrazam.

Exposure Assessment:

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

Acute: A conservative acute dietary (food only) exposure analysis was performed for the general U.S. population and various population subgroups. Parent plus metabolite residues (Isopyrazam SYN520453 + CDCD459488) and 100 percent crop treated assumptions were used. DEEM default processing factors were used for processed commodities, since separate tolerances are not considered necessary for processed banana commodities. Acute dietary risk estimates are not of concern for general population or other population subgroups. The 95th percentile aPAD is less than 1% for all populations.

Chronic: Conservative chronic and cancer dietary (food only) exposure analyses were performed for the general U.S. population and various population subgroups. Parent plus metabolite residues (Isopyrazam SYN520453 + SYN459488) and 100 percent crop treated assumptions were used. DEEM default and empirical processing factors were used for banana processed commodities, since separate tolerances for these commodities were not considered necessary. The % cPAD for all populations is less than 1.

Cancer: Isopyrazam was classified as likely to be carcinogenic to humans. The cancer risk estimate was 2×10^{-7} for the general U.S. population.

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Disclaimer: The information in this Pesticide Fact Sheet is a summary only and is not to be used to satisfy any data requirements for pesticide registration or 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
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
PAI	Pure Active Ingredient
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 II: Citations Considered to be Part of the Data Base Supporting the Registration of Isopyrazam.

MRID	Citation Reference
47746800	Syngenta Crop Protection, Inc (2009) Submission of Product Chemistry, Toxicity, Fate and Residue Data in Support of the Petition for Tolerance of Isopyrazam for Use on Banana Commodities. Transmittal of 74 Studies.
47746801	Braun, L. (2008) SYN520453: 4-Week Oral (Capsule) Toxicity Study in the Dog: Final Report. Project Number: T000876/07, B43841, OCR. Unpublished study prepared by RCC, Ltd. 154 p.
47746802	Goetz, A.; Parsons, P. (2009) SYN520453 - Waiver Request for Developmental Neurotoxicity Study: Assessment. Project Number: T000958/09. Unpublished study prepared by Syngenta Crop Protection, Inc. 24 p.
47746803	Goetz, A.; Parsons, P. (2009) SYN520453 - Overview of Mammalian Toxicology Data Base for Banana Import Tolerance: Assessment. Project Number: T000957/09. Unpublished study prepared by Syngenta Crop Protection, Inc. 59 p.
47746804	Fox, V. (2006) SYN520453: In Vivo Rat Liver Unscheduled DNA Synthesis Assay: Final Report. Project Number: T009715/05, SR1335/REG, SR1335. Unpublished study prepared by Central Toxicology Lab. (Syngenta). 27 p.
47746805	Lees, D. (2007) SYN520453 - Preliminary Oral Toxicity Study in Dogs: Final Report. Project Number: T019059/04, KD1610/TEC, KD1610. Unpublished study prepared by Central Toxicology Lab. (Syngenta). 98 p.
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